CHEManager EUROPE

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THE NEWSPAPER FOR THE CHEMICAL AND LIFE SCIENCES MARKETS

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Ineos completes **Borealis** deal. Following clearance by the European Commision, Ineos has completed the purchase of the Borealis petrochemicals business in Norway for €290 million. The business includes a 50 % interest in the Noretyl ethylene cracker at Rafnes and three polyolefin plants based at the nearby Bamble site. The cracker was commissioned in 1977 and expanded by 100,000 t/a in 2005, and currently has a capacity of 557,000 t/a in addition to a propylene capacity of 80,000 t/a.

▶ www.ineos.com

Cognis to sell **Pulcra.** Shortly after separating the process chemicals business from the core business Cognis is intensifying efforts to divest the division, which is called Pulcra since July 1. In order to find a partner or an investor, Cognis has hired the M&A specialist Lincoln. Pulcra had sales of €258 million in 2006 and has production sites or service centers in germany, Turkey, Italy, Spain, Mexico, Brazil, China, India, Indonesia and the US. Pulcra's products are mainly used in the textile and leather industries.

▶ www.cognis.com

Bayer to withdraw from NYSE. Bayer follows Ciba, BASF and Eon as all companies are delisted from the New York Stock Exchange. The company expects some €15 million annual savings. The management expects the delisting by early October.

▶ www.bayer.com

OM Group buys **Borchers.** North American OM Group will buy additive specialist Borchers from **Lanxess.** The transaction is due to the agreement of German authorities. The closing of the deal is expected for the end of September. Borchers employs 90 people and had total sales of €36 million in 2006.

▶ www.lanxess.com

Nestlé integrates **Gerber.** Nestlé finishes the acquisition of US baby food company Gerber after all government authorities agreed. Nestlé acquired Gerber from Novartis in April for US-$5.5 billion. Nestlé is quickly looking to integrate the new business, which includes 4,500 employees. The takeover was effective September 1.

▶ www.nestle.com

Long-term Investment

Lonza's Aim is Continuous Growth with Above-average Profitability

By making several changes, Lonza has focused its portfolio on the life-sciences market. After previously divesting itself of its special portfolio and chemical/industrial chemical business, the Swiss company took over the bio areas of the US-company Cambrex in February 2007. So this year, for the first time, life sciences make up over 90 % of the total turnover. Birgit Megges and Michael Reubold asked Stefan Borgas, CEO of Lonza, about the integration of the new business areas and the strategy behind concentrating on the life science markets.

Stefan Borgas
CEO of Lonza

CHEManager Europe: Mr Borgas, Lonza took over the bio areas of Cambrex six months ago. What was the strategy behind this acquisition?

S. Borgas: We took over two areas from the American company Cambrex. The first one will strengthen our microbial biotech business and help to extend Lonza's leading position as a custom manufacturer. The other one will form an independent business unit for us under the name of Lonza Bioscience.

Lonza Bioscience, the larger of the businesses purchased from Cambrex, is a new business area for Lonza. What expectations do you have?

S. Borgas: Lonza Bioscience deals in specialised consumer goods for bio-production, such as media, serums, cell cultures, analytical test kits and so on. Then there is the classic contract manufacturing business in a brand new technology: cell therapy. Here we grow new therapeutics that in 5–10 years will perhaps be able to cure illnesses such as Parkinson's or bone marrow incompatibility that have so far remained untreatable. And Lonza would then be there as a production expert, which is a further option for the future.

At the end of July, you presented a strategy for this business area. Could you explain this briefly?

S. Borgas: Our aim is to position Bioscience as the leading supplier of services and bio materials for the life-sciences industry. Lonza's new business area completely met all of our expectations in the first half of 2007 and, after excluding short-term integration costs, achieved a high margin. The integration is running to plan. We have divided Bioscience into four business units: cell therapy, rapid testing systems, media, and cell discovery & molecular biology. In order to ensure the development of the bioscience business, we intend to open up new business areas and access some very promising technology platforms.

How will the area of microbial bio-pharmaceutics be organised in the future, and how are you integrating these locations into your existing business?

S. Borgas: By taking over the bio-pharma business of Cambrex, we have strengthened our existing microbial business and, in 2007, Lonza was the market leader in microbial bio-pharmaceutics. In addition to our large- and small-scale existing capacity in Visp, Switzerland, we have gained further medium- and small-scale production capacity as well as skills in the field of bio-pharma services. We have already revised our strategy for this area and communicated this in mid May.

We will consolidate our US activities in this field in Hopkinton, Massachusetts. This will take place in close collaboration and with the full agreement of our customers. We will additionally invest over US$30 million in Hopkinton, in order to support our plans for growth in production and microbial process development. Through this expansion we will be able to create up to 250 additional jobs.

▶ Continues **Page 11**

Competence And Dedication

In Custom Manufacturing Size is Not All that Matters

Dr. Karl-Gerhard Seifert, who has been working in the chemical industry for 35 years, resigned from his function as Managing Director for AllessaChemie in January. He is now an "active chairman", who discusses the strategy and future development of the company with the managing directors. He is also a member of the Advisory Board of AllessaSyntec. Dr. Seifert played an active role in the management buy-outs (MBOs) leading to the creation of both companies. He combines a distinguished track record in international senior management in the chemical industry and an excellent knowledge of global finance and investment environment. Prior to Allessa, he served as a member of the Board of Management of former German conglomerate Hoechst AG (1988 – 1997), as CEO of Clariant (1997 – 1999) and head of Morgan Grenfell Private Equity Ltd, Germany (1999– 2000). Michael Reubold asked him about his strategies for AllessaChemie and AllessaSyntec, and how he appraises the current situation of the global fine chemicals industry.

Dr. Karl-Gerhard Seifert
Chairman of AllessaChemie and member of the Advisory Board of AllessaSyntec

CHEManager Europe: Dr. Seifert, you have been a driving force during both management buy-outs, which have resulted in the formation of AllessaChemie in the year 2001 and AllessaSyntec in 2004. What has been the starting position in both cases, and were those comparable?

K.-G. Seifert: The starting positions were similar, but not completely comparable. AllessaChemie had been formed in 2001 mainly as a custom manufacturing company

▶ Continues **Page 9**

Rules Of The Game

Distribution of Pharma Chemicals Requires Expertise

With external sales of €6.1 billion in 2006 and over 300 sites around the world, Brenntag is a leading international company in the distribution of industrial and speciality chemicals. Building on its considerable market penetration in basic chemicals, Brenntag is now focusing on its speciality chemicals business in Europe, and the field of pharmaceuticals is one of the strategic growth segments. Michael Reubold asked Wilhelm Gierling, European Business Development Manager Pharma at Brenntag's German central office in Muelheim/Ruhr about the strategy for expanding their pharmaceuticals business, and the particular demands this market makes on chemicals distributors.

Wilhelm Gierling
European Business Development Manager Pharma at Brenntag

CHEManager Europe: Mr. Gierling, in the distribution of chemicals, there are very few full-line distributors with a balanced portfolio of industrial and speciality chemicals. How does Brenntag manage the successful coexistence of two such different fields as commodities and pharmaceutical chemicals?

W. Gierling: Brenntag's many years of experience with pharmaceuticals customers in Europe enables us to identify customers' needs well in advance and offer services to optimise sourcing and production processes. With regard to basic chemicals, we already offer tailor-made solutions for many of our customers: in terms of specifications, package size, labelling and documentation, right up to disposal and auditing of the manufacturer. For customers who require support with the synthesis of active ingredients or want assistance in developing formulations, we

▶ Continues **Page 14**

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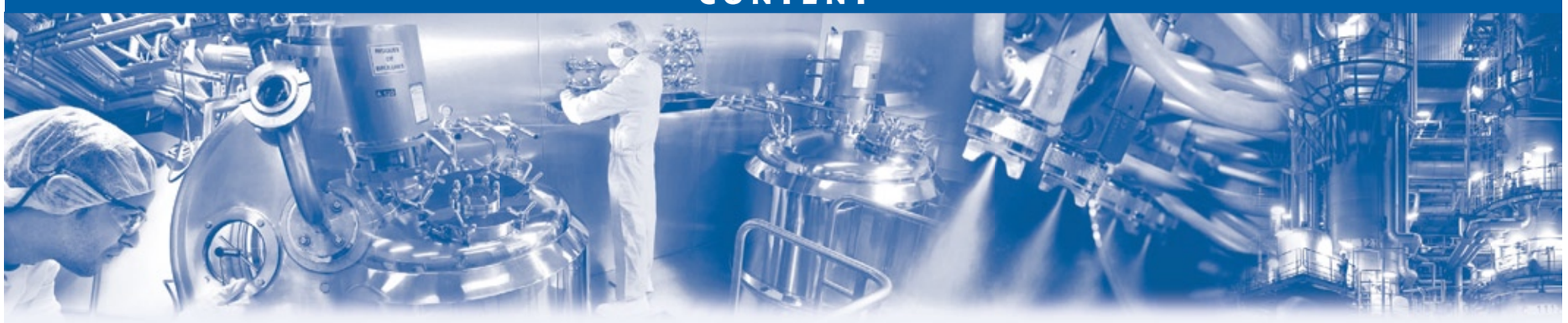

Clinical Imaging Research

A new Clinical Imaging Research Centre (CIRC) will be set up by the Agency for Science, Technology and Research (A*Star) and the National University of Singapore (NUS) to undertake clinical research and advanced biomedical imaging in humans using an extensive suite of state-of-the-art imaging tools from Siemens Medical Solutions.

The centre will be one of the few clinical research sites in the world to use the MR-PET, an advanced medical imaging solution being developed by Siemens.

▶ www.a-star.edu.sg

Oxea Expands in New Markets

Oxea, supplier of oxo-chemical products, has opened new subsidiaries in Mexiko and Singapore. The company is looking for additional markets in South America and Asia, since it generates the better part of its US-$1.7 billion annual sales in Europe and North America. Oxea manufactures solvents, polyols, olefin derivatives and oxo-derivatives such as carboxylic acids and alkyl amines for wide-ranging uses in the production of coatings, dyes, lubricants and plastics. The company was established in March as a result of the merger of European Oxo and selected businesses of Celanese Chemicals.

▶ www.oxea.com

Total Expands Leuna Refinery

Total announces the construction of a 1-million t/a desulfurization unit at its Leuna refinery in Germany. Scheduled for commissioning in fall 2009, the new unit will supply the domestic market with ultra-low sulphur home heating oil. The €120 million investment will enhance the performance of the Leuna refinery. With a capacity of 11.4 million t/a, the facility has extensive deep conversion capacity allowing it to process sour crude oil without producing heavy fuel oil. The investment is in line with Total´s strategy of upgrading its refinery base. In follows on from the commissioning of a distillate hydrocracker at the Normandy refinery in late 2006, the construction of a desulfurization unit and steam methane reformer at the Lindsey oil refinery in the UK and desulfurization capacity extensions at the Feyzin, Flandres and Provence refineries in France.

▶ www.total.com

BASF Expands Catalyts Business

BASF is expanding its production sites for automotive catalysts in China and India in order to meet high demand in these two countries. According to a BASF spokesperson, in the first six month of 2007, sales numbers for new cars in China were up 26%. In addition, India is expecting a 20% growth this year. To meet the demand, BASF will double its capacity in Shanghai and almost triple its capacity in Chennai, India. No financial information about the investments were given, however the investment plan of the company includes €110 million for the catalyst business. The catalyst business came to BASF due to the Engelhard acquisition last year and had sales of €2.4 billion in the first half year.

▶ www.basf.com

DSM Invests in Finnish Start-up

DSM Venturing announced that is has made an equity investment of €2 million in Jurilab, a Finnish company specialized in the discovery of gene-disease associations and their applications in healthcare. Following the investments in Sciona and Integragen, the deal is DSM's third investment in personalized nutrition, one of DSM's emerging business areas selected in their company strategy. Jurilab has know-how in the identification of metabolic disease markers and pathways, drug targets, and diagnostic content. The investment follows a joint discovery program in the area of hypertension started a year ago.

▶ www.dsm.com

Preclinical Services Facility in Quebec

Charles River Laboratories intends to build a new facility in Sherbrooke, Quebec, Canada, to support the company's expanding preclinical service business. Located in the newly constructed Sherbrooke Biomedical Park, Charles River's newest facility shall provide drug discovery and development services to pharmaceutical companies. When completed, the facility will be app. 300,000 square feet. Approximately 25% will be constructed by the first quarter of 2009. Timing of construction of the remaining part will be dependent on market demand. The Sherbrooke facility is ultimately expected to employ 1,000 people.

▶ www.criver.com

Drug Royalty Announces Acquisition

Drug Royalty (DR) announced the purchase of 25% of Enzon Pharmaceuticals worldwide interest in Peg-Intron for US-$92.5 million. DR will also provide a US-$15 million milestone payment in 2012 should certain royalty recognition levels be met. Peg-Intron is a Peg-enhanced version of Schering-Ploughs alpha interferon product, which is used both as a monotherapy and in combination with ribavarin for the treatment of chronic hepatitis C.

▶ www.drugroyalty.com

Lanxess: New Plant in India

Lanxess is to build a new ion exchange plant in Gujarat, India. Construction work on the €30 million site at the new Jhagadia Chemical Park is set to begin in the second quarter of 2008. Production is scheduled to to start in 2010, with 200 employees being taken on. The plant will manufacture products for industrial water treatment and the generation of ultra-pure water for the semiconductor and pharmaceutical industries. The ion exchange business is part of Lanxess' performance chemicals segment, which achieved total sales of €1,812 million in 2006.

▶ www.lanxess.com

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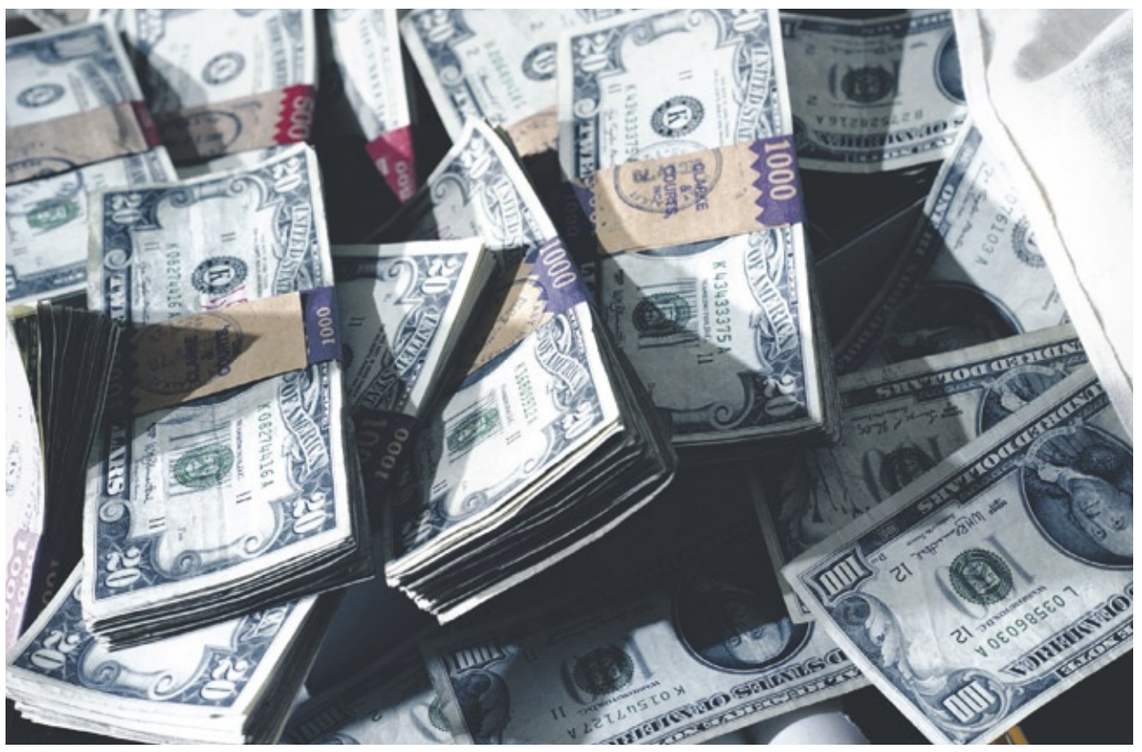
Shareholders Pay For ROA

Then Why Are We Still Living in a Margin-only World?

No one – particularly management accounting experts – would dispute the old saying, "You can't manage what you can't measure." Yet consider for a moment what is perhaps the most critical financial goal of manufacturing firms: return on assets (ROA). Investors rate the management performance of CEOs and CFOs of manufacturing firms largely by their ability to wring profits from the assets under their control.

Michael Rothschild

Oliver Braun



As such, ROA is perhaps the premier metric of quarterly and annual results. But how many manufacturing firms are able to measure and report on ROA at the transactional level of detail? How many provide their middle-management ranks accurate, timely, detailed reporting of ROA by invoice line item, production run, customer order, production line, etc.? Virtually none.

ROA may be the central financial goal of manufacturing firms, but even today's "advanced" management accounting systems, including sophisticated ABC costing and ERP systems, aren't capable of calculating, reporting, or modeling ROA at a level of detail sufficient to allow managers to know the ROA impacts of their day-to-day, deal-by-deal choices and trade-offs. Consequently, ROA is really nothing more than a high-level, after-the-fact, end-of-the-quarter or end-of-the-year rearview mirror report card on CFOs and CEOs. ROA can't be managed because it can't be measured at the transactional level where profit-making business decisions actually get made. If truth be told, there is no effective linkage between the key financial goal of manufacturing firms and their daily operating decisions, because the strategic ROA goal hasn't been translated into a pragmatic, tactical measure of business activity.

Following this logic, it's my contention that, despite decades of massive investment in sophisticated information systems, when it comes to the management accounting challenges facing managers of complex, asset-intensive manufacturing enterprises, an enormous gap remains between management's need for actionable, profit-optimizing information and the capabilities of today's "advanced" systems.

Further, I would argue that, as a direct consequence of this weakness in management accounting systems used by complex, asset-intensive manufacturers, shareholder returns in industries including chemicals, steel, semiconductors, electronic components, paper, packaging, plastics, and several others, often fall well below an acceptable rate of return on investor capital. Viewed on the global scale, in this US-$ 2 trillion sector of manufacturing, I estimate that this problem causes an annual profit shortfall of more than US-$ 100 billion. In short, inadequate and superficial measurement of ROA allows misguided management decisions that, in turn, are causing US-$ 100 billion per year to be frittered away. That's real money.

What About Profit?

Before we drill into the details of this problem, let's go back to basics. First, consider how most well-trained business people think about and define the ultimate goal of any business: profit. If you were to ask a dozen experienced managers seated around a conference table to suggest the "best" definition of profit, a few would undoubtedly mention gross margins, and others would say operating earnings or profit after tax, earnings per quarter, earnings per share, return on assets, or return on equity. Still others would show their sophistication by spouting an alphabet soup of acronyms: ROS, EBITDA, ROCE, ROIC, RONA, EVA, etc. Isn't it remarkable that such a hodgepodge of labels, each with its own underlying definition, could reasonably be suggested as the proper definition of profit?

Despite the confusion, none of these terms is wrong per se. Each one can be a useful definition of profit under certain circumstances. But there's a hierarchy of profit definitions, and not all definitions of profitability are created equal. Some measures of profit are far more important than others.

As any Wall Street analyst or finance professor will attest, the ultimate measure of profitability is return on equity (ROE), the ratio of the current year's profit divided by shareholders' equity (all accumulated past profits), or profit/equity. The higher the ROE ratio, the faster total shareholder equity – and stock price – will grow as each year's profits are added to the stockpile of shareholder wealth.

Unfortunately, even though achieving and sustaining a high ROE is the ultimate goal of any financial strategy, the ROE ratio itself is too abstract and removed from day-to-day business operations to be of any practical use in measuring and managing profitability. To gain real control over profitability, the profit/equity ratio needs to be broken down into its components.

The Dupont Formula

The most elegant explanation of the three components driving ROE is the famous "DuPont Profit Formula." In a nutshell, this formula shows how three financial measures interact to yield the ultimate result of ROE (see Figure 1, page 7). Control over all three ratios leads to control over the return on equity.

By far, the simplest to control is the nonoperating ratio, assets/equity. If a company carries no long-term debt, all of its assets must have been purchased with shareholder equity, and its assets/equity ratio equals 1. But if a company finances its assets by both equity and debt, the more debt it carries, the more assets it can acquire with the same equity. This financial leverage works wonders in boom times, but a high assets/equity ratio can lead to disaster when times get tough.

Banks and other lenders allow roughly the same range of debt leverage for all competitors in a given business segment since all the players face similar operating risk. For example, as a group, electric utilities are allowed to borrow heavily because their revenues are highly predictable and their hard assets are easy to attach. Advertising agencies, by contrast, tend to carry little or no long-term debt because their revenues are highly uncertain and their key assets walk out the door every evening.

So even though the assets/equity ratio, or debt leverage, is one of the three components driving ROE, from an operational and competitive standpoint the assets/equity ratio isn't terribly interesting. Debt leverage is a matter of long-term financial strategy, not daily business operations. And since lenders tend to allow direct competitors similar ratios of debt leverage, there's no way to consistently beat the competition's return on equity by borrowing more heavily.

To run a business for optimal profitability, management must focus on the interaction between the two remaining ratios of the DuPont Profit Formula: profit/sales and sales/assets. Multiplied together, these two ratios compose ROA – the final measure of a management team's effectiveness in squeezing profits from the assets under their control.

Of these two vital operating ratios, profit/sales, or margin, is the focus of enormous attention in every company. Indeed, whatever method is employed, much of management accounting boils down to an effort to measure margins accurately. To calculate the profit margin generated by each unit shipped or each dollar of revenue sold, companies expend huge resources attempting to accurately calculate the full cost of each product type made. Financial controllers and management teams pound away at costing studies, standards setting, activity-based costing, margin analysis, overhead allocation, etc., all in a relentless effort to make detailed profit/sales figures as close to perfect as possible.

Speed Counts

No such claim can be made for the equally crucial sales/assets ratio. Sales/assets, or the velocity ratio, measures the speed at which sales are generated from a company's asset base. The arithmetic is simple and unforgiving. Sales/assets, or velocity, is just as important as profit/sales, or margin, in determining a company's ROA. Margin x Velocity = ROA. Low-margin products can yield exactly the same ROA as high-margin products if those low-margin products are easier to make and flow through the assets

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Shareholders Pay For ROA

Then Why Are We Still Living in a Margin-only World?

Continued Page 4

at higher velocities. Conversely, high-margin products won't deliver a superior ROA if those high margins are offset by slow production velocities.

Maximizing a company's ROA (and ultimately ROE) requires managers to understand in great detail the trade-offs between margin and velocity product by product, order by order, customer by customer, etc. Knowing this, you would reasonably assume that management teams of complex, asset-intensive manufacturers already work just as hard measuring and controlling the velocities of the products they make as they do measuring and controlling the margins of those products. But this isn't the case. My experience, which stretches back over a decade in a variety of industries at nearly 100 manufacturing firms around the world, indicates that management teams lack the management accounting systems needed to measure and control velocity in conjunction with margin in order to maximize ROA.

Yet the CEO and CFO are extremely focused on producing better ROA results. Nonetheless, virtually no one down in the managerial ranks of manufacturing firms, where all the day-to-day decisions are made, knows precisely how their choices will impact ROA. In almost all manufacturing firms, the metric used by marketing managers, sales managers, production planners, and others to rank and evaluate daily operating trade-offs is margin and margin only.

Production velocity data exists somewhere in the manufacturing organization, usually at the plant level. But it has been too complex a challenge to link detailed production velocity data to margin information in a rigorous way. Lacking access to robust management accounting systems that can seamlessly integrate margin and velocity data, managers have no choice but to rely on traditional "margin only" metrics.

Decisions Based On Margins

In a phrase, shareholders pay for ROA. As I mentioned earlier, even though ROA doesn't equal margin, the vast majority of operating decisions are based on margin. Further, even though Margin x Velocity = ROA, virtually no manufacturers have systems that can properly take into account the role of velocity in driving ROA. In my view, the absence of management accounting tools that deal with the pivotal role of velocity and management's consequent inability to adroitly manage velocity in conjunction with margin are the root cause of roughly US-$ 100 billion per year in foregone profits at complex, asset-intensive manufacturing firms.

Although the DuPont Profit Formula applies to all businesses, it's worth noting that a failure to accurately measure and manage velocity, or sales/assets, isn't important in all businesses. For example, many service businesses require very few assets. In service businesses, there is often no physical linkage between the volume of sales produced in a given time period and the value of the assets owned. In service firms, as in all businesses, controlling margins matters greatly, as does controlling the volume of sales produced. But if there's no hard linkage between sales and assets, monitoring sales/assets isn't terribly meaningful.

At the other end of the economic spectrum, however, in industries where asset-intensive manufacturing firms struggle to maximize financial results for shareholders, velocity matters just as much as margin in determining financial performance. This is especially true for "highly complex" manufacturers who produce an extremely wide variety of products for an array of customers from a number of different production facilities. In industries such as chemicals, steel, semiconductors, electronic components, packaging, and paper, a single company will often produce hundreds, if not thousands or tens of thousands, of distinct product items.

Integrated steel producers, for instance, can adjust their multi-hundred-million-dollar rolling mills to make sheet steel in literally thousands of different thicknesses, widths, coatings, etc. In addition to producing flat sheet steel for cars and appliances, integrated steel makers also make bars, tubes, plates, rebar, etc. And within each of these broad product categories are thousands of specific product items – each with its own unique characteristics, pricing, margin, production velocity, and, therefore, ROA.

To optimize the ROA generated each year from their hugely expensive production assets, management teams must make a bewildering array of choices with great precision every day. Those choices can be grouped into four key areas, which are shown in Figure 2.

Let's take a very simple example of a product mix choice (see Figure 3). Would we rather accept a new order for US-$ 1,000 of Product A with its US-$ 200 margin above material costs or an order for US-$ 1,000 of Product B with its US-$ 100 margin? On a margin-only basis, we clearly prefer Product A. But what if we know that Product A, because of its physical properties, is half as fast as B when running through the rolling mill? In one minute of rolling mill time, Product A will generate US-$ 600 (3 x US-$ 200), while Product B will also generate US-$ 600 (6 x US-$ 100). From an ROA standpoint – generating profit within a given period of time from the assets – Products A and B are equally profitable. Product A's higher margin does not translate into a higher ROA.

In the real world of modern manufacturing where complexity rules, what are your optimal ROA choices if are you making 2,000 or 20,000 varieties of products on 40 different production lines in production runs of various quantities for 200 different customers, all paying different prices? Do you really know how to commit your capacity optimally or what your best price bid should be on a given day to a particular customer for a specific product quantity? In a nutshell, unless you can measure, report, and model both the velocity of production (sales/assets) at critical manufacturing steps and the margin (profit/sales) of each transaction to compute transaction-level ROA, you simply can't gain effective management control over your ultimate ROA performance.

Having long recognized that choices based solely on margin can't, by definition, lead to maximum ROA, dozens of leading manufacturers have been eager to implement an innovative management accounting system that fully integrates velocity and margin metrics at the transactional level. By allowing managers to model the ROA implications of their choices, before they make those choices, these companies have made significant adjustments to their product mix, customer mix, asset mix, and pricing levels. Substantial increases in profitability, typically in the range of 3% to 5% of revenues, have been reported, which has translated into notable improvements in ROA performance.

But most of the profitability gains made possible by converting ROA from a year-end report card for senior executives into a robust daily measurement and planning system for all managers remain to be harvested. I estimate that it will take nearly a decade before the leading manufacturing organizations who have already implemented this approach and the thousands who will follow in their footsteps learn how to fully exploit actionable ROA metrics and put that missing US-$ 100 billion a year on their bottom lines. Nonetheless, substantial profit and ROA gains have already been achieved by advancing the tools of management accounting to the point where complex, asset-intensive manufacturers can measure and manage at a transactional level the ROA results shareholders demand.

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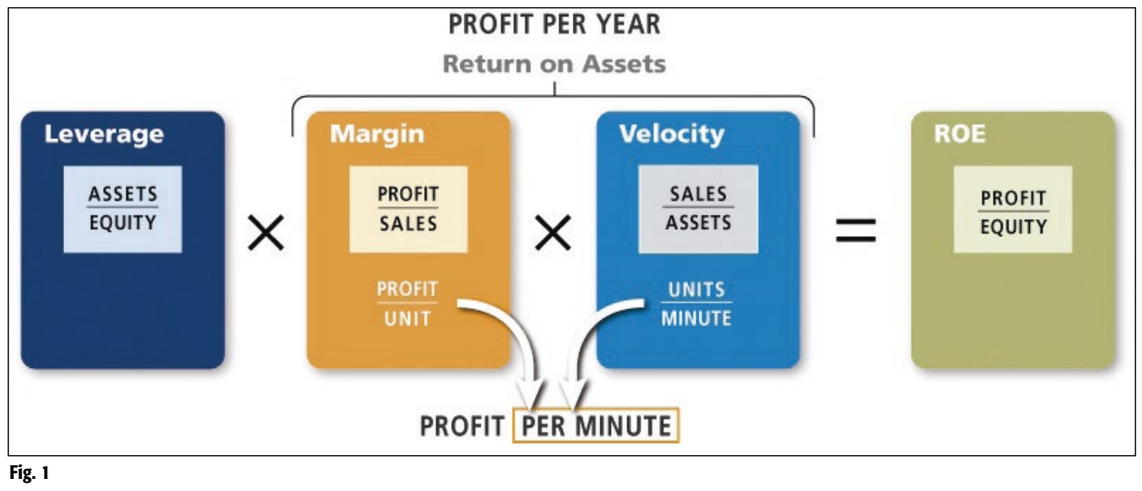

Fig. 1

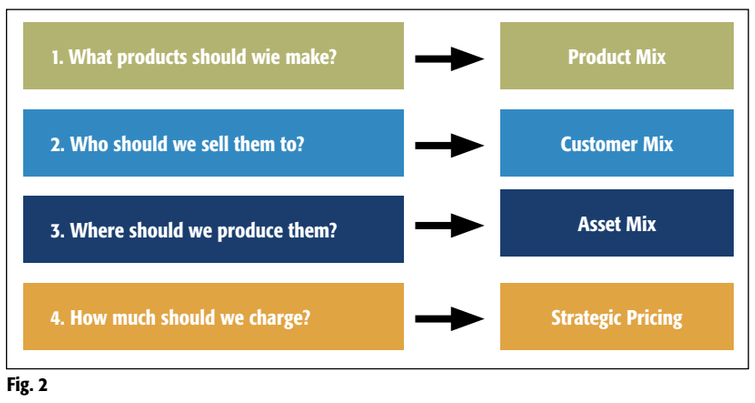

Fig. 2

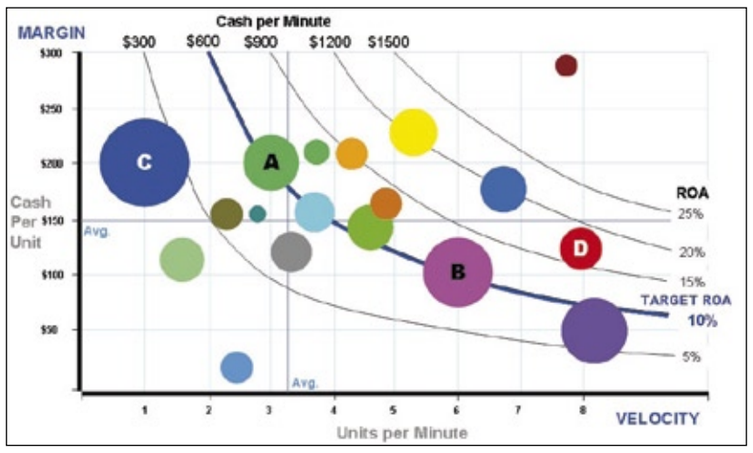

Fig. 3: With margin on the vertical axis and production velocity on the horizontal axis, this profit topographical map shows contour lines that represent levels of cash/profit per minute and ROA. The bubbles can represent products, customers, markets, sales regions or production facilities. The profit topo map shows a dramatically different view of profitability than a "margin only" approach. High-margin products, customers etc. may be significantly less profitable and generate lower ROA than ones which are produced faster and generate higher profit per minute (e.g. C vs. D).

A Global Public Health Crisis

Counterfeit Medicines Can Harm and Kill, WHO Takes Action

Pharmaceutical products are a fundamental component of both modern and traditional medicine. It is essential that such products are safe, effective, and of good quality. Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals – medicines manufactured below established standards of quality and therefore dangerous to patients' health and ineffective for the treatment of diseases. The difference is that counterfeits are deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

The issue of domestic production of drugs in developing countries has provoked lively discussion since the end of the 1970s. Several international organizations supported efforts to establish pharmaceutical industries in these countries in order to reduce dependence on imported drugs and improve access to quality drugs.
(Photo: Ethiopian Pharmaceuticals Manufacturing Factory (EPHARM), Addis Ababa, Ethiopia, © WHO/P. Virot)

Counterfeit medicines represent an enormous public health challenge. Anyone, anywhere in the world, can come across medicines seemingly packaged in the right way, in the form of tablets or capsules that look right, but which do not contain the correct ingredients and, in the worst case scenario, may be filled with highly toxic substances. In some countries, this is a rare occurrence, in others, it is an everyday reality.

Counterfeit medicines range from random mixtures of harmful toxic substances to inactive, useless preparations. (In 2001, in South-East Asia, a Wellcome Trust study revealed that 38% of 104 anti-malarial drugs on sale in pharmacies did not contain any active ingredients.) Occasionally, there can be "high quality" fakes that do contain the declared active ingredient. In all cases, contents of counterfeits are unreliable because their source is unknown or vague and always illegal. Fake drugs can cause harm to patients and sometimes lead to death.

Any kind of product can be and has been counterfeited: expensive lifestyle and anticancer medicines, antibiotics, medicines for hypertension and cholesterol lowering drugs, hormones, steroids and inexpensive generic versions of simple pain killers and antihistamines. In developing countries the most disturbing issue is the common availability of counterfeited medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV/AIDS.

The regular use of substandard or counterfeit medicines can lead to therapeutic failure or drug resistance. In some cases, it can lead to death.

Estimates

The US based Centre for Medicines in the Public Interest predicts that counterfeit drug sales will reach US$75 billion globally in 2010, an increase of more than 90% from 2005.

Although precise and detailed data on counterfeit medicines is difficult to obtain, estimates range from around 1% of sales in developed countries to over 10% in developing countries, depending on the geographical area.

Currently, the sources of information available include reports from non-governmental organizations, pharmaceutical companies, national drug regulatory and enforcement authorities, ad hoc studies conducted on specific geographical areas, and occasional surveys.

Counterfeiting is greatest in those regions where the regulatory and legal oversight is weakest.

- Most industrialized countries with effective regulatory systems and market control (e.g. USA, most of EU, Australia, Canada, Japan, New Zealand) have a low proportion, i.e. less than 1% of market value.
- Many countries in Africa and parts of Asia and Latin America have areas where more that 30% of the medicines on sale can be counterfeit, while other developing markets have less than 10%; overall, a reasonable range is between 10% and 30%.
- Many of the former Soviet republics have a proportion of counterfeit medicines which is above 20% of market value – this falls into the developing country range.
- Medicines purchased over the Internet from sites that conceal their physical address are counterfeit in over 50% of cases.

Internet Sales

In industrialized countries and to some extent in poorer countries, Internet-based sales of pharmaceuticals are a major source of counterfeit medicines, threatening those who seek cheaper, stigmatized or unauthorized treatments. Some Internet pharmacies are completely legal operations, set up to offer clients convenience and savings. They require patient prescriptions and deliver medications from government licensed facilities. Illegal Internet pharmacies sell medications without prescriptions and use unapproved or counterfeit products. In some cases, Internet pharmacies are operated internationally and sell products that have an unknown or vague origin.

Counterfeiting Grows More Sophisticated

Trade in fake medicines is more prevalent in countries with weak drug regulation and enforcement, scarcity or erratic supply of basic medicines, unregulated markets and unaffordable prices. But as counterfeiting becomes more sophisticated, these products are also being exported or re-exported and, thus, are increasingly present even in better controlled markets.

Some policy-makers have argued that drug regulation represents an unnecessary barrier to trade and should be reduced to a minimum. Pharmaceuticals, however, are not a standard commodity, since consumers and prescribers are unable independently to assess their quality, safety and efficacy and the consequences of ineffective regulatory oversight can be deadly to patients.

A Lucrative Business

Counterfeiting of medicines is a hugely lucrative business due to the continued high demand for medicines and low production costs. (The majority of the counterfeiters apprehended so far carried out their activities in ordinary households, small cottage industries, or in backyards.) The absence of deterrent legislation in many countries also encourages counterfeiters since there is no fear of being apprehended and prosecuted.

When prices of medicines are high and price differentials between identical products exist there is a greater incentive for the consumer to seek medicines outside the normal supply system. In many countries the official supply chain fails to reach many communities, especially in rural areas. Poverty, and the lack of an official supply chain, are major factors in creating markets for counterfeit products.

Combat Counterfeit Medicines

In order to mobilize awareness and action in the fight against fake drugs, in February 2006, WHO created the first global partnership known as the International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT). IMPACT is comprised of all 193 WHO Member States on a voluntary basis and includes international organizations, enforcement agencies, national drug regulatory authorities, customs and police organizations, non-governmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups. These groups have joined to improve coordination and harmonization across and between countries so that eventually the production, trading and selling of fake medicines will cease.

Upcoming events on this topic

International Conference: Developing Effective Legislation to Combat Counterfeit Medical Products, Lisbon/Portugal, 10 – 11 December 2007

Annual General Meeting: Providing the Results of IMPACT's First Year, Lisbon/Portugal, 12 – 14 December 2007

International Conference Using Technology to Combat Counterfeit Medical Products: Technology developers meet manufacturers and regulators, Singapore, 13 – 15 February 2008

▶ www.who.int/impact

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The WHO publishes reports of counterfeit medicines from around the world on its website (e.g. fact sheet N°275).

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Cyclicality, Complexity and High Asset Intensity

What Makes Chemicals M&A Deals Different?

A recent KPMG firms' workshop with chemical industry professionals highlighted that, in addition to the generic challenges of transactions in the manufacturing sector, particular issues which make deals in the chemical industry challenging include: The cyclicality of the business, the high asset intensity of the industry, and the complexity of production sites – with potential environmental issues and resulting carve-outs.

Simon Jones

Olga Rauch

M&A activity in the Chemical industry appears to be correlated to the performance of financial markets as can be seen by the comparison of the Dow Jones index with the total value of Chemical deals (figure 1).

The majority of M&A transactions are in specialty chemicals and formulations. Private equity (PE) activity in this segment has further boosted M&A activity, thereby increasing company valuations, which has been beneficial for potential sellers. Private equity is estimated to have accounted for about 23 % of deal value from 2000 to 2006 (source: David Ingles Consulting, July 2007). Companies active in "value-added" chemicals are attractive to PE investors for a number of reasons, including

- attractive levels of profitability due to innovative technology / products addressing niche applications with high entrance barriers
- size of deal/enterprise value in the appropriate range for a large number of mid-cap PE houses
- shorter investment cycles compared to commodity chemicals companies
- typically lower exposure to the chemicals cycle, as customers are often active in less cyclical markets themselves, and companies are not directly exposed to the volatility of the oil & gas markets.

Identifying M&A Opportunities

Consolidation is expected to continue with some industry segments still being very fragmented. In particular, specialty and fine chemicals will offer opportunities with overcapacities, restructuring needs, and price pressure from China/Asia. Further focus on core businesses leads major chemical players to continue making small or medium-sized adjustments of their portfolios, providing attractive opportunities for potential buyers. Finally, succession in small or mid-sized family-owned companies may also present an opportunity for M&A.

Pricing And Cyclicality

Cyclicality and relocation are generally regarded as part of the continued challenges in the chemical industry. A chemicals business may be subject to a number of cycles, including those of downstream industries (e.g. automotive, etc.). Industry and financing cycles need to be taken into account in the cash flow, which directly affects the price a financial investor is willing to pay for an asset.

Valuation multiples have steadily increased for chemicals assets over the past few years, from typically 4 to 5 times EBITDA to typically 8 to 9 times EBITDA (in some segments even 10 to 12 times EBITDA). This increase in prices is attributed to recent high levels of liquidity in the market as well as the increasingly professional sales processes. Very few assets are sold nowadays without some form of auction.

Multiples are expected to remain at the current already high levels or increase slightly due to stiff bidding competition and PE activity. High liquidity of private equity funds as well as increasing activity of players from the Middle East but also India and China is impacting prices of assets in the European chemicals M&A market.

Reach Impact

For many investors issues related to environmental, health and safety risks inherent to the chemical industry is challenging in terms of the transaction and contract. Typically, a PE fund will discount value if unexpected issues arise; the less certainty, the lower the price.

Reach, in force since June 1, 2007, is seen by some to be merely a cost issue. Buyers of chemical businesses might reduce a purchase price because of Reach. However, it is unlikely to be a deal-breaker.

Some Reach considerations in M&A activity are:

- How far has Reach planning and implementation progressed in the company?
- What costs are expected and when for the Reach implementation?
- How will Reach impact the company's business? Positively (higher revenues due to less competition for a certain substance) or negatively (lower revenues due to unregistered substances or discontinuation of products)?
- How well are the effects of Reach accounted for in the implementation planning (e.g. on IT systems, supply chain, tax, and accounting)?

Integration/Carve-out

Integration is challenging – as it is in many industries. Speed, a well-prepared business and integration plan, and rigorous project management are critical.

The chemicals industry is a complicated network of supplier and customer relationships; the industry is its own largest customer. Due to mergers or acquisitions, suppliers may become competitors and/or customers. Other industries, such as the automotive industry, have linear supply chains, where materials flow only in one direction, typically do not have these types of interactions. The integration of a chemicals business may therefore be more complex with respect to the carve-out of the acquired business and the restructuring of a new entity as interactions in the market, within the business and operations may be obvious; others more subtle.

Private Equity View

The chemicals sector is of interest to many PE houses. However, many PE houses are cautious with respect to the industry as only a few have the resources and background to understand its business models. Additionally, chemicals companies' long investment cycles and payback periods are difficult to fund. Understanding the cyclical nature of the relevant markets is critical, and the expert will attempt to play the cycles. Investors are well advised to be very selective in this sector. At the same time, the fact that many PE houses are wary to invest in the chemical industry presents an opportunity for those organizations with the necessary experience and resources: fewer of their peers compete for these assets.

Summary

Deals in the chemical industry are not very different from deals in other manufacturing industries. At the same time, there are some peculiarities to M&A processes in the chemicals industry, in addition to the generic challenges of any transaction. In order to conduct successful M&A transactions in the chemical industry, an in-depth understanding of the target markets, its customers and product pricing mechanisms is required. The underlying dynamics of these markets, as well as the interactions and substitutions between different types of chemicals, should be assessed to identify market potential and deal-breakers at an early stage. The more thoroughly those factors are understood, the easier it is to price the target and win the deal.

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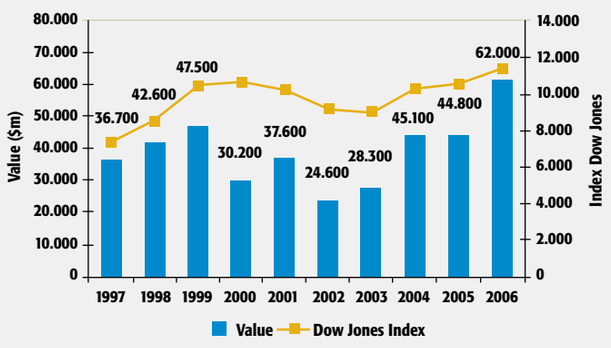
Total value of M&A transactions and Dow Jones Index annual average Fig. 1



Note: M&A transactions in the Chemical industry > US$ 50 million

Source: David Ingles Consulting, Bloomberg, KPMG analysis, July 2007

Fine Chemicals Custom Manufacturing

Satisfying the Needs of the Pharmaceutical Industry, Part I – Markets and Products

The marketing activities of a fine chemical company have to be structured in a way to allow the most efficient pursuit of its main activities, namely custom manufacturing of pharmaceutical fine chemicals and supply of API-for-Generics. This affects the business processes all the way from identifying business opportunities along a customer's product life cycle to pricing, and the selection of target markets and distribution channels. As the majority of fine chemicals are still produced in-house by the pharmaceutical and other specialty chemical companies there is a huge reservoir of opportunities. Part I of this three-part series discusses the customers and markets (mainly the global pharmaceutical industry), and the product the fine chemicals industry provides for these markets.

Peter Pollak, Ph.D.

In the Fine Chemicals industry, marketing is understood primarily as an operational function. As such, it comprises business development, sales, pricing, distribution and promotion. As the life sciences, first of all the pharmaceutical industry constitutes by far the most important customer base for the Fine Chemical industry (see table 1), the organization and tasks of the marketing function, or, in a broader sense, the company as a whole, should be designed in order to best satisfy the pharmaceutical industry's needs. A fundamental distinction has to be made between the needs of the ethical, or innovative pharmaceutical and the generics industry. Whereas the former requires primarily "exclusives", i.e. tailored pharmaceutical fine chemicals (PFCs), which are supplied under custom manufacturing agreements, the latter buys API-for-Generics, i.e. commercially available active pharmaceutical ingredients (APIs) from stock. The substantial differences between these two categories of products/services provided by the Fine Chemical industry are described in table 2.

The situation is further illustrated by examining/scrutinizing the four "entry gates" or windows of opportunity that emerge during the life cycle of a drug (figure 1).

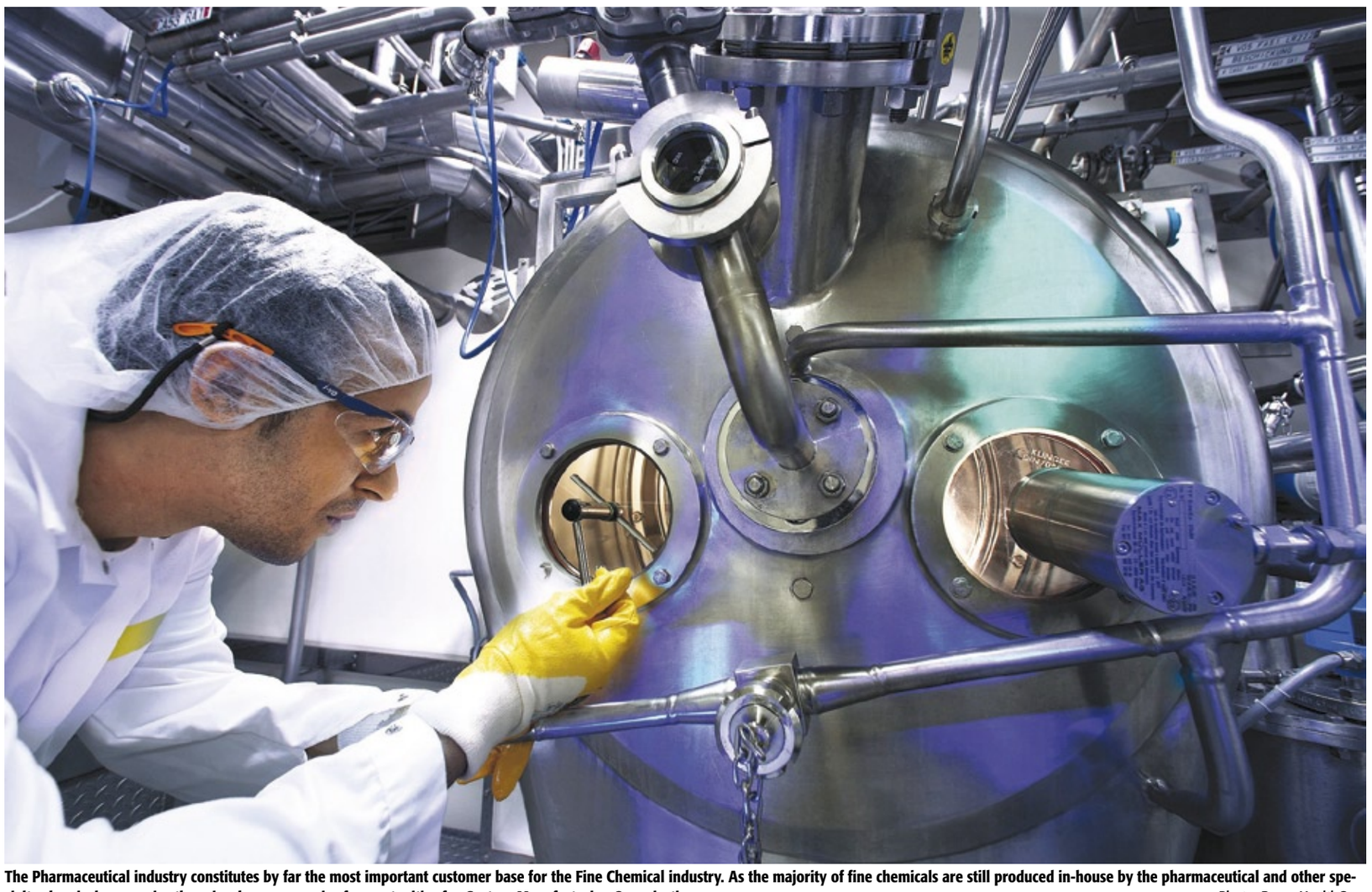
The number of possible product candidates, the chances of success of the developmental drug to make it to the marketplace and the chances of a specific Fine Chemical company to get the business all change substantially along the product life cycle. The first three opportunities comprise a period of approximately 20 years, during which the drug is protected by patents. They are the domain of custom manufacturing (CM), i.e. the antonym of outsourcing. At the beginning there are thousands of development drugs in the R&D laboratories of the world's pharmaceutical industry … with only a minuscule chance for any individual molecule to make it to the marketplace and therefore ultimately requiring substantial quantities of PFCs. The emphasis is on quickly producing small scale samples by simple processes without economical or ecological considerations. During the subsequent clinical development, chances of a commercial success become gradually more tangible. Phase II of clinical development constitutes a pivotal point. Pharmaceutical companies lock in the final route to be used for manufacturing their new APIs. The intellectual property of the product, and generally also the manufacturing process, belongs to the customer during this first part of the drug life cycle. The supplier is bound buy an exclusive supply agreement.

The third gateway is located at the peak level of the drug production volume. Drugs that are introduced in the same therapeutic class by competitors start to negatively impact on the market share. At this point, costs of goods sold (COGS), become a major concern and therefore more cost effective second generation processes are urgently wanted. This presents a chance for a new supplier.

The fourth gateway is linked to the decline phase of the life cycle, when patent expiration is approaching. In order to fence off generic competition, it becomes a question of survival for the originator company to develop the most economic process. Business opportunities surface both with the ethical pharma company which holds the patents and attempts to keep at least a portion of the market, and with generic houses which are preparing for the launch of generic versions. The latter are vying for market share – and also looking for competitive suppliers. This is then the domain of the API-for-Generics producers.

The combination of the CM and API-for-Generics activities can lead to better capacity utilization. The production schedules for exclusive products are rigid, on the other hand there is more freedom in planning campaigns for API-for-Generics. Whereas it makes sense to form separate business units for marketing "exclusives" and "generics" respectively, production should not be subdivided except for large Fine Chemical companies.

As most generic companies are only formulators and marketers, they rely more heavily on sourcing from third parties than ethical pharmaceutical companies, most likely about 70 % versus about 40 %. Because low prices are the raison d'être for generics and the entry barriers are low, marketing of API-for-Generics is an uphill fight against a ruthless competition, especially from Asian countries. Also, customer loyalty is almost non existent. Marketing must first of all identify potential target molecules among more than two thousand existing and forthcoming API-for-Generics on the basis of existing leads, the market size and growth, the competitive situation (a.o. the "first-to-file" doctrine), conflicts with existing business, the fit with in-house capabilities, the patent situation, etc. Within the technical criteria, products needing only pots-and-pans for their manufacture should be ignored in favour of those requiring one or more niche technologies, External issues, such as legal and market aspects require support from third party specialists, e.g. specialized agents.



The Pharmaceutical industry constitutes by far the most important customer base for the Fine Chemical industry. As the majority of fine chemicals are still produced in-house by the pharmaceutical and other specialty chemical companies there is a huge reservoir of opportunities for Custom Manufacturing Organisations. Photo: Bayer HealthCare

Target Markets

In a "customer category/geography" matrix, pharmaceuticals and the United States are the most attractive combination for Fine Chemical companies in terms of target markets. As there are only few domestic suppliers, the market is also attractive for non-U.S.-based Fine Chemical companies

Nine of the top twenty pharma companies are based in the US, accounting for just over 50 % of the US-$350 billion sales. Europe, where four out of the top ten ethical pharma, and the majority of the generics companies are headquartered, follows at the second place. The United Kingdom and Switzerland are most important. In England, both AstraZeneca and Glaxo SmithKline are large purchasers both for custom manufacturing services and API-for-Generics. Switzerland is not only the home for Novartis and Roche, but also Sandoz, the world's number 2 generics company. With the merger of Bayer Health Care and Schering AG to form Bayer Schering Health Care in 2006, a German pharmaceutical company made it again to the top tier. Germany also prides itself of a number of sizeable generics companies: Merck KGaA, Ratiopharm, Schwarz Pharma and Stada. Japan ranks third. There are two Japanese pharmaceutical companies among the top twenty, namely Takeda and Astellas (formed by the merger of Fujisawa and Yamanouchi in 2005). As the sourcing priority rapidly decreases in the sequence captive production >> national fine chemical companies >> foreign fine chemical companies it is a difficult market to penetrate for the latter! Some softening of the "insular attitude" has been noticed recently.

Within the global pharma industry, all three categories of companies, namely big (> 20 companies, sales > US-$5 billion/year), medium (50 – 100, US-$0.5 – 5 billion/year) and small pharma (4 – 5,000, < US-$50 million/year) have advantages and disadvantages and should be considered as target customers.

In terms of potential business volume, "big pharma" ranks highest with a share of about 55 – 60 % of the total PFC market (mainly "exclusives"), "medium pharma" ranks second with a share of about 40 % (mainly API-for-Generics), "small pharma" comes last with about 10 % (see table 3). On a "business potential per company" basis, "big pharma" obviously is most attractive. Also, companies are easy to identify. However, competition for business is very strong and procurement is well aware of its purchasing power. Only Fine Chemical companies that have a proven track record of superior performance and maybe even achieved "preferred supplier" status have a realistic chance to be considered for new business.

Small or virtual pharma typically do not have established products and a limited new product pipeline. Therefore, they offer few business possibilities on an individual company basis. This is compensated by the large number of companies (well over 1,000 in the US alone) and their lack of manufacturing assets and expertise. Also the number of approvals for New Chemical Entities, NCEs, originating from virtual pharma companies has surpassed that of the top twenty for the first time in 2003. A substantial desk work is required in order to identify developmental drugs that have both a good chance of success and a fit with the technologies of a given Fine Chemical company. Also, its business is at risk, once the small pharma company licenses its new drug to big pharma. On the positive, small pharma's share of the total business is growing

▶ Continues Page 9

Table 1: Size of Fine Chemicals Markets in Developed Countries

		Total A.I.	Captive	Merchant
Life Sciences	Pharmaceuticals	$60 bn	$35 bn	$25 bn
	Agrochemicals	$10 bn	$6 bn	$4 bn
Various Specialty Chemicals		$15 bn	$10 bn	$5 bn
Total Fine Chemicals Industry		**$85 bn**	**$50 bn**	**$35 bn**

A.I. = Active Ingredients

Table 2: Characteristics of "Exclusives" and "Generics"

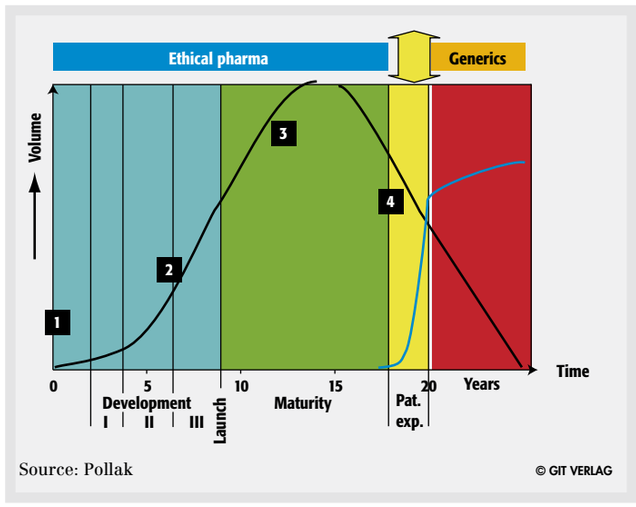
	Exclusives (= Custom Manufacture)	Generics (= API-for-Generics)
Business Model	Project Driven	Product Driven
Products	Advanced Intermediates	End Products (Apis)
Pricing	"Buttom-Up"	Market Price
Distribution Channels	Direct	Agent
Customers	Ethical Pharma Companies	Generic Pharma Companies
Competitors	Captive Production 1 – 2 Suppliers/Product	Asian Producers
Competitive Advantage	Project Management	Price, Quality, DMF
Origin of Know-how	Customer	Supplier
Technical Assistance	Close Cooperation	Sporadic
Legal Assistance	Sporadic	Intensive
Production Planning	On Order	Min./Max. Stock

Table 3: Breakdown of the Merchant Fine Chemicals Market

Type of Company	Position on the Drug Life Cycle		
	Patented		Generic Acess Point 4[1]
	Phase II/III Access Point 2[1]	Phase IV Access Point 3[1]	
"Big Pharma"	$1.0 bn	$5.0 – 5.5 bn	$1.5 – 2.0 bn
"Medium Pharma"	< $0.5 bn	$2.0 – 2.5 bn	$3.0 – 3.5 bn
"Small Pharma"	> $0.5 bn	$0.5 bn	–
Subtotals	$2.0 bn	$8.0 bn	$5.0 bn
Building Blocks		$5.0 bn[2]	
Grand Total		**$ 20 bn**	

[1] see figure 1
[2] do not require production under cGMP

Source: adapted from: Prochemics, Zürich (April 2004)



Source: Pollak © GIT VERLAG

Figure 1: Product Opportunities along the Drug Life Cycle

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Competence And Dedication

In Custom Manufacturing Size is Not All that Matters

AllessaSyntec operates a large number of flexible multi-purpose facilities that can be quickly interconnected to complex units to perform highly complex, multi-stage syntheses

Continued Page 1

with an existing portfolio of products for its main customer Clariant. Our main target has subsequently been to use third-party custom manufacturing to stabilise the company and expand our business.

AllessaSyntec, which has its roots in the central R&D department of the former Hoechst AG, at the time of the MBO was part of Siemens-Axiva and focused on process optimisation and production of complex intermediates. Previous to the MBO, the market did not recognise this potential sufficiently in the then existing business environment. The broad technology portfolio of 50 years within Hoechst convinced us that we would succeed in establishing the company as a stand-alone business in close cooperation with AllessaChemie.

> *"Even venture capital has to obey social responsibilities"*

How have both companies positioned themselves in their markets, and how has the business been doing so far?

K.-G. Seifert: AllessaChemie has had to enter a restructuring process right from the beginning. Regretfully, our staff had to be reduced to about 1,000 people – as estimated for the end of 2007. The production had to be concentrated mostly at our Fechenheim site. In addition, we are still operating a plant in Offenbach and a production facility in Frankfurt-Griesheim. Our business segment dealing with third-party manufacturing has been expanding from zero at the start of AllessaChemie to about €25 Mio. turnover in 2007. We have acquired major chemical companies as customers and have a full pipeline of custom synthesis projects.

In addition, we have developed a portfolio of our own products using the logo Allessan, and several of them have already been launched, with more to come in the coming months.

The turnover of AllessaSyntec has been significantly increased in the last three years. Well-known companies have contracted AllessaSyntec to develop processes and produce precursors of APIs, sophisticated intermediates for the electronics industry, or other specialty chemicals, which usually require multistep, complex syntheses and/or modern technologies.

Despite the formal independence of both companies they are approaching potential markets together. What is the particular point in the combination of AllessaChemie and AllessaSyntec?

K.-G. Seifert: AllessaChemie and AllessaSyntec are legally separate companies, who are connected by joint service departments in Marketing and Sales as well as Administration. In their markets they are operating as cooperating partners, who complement each other very nicely in their technologies and production capabilities. This enables our customers to choose themselves which of the technological strengths to use and eventually to combine.

Moreover, AllessaChemie can produce large volumes up to several thousand tons per year. AllessaSyntec is typically active in market segments from 10 kg to about 50 tons per year. This large range results in many advantages for our customers, for example in high flexibility regarding production and supply.

Which are the main features that in your opinion differentiate AllessaSyntec from other fine chemicals companies? What are the core technologies?

K.-G. Seifert: AllessaSyntec has special strengths in the fields of low-temperature syntheses, phosgenations, high-pressure reactions and many more. The plant formerly used to report directly to the R&D board member of Hoechst AG, and therefore no costs and efforts were spared to achieve an extraordinarily high technological standard. Just an example: low temperature synthesis at industrial scale was started over 15 years ago, long before others have utilised this technology. Based on the know-how gained early on, there are many benefits for the customers, be it the hardware used or the chemical and process know-how.

Complementary to those special technical abilities, the scientists of AllessaSyntec can draw on the experience of over a thousand scale-ups during the last decades – and not the least: they are flexible. High personal and technological flexibility forms the basis for the achieved successes. This flexibility has been preserved and expanded by the current organisation.

Are you planning to expand your portfolio by investments, and if yes, where?

K.-G. Seifert: We are currently talking about co-operations with companies who have technologies to complement our portfolio. But it is too early to disclose details.

Both AllessaChemie and AllessaSyntec are based in the Rhein-Main area. However, most market analysts think that a critical mass and the presence in North America and Asia are critical factors for success in the fine chemical market. What are the advantages of being a smaller, locally based company compared to large, globally acting conglomerates?

K.-G. Seifert: The Rhein-Main area in Germany has traditionally been the base of one of the leading chemical companies worldwide, Hoechst AG, of which AllessaChemie and AllessaSyntec are small successors. Technologies of Hoechst have been successfully transferred to our company and are being expanded. We are running our plants with highly dedicated and excellently trained workforce. Our people have had traditionally a high qualification and competence. We have the ability to decide and act quickly. Those all are criteria which convince global companies to work with us as partners. A consequent customer focus and reliability are essential, too.

> *"I would certainly welcome the reemergence of a large, strong Fine Chemicals concern in Europe, preferably in Germany"*

Consolidation in the Fine Chemicals sector is in full swing. How do you assess the current situation, and which changes in the industry do you expect in the coming years?

K.-G. Seifert: The current trend for consolidation will, at least in my opinion, last a few more years. We are currently observing that the euphoria about China is fading quite a bit, which is good for the European chemical industry. I cannot and do not want to comment on other companies, but I would certainly welcome the reemergence of a large, strong Fine Chemicals concern in Europe, preferably in Germany. First beginnings are already starting to be visible.

Private Equity companies are playing a more and more important role in the consolidation of the market. What do you feel about the participation of venture capital at chemical companies?

K.-G. Seifert: Having worked myself from 1999 to 2000 for a private equity company, I certainly welcome the participation of venture capital in many cases. There are quite a few examples in which financial investors have managed companies more successfully than their predecessors.

However, as a manager who has participated for many years in the German model of employee participation and has successfully cooperated with workers' representatives, resulting in the prosperity of the companies, I do condemn the practices of some financial investors. Even venture capital has to obey social responsibilities. Thus, we can serve and guarantee the benefit of all participants: the company, the workforce, and the public welfare.

Which requirements have to be fulfilled and which other factors are crucial for a successful management buy-out?

K.-G. Seifert: This depends on many factors. Especially important are a reasonable financial structure and a valuable technology portfolio. The most important factors for our company were having a team, which is obsessed with the successful development of both companies, and having a workforce which supports the management buy-out wholeheartedly.

> *"The euphoria about China is fading quite a bit"*

▶ www.allessa.com

CPhI: Hall 12, Booth E39

Fine Chemicals Custom Manufacturing

Satisfying the Needs of the Pharmaceutical Industry, Part I - Markets and Products

Continued Page 8

above average, the competition for business is smaller, its procurement is less hard-boiled, and last but not least depends totally on outsourcing.

Mid pharma plays a modest role in blockbuster drugs (all but 4 out of 103 blockbuster drugs were not marketed by top twenty pharma companies in 2005), but are important users of API-for-Generics.

Distribution Channels

International commerce prevails in the Fine Chemical industry, because suppliers and customers are often located in different countries, or even continents, and because transportation costs are almost negligible. For managing their international business, Fine Chemical companies have to choose the most appropriate distribution channels. Basically, they can do it with their own means – either directly from their headquarters, or indirectly through a local office – or with the help of an agent or distributor. The total control of the supply chain is the main argument in favour of an in-house solution. Also, it avoids a conflict between the principal's goal of a long term profit optimization and the agent's interest in short term profit maximization. For this reason, agents generally are hardly interested in business development activities, which generate commissions after several years only.

The main advantages of an agent are his long standing network of customer contacts and his knowledge of the local conditions. This is particularly important if customers and suppliers are part of different cultures, like East and West. Japanese trading houses, such as Mitsubishi Corp., Mitsui, Sumitomo Corp. and Watanabe, have a vast experience in bridging the gap. By representing different companies, agents are able to offer a large range of products and services. They are in a position to "open the doors" at accounts that otherwise would not be accessible, particularly for small companies with a limited product/services range. The disadvantages are potential conflicts of interest because of overlapping product ranges of principals and concerns regarding leakage of intellectual property.

For the selection of the most suitable distribution channel, the following elements should be considered:

- Knowledge of the country of destination, comprising both the familiarity with the culture in general and the extent of business experience in particular. If a European Fine Chemical company wants to enter the Japanese market for the first time, the services of an agent are almost mandatory. On the other hand, if the same company has gained many years of experience selling its products and services to the USA through an agent, it will consider setting up its own office.
- Actual, respectively potential size of the business. If there is only a small sales potential in a given country, let's say in Taiwan, an agent is the distribution channel of choice. The minimum sales proceeds that are needed to justify a local representative is about US-$5 million per year.
- Customer categories. Big Pharma companies, which are mainly customers for exclusive products and which have extensive logistics departments of their own, prefer to deal directly with the supplier, regardless of its location. Mid sized and virtual pharma companies welcome the logistic assistance from agents, for example for custom clearance and local transportation.
- Product categories. Contract manufacturing projects, which require multi line and multi level contacts are better managed through direct contacts; API-for-Generics are preferably channelled through agencies, whose assistance for local registration is a valuable asset.

As in actual business life not all elements coincide, a compromise has to be made. A solution is gaining ground, whereby the key accounts are served directly from the headquarter, the other customers requiring contract manufacturing services by the local office, and the generic companies by specialized agents.

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Icing On The Cake

Pharma Event CPhI Worldwide 2007 Comes to Milan

Have you ever been to Milan during Fashion Week? Have you ever booked a hotel room or tried to get around town by taxi or public transportation that time of the year? You will love it – unless you suffer from a fear of crowds, also known as enochlophobia. But still, you tell yourself it won't be that unpleasant because during Fashion Week, a big part of the crowd consists of pretty models. Think again!

First, you won't be surrounded by models on the train during rush hour – they go to their shows by limousine. And second, the fashion community won't be the only crowd that will be there: The Champions League match Internazionale vs. PSV Eindhoven at Guiseppe Meazza stadium on 2 October will see another 70,000-plus crowd afoot; or rather, in cars, busses and trains, and many of them in hotels and restaurants, too.

Can it get any worse? Yes, it can: Add another 20,000 visitors – most of them from Asia – to that already packed city and picture them trying to make it in time to their business meetings at the far end of town. You guessed it: it's CPhI time!

That's a foretaste of what you might expect in Milan in a few weeks, but since it's CPhI, there's no way to avoid it. From 2–4 October, the world's largest and most important gathering for suppliers of pharmaceutical fine chemicals (PFC) will take place at Fiera Milano's Rho Exhibition Centre. The conference and exhibition on pharmaceutical ingredients and intermediates is a must-attend event every year, and this time the organisers chose Milan as the location.

The importance of the CPhI, underlined by the attribute "Worldwide", lies in its compulsion for manufacturers of fine chemicals and custom manufacturing organisations (CMO) to exhibit in order to get a big piece of the pharma cake. A cake whose real indulgence is its icing, that is the considerable number of visitors from big pharma who are involved in sourcing and buying decisions.

However, the size of CPhI Worldwide seems to have gone beyond the scope of being manageable. The fact that more than half of the almost 1,800 exhibitors is from Asia tempted several Western attendees to request a name change to "CPhI China in Europe". China represents by far the largest number of exhibitors (approx. 730) followed by India (approx. 200). The biggest Western exhibitors' countries are Germany, Italy and the U.S. (around 100 each), France (70), UK (60), and Switzerland (50).

Photo: Pixelio

CPhI Worldwide 2007 will take place in Milan, Italy, October 2 – 4

But racking one's brains about the vast number of Asian exhibitors and visitors is a moot point. Accept the fact that [quote] "the Asia-Pacific market evolves more quickly than many had anticipated" and that a big portion of the chemical industry in the dawn of the 21st century is shifting to China and India, in particular. With one third of the world's population in these two countries quickly emerging from developing to developed nations, this region is building up a demand for resources and products unprecedented in the history of this planet.

However, as everybody knows, this trend does not only open new markets for the traditional chemical industry, but also generates new competition. Have you ever wondered what has become of the fellow chemistry students from China and India who once shared the lab bench with you? Chances are that they went back to their countries, became company founders or at least research chemists, and that you might meet them at CPhI and even source chemicals from their companies.

For our CPhI preview, we asked industry experts a few business- and market-related questions to find out what's on their minds these days. You already read one of the statements, marked as quote in the passage above. The most important topics according to our survey are globalisation, consolidation, outsourcing, regulation and innovation – all adding up to the overall state of the industry.

"Globalisation will continue to affect the fine chemicals industry," according to Saltigo. Staying with the topic of globalisation for another moment, Pfizer CentreSource recognises "the value of globally competitive pricing, but also acknowledges the crucial role of other factors that their customers have to consider, including consistency, quality standards, strong GMP compliance, and rapid access to customer service and regulatory support."

Consolidation of the chemical industry is closely linked to globalisation. Not only as Western companies are seeking to maintain their competitive edge by restructuring their portfolios through acquisitions and divestments, but also since "major western CMOs [are] being acquired by Indian companies," as Codexis points out.

Therefore, "globalisation remains key." According to SAFC, "international companies now have to look very carefully at their business strategies when setting up facilities in India and China, with particular emphasis on scale of operations and cost efficiency. For example, in India, it may now be too late for a company to enter the market in the hope of gaining a cost advantage, with Indian manufacturing costs now virtually equivalent to those of the US and Europe. While China remains attractive on cost, there are still on-going concerns regarding IP control and quality.

Indeed, the quality of APIs from China is a serious concern, and fake drugs that were consumed in or exported from China have been linked to a significant number of deaths. The WHO article on counterfeit medicines (page 5 of this issue) shows that this is not only a problem of China, but of virtually all countries lacking proper regulation. These countries are being urged to implement international quality standards.

For the time being, the high quality standards and the tight net of inspections in the Western hemisphere are a competitive advantage for companies manufacturing in Europe and North America. Archimica sees "that several big pharma firms have collected disappointing experiences with some low-cost country manufacturers and tend to go back to European suppliers." Saltigo points out that "keeping pace with changing regulatory requirements is an imperative for professionals involved in supplying to and supporting the supply chain of the pharmaceutical industry", and that "custom manufacturing of pharmaceuticals will always be based on regulatory guidelines from agencies like [U.S. Food and Drug Administration] FDA or [the European Medicines Agency] EMEA. It can be expected that the regulatory guidance will get tighter."

Competition for PFC manufacturers and CMOs not only arises from emerging countries, but also from their customers themselves. "Pharmaceutical companies getting under cost pressure will always turn to insourcing to cover as much of their fix costs as possible."

So, how is the business climate and what is the pharmaceutical industry doing? Archimica currently observes "a positive development of the PFC market, including another outsourcing wave from several big players." Saltigo agrees that "most pharmaceutical companies have announced major investments in biologics facilities and cut back on investing in small molecules production. This has led to more outsourcing of [active pharmaceutical ingredients] APIs and intermediates and an improved business climate for custom manufacturers."

According to SAFC "the major issue, as far as the drug pipeline is concerned, is the trend of large pharma to continually decrease its R&D spend, while increasingly in-licensing its technology from biotech." And Saltigo hopes "that the pharmaceutical industry will overcome its recent weakness in innovation and return to its previous performance."

On the technology side, biocatalysts and biocatalytic processes are on the rise. Codexis explains "benefits derived from efficient biocatalysis technology can be important drivers in the decision to outsource. Pharma pipelines now include more complex chiral molecules, which present synthetic difficulties using traditional chemistries. These are excellent candidates for biocatalysis." Saltigo accedes "in the near future we expect to see an increasing use of enzymes, which can manufacture complex molecules more effectively than traditional organic chemistry." And Archimica, too, expects "increasing importance of areas like organometallics, asymmetric synthesis using especially enzyme-type catalysts."

There is a lot more to talk about, but we want to let the industry experts speak for themselves. Enjoy reading the interviews on pages X/Y and feel free to comment on the topics covered there by e-mailing us at chemanager-europe@gitverlag.com. And last but not least, have a safe trip to Milan. The team from CHEManager Europe will be around, too.

Dr. Michael Reubold

From Bench To Market

Fluorinated Building Blocks, Peptides and Oligonucleotides

Solvay Organics specialises in organic molecules for a wide range of uses. Innovative molecules, materials and solutions are designed to help clients develop new applications. The main areas of operation that will also be presented at CPhI 2007 are fluorinated building blocks, peptides and oligonucleotides, as well as process development and custom synthesis of active ingredients.

About 50 percent of all newly developed drugs and 20 percent of agrochemicals contain fluorine. However, it is not easy to introduce fluorine into target structures because fluorination reagents are highly reactive, often explosive and can be harmful to the environment. Their use also requires highly specialist expertise and engineering technology. Moreover, fluorination reactions generally cannot be scaled up from laboratory to industrial production. It is much more economical and effective to incorporate fluorine into target structures in the early stages of development with the aid of building blocks.

At CPhI, Solvay Organics will therefore be presenting a whole range of fluorinated – particularly aliphatic – building blocks, including esters, ketones and acrylates. In addition, application technologists with practical experience will assist interested parties and are happy to discuss issues including the use of highly innovative, chiral building blocks.

Oligonucleotides and peptides can have a targeted effect on the body's cellular functions and open up a number of treatment options. The technologies for their use and production are still new and therefore require a great deal of expertise. For example, typical oligonucleotides such as 20-base DNA and RNA fragments require about 100 chemical reactions.

Girindus, majority-owned by Solvay, is focusing on therapeutic DNA and RNA oligonucleotides with all relevant modifications – for example phosphothioates, 2'-modified RNA or PEG conjugates. Girindus will be present at the Solvay-Organics stand to share their knowledge and provide information about production capacities at the American plant in Cincinnati and the German plant in Künsebeck. Large-scale production under GMP conditions uses both solid phase synthesis and a newly developed liquid phase synthesis process.

Peptisyntha, a subsidiary of Solvay Organics, offers production capacities for therapeutic peptides, together with developmental expertise. Eptifibatide is a good example of Peptisyntha's capabilities. A cyclic heptapeptide with a disulphide bridge, Eptifibatide is the active ingredient of Integrilin, an anticoagulant used in heart surgery.

Girindus offers a range of technology, expertise and equipment for process development to pharmaceutical and cosmetics companies which have developed an active ingredient and wish to bring it from the laboratory to the market. These include reactions which take place under special process-technology conditions such as high pressure or extreme temperatures, as well as demanding synthesis techniques such as nitration, hydration or Suzuki coupling. The company can produce active ingredients and intermediates at virtually any scale – whether in laboratories, technical units or production plants.

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CPhI: Hall 11, Booth L96

Long-term Investment

Lonza's Aim is Continuous Growth with Above-average Profitability

Continued Page 1

In Baltimore, Maryland, we will continue with both production and bio-pharma services as long as necessary, which we expect will be until the start of 2008. This will allow us to ensure a completely concurrent technological transfer to Hopkinton and the required quantities for all the products currently manufactured there.

With this new way of organising our microbial business, we can offer our customers not just a unique service in process development and production but also a world-leading technology platform.

You have clearly restructured Lonza in recent years. How will you position the company after this purchase?

S. Borgas: Lonza has been aiming its strategy towards the life-science industry for a few years now. In the past year, we almost completely divested ourselves of our non-life-science business: such as LOFO, the film business in Weil-am-Rhein, Germany, and Polynt, the chemical/industrial chemical business in Italy, which we floated on the stock exchange. As a countermove, we purchased companies that fit our core business. By also purchasing both the Cambrex businesses, there has again been a considerable change to the Lonza profile: this year, for the first time, life sciences make up over 90% of our turnover.

How do you intend to ensure future growth in this contested market?

S. Borgas: We will ensure future growth by concentrating on specifically defined life science markets and, in these, on the production value-creation stage, the development of procedures and the production of substances. That is the core business of Lonza. We use high-tech bio-technology and chemical platforms, which we must also naturally develop. We want to be better at this that anyone else in the world.

You have already mentioned investment plans for the USA. What is your additional mid-term investment strategy, and what are your priorities?

S. Borgas: Up to 2011, we will be investing over a billion Swiss Franks in different projects for growth, such as the construction of two production plants for bio-pharmaceutics based on mammalian cell cultures in Singapore, in expanding our bio-pharmaceutical production plant in Portsmouth, USA, and in converting our plant in Porrino, Spain, into a multi-purpose plant. Investments are also being made in new plants in Visp for producing medication conjugates and highly-active pharmaceutical ingredients, and also in China in new plants for producing pharmaceutical agents. In addition, there will certainly also be one or two acquisitions to round off our portfolio. We spend approx. 125 million Swiss Franks each year on maintaining our existing plants.

> *"We want to be better at this than anyone else"*

The economy is moving ever faster and investors are increasingly looking for quick profits. What are the particular features in your sector regarding profitability and ROI, and how do you convey these to your shareholders?

S. Borgas: The planned investments in new plant will bring in a return on investment of approx. 30%, calculated as EBITDA. This means that we can show ourselves to be an interesting opportunity for investors. All together, the Lonza EBIT will grow at 15–20% per year until 2012. There is no reason why the value of the company shouldn't grow in step with this. But we have clearly stated that it is only worth investing in Lonza in the long term. Our investors understand that, and understand that particularly well in the allegedly fast-moving USA. One further argument for investment is in the design of the whole Lonza life-sciences portfolio, which is not just based on a really risky CMO (contract manufacturing organisation) model, but also contains significant product business that attracts less attention but provides better stability. This portfolio not only generates real synergies, it is also an important element of our risk management.

For many people, Lonza is a model profitable fine chemical company. What lies behind this success?

S. Borgas: As already described, Lonza has consistently focused itself on the life-sciences area in recent years. This gives a clear profile to our company and what we can offer. We focus on the production value-creation stage for our customers in the life-sciences markets. These markets are characterized by three things: continually increasing, strict regulatory requirements; demanding customers and lengthy test procedures, as well as many unsolved problems and thus a great need for innovation. By focusing in this way, we can also expand our technological leadership into these areas in a targeted way. In order to generate value for our customers, we use our high-tech chemical and bio-tech technology platforms. In this way, we can position ourselves as the leading company in our areas. However, the actual basis for our success is of course the people at Lonza: the management and specialists, as well as project employees.

> *"It is only worth investing in Lonza in the long term"*

What is the most interesting aspect for you in the life-sciences markets?

S. Borgas: The life-sciences industry is interesting because it demands particular skills; the products are strictly regulated, which means that you need experience in complex official approval procedures. And because these preparations are used in or on the human body, their tolerability must be guaranteed, which again demands a great deal of knowledge. In addition, there is still significant potential for innovation in the life-sciences industry, whether in medication, food supplements or agro-chemicals. For Lonza, this means that we can see good opportunities for growth.

> *"There is still significant potential for innovation in the life-sciences industry"*

Do you see the fast-growing and maturing chemical industry in Asia as an opportunity or a threat? What strategy are you pursuing in Asia, and where do you see the potential for differentiation?

S. Borgas: The development in Asia and in China in particular is a challenge for any company that is globally active. We have of course been accustomed to this continuous pressure for years and Lonza is well established in this competitive arena.

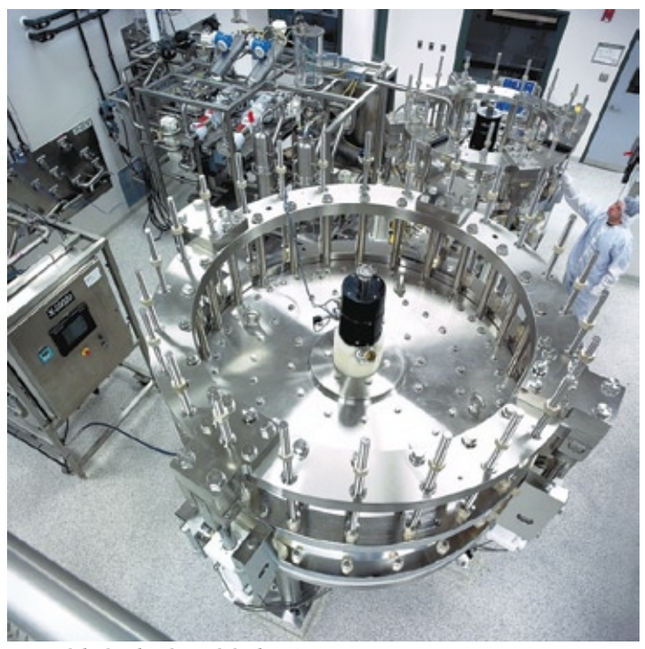
With our production plants in China and Singapore, we are directly represented in these markets. This means that we can supply the local markets directly with our products and also profit from cheaper production costs, which particularly pays off in the area of large volume mass products. However, this is on its own not enough. Lonza must primarily stand out among its competitors through innovative technologies and through a comprehensive range of services. The conditions exist for this.

With this investment strategy, we are reaching market leadership in the contract manufacturing business and, in the other two areas of fine chemicals and bio-science, are building up a number of strong niche businesses that we can defend well.

What are your prospects, and what immediate aims do you want to achieve for Lonza in the next 2 years?

S. Borgas: The next two years will take place against a background of implementing our strategy and integrating the new plants and business units into the existing Lonza company. In addition to the whole project management aspect, this is a giant challenge, particularly for Human Resources. The change in our portfolio means that at the middle of this year over one third of Lonza employees around the world will have been in the group for less than 15 months. We want all our employees to understand our strategy and vision. They should also live our management culture, and be mutually dependent and trusting of each other. These integrations should be completed as quickly as possible so that more experts than ever before can give a new impetus for growth to our core businesses.

If we concentrate on these elements and then do a lot of things right, we will create the conditions for continuous growth with above-average profitability.



Lonza Biologics cleaning unit in the USA

▶ www.lonza.com

Meeting Pharma's Future Challenges

The Fine Chemical Industry Needs to Ensure that it is Able to Supply the Pharma Market

In the run up to CPhI Worldwide in Milan, Oct. 2 – 4, 2007, CHEManager Europe asked industry experts a few business- and market-related questions to find out what's on their mind. The company representatives who responded are presented in the photo gallery on this page. This is what they replied.

Topic 1: Business

CHEManager Europe: What is your core business and what do you highlight at this year's CPhI?

Symonds: Pfizer CentreSource is a global leader in pharmaceutical chemical manufacturing and custom and contract manufacturing services. We will be highlighting our international capabilities in a variety of expertise areas including steroid active pharmaceutical ingredients (APIs), fine chemical intermediates, fermentation and bioprocess technologies, and a broad range of dosage form production, packaging and labeling services.

Stahl: Saltigo's Business Line Pharma offers exclusive custom manufacturing services to emerging and established innovation-driven pharmaceutical companies. We provide support and supply for development and commercial APIs as well as advanced intermediates including: route selection, process development, scale-up, commercial production, analytical services, regulatory expertise and professional project management.

Seufer-Wasserthal: Codexis develops powerful biocatalysts for pharmaceutical manufacturing by integrating biology and chemistry. Codexis technology makes pharmaceutical chemical manufacturing faster, cheaper and greener. At this year's CPHI, the company will highlight its expanding product line in custom biocatalysts and pharmaceutical intermediates which can reduce development time, cost and environmental waste.

Feldker: SAFC Pharma is focused on cGMP manufacturing, process development, contract services for small organic APIs and advanced intermediates and development of large-molecule APIs for the biologics industry. The company provides fit-for-purpose support from the preclinical stage through clinical development and commercialisation.

This year, SAFC will focus on its large molecule API's for Biologics offer, extensively enhanced since last year through multiple investments and acquisitions.

Meudt: Archimica is a privately held pharmaceutical fine chemical company with over 700 employees at seven manufacturing facilities in Italy, France, Germany, UK and U.S. It has decades of experience in custom synthesis of high-quality intermediates and active pharmaceutical ingredients in close cooperation with our clients.

At this years' CPhI, we will highlight our latest developments in organometallic and enzymatic chemistry, e.g. a new and highly economic process for the enzymatic production of chiral epoxides. Also, we will inform about our latest expansion in aseptic/sterile filtration possibilities, the successful FDA inspection at our site in Tonneins, France.

Schrickel: SF-Chem's core business consists in the manufacture of intermediates and fine chemicals, which are derived from chlorination, sulphonation or methylation reactions. SF-Chem runs two business units: one for the supply of standard catalogue products for broad applications and customers, and the other unit is focused on the manufacture and development of specific custom projects. Both activities are based on the focus on chlorine and sulphur derived intermediates.

The highlight this year will be the integration of SF-Chem and the German CABB to form a new company. This merger will lead to a strengthened player in the fine chemicals industry with the focus on chlorinated, sulphonated and methylated intermediates and further processed compounds. Both companies are similar in size and will form a new European market leader in this field with three state-of-the art production sites, in Pratteln, Switzerland and in Knapsack and Gersthofen, Germany.

Ide: Degussa Pharma Polymers is manufacturing Eudragit polymers for coatings of solid oral dosage forms and offering drug delivery technologies for targeted drug release. We are supporting our customers by a global network of technical service centers in the pharmaceutical key markets.

This year we are present at CPhI with a big team of Sales and Marketing staff, supported by our colleagues from the U.S., India and China.

What are your key differentiating factors in terms of technologies, assets, know-how or services?

Symonds: There are several factors that put Pfizer CentreSource in a unique position. First, we are a leading innovator in steroid synthesis and production with a legacy that goes back to our origins within the previous Upjohn business. Our fully integrated, soya-derived steroid production approach encompasses some of the most efficient and cost-effective processes in the market today, resulting in a broad platform for corticoid and hormonal steroids.

Strong Technology Platform
Dr. Andreas Meudt
Global R&D Director and Managing Director of the business unit Molecules Synthesis Centre (MSC), Archimica Group

Fit-For-Purpose Support
David Feldker
Vice President of SAFC

Challenging Chemistries
Dr. Wilhelm Stahl
Head of the Business Line Pharma of Saltigo

Can-Do Attitude
Martin Widmann
Head of Global Business Unit Pharma Solutions, BASF

Formation of a New Company
Dr. Joerg Schrickel
Marketing Manager Chemicals, SF-Chem

Efficient and Cost-effective Processes
Doris S. Symond
Vice president, Global Fine Chemicals, Pfizer CentreSource

State-of-the-Art Facilities
Carlos R. Fernandez
Vice president, Global Contract Manufacturing, Pfizer CentreSource

Global Network of Technical Service Centers
Jonas Ide
Product Manager Eudragit, Degussa Pharma Polymers

Faster, Cheaper And Greener
Peter Seufer-Wasserthal
Ph.D., Vice President and General Manager, Codexis Pharma Services

Fernandez: On the dosage form manufacturing side of our business, we have a unique ability to tap into the broad global manufacturing network of Pfizer, our parent organisation, which ensures our access to the state-of-the-art facilities and specialised expertise needed for complex activities that go beyond what many other custom manufacturers can provide. This is important in high-containment and cytotoxic manufacturing, sterile solutions and suspensions, and manufacturing of lyophilised product, among other areas.

Stahl: We focus on providing development and manufacturing services for late stage development and commercial APIs and advanced intermediates. Our key expertises are rapid scale-up and challenging chemistries. Saltigo has scaled up repeatedly more than 120 chemical steps per year to produce at least several hundred kilograms. Another differentiating factor is our expertise in handling many challenging chemistries at commercial scale, including phosgenation, high-pressure hydrogenation, metal hydrides, low temperature and exothermal chemistries.

Widmann: It is the can-do attitude that has made BASF the partner of choice for manufacturers of pharmaceutical products around the globe. We accompany the entire life cycle of products in the pharmaceutical industry from the early development stages and market launch right through to the commercial production process. In so doing, we regard the requirements of our customers as a challenge and stand for highest quality and flexibility. Our customers benefit at every stage from BASF's unique chemical expertise and innovative strength.

On the one hand, we offer a comprehensive portfolio of generic active ingredients and highly functional excipients. And on the other, we provide tailor-made custom synthesis services according to specific needs. This includes, for example, phosgene and azide chemistry, asymmetric hydrogenation and low-temperature reactions. With service centers across the globe, we guarantee our customers expert support and offer advice for developing products and processes.

Seufer-Wasserthal: It is not always possible to find enzymes in nature that are suited to catalyzing a specific chemical reaction. Using proprietary technologies, Codexis rapidly generates unique new enzymes that improve chemical manufacturing processes and significantly reduce manufacturing costs. The company develops custom biocatalysts tailored specifically to meet the manufacturing needs of the customer, and also produces gram to multi-ton quantities of APIs.

Feldker: From discovery and optimisation, to the supply of clinical trial and commercial material, SAFC Pharma can streamline and support the drug development program at every stage of the clinical pipeline. With over 20 years of experience in GMP manufacturing, nine GMP FDA validated sites in three continents, SAFC Pharma is a reliable partner with high expertise including high-potency and cytotoxic API manufacturing, solid state chemistry services, vaccine manufacturing and gene therapy, API from plants as well as potent fermentation and fungal APIs.

Meudt: Our main differentiators in technologies are in the field of organometallic, enzymatic and heterocyclic chemistry. In terms of assets, Archimica has a unique set of cryogenic assets at all scales up to 10-m^3 reactors and can even combine more than one cryogenic reactor, allowing to perform combined cryogenic steps. Also, we have large-scale hydrogenation assets capable of operating at up to 80 bars.

Most of our sites and assets are operating at very high cGMP levels at FDA-inspected sites. In terms of service, new product development is handled

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Meeting Pharma's Future Challenges

The Fine Chemical Industry Needs to Ensure that it is Able to Supply the Pharma Market

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in our business unit MSC, in which our prime targets are a strong service orientation and culture with regular progress updates, best-in-class technical solutions and at the same time already preparing for later upscaling while focusing on rapid delivery of current customer needs.

Schrickel: SF-Chem's sound position is based on the focus on chlorine and sulphur derived intermediates and the back integration into the reagents for chlorination, sulphonation and methylation reactions. The combination of the primary starting materials, chlorine and sulfur trioxide, leads to a variety of reagents like thionyl chloride, sulfuryl chloride, chlorosulfonic acid, dimethyl sulfate and other reagents, which are used and processed on-site. Supported by the necessary infrastructure and a recycling system for off-gases, reactions can be carried out in a safe, clean and highly efficient way – not only in small scale but also in large volumes. All plants are therefore equipped to handle corrosive and hazardous materials and one of the strengths of SF-Chem is the know-how to process and use the materials in a safe way. The use of the reagents leads to a broad portfolio of products out of acid chlorides, chloroethylamines, chloromethyl ethers and ester, chloroalkyl ethers, aromatic and aliphatic sulphonyl chlorides and sulphur trioxide amine complexes.

Ide: Pharma Polymers is a strategic partner, providing customer tailored technical service support packages: from feasibility studies over formulation development and proof of concept via clinical sample manufacturing to drug delivery technology licensing. Our international network of technical service centers gives customers on-site support at every stage of pharmaceutical development, with the same high quality standard and flexible performance anywhere in the world.

Have you made any significant additions to your portfolio since last year's show?

Symonds: We are increasing our marketing focus on promoting our strength in our broad fermentation, recovery, and purification capabilities. In fact, our flagship facility for this production activity is our facility in Kalamazoo, Michigan, a Pfizer "Center of Excellence" site for fermentation.

Fernandez: We have a similar approach on the dosage form manufacturing side of our business. While there is nothing distinctly "new" this year, our approach to serving our customers is maturing into an increasingly global effort. We can tap into Pfizer's specialised manufacturing network of facilities around the world, offering production capabilities and expertise of some dozen different facilities in more than eight countries, and the list continues to grow.

Stahl: Over the past 12–18 months we have constantly improved our cGMP manufacturing capabilities and capacities. Last year we have invested in additional low-temperature equipment further extending our capacities to produce at temperatures as low as –100 °C and introduced high pressure hydrogenation capabilities that enable us to perform hydrogenations even at 200 bar. We have also announced a €10 million investment to upgrade an existing facility to a cGMP multipurpose plant with 4 individual trains with reaction vessels ranging from 2500 to 8000 liters. This fully automated and recipe controlled facility will be dedicated to the production of APIs and high-value intermediates. The plant will become fully available by the end of 2007. In addition we have qualified another 60-m^3 vessel volume for the production of sophisticated intermediates under cGMP during 2007.We are also in the process of expanding our process development group by up to 20 % according to match the growing demand.

Catalysis is crucial to chemical syntheses. A catalyst is filled into an experimental reactor.
Photo: BASF

Seufer-Wasserthal: In July, Codexis acquired BioCatalytics, creating the world's leading biocatalysis company using specialised enzymes to accelerate and improve the economics and environmental impact of pharmaceutical manufacturing. This brings the power of clean bio-based manufacturing technology to customers seeking alternatives to undesirable or unsustainable chemical processes. In February, Codexis introduced the Codex Biocatalyst Panels, a next-generation research product enabling pharmaceutical manufacturers to harness the power of unnatural biocatalysts to increase R&D and manufacturing productivity while significantly reducing cost.

Feldker: Since October 2006, focusing on enhancing our niche technology offer in the biologics market, SAFC Pharma completed the construction of a new US-$20 million protein extraction and purification site in St. Louis, one of the world's biggest facilities for plant-origin API's. In April, SAFC acquired Molecular Medicine Bioservices Inc., based in Carlsbad California and focused on vaccine manufacturing and gene therapy. SAFC also announced the start of a new US-$29 million site construction in Israel. Scheduled for completion late Q1 2009, the facility will produce high-potency active pharmaceutical ingredients (HPAPIs), including large-molecule secondary metabolites and cytotoxins. In November 2006, SAFC Pharmorphix's solid form studies facility in Cambridge announced a 2,500 sq.ft. laboratory extension, as part of a US-$600,000 expansion program. SAFC's Safebridge-certified Madison HPAPI site will feature a new US-$4.5 million large-scale kilo lab, scheduled for validation early 2008. SAFC also announced a US-$10 million development package to increase cGMP commercial-scale API manufacturing capacity at its Arklow, Ireland site, and to expand capacity and enhance manufacturing operations at its Buchs, Switzerland facility.

Meudt: Since last CPhI, we have added several new technologies in our core areas. To mention just one, we have developed and already successfully up-scaled an enzymatic route to chiral epoxides, which has already yielded several high purity enantiopure Epoxides of carbo- and heterocyclic products. Typical ee's of such products are >99.5 %. Additionally, we have a large pipeline of multi-heteroatom heterocyclic boronic acids and have developed different new technologies for such compounds.

Schrickel: In 2007, SF-Chem completed the installation of a Hastelloy production line with the addition of a 8000-liter Hastelloy reactor. The whole production line now enables the processing of not only acidic, but also alkaline media and to further carry out processes with the isolation of particulate material from ultrafine, almost unfilterable suspensions.

The Hastelloy line contains a reactor for reaction, one for crystallisation, a sliding-centrifuge as well as a high-capacity universal paddle dryer. This production line excels in the isolation and drying of material from ultrafine suspensions with a 2/3 reduction in residence time.

Ide: Since the last years show we have introduced the new Eudragit NM 30 D polymer to the market. This polymer is designed for formulating matrix tablets. Its chemistry allows designing special release profiles with up to 24 hrs drug release.

We also hosted two symposia on hot melt extrusion technology together with the company Leistritz Extrusion. These symposia underlined our expertise in the field of innovative drug formulations.

Did you or do you plan to expand your geographical presence?

Fernandez: Pfizer CentreSource continues to expand its marketing efforts to include more sites within the Pfizer network. In that sense our global presence is expanding.

Seufer-Wasserthal: Codexis will soon open Codexis Laboratories Singapore, the company's first facility in Asia. The Singapore lab will open this fall as an expansion of the company's research and development operations. The acquisition of BioCatalytics expanded the company's presence in California.

Schrickel: The combination of SF-Chem with CABB provides both partners access to a fine-mesh distribution network in Europe, North America and Asia, as well as to each other's specialised production technologies in the same core business of chlorine and sulphur chemicals. This will result in a mutual benefit for both companies. Therefore it will be less an expansion than the more efficient use of the distribution channels of both companies.

Ide: We are permanently expanding our global presence by opening new Pharma Polymers offices and cooperating with agencies. Recently we expanded our team in India and opened a new laboratory in Mumbai. This laboratory helps us to support our customers in the field of formulation development and drug delivery technology support.

Topic 2: Market

Which market trends, from your point of view, are most importantly shaping the fine chemicals industry?

Symonds: The ways in which pharmaceutical outsourcers are dealing with suppliers today, particularly from Asia, has proven to be an interesting development. In our case, Pfizer CentreSource recognises the value of globally competitive pricing. But we also acknowledge the crucial role of other factors that our customers have to consider, including consistency, quality standards, strong GMP compliance, rapid access to customer service and regulatory support, and other elements. In our steroid intermediate and API business, we are taking an approach that we think gives our customers the 'best of both worlds.' We are leveraging the long-standing Pfizer advantage in early-stage bioconversion operations at the company's plant in Kalamazoo, Michigan, by using proprietary fermentation processes to create a broad intermediate platform, at extremely large scale and, in some cases, in a single processing step. Then, to achieve better economics for our customers, we are leveraging our relationships with trusted Asian suppliers to handle the labor-intensive synthetic chemical processing stages. Outsourcing only these steps allows Pfizer CentreSource to maximise value to customers through Pfizer's unique steroid intermediates process – retaining in-house the value-added customer and regulatory support services customers require.

Stahl: Custom manufacturing of pharmaceuticals will always be based on regulatory guideline from agencies like FDA or EMEA. It can be expected that the regulatory guidance will get tighter in the interest of patient safety and protection. In addition, the Reach legislation will have some negative impact for the fine chemicals industry. It will in particular add significant cost disadvantage for EU based companies doing business outside the "Reach territory".

We expect consolidation to continue on a reduced level in the near future, as still not everybody is happy with the business despite the recent upturn of the overall business climate. Also globalisation will continue to affect the fine chemicals industry.

Seufer-Wasserthal: Recent trends have been predominantly driven by globalisation, with the "non-registered" end of the Contract Manufacturing Organisation market moving to China, and major western CMOs being acquired by Indian companies. This trend is likely to continue. Survivors will need a capability/technology/service niche. In addition, the rapidly rising cost of raw materials and energy, along with the continuing focus on cleaner manufacturing, has led to a rethinking of many existing processes. Methods that have worked well historically need to be updated by more efficient processes.

Feldker: Certainly outsourcing from large pharma will continue to be one of the principal drivers for the fine chemicals industry, as the majors remain focused on manufacture as their core competency. Research and biotech will increasingly be outsourced and the fine chemicals industry will need to ensure that it is able to meet pharma's future challenges, both in terms of technology and capacity.

Globalisation also remains key, as the Asia-Pacific market continues to evolve more quickly than many had anticipated. International companies now have to look very carefully at their business strategies when setting up facilities in India and China, with particular emphasis on scale of operations and cost efficiency. For example, in India, it may now be too late for a company to enter the market in the hope of gaining a cost advantage, with Indian manufacturing costs now virtually equivalent to those of the U.S. and Europe. Only a few years ago this would have been seen as a highly unlikely scenario.

While China remains attractive on cost, there are still on-going concerns regarding IP control and quality. A major advantage for Western companies establishing a base in China is that they can maintain absolute control over these issues.

Meudt: We currently observe a positive development of the PFC market, including another outsourcing wave from several big players. We also see that several big pharma firms have collected disappointing experiences with some low-cost country manufacturers and tend to go back to European suppliers with more complex developments and products.

Which issues of the pharmaceuticals industry are most critically affecting your business?

Stahl: Pharmaceutical companies getting under cost pressure will always turn to insourcing to cover as much of their fix costs as possible. However, a few of them have started to reduce the manufacturing capacities and focus their involvement on producing the final steps in tax havens. Most pharmaceutical companies have announced major investments in biologics facilities and will cut back on

Continues Page 14

Rules Of The Game

Distribution of Pharma Chemicals Requires Expertise

Continued Page 1

also offer consulting expertise and a comprehensive range of intermediates, excipients and active ingredients. In some countries, the proportion of speciality chemicals accounts for up to 40% of the respective sales in pharmaceuticals. Expertise is a crucial factor in being accepted by customers and suppliers as a part of the value chain. To ensure this, we concentrate on the expertise and experience of our employees in Centres of Excellence.

Pharma is one of three strategic growth fields. What significance does this market currently have for Brenntag, and what growth expectations do you have?

W. Gierling: The distribution market for pharmaceuticals products which is currently accessible to us in Europe is estimated to be about €3 billion, and it is growing at a rate of approximately 4% per year. From 2003 to 2006, Brenntag was able to double its market share. In this heavily fragmented market, however, there is still a lot of upward potential: for the next few years we are intending to grow at a significantly greater rate than the market.

What special demands does the pharmaceuticals market make on the distribution of chemicals?

W. Gierling: The pharmaceuticals market currently finds itself in a period of structural change and under increasing cost pressure. On the one hand, for distribution this means remaining competitive and supporting relocation processes on an international level. On the other hand, demands made on the range of products – e.g. biotechnology and neutraceuticals – are increasing, and so is the need to tap into new sources of supplies.

Speaking about sources of supply: what is your sourcing strategy for pharmaceuticals?

W. Gierling: Our objective is to relieve our customers of some of the burden in terms of procurement logistics, to enable them to concentrate on the strategically important issues. In this way, Brenntag makes a significant contribution to increasing the added value. So our customers are able to utilise a global network of approved suppliers and profit from their know-how. Additionally, with excipients we fully embrace the sound working relationship that we enjoy with established manufacturers. With 30 depots throughout the EU, which lend themselves to the correct and proper storage of excipients, we are able to combine purchase quantities as and when the need arises.

Photo: Pixelio

What are the main product groups in your portfolio, and which do you still want to develop?

W. Gierling: A good two thirds of our portfolio consist of basic and process chemicals, which our customers source from over 100 local branches. The remaining products are made up of excipients and intermediate products for the synthesis of active ingredients. Active ingredients themselves represent a smaller, but in some countries increasing share of our portfolio. Fundamentally, we want to continue to grow in terms of complex intermediate products, excipients and raw materials for biochemical processes.

What services does Brenntag provide for pharmaceuticals customers?

W. Gierling: Our products and services range from providing advice on synthesis and the development of formulations, to the procurement, storage, packaging and transport of solvents and their disposal and reprocessing. Filling and mixing form a key part of our range of services – both in units of just a few millilitres as well as in IBC containers. Furthermore, at five locations it is also possible to fill under GMP conditions. Other services include analytical processes and manufacturer auditing, which we are increasingly being commissioned to do by our customers.

'Good Manufacturing Practices' are soon to be legally enforced throughout the EU, not just for active ingredients but also for a number of excipients. Which of your facilities already meet the GMP requirements?

W. Gierling: Our sites in Denmark, Switzerland, Austria and Poland are GMP-certified. In Spain too, Brenntag has a GMP site. In Germany, we are already working in accordance with GMP requirements and have applied for certification. Brenntag has already set high standards here, from which not least the customers also profit.

In the pharmaceuticals distribution business, what are the most significant differentiating features that set you apart from your competitors?

W. Gierling: As a company, you have to understand and observe the special rules of the game in the industry with regards to product safety and availability, and you have to be flexible in addressing the customers' needs. Furthermore, you need to be prepared to invest accordingly in personnel and equipment. Brenntag has done this successfully in the past and has thus established a clear positioning for itself.

What influence will the EU chemicals legislation Reach have on your business or your customer relations, and how are you preparing yourselves for this? Which products are affected by the regulation?

W. Gierling: Active ingredients, raw pharmaceutical materials as well as substances which are incorporated into the end product are exempt from Reach, since their use is already regulated in various other directives. Brenntag has prepared itself in good time for basic chemicals and intermediate products as well as excipients which are used in other applications, and we have set up an international Reach implementation team. In this respect, we have done our homework.

Counterfeit drugs or drug formulations with substandard active ingredients are increasingly causing not only worldwide economic damage but, more importantly, they also put the patients' health at risk. To what extent does this topic affect the distributors of chemicals?

W. Gierling: The highest level of product safety and quality are a key component in all our activities. That is what the name Brenntag stands for. To answer your question more specifically: the subject of falsified or inferior standards of quality has not been a major problem for us. To ensure that this also remains so in the future, we are systematically investing in the high quality of our employees and facilities. Ultimately, distribution is a crucial interface between preliminary and end products, and thus bears a corresponding level of responsibility in the overall production process.

> **"There is still a lot of upward potential"**

www.brenntag.com

CPhI: Hall 12, Booth F11

Expertise is a crucial factor – Brenntag concentrates on the expertise and experience of its employees in Centres of Excellence.

Meeting Pharma's Future Challenges

The Fine Chemical Industry Needs to Ensure that it is Able to Supply the Pharma Market

Continued Page 13

investing in small molecules production. This has led to more outsourcing of APIs and intermediates and an improved business climate for custom manufacturers. The degree of outsourcing will persist to drive the development of the custom manufacturing industry one way or the other.

As Saltigo is only offering services to innovation-based pharmaceutical companies their power to innovate will continue to be the basis for our business. Therefore, we strongly hope that the pharmaceutical industry will overcome its recent weakness in innovation and return to its previous performance.

Seufer-Wasserthal: Benefits derived from adopting efficient biocatalysis technology can be important drivers in the decision to outsource. Pharma pipelines now include more complex chiral molecules, which present synthetic difficulties using traditional chemistries. These are excellent candidates for biocatalysis.

Cost focus and patent expiration on more complex structures also open opportunities for Codexis technology to drive down production costs allowing innovators to maintain a competitive position.

Feldker: The major issue, as far as the drug pipeline is concerned, is the trend of large pharma to continually decrease its R&D spend, while increasingly in-licensing its technology from biotech. Obviously this has been happening for many years, but what we are seeing now is pharma undertaking the in-licensing of technology at a later stage in the pipeline than previously, often in Phase IIa or even IIb, before committing to an investment.

SAFC's business model has evolved along with these changes to the pattern of the drug discovery pipeline, providing a good partnership 'fit' at every stage. Through early stages, up to Phase II, we are able to draw upon vast quality knowledge, R&D and scale-up expertise to ensure everything is in order when a candidate is in-licensed by a pharma company.

Once the technology has been acquired by a pharmaceutical major and progresses through the pipeline, it is then down to the fine chemical industry to ensure that it has the capacity to supply the pharma market.

What technologies to develop and manufacture APIs and pharmaceutical intermediates do you see as having high potential for the future?

Stahl: Many new reactions introduced by medicinal chemists have found their way into production over time and this trend will continue. In the near future we expect to see an increasing use of enzymes, which can manufacture complex molecules more effectively than traditional organic chemistry. This will be due to recent methodological progress in designing enzymes and tailoring their properties towards specific profiles.

Another continuing trend will be the application of flow reactor technologies and micro reactors. We see already some use for the production of early intermediates applying highly exothermic reactions which will continue to spread over time and eventually also find their way into cGMP production once regulatory issues will have been solved.

Seufer-Wasserthal: The best process is often in the end the cheapest process. When all components – capital expense, energy cost, waste handling – are considered, a well-optimised bioprocess compares very favourably to conventional methods. Until recently, development times of biocatalysts and biocatalytic processes tended to be longer than their chemical counterparts. With the panel strategy of Codexis this has now changed completely. Choose the optimum process conditions and then create an enzyme that meets those requirements exactly; this will be the future.

Feldker: We will continue to expand upon and invest in our high potency offer as mentioned above with our investments in our HPAPI facilities in Madison and Jerusalem. The other area where we see a bright future is in what we term 'niche biologics', underlined by the investment in a new manufacturing facility in St. Louis and the acquisition of Molecular Medicine BioServices Inc.

Meudt: Archimica expects increasing importance of areas like organometallics, asymmetric synthesis using especially enzyme-type catalysts, and more complex heterocyclic structures. This is the prime reason why we are increasing our efforts in these areas in which we already have a very strong technology platform.

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Knowledge for Generations

Using Energy More Efficiently

How Chemistry and Chemicals Can Help

Chemicals can not only increase the energy efficiency of chemical processes and products themselves, they also affect the energy consumption of clients and suppliers and of society as a whole.

By 2020, Germany wants to double its energy efficiency compared to 1990 and in doing so use 20% less energy than in 2005, according to a major interim finding by the German Energy Summit held in October 2006. In economic terms, energy efficiency means the monetary value gained per energy unit. In 2005, Germany needed for its gross domestic product of 2,245.5 billion euros over 485 million tonnes of hard coal equivalent (HCE), in other words 4,622 € per t of HCE.

Energy Efficiency in the Chemical Industry

The figure for energy efficiency can be misleading. For example, BASF with its high energy consumption would then be clearly more inefficient than Deutsche Bank, although in fact the industrial compound network of BASF is a benchmark for high energy efficiency. Even within the chemical industry there are differences: basic chemicals account for around 80% of the energy consumption of German chemicals, other chemical processes just 20%, although in fact basic chemicals have optimised their energy consumption the most. In common parlance, the term energy efficiency is used in different ways. The general public associates it with a more intelligent use of energy, buying modern electrical appliances, an alternative lifestyle or switching to renewable forms of energy. The German Chancellor said in the Financial Times Deutschland in January 2007: "Basically it all comes down to the fact that the bottom line is energy efficiency, economical use of energy, good technology with high degrees of effectiveness and a balanced energy mix". So if research, the economy, consumers and politicians pool their ideas and concepts to produce smart projects, our national energy efficiency will increase, our competitiveness will be sharpened and our contribution to the conservation of resources and climate protection achieved.

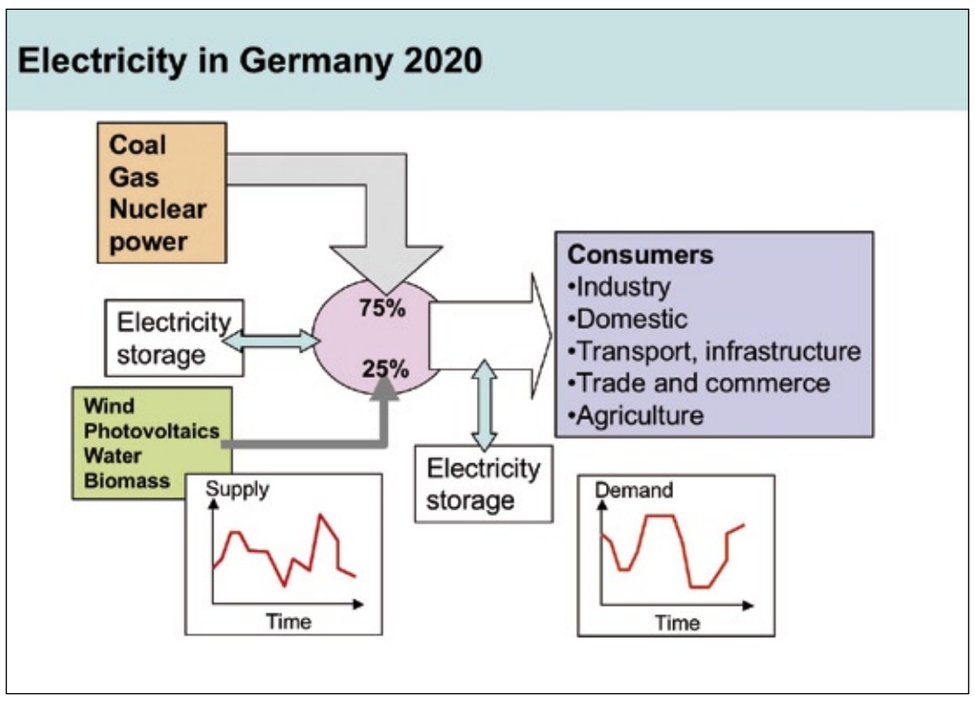
Contributions Towards Increasing Efficiency

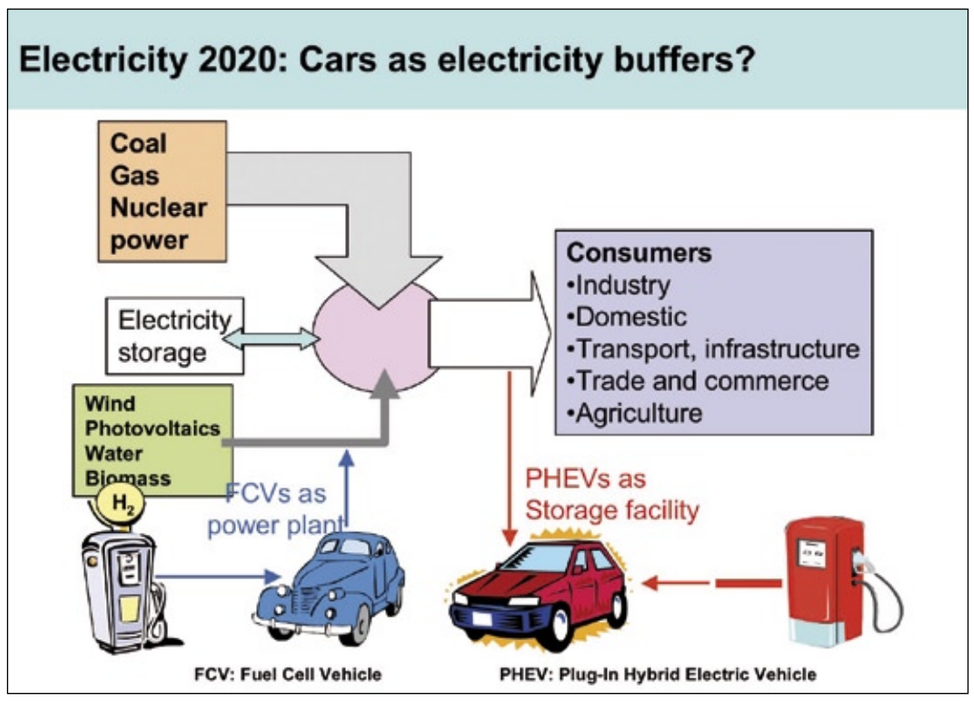
Chemicals contribute to energy efficiency in three areas: in chemical processes and products themselves, in the energy consumption of their customers and suppliers, and in the energy consumption of the public, and therefore society as a whole. Processes in the chemical industry are subject to ongoing energy-saving measures, but their contribution towards improving efficiency is limited for two reasons. Firstly, energy-intensive processes are already geared to making savings, and secondly the total energy requirement of the German chemicals industry just accounts for 5% of the national total energy consumption, but there are some surprises.

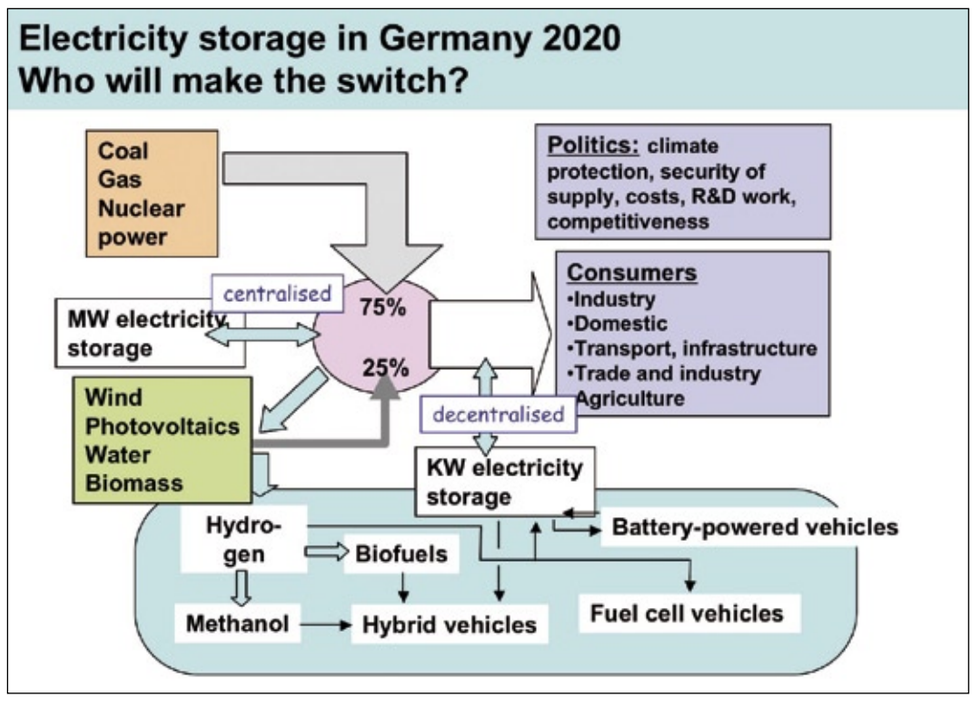
The potential for efficiency gains by chemistry is clearly greater for its beneficiaries – on the one hand the chemical industry's customers, such as the automotive industry, and on the other hand in sectors where chemical processes play a key role, i.e. in the glass, ceramics, paper or metal industries. This is a message the chemical industry needs to share and get the message across to their customers. Industry as a whole, excluding chemicals, accounts for 20% in Germany's total energy consumption. High efficiency deficits also occur in the public sector – transport, domestic, trade and commerce, and services – which use 75% of the total energy. As the main user of electricity and fuels, the public sector is also indirectly responsible for losses in the conversion of primary energy to useful energy. The chemical industry again could score here at the beginning and end of the energy chain, but haves problems communicating this fact.

Example 1: HCl electrolysis

One example for increasing energy efficiency in the chemical industry itself is HCl electrolysis which recycles chlorine, for example in the synthesis of isocyanates, producing chlorine and hydrogen from hydrochloric acid. Bayer is a leader in this technology which has an atom economy and energy efficiency that is hard to further increase. Furthermore, Bayer has had tremendous success in this field. 315 m^3 of hydrogen, some of which cannot be recycled, are produced per tonne of chlorine. The idea of converting the hydrogen into electricity in a fuel cell and feeding this current back to the cell was not implemented for technical and economic reasons. Bayer has therefore taken another radical step and converted the cathode in HCl electrolysis to a fuel cell. Instead of producing hydrogen first and then converting it in a separate plant with oxygen to electricity, oxygen is directly reduced on an oxygen consumption cathode which clearly reduces the energy required for the process. Even if the hydrogen deficit and the energy demand for supplying oxygen are taken into account, the saving should run to approximately 30% of the previous figure. The first industrial plant in Brunsbüttel is running successfully, Bayer Material Science is now planning a plant in Shanghai five times the size at 215,000 tonnes per year.







Example 3: Electricity Storage

Chemicals can also influence the energy efficiency of society as a whole. Regenerative energies, particularly wind and water power, already account for 11.8% of German electricity generation. If Germany achieves its ambitious goals by 2020, a quarter of its electricity will come from regenerative sources, but this will create a critical imbalance between electricity production and demand. Seasonal and daily variations in production cannot be synchronised with demand by current networks and storage capacities. There are already a large number of technically well-developed electricity storage facilities. The biggest German storage facility is the pumped storage power station in Goldisthal in Thuringia. Pumped storage power stations are important worldwide, but their potential for development is limited. Most other storage facilities are electrochemical, in other words accumulators or batteries. The most progressive power storage system in the megawatt range is the sodium-sulphur battery from the Japanese company NGK. There are a vast number of types of batteries for transport and consumer applications, from the kilowatt through to the milliwatt range. Our motor vehicle fleet has the largest storage capacity in Germany; with around 100,000 megawatts it outstrips Goldisthal by two decimals. Could this huge system composed of 45 million cars and several million other vehicles be connected up to a large power buffer? We don't have the answer yet, but there have been an increasingly frequent number of suggestions on this recently. A fuel cell vehicle with a full tank could supply its owner's house and those of his neighbours with power without any problem for a weekend (or a blackout). A hybrid car could be supplied with power from the socket and so save fuel. Both concepts stand or fall with the future efficiency chain of the national energy supply. In the USA, the vehicle to the grid (V2G) concept for plug-in hybrid electric vehicles (PHEVs) in the future only makes ecological sense if power generation is modernised, but these ideas are now being taken seriously. The critical factor is when these cars become active: At peak times they feed into the network, at times of surplus they supply their own needs. Apart from the power supply network, a functioning communication network is also needed. The term "virtual power station" has been coined for small suppliers and consumers joining together like this. Storing power in the form of hydrogen is the subject of the hydrogen economy. In future regenerative hydrogen should be available as a fuel as part of the hydrogen economy. Just a few years ago, the Freiberg company Choren put forward an attractive route for producing biofuels which would significantly increase the yield of biofuels using hydrogen. That this is plausible is shown by the stoichiometry and by the fact that hydrogen is not just a reagent here but is also an energy carrier. Whilst hydrogen resolves one storage problem as a biofuel, it in fact causes one itself in the hydrogen economy. A concept put forward by the Japanese RITE Institute at the Climate Conference in Kyoto uses regenerative hydrogen to hydrogenate carbon dioxide from power stations to methanol. The winner of the Nobel Prize in Chemistry, George Olah, propagates methanol for a "methanol economy". It is important not to develop technical solutions independently of politics. On the other hand, social and political demands cannot be fulfilled without technical expertise. The end user with his needs and financial preferences must be included from the start; only then tailor-made and efficient solutions are possible. Chemistry plays a part in the overall energy chain, from primary energy through to useful energy for the end user. To succeed here, chemists need the active cooperation of the media and the politicians and have to make their own role in the energy field more comprehensible and clearer than ever before.

Example 2: Metal Organic Frameworks

The way that chemicals can increase the energy efficiency of its customers can be shown by the new substance class of metal organic frameworks (MOFs). The possible structures of MOFs are very multifarious. An MOF consists of a metal node, for example M++ or M4O6+, and a linker, often an aromatic di- or tricarboxylic acid joining these nodes together. The nodes and linkers form a three-dimensional network with free inner volumes that can store the gases. Conventional synthesis is based on metal salts or oxides which react with the corresponding carboxylic acids in suitable solvents, often with auxiliary bases, under pressure and at higher temperatures. Low solubilities, long reaction times and processing problems mean that synthesis is often complicated. BASF has found a simple and multi-faceted route to MOFs – electrochemical synthesis using sacrificial anodes. A solution of the carboxylic acid is pumped through an electrolysis cell under current. The MOF immediately forms and can be separated. Since hydrogen is the only by-product produced, the solvent can be used again. With the new process, it is now possible to provide larger sample quantities to interested customers quickly and flexibly. The development of this process shows, for example, how chemistry is opening up a new field for their customers. MOFs are interesting media for the storage, separation or purification of gases. The storage of hydrogen and natural gas or the separation of CO_2 from biogas are good examples – all highly interesting topics in terms of energy efficiency.

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References available from the author.

Criterion For Equipment Service

Uniform Standard for all European Service Stations of Cotac Europe

Since January 2006 cotac Europe has been operating a pan-European network of tank cleaning facilities and service stations as an independent company. Pursuing a clear-cut expansion strategy cotac aims to increase the number of locations and to strengthen its leading position on the market as full service provider for the chemical, pharmaceutical, petroleum and food industries.

Based on standardised structures and new synergies all technical services in tank cleaning, workshops and depots are promoted in the European market under the brand name of cotac. As an independent provider cotac can operate on a more service-oriented level; all customers within the European cotac network will benefit from the same high quality standard and service as well as a uniform, transparent and attractive price structure.

The currently eight cotac stations in Belgium, Germany, France and the Netherlands as well as cooperations in several other countries (e.g. UK, Italy, Finland) are providing complex solutions focusing on cleaning, maintenance and repair of all kind of transport equipment. This includes road tankers, tank containers, rail tank wagons and Intermediate Bulk Containers (IBC), used for the transport of chemicals and additives, among others. And, of course, there are special cleaning bays for foodstuff equipment.

Inside cleaning will not only prevent the contamination of new loads by residues, but will also prevent the formation of germs and bacteria, or damage to the containers by corrosion. "When cleaning we have to adapt to a variety of materials – from high-grade steel to synthetics and special material, used for the lining of tanks, to avoid chemical reactions between equipment and cargo", Bernd Kolbe, Operational Director cotac europe, explained the demanding service.

Apart from cleaning cotac offers a broad range of additional services: workshops offer maintenance and repair or even modification for all international tank containers in use. Just recently Rotterdam handled a quite remarkable task, in shortening a large number of aluminium silo containers by ten feet to a length of 30 feet. "Our customers can benefit from one-stop-shopping for all types of services", Kolbe said. This includes the demanding automatic interior grinding of tank containers. Container storage is offered at all depots and – if required – heating by steam, hot water or electrically.

In line with the expansion strategy cotac is always exploring new possibilities to broaden the range of services. "A few months ago the Rotterdam station received the so-called STEK-permit, which allows the repair and maintenance of refrigerator units and reefer tanks". Maintenance and repair of gas containers is also feasible.

To provide an even closer meshed network of locations across Europe cotac aims to supply the service where it is needed, near the customers both from the transport companies and the producing industry.

Cooperation in the cotac network is subject to thorough checks of prospective partners with regard to meeting the requirements in service and operation as well as compliance with all quality and safety standards. "We are combining our full-service package with the most stringent safety and environmental standards", Kolbe points out, "and all our stations are audited in accordance with SQAS, the safety and quality assessment system".

All locations are equipped with sophisticated waste-water treatment; some stations even with vapour recovery facilities. The European Cleaning Document will be issued upon completion of each tank cleaning. In periodical trainings the cotac staff is brought up-to-date on all matters regarding safety, protective labour legislation and the day-to-day operation.

▶ www.cotac-group.com

New Intermodal Terminal in the Port of Rotterdam

August, 31. 2007 Bertschi inaugurated a new rail terminal in the Port of Rotterdam with intermodal connections to southern Germany and Italy. Additional links to Eastern Europe and other destinations will be incorporated later in the year. The new rail hub will play an important role in the pan-European intermodal network of Bertschi, a leading bulk logistics service provider for the European chemical industry. The new terminal will offer both local producers and the deep-sea market the opportunity for a broader modal shift, i.e. to switch more of their flows from the congested roads to rail and waterways. Further expansion of the current terminal handling capacity of 120.000 TEU's is planned in the near future.

▶ www.bertschi.com

CEVA Merger With EGL

CEVA Group announced the completion of its merger with EGL. As a result of this merger transaction, EGL is now a wholly owned indirect subsidiary of CEVA. CEVA, a leading global logistics company, is a UK public limited company owned by affiliates of Apollo. EGL's former shareholders are entitled to receive US-$ 47.50 in cash, without interest, for each share of EGL common stock they owned at the effective time of the merger. CEO Dave Kulik commented, "Our combined companies can offer customers a portfolio of world class supply chain management services globally, while maintaining our commitment to operational excellence and customer orientation." Joe Bento, President Global Freight Management said, "Both EGL and CEVA possess unique strengths in logistics and supply chain management and we are excited about leveraging these synergies to provide greater flexibility, enhanced service offerings and more powerful solutions for our customers."

▶ www.cevalogistics.com.

Partnership in Cold Chain Products

Continental Airlines Cargo, the first US airline to implement a structured cold chain product, has signed a new global contract with Envirotainer, setting the stage for expansion of its temperature-controlled product line. The new agreement will see the increased use of Envirotainer's active temperature-controlled air cargo containers for customers using Continental Airlines Cargo's ClimateSecure service. The airline says using these advanced ULD containers provides its customers with a "superior alternative to traditional cooling means such as foam, gel packs or insulating blankets, which add expense to shipments and waste space." ClimateSecure provides an unbroken door-to-door cool chain for up to 72 hours or longer when dry ice and batteries are replenished in transit. The service is designed for customers shipping high value and sensitive goods including pharmaceuticals, electronics, cosmetics, fine art and perishables. As part of its new agreement, the airline will also participate in Envirotainer's training program, which was developed in consultation with the pharmaceutical industry and aims to become a QEP-CEP accredited airline. Continental will commence with the formal technical training and accreditation program in Newark and Houston followed by locations in Western Europe.

▶ www.cocargo.com
▶ www.envirotainer.com

Global Security Forum with FFI Representative

Luc Clauwaert, in addition to his function as Group Security Manager for ABX Logistics Worldwide, has been appointed member of the Executive Committee of ACSIF (Air Cargo Security Industry Forum) to represent FFI. ACSIF is a new initiative created by IATA (International Air Transport Association) and AFI (Airfreight Institute of FIATA). ACSIF's aim is to harmonise security standards and improve efficiency and effectiveness in the regulation of air cargo security. The forum will develop and defend industry positions that protect the integrity of supply chain security while ensuring that cargo reaches its destination on time. FFI (Freight Forward International) is a grouping of seven leading global forwarders and logistics service providers: ABX Logistics, Kuehne + Nagel, Agility, DHL Logistics, Panalpina, Schenker and UTi.

▶ www.abxlogistics.com

STATEMENT

Key To Competitiveness

Chemical Industry: Supply Chain Collaboration is Useful

The Logistics Committee of EPCA (European Petrochemical Association) is a unique forum where representatives of chemical producers and logistics service providers meet to explore opportunities for improving the competitiveness of Europe's chemical industry, with a focus on optimising the supply chain.

Hans-Jörg Bertschi
Chairman of the EPCA Logistics Committee

Europe's chemical industry spends 8 to 10% of its turnover or up to 35% of its value-added on supply chain and logistics activities. As optimisations in the past have focussed on production, a significant potential still exists in the supply chain – not only for margin improvements, but also safety and environmental performance.

In their 2004 and 2005 reports, two EPCA Think Tanks concluded that there is a huge potential to be achieved through supply chain collaboration between producers, customers and logistics service providers. Recommendations were made to actively promote the results of the Think Tanks in the industry in order to change attitudes and perceptions, to alert stakeholders of business opportunities and to continue the Think Tank activities in specific areas.

The EPCA Logistics Committee proposed to study the supply chain collaboration in chemical clusters, using Tarragona and Antwerp/Rotterdam/Rhein-Ruhr (ARRR) as examples. During the first half of 2007, 53 senior representatives of chemical companies, logistics service providers, public authorities and institutions, as well as researchers from INSEAD, engaged in this study. The final results will be presented at the EPCA Annual Meeting in Berlin on October 2nd 2007.

The study concludes that information sharing and the set-up of an institutional platform of producers, service providers and authorities are the key to the competitiveness of a chemical cluster. Despite the various case studies provided in the report, the paradigm shift on collaboration has not taken place yet. A significant gap between words and facts still exists when it comes to collaboration.

The Think Tank recommends that producers develop long-term relationships with selected logistics providers, allowing them the possibility of fulfilling the collaborative role that producers expect from them. On the other hand, service providers will have to put greater emphasis on strategic questions and propose collaboration models more pro-actively.

Many of the current logistics shortcomings, e.g. the actual driver and transport capacity shortage in the chemical transport market are a result of the prevailing traditional confrontational relationships between shippers and service providers with frequent tenders, encouraging fragmentation. Other industry sectors like the automotive and consumer electronics sector have led the way, showing that collaboration and competition can effectively co-exist, to the benefit of all stakeholders.

Europe is still the largest and most sophisticated global market for chemical products. Leveraging supply chain opportunities through intensive collaboration will become crucial for the European chemical industry to defend its strong competitive position in the global economy.

Distribution Centre for European DIY Logistics

Following the completion of Europe's most modern lacquer factory in 2006, J.W. Ostendorf (JWO), as a further step in the unabated pan-corporate optimisation of its processes, has initiated a large-scale project aimed at centralising its European logistics at its main site in Coesfeld/Germany. A newly-engineered European centre which will provide more than 30,000m² for integrated DIY logistics following completion of the first building phase on a 100,000m²-large site, will be built in co-operation with Fiege by the beginning of 2008. The centre is a completely new logistics concept which allows the optimum supply of DIY markets with multiple consignment structures from several suppliers. JWO, the market leader for interior paints and lacquers in the DIY sector, sees this as the logical consequence of its long-standing strategy to secure its quality and services leadership for the entire supply chain in order to further expand its international competitiveness.

▶ www.fiege.com

Pharmaceuticals at the Right Temperature

Air Transportation of Pharmaceuticals Managed by Cargolux

Pharmaceutical products are manufactured in many industrial centres in Western Europe, the United States and Asia. Cargolux of Luxembourg transports the finished products to worldwide destinations. Such shipments include products of daily requirements, such as insulin, plasma, vaccines, and "emergency or seasonal products" such as antibiotics, and general medication.

Pharmaceuticals require temperature controlled transportation on ground and in the air and do not admit long transit times. Major international forwarders are involved in this transportation, as well as smaller, specialized forwarders.

Currently, Cargolux's pharmaceutical shipments are regularly generated by the company's stations in Belgium, Germany, Switzerland, and Denmark, plus ad-hoc shipments from France, Spain, Italy and the U.K.

Cargolux Brussels has mostly been involved in the transportation of human vaccines, destined for Asia, Australia, New Zealand and the U.S., plus some ad-hoc shipments to South America. In order to offer a better service to their clients, the vaccines are directly picked up at the client's plant, guaranteeing perfect temperature control.

Furthermore, regular insulin shipments from Denmark for South America and Lebanon have been carried out. Switzerland is the traditional market for pharmaceutical and chemical products with a worldwide distribution platform, fully supporting the Cargolux service. The latest developments on this sector include regular shipments from Frankfurt, on behalf of important pharma companies with impressive overall yearly volumes.

Major forwarding companies are taking care of these shipments on behalf of Cargolux, offering increasing experience for this type of cargo. The company has been well established in the pharmaceutical community, with more and more pharmaceutical companies shifting their business to Cargolux, offering better services compared to traditional transportation schemes.

Approx. three hours prior to departure to Luxembourg, the thermo-trucks are pre-cooled to the required temperature. Upon arrival in Luxembourg, the precious shipment is stored at the same temperature during their short transit time in Luxembourg, then loaded o/b Cargolux's B747-400 freighters by expert load controllers and flown at the required temperature, to the final destination.

The unbroken cool chain is assured as all cool trucks bring the pharmaceuticals directly to Luxair's Cargo Center in Luxembourg, with all processes being streamlined. In case of any discrepancy during storage or transportation, forwarders and shippers are informed pro-actively.

Currently, those shipments are mostly destined for the United States and Australia. Upon arrival at their final destination, shipments are immediately dispatched on refrigerated trucks and forwarded to the consignee. At selected airports, complete ULD's can be picked up at the aircraft and immediately stored in the cool truck.

In order to provide the required space for those shipments and to prepare the thermo trucks in line with the client's request, the forwarders communicate their space and service requirements in time. Confirmation of the booking has to follow within 96 hours prior to shipping, and instructions to Cargolux have to be clear and precise.

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Plastics Rather Than Wood

Pharmaceutical Logistics Chain Prescribes Plastic Pallets

More and more pharmaceutical and cosmetic companies are choosing plastic pallets for their logistics chain. Plastic pallets are increasingly being used to handle, store and distribute pharmaceutical and over-the-counter products. One reason may be the FDA's increasing emphasis on ensuring that the efficacy and safety of drugs and cosmetics is maintained throughout manufacturing and distribution.

Re-useable plastic pallets offer a high-quality and an economic solution, providing the industries with a safe, stable, and long-lasting method of moving products through process areas that would normally exclude the use of wood pallets.

Advantages Of Plastic Pallets

Plastic pallets provide an option with many advantages over wood. They weigh up to 40% less than equivalent wooden pallets, but are more durable. Their material and structure is more resistant to damage from handling equipment such as fork trucks and they have no splinters or nails that can cause potential quality and contamination issues.

Wooden pallets can absorb moisture, which could cause tainting or contamination of packed products or lead to inconsistent tare weights. Plastic pallets are non-absorbent, so they are much more hygienic and less subject to contamination. Plastic pallets can be sterilized in a fully automated washing and drying system or with solvents, steam cleaning or high pressure washing up to 120 °C, making them ideally suited for clean room applications in the food and pharmaceutical industry.

RFID systems embedded in a plastic pallet can be used to maintain and transmit data of the products that it is carrying, as well as to track the pallet. This further helps to comply with the FDA standards.

Effective Logistics Solution: Craemer Pallets

By developing the world's first "one shot" molded plastic pallet in 1967 Craemer has 40 years of experience in manufacturing plastic pallets. Since then, the company has continued to provide quality pallet solutions based on the highest hygienic standards and latest innovative technology.

A comprehensive range of plastic pallets is offered: e.g. the Hygienic Pallet with an excellent load capacity, durability, runner stability, resistance to temperature changes, and easy cleaning and handling. The CR pallet provides a unique anti-slip top deck, the latest RFID technology, and high load capacity through integrated metal profiles. Craemer's hygiene and conductive pallets have proven themselves for applications where maximum hygiene and safety is necessary and wherever protection against static charges is required. Both pallet types meet the highest demands of the international pharmaceutical and food industries.

Quality Design Ensures Long Life

Craemer re-usable pallets far exceed the life span of wooden pallets and many competing plastic pallets now available on the market. This is a result of their design and the use of only pure, high quality plastics.

A recent study by the Fraunhofer Institute (Institute of Material Flow and Logistics) examined the mechanical properties of a number of Craemer EURO H1 food quality plastic pallets, which had been manufactured in 1995 and in service for several years. Following the German DIN 55423-6 standard, the pallets had to go through the following test procedures:

- To evaluate loading deflection responses during rack storage
- Corner-fall tests carried out on EURO H1 plastic pallets that had been stored at temperatures of –25 °C and +40 °C, to determine any fall damages.
- Horizontal impact tests simulating transportation and the effects of braking on pallet loads of 850kg distributed over 28 FLC units.
- A continuous roller conveyor test with pallet loads of 850kg mass with FLC to look at the effects on the runners and pallet feet.

The results proved that Craemer plastic pallets are extremely robust. The pallets had no signs of structural weakness or material changes, even after long use. The Fraunhofer Institute confirmed a service duration for the Craemer EURO H1 pallet of at least 12 years, which should provide the basis for future investment calculations. (Details of the document "Longlife pallet: Study of the Fraunhofer Institute with the EURO H1" can be supplied on request.)

Pharmaceutical Supply Chain and RFID Technology

The pharmaceutical industry operates one of the world's most complex supply chains and is faced with a rising tide of drug counterfeits. Therefore, companies are turning to technology such as RFID to track products and shipments more effectively throughout their global supply chains. Craemer CR1 returnable plastic pallets are equipped with a transponder that enables pallets to interface with RFID in a complete turnkey system to provide full management information.

Alexander Korell, Craemer's Export Area Manager, reported, "Craemer was one of the first to manufacture pallets equipped with RFID transponders. Based on our long-term experience with RFID, the company has become a partner of the pharmaceutical and e-supply chain and has worked closely to improve inventory and transport management for many companies. Craemer has successfully supplied high-quality pallets to international companies such as GlaxoSmithKline and Wyeth Pharmaceuticals."

Today, Craemer is one of the leading European manufacturers and a full service provider of a diverse product range for storage and transport. Craemer offers extensive and customized services. The company has played a pioneering role in developing innovative solutions for many years.

Many companies have taken the time to consider the benefits of plastic pallets and are now convinced of the cost efficiency of multi-trip logistics solutions using returnable plastic pallets.

▶ www.craemer.com

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Supply Chain Champions

Setting Standards for the Industry

Size does not mean class. Only every fifth consumer goods producer manages to master its supply chain, most show major performance deficits. The virtues that make a champion are clear from four criteria: logistics costs, inventory of finished goods, level of service and delivery time. The champions are not only better than the industry average in these four areas, they also set standards for the industry. This is the outcome of a research project jointly conducted by Prof. Thonemann of the University of Cologne and McKinsey & Company. The scientists and management consultants studied the supply chain management of 40 of the 74 largest German consumer goods producers with a predominantly fast-moving product range.

Prof. Ulrich Thonemann

The differences in supply chain management performance are staggering. Only seven out of 40 producers have a supply chain that earns an "efficient" rating; the other 33 producers partly show some significant performance deficits. An example of the differences: The service level on the position level ranges from very good 99.9% to 90.5% of the order positions – fluctuation between permanent availability and acute bottlenecks. The best five producers report an average service level of 99.8%, whereas the average is 97.5%. Any outliers at the low end would make themselves even more apparent for smaller companies or critical categories (such as in the fresh goods sector).

A similar picture emerges when examining three further objective performance dimensions: The inventory coverage of the best companies is 6.5 days compared with 30.6 days on average. The logistics costs (transport and storage) of the top runners is 3.2%, whereas it is 5.0% on average. And the average delivery time of 3.5 days is only 1.7 days for the best companies.

Low Cost and Top Service

The detailed evaluation of the results brings something surprising to light: Companies that do well in terms of performance indices in the service dimension (service level, delivery time) do not necessarily pay for this with high costs (inventory, logistics costs). Low costs and the top service are not mutually exclusive – the widely claimed trade-off between service and costs is not empirically verifiable. It is more the case that the two factors possibly supplement and reinforce each other. Because seven supply chain champions have a service logistics and inventory costs combined. But production is under pressure in many companies and frequently has to fill in at short notice to maintain a low level of inventory and avoid bottlenecks.

Supply chain champions therefore take two steps in reforming their production processes. Firstly, production is designed to be more flexible, through changes in infrastructure or optimising lines, for instance. Once these measures are exhausted, the remaining rigidity has to be intelligently managed. Here it is necessary to integrate production in rule-based planning processes designed to ensure a certain level of planning security for production.

Integrated Supply Chain Organisation

The bundling of responsibility for the supply chain is the cornerstone of efficient supply chain management. The clearer the responsibility and the fewer different departments there are in planning and control of the value creation chain, the lower the frictional losses and therefore the more efficient the supply chain will be.

Empirical evaluation also shows that the responsibility for the supply chain should not be focussed on sales. Bundling of the planning processes in an independent supply chain or logistics department is ideal. In one of the companies studied, the logistics area has wide-ranging competences extending from order acceptance, to planning demand and production, through to scheduling. The neutral status of logistics can go a long way to deescalating conflicts in the company. At the same time, the broad range of tasks of the department ensures that an extensive information base is available for planning.

Supply Chain Cooperation

The close working relationship between the producer and its dealers is an important aspect of supply chain management. Best practice is characterised by logistics providers and other operative supply chain players, such as sales planners and IT specialists, being in direct contact with the dealers. If, for example, the sales planners have direct access to information on promotions planned by their most important customers, planning accuracy can be raised significantly as a result.

Several cooperation projects, e.g. Collaborative Planning, Forecasting, and Replenishment (CPFR), institutionalise the cooperation on a more strategic level. Nevertheless, not every cooperation project is profitable. Supply chain champions precisely post calculate cooperation projects of a high investment volume on implementation in particular and ensure that they achieve the anticipated advantages.

Flexible Production

Supply chain champions understand the special importance of production and material costs for the supply chain. Efficient production can often contribute more to improving return than reducing inventory or optimising logistics, because the proportion of production costs in the overall supply chain costs is generally three or four times higher than the proportion of

Segmentation Strategy

The vast number of different customers and products with diverse requirements and the resulting complexity can represent an obstacle on the way to achieving an efficient supply chain. Supply chain champions therefore strive to reduce this complexity and pursue the value contribution of additional product variants on the basis of article and customer-oriented cost attribution.

The method of separately optimising supply chain segments and adapting processes for specific segments also hold great potential. For especially demanding customer groups or important products, a higher than average level of service can be aimed for. Ideally, differentiation begins with the very design of the processes: High volume money-spinner products, for example, can be planned with a higher frequency than marginal product ranges.

Supply Chain Planning

Good planning quality calls for individual, separate planning processes; these are frequently lacking. Sales planning has to deliver the most realistic prognoses possible and must therefore be independent of the company's financial planning. Supply chain champions also set out clear rules and binding agreements for dealing with unforeseeable events, such as unplanned promotional quantities. This helps improve the acceptance of the planning processes.

Supply Chain Controlling

Supply chain champions establish a system of indices with company-wide unified KPIs (Key Performance Indicators). These indices, each of which can be broken down to the customer/product level, include the service level, planning accuracy and the reliability of the delivering products, as examples. The indices also encompass the trading partners, e.g. through systematic logging of shelf availability.

The considerable differences in performance and their causes and effects show one thing above all: Differentiation by means of the supply chain is possible – consistent exploitation of the performance reserves offers major opportunities for consumer goods producers. These lie in internal processes, on the one hand, and in the interfaces with trade on the other. Their utilisation is becoming increasingly important. But caution is due: Many companies are lacking a solid basis for these mutually profitable cooperative arrangements. These companies, that we call followers, should firstly concentrate on internal optimisation. Only then is it possible to build up advantages by means of a supply chain and to develop new cooperation models – this is where the champions reign.

The following applies for champions and followers alike: The analysis of one's own supply chain is the first priority. Benchmarks help here, as well as best practice examples. The analysis gives rise to the individual main fields of action for the respective company. Why do the deficits lie? What are the priorities? Everyone needs to be active. No company can afford to rest on its laurels – today's champion can be tomorrow's follower. The supply chain is as dynamic as the product range of the company studied.

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Keep Cool

Challenges and Solutions for the Micro-distribution of Temperature Sensitive Healthcare Products

The simple fact is "pharmaceutical products need to be stored and transported in a way that their integrity is not impaired". This is one of the key messages for healthcare companies, when distributing their temperature sensitive products. But what does this mean?

Andreas Olpeter, Manager Sales & Business Development, AS Healthcare

In the past, legal requirements such as 21 CFR in the United States, EU directive 2001/83/EC or the EU guideline 94/C63/03 on "Good Distribution Practices" unfortunately did not provide further references or detailed guidelines as to how this should be secured.

Therefore, in recent years, various industry-internal discussion groups (e.g. PCCDG – Pharmaceutical Cold Chain Discussion Group in the U.S.A., C3 – Cold Chain Committee in Europe or the Pharmaceutical Logistics Forum – PLF in Europe) evaluated these requirements and developed standards and guidelines, covering topics like

- Global distribution practices for temperature sensitive products
- Transport packaging for such products
- Temperature monitoring
- Qualification of shipping containers

This, combined with more detailed information now provided with USP [1079] resulted in a common approach, harmonised documentation and reference standards in order to fulfil the requirements.

The Impact

Whilst a lot of solutions have been developed for the worldwide distribution of temperature sensitive products up until now, the main focus is on the transportation of products in larger quantities, e.g. pallets from one manufacturing plant to another or – once finished products are ready for sale – from the manufacturing site to a distribution centre (DC). These centres serve as a platform for the fulfilment of customer orders (hospitals, laboratories, pharmacies or wholesalers), whether this is done on a national (one country), regional (multiple countries) or even central (e.g. European) basis.

I would like to call the above mentioned distribution of larger volumes as "macro-distribution" and the distribution of smaller volumes to end-customers as "micro-distribution". When looking at various models of micro-distribution, one has to distinguish two basic process streams:

- 1. Product flow from manufacturing site to a DC and process flows within the DC
- 2. Product flows from the DC to the customers

The transportation of products to a DC (= replenishment of stocks) and activities within the DC are processes typically under the direct control of the healthcare company itself (or – if outsourced to a third party logistics provider, 3PL) under indirect control of the product owner.

In most cases neither the healthcare company nor the logistics partner perform the "final" transportation of the products to the individual customers themselves, but make usage of specialized carriers. Their networks enable customer orders to arrive in time, may it be within 24 or 48 hours, or even – for urgent shipments – within a couple of hours.

Transport of finished products to a DC are usually in bulk shipments (multiple pallets per shipment, by air, sea, truck or even by railway, or any kind of combination thereof), in order to keep transportation costs low. Logistics solutions and systems have been developed for temperature sensitive products; these enable a constant maintenance of temperature ranges during transport. The products/pallets typically remain in a closed environment (e.g. sea freight container, air freight container or truck) during the whole transportation time.

This transport mode is one-dimensional – from point A to point B. The harmonisation of requirements for this kind of bulk shipment and the existing solutions (availability of suitable trucks or containers and temperature monitoring devices) helps the industry and its service providers manage to keep this process well under control.

Looking at the processes within a DC, however, incoming shipments are "fragmented" – i.e. products are removed from their "closed" environment. Pallets are broken down to cartons, and cartons to single packs. This results in a constant and increasing complexity.

In addition, there are internal product movements between different areas (from goods receipt to high rack storage, to replenishment storage, to picking area and goods dispatch), before the products are finally handed over to a carrier for final transportation to a customer.

Whilst high rack storages and replenishment storages are normally cooled to the product requirements (e.g. +2 °C – +8 °C), other areas might only be kept at room temperature (+15 °C – +25 °C). Therefore, in order to "maintain the quality and integrity of products at all times", companies must ensure that cool products are only outside of their designated temperature range for a limited period of time, as per specification.

For certain products the cool chain may not be interrupted at any point, meaning all DC areas must be set-up accordingly. This is of course an ideal situation – but not an industry standard, as it would be very cost intensive.

During quality audits questions like "how long do you need for the picking/packing process" are often answered with "it does not take very long" or "normally the product is back to a cool environment within 30 minutes". We all know that this statement leads to further questions, often resulting in corresponding findings.

In order to ensure the product quality at all times, AS healthcare has developed unique IT solutions for these "in-DC" processes. Either all processes are performed in a temperature controlled environment, or – as per specification – the limited time for a product allowed outside of a cool environment is constantly tracked and monitored. Every internal movement is captured using a barcode scanner system, each scan generates a time stamp in the WMS system. Thus every movement of a temperature sensitive product outside of its designated environment is logged. Whenever this product is brought back to its original temperature environment, this scan will determine the total time spent outside of e.g. 2 – 8°C. If during these processes a pre-set time limit is reached, then an automatic warning is generated in order to either perform the transaction within the remaining time, or if not possible to cancel this transaction and bring the product back to its original location. If the time limit is exceeded, this individual item will automatically be placed into quarantine – deviations are generated accordingly.

By following this process design and combining this data with a central temperature monitoring system, one is able to identify where this product has been, at what time, for how long and at what temperature during its journey through the DC. Of course, this data is archived and readily available, if required at a later stage.

But what now? How to ensure the final process in micro-distribution, the transportation of a customer order to the final recipient, is performed according to these guidelines? Two main options are available: actively cooled distribution or passively cooled distribution (in insulated boxes).

When looking at the basic systematic of carriers' networks for a next-day delivery of such shipments, regardless of what option is preferred, the scenario shown in fig. 2 may apply (for example).

In addition to the increased complexity during the "in-DC" processes, another challenge arises: how to ensure the quality and integrity of temperature sensitive products when several hundred or thousand different parcels are shipped to customers like this every day.

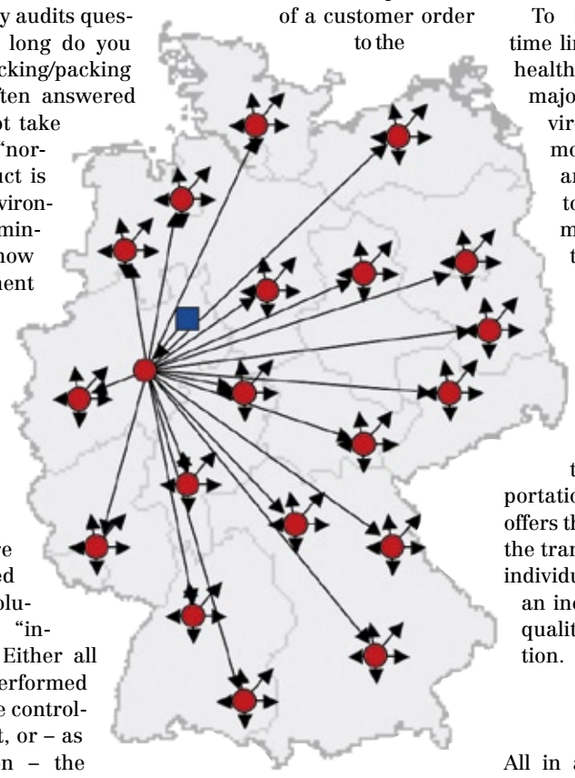
Of course, this can no longer be compared to the "one-dimensional" transportation of "bulk shipments" and solved with the same solution. The use of temperature loggers for example, whether electronic or chemical, is not feasible, both for cost and performance reasons. Such data loggers only provide post-event information, when the product has been handed over to the customer.

In order to keep the products in the required temperature environment during this fine transportation, more use is being made of actively cooled transport solutions offering a good alternative for polystyrene cool boxes. Unfortunately, these solutions are restricted to national or limited regional areas – there is not yet a pan-European solution for instance. But regardless of which distribution model is chosen (either actively cooled or passively cooled): it is up to the product owner to ensure the product integrity at all times.

In order to fulfil this requirement it has become an industry standard to perform so called "type qualifications" or "black-box qualifications" in this respect. For actively cooled distribution, whereby the product is transported in cool trucks only and the corresponding carrier's HUB's and depots are also cooled, this results in a series of test shipments. Should these test shipments deliver positive results, the assumption is made that the delivery process is suitable (in addition to regular audits). However, this is not a 100 % guarantee for all parcels distributed this way. It will always be just a glimpse at the tip of the iceberg.

With regard to passively cooled distribution, the corresponding cool-box is validated using different configurations (e.g. summer/winter) setting the time limit during which the required temperature can be maintained (e.g. 48 hours). Delivery must now be made within this time window.

To make sure that this time limit is not exceeded, AS healthcare has integrated all major carriers into its IT environment. As a result the movements of all parcels are tracked and monitored. An IT-based event manager delivers real time information about any disruption of the transportation process, enabling immediate corrective actions. Of course, this shipment model has certain disadvantages compared to actively cooled transportation. On the other hand, it offers the opportunity to control the transportation time of each individual parcel, resulting in an increased robustness and quality of the micro-distribution.



Conclusion

All in all, the micro-distribution of temperature sensitive healthcare products is not easy to manage, but it is not impossible.

Being a leading provider of outsourced SCM in Europe, AS healthcare offers tailor-made solutions for the healthcare industry. The portfolio of services comprises customer call centres, warehousing and transport management, IT solutions as well as financial services. Validated processes for the warehousing and distribution of sensitive products, value-added services (e.g. licensed manufacture in view of repackaging and labelling), the logistics of clinical trials and promotional material are also available, in order to support our customers' business.

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Figure 1

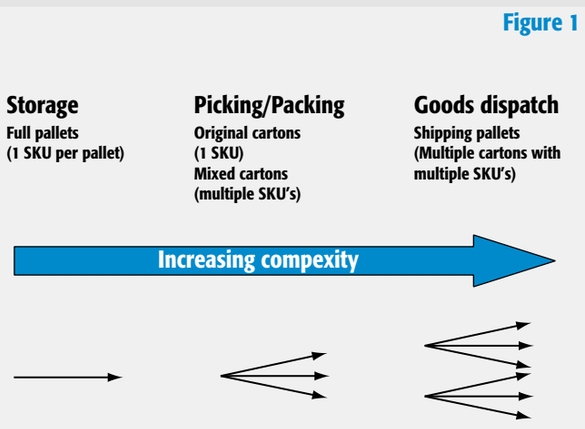

Fig. 1: Micro-distribution: typical process flow within a DC

Figure 2

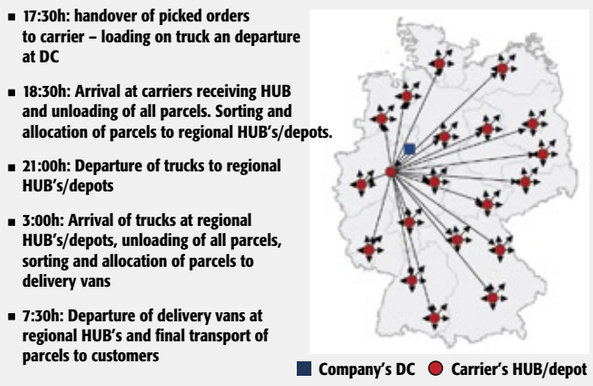

Fig. 2: Basic systematic of carriers' networks for a next-day delivery (example)

Production
FACILITIES · PROCESSES · TECHNOLOGIES

Dueling Technologies

The False Debate

The enthusiasm for radar and new technologies has led some to predict ultrasonic level measurement may be in decline. Not so, says Dave Bignell, President and CEO of Siemens Milltronics Process Instruments Inc., who points out that ultrasonic technology is still showing on-going market growth because of its inherent advantages. CHEManager Europe went into more detail with Dave Bignell.

Dave Bignell
President and CEO of Siemens Milltronic Process Instruments Inc.

Some people say ultrasonic is aging technology, and will be surpassed by radar. What do you say?

The overall ultrasonic market is still growing at about 3% a year according to industry research groups. Siemens Milltronics is already the market leader in ultrasonic level, and our ultrasonic product sales grew 4 % last year, even though there are more suppliers and this market is more competitive than ever before. Of course, radar sales are also growing and, because it is a new technology, our radar sales are growing at an even faster rate than the more established technologies. Frankly, I think this duel between technologies is a false debate that does not serve customers well. Unfortunately, suppliers with only one technology may promote a message that their solution can do everything, but this eventually creates problems when technologies are misapplied. The truth is that no single technology is right for every application. They all have their strengths and applications. That is why, some years ago, we broadened our level measurement line to include radar, capacitance, and electro-mechanical. Siemens also offers pressure transmitters and other technologies. All of these have their uses. It is important to look at the application first, then recommend the best solution for the customer.

Why does ultrasonic technology remain so popular?

Ultrasonic technology remains popular because it has a number of practical advantages. In a great number of applications, it equals any technology in accuracy and reliability and is generally less expensive. That is why it continues to represent about two-thirds of the non-contacting level market.

What are the advantages of ultrasonic technology?

Ultrasonic is a well proven technology with an excellent track record. It is non-contacting and requires very little maintenance. It is virtually self-cleaning because of the vibration of the transducer face. Ultrasonic is a very cost-effective technology, generally lower in price than radar. Furthermore, you can multiplex; for example, you can connect up to 10 transducers to one ultrasonic controller, and this really drops the price per measurement point.

A big advantage of ultrasonic technology is the ability to mount the controller/display panel remotely from the sensor, which is very useful in certain applications such as on a primary crusher, in a wet well, or in harsh chemical environments. Radar's high operating frequency cannot be well contained in long cable runs, and the electronics must usually be located within 10 feet of the antenna. On the other hand, an ultrasonic controller can be located 1,000 feet or more from the transducer. These practical considerations are important; for example, mounting a radar transmitter in a sump or wet well would be unnecessarily difficult when an ultrasonic system will perform the task and is easily installed.

Remote mounted electronics also make sense for pump control and alarm relays. While some end users connect to a PLC, many more rely on the ultrasonic device. For this reason, we have sophisticated pump control and rotation routines built into many of our ultrasonic controllers.

Dave Bignell, President and CEO of Siemens Milltronics Process Instruments Inc., presenting the product portfolio of ultrasonic level technology

Will popularity of ultrasonic decrease as the cost of radar decreases?

The cost of radar technology is gradually going down, and this will encourage plants to consider radar when there are applications involving vapors, vacuum, or heavy dust. These are applications radar does very well and where ultrasonic is not the best choice. Even so, I believe ultrasonic will continue to be the technology of choice for its proven applications.

Is radar a technology fad?

I know technical people can sometimes fall in love with the latest technology. When radar level measurement first appeared, many people jumped on the bandwagon. They wanted to install radar everywhere, including applications that were not appropriate or even where radar was more expensive. Ironically, when ultrasonic was first introduced, some people were so keen to use it everywhere that it was sometimes misapplied as well.

Sometimes vendors with only a single technology to offer may sell their solution into marginal applications. This ultimately hurts acceptance of that technology in any application. Instrument suppliers have done an excellent job promoting the newest technologies, and some people became convinced radar is a do-all product. Unfortunately, the result is that service technicians are now troubleshooting applications where radar was installed when, in fact, ultrasonic or a different technology would have been the better fit.

Like every technology, radar has its strengths and its limitations. As people discover the limitations and as some of the hype subsides, they focus on the real question which is choosing the best technology for the job.

How has the emergence of new technologies affected ultrasonic sales?

At one time, ultrasonic was the only non-contacting technology available, so it was sometimes misapplied. In instances where it hasn't worked well such as the extreme dust of a cement silo or on tanks storing volatile chemicals, customers now have other options like radar and TDR. I think it is a good thing for customers to have choices. Different technologies serve different needs in a process plant, and we should always choose the one that serves the application best. For this reason, the Siemens portfolio offers multiple technologies for our customers.

Is ultrasonic technology only for the water and wastewater industries?

Ultrasonic has somehow become labeled a water product, and this may be partly our own fault for first promoting it with such great success in the water industry. The water industry values ultrasonic because it is adaptable to most applications found in water plants. Water plants also tend to be cost-conscious and ultrasonic performs well and costs less than radar or other technologies.

The chemical industry generally tends to think of radar first because radar is usually the best choice for hydrocarbons with vapors and pressure extremes. The knowledgeable technician, however, knows that ultrasonic technology is effective on chemicals such as sulphuric acid, caustic soda, phosphoric acid and oils because the vapors from these materials do not seriously affect the speed of sound. Our customers in the mining, aggregate and cement industries also use ultrasonic technology widely for many level applications such as flotation tanks, crushers, stockpiles, and storage silos.

What makes ultrasonic technology so versatile?

The heart of an ultrasonic system is the sensor or transducer. Good suppliers offer a wide range of transducer models so you can select the one with the right range, beam angle, sensor facing material, and other characteristics for the particular application. If required, you can select a sensor that will withstand low or high temperatures, or one that has housing or facing compatible with harsh chemicals. This ability to combine a controller with many different transducers makes ultrasonic technology very versatile.

Fig. 1: The Sitrans Probe LU is a 2-wire loop powered ultrasonic transmitter for level, volume and flow monitoring of liquids in open channels, storage vessels and simple process vessels

Fig. 2: The MultiRanger is a versatile short to medium-range ultrasonic single and multi-vessel level monitor/controller for virtually any application in a wide range of industries

When should I use ultrasonic and when should I use radar?

It all depends on the details of the application – the vessel characteristics, the material being measured, the process connections, chemical compatibility, power requirements, and measurement environment. As general rule of thumb, ultrasonic is a great solution for water applications, most liquids, and medium-range solids storage silos.

We generally recommend radar for long-range measurement on high storage silos, extremely dusty applications, and applications involving continuous feeding and extraction such as lime or activated carbon. Volatile chemicals with vapors above the liquid surface, or applications with extreme temperatures or pressure are also best suited to radar, or may require capacitance technology for interface measurement.

What are the key customer demands for ultrasonic level technology today?

Customers are looking for new features, primarily advanced echo processing, diagnostics, and networking capabilities such as Profibus.

Cost is important, but it is more than just the initial cost of the product. Because staff and maintenance time is precious in process plants, customers want instruments that are simple to install, set up, and swap. They want accurate, reliable products that are low maintenance. They want products they can "fit and forget." Many plants have reduced their staff, and rely more and more on vendors or contract installers for pre-and post-sales advice and support. All these elements are part of the overall cost of ownership. Most customers today prefer to deal with a large, established supplier like Siemens that offers a big product portfolio and can meet the full range of instrumentation needs.

How is ultrasonic technology changing to meet today's customer needs?

Ultrasonic technology continues to evolve. Today's ultrasonic devices have enhanced hardware and advanced echo-processing software with greater accuracy and more capabilities than ever before. Comparing early ultrasonic technology with what we have today is a lot like comparing 1960s AM radio to today's satellite radio. Ultrasonic is an established technology, but we continue to invest in refinements that bring real benefits to customers. With the launch of our new Sitrans Probe LU transmitter in 2004, for example, we further enhanced what was already the best echo-processing software in the market. It is a low cost 2-wire, easy-to-use transmitter that offers high accuracy and virtual plug-and-play installation, as well as Profibus and Hart for easy integration. The Sitrans Probe LU and also our MultiRanger and HydroRanger controllers are examples of advanced ultrasonic solutions for a wide range of applications.

What is the future of ultrasonic level technology?

Ultrasonics will continue to be a valuable, growing technology in the marketplace. It meets customer needs for proven, easy-to-use, low maintenance level measurement at a reasonable cost. Its continued success will depend on our ability to meet change customer needs for increased energy savings, simple operations, and networking capabilities.

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Maintenance Strategies for pH Systems

Merck to Use New pH Technology

The memosens sensor technology introduced by Endress+Hauser in 2004 has proven its worth in the tough day-to-day industry environment. These digital systems not only increase process safety but also reduce costs since they are cheaper to maintain than equivalent analog measuring points. An integral part of this strategy is central calibration in the labs of the measurement and control workshops where the sensors are regenerated and calibrated under ideal conditions. This approach is particularly worthwhile for process analysis parameters such as pH measurement as they have to be calibrated and adjusted frequently.

Fig. 1: Central calibration at Merck

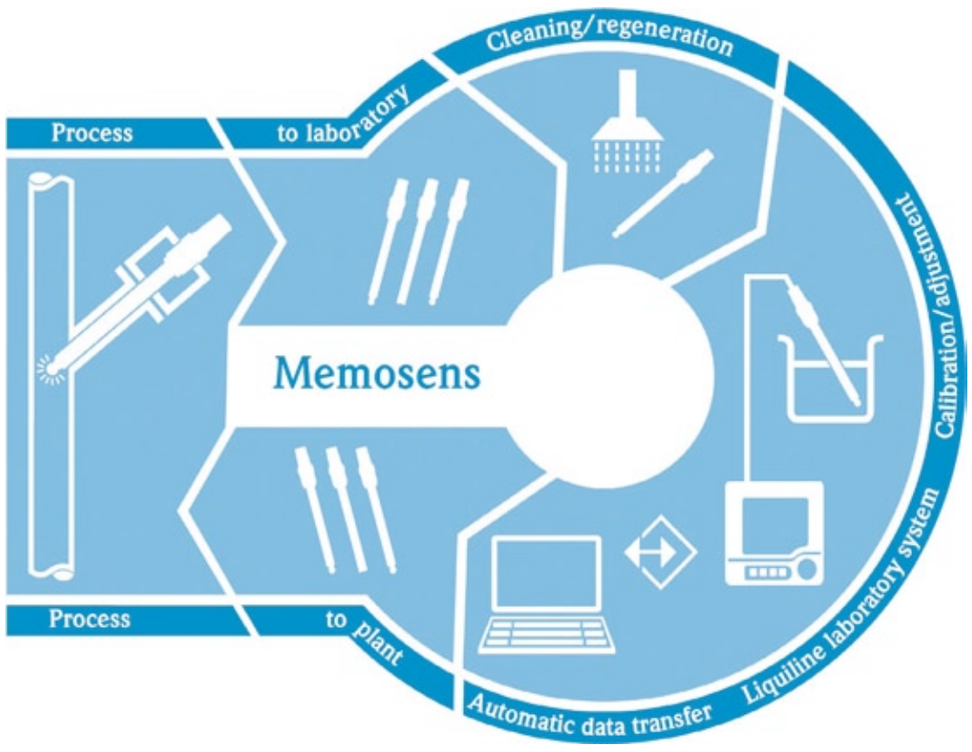

Fig. 2: Life cycle of Memosens sensors

Fig. 3: Memosens plug-in-head with Memoclip

At its center in Gernsheim, Germany, Merck KGaA switched its pH measuring points in the chemical production section over to memosens sensor technology more than a year ago. Here, chemicals are produced in batch processes at temperatures between 75 and 85°C. The pH value is usually in the very acidic range but can go as far as the alkaline range at times. Since the pH value is very relevant to the quality of the process, it is measured redundantly with an Orbipore electrode CPS91D with memosens technology in conjunction with a 2-channel Mycom S CPM153 with a digital sensor input. The measuring system is integrated into the process control system by means of the Profibus output in Mycom.

The harsh process conditions take a considerable toll on the sensors used. Both the pH and temperature ranges of the process, and the medium itself, make tough demands in terms of sensor performance and robustness. The medium attacks the leached layer of the pH-sensitive glass, with the glass becoming „unclear and dull“ as a result. This reduces the sensitivity of the sensor and thus the quality of the pH measurement. The leached layer can be brought back to an optimum state by regenerating the sensors regularly which, in turn, extends the operating life of the electrodes.

The advantages of sensor technology come to the fore particularly in such harsh process conditions. Inductive data transmission eliminates the difficulties of analog pH measurement, such as moisture, salt bridges, potential overlay or EMC interference. Mr. Werske, measurement and control specialist at the Gernsheim plant, cites another advantage that was a decisive factor in making Merck switch to the new sensor technology: „Being able to simply replace the sensors on site and then service them centrally in the lab under ideal conditions gives us such quality and cost advantages that more than justify the costs for upgrading.“

Within the context of the innovative calibration and maintenance strategy, Merck is focussing on predictive maintenance as the operating staff simply replaces the sensors on site with calibrated sensors at regular intervals. The measurement and control specialists then maintain the replaced sensors in the company‘s measurement and control workshop by:

- Qualifying the condition of the sensor
- Cleaning and regenerating if necessary
- Calibrating/adjusting

The sensor is then ready for operation again afterwards, is brought back to the plant and used in the process.

How does predictive maintenance affect the operating life of the sensors? Manfred Walter, also a measurement and control expert at Merck in Gernsheim, and responsible for pH measurement, finds that „the operating life of the sensors has been extended by about 30 %. Some sensors were even in operation for 6 months – the analog sensors deployed previously never achieved such a long service life.“ To quantify this subjective observation, the measurement and control specialists kept statistics on all the data saved in the sensor. The data were read out at the transmitter and added to the statistics by hand. This process was time-consuming, susceptible to error and thus resulted in high costs.

End-to-End Documentation

For this reason, Merck is now using the new intelligent data management system. The data management software is based on a server-enabled database and, in conjunction with the laboratory measuring system, is an essential part of the cost-saving maintenance strategy.

The software records all the data stored in the sensor, the calibration/adjustment data and the process- and measuring point-specific data during central sensor calibration. The data is thus also managed centrally and automatically. In this way, the client can track and document the entire life cycle of his sensors end to end from the results of factory calibration, to storage and operation, and on to final sensor scrapping. In addition to the unique serial number of the sensor, the measuring system where the sensor has been operated in the plant also acts as the data management allocation key. Using the TAG information, the database always links the sensor-specific data – such as the serial number, sensor type and factory calibration data – to the data of the measuring points such that these data cannot be modified or confused with other data.

By automatically transmitting all the data saved in the sensor following calibration in the lab, an additional data record is recorded for the sensor history, including the operating location, by means of the TAG. Mr. Walter regards the graphic display showing the slope and zero point over time as particularly useful – „here you can see the condition of the sensor at a glance,“ he says. Based on the information on the operating hours - particularly in extreme pH and temperature ranges – and using a number of other criteria, the company decides when a sensor is to be regenerated or scrapped.

Thus, measuring systems and maintenance concepts are analyzed on the basis of the sensor and measuring point data recorded centrally, and optimized where necessary. The following analysis options are available here:

- Sensor history with serial number
  Graphic display of the calibration results over time and information on the various operating locations and conditions.
- Measuring point history with TAG
  Information as to which sensors have been in operation at a certain measuring point, how long they were in operation and when.

As a result, predictive maintenance with improved asset management becomes an integral part of the new maintenance strategy.

Clear Assignment of the Sensors to the Measuring Point

This maintenance strategy also has an effect on processes during operation and on the day-to-day working scenario. The sensors no longer only remain at the measuring point. Instead, they are taken to the central calibration system in the measurement and control workshop to be maintained and then brought back to the operating facility and deployed again in the process. This movement of the sensor from place to place requires viable measures to ensure that the sensors are reconnected to the correct measuring system.

With memobase, the sensors are recorded in the central calibration system during initial commissioning. Here, the client can assign the sensor a specific measuring point TAG X or a measuring point group TAG group 1. This assignment is stored in the database and in the sensor itself. With the Memoclip accessory, this assignment can also be made visible from the outside so that the sensor is clearly labeled throughout its entire life cycle, even when being transported and calibrated.

When the sensor is replaced on the online measuring point, the Liquiline transmitter uses the TAG or TAG group to check whether the correct sensor has been connected. If a sensor with the incorrect assignment is connected by mistake, an alarm is automatically output. For reasons of safety, the measuring point cannot be put back into service until a correct sensor has been connected. This simple operation ensures that the right sensors are used. Consequently, the sensor can be replaced correctly 24x7 by the operating staff on site – either in rotation or in the event of an error.

Summary

The sensor technology has revolutionized analytical measuring technology. Sensors are already available for the pH, dissolved oxygen and conductivity parameters and the platform is being continuously expanded. For the pH sensors in particular, all sensor types are available which ensure safe plant operation. Users can choose between sensors with a liquid, gel or polymer electrolyte and different types of membrane, such as ceramic and Teflon membranes, or the „open“ membrane, to find the optimum sensor for their process. The various electrolyte and membrane combinations are available both for glass sensors and the non-glass ISFET sensors from the Tophit product family. Pfaudler enamel sensors with memosens technology will soon be added to the portfolio. In this way, our clients can choose the ideal sensor for every application.

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Solution Provider for the Polymer Industry

PRODUCT Swiss company List develops and industrializes advanced and customized solutions for processing of viscous, sticky and crust-forming products for the polymer, chemical, fiber, food and environmental industries.

The company is suited for the demands of many polymer applications: providing long residence times, highest mixing efficiency, intensive surface renewal, self-cleaning of the large heat transfer surface area and precise control of the process temperature.

At the K 2007 show, List will illustrate technology for polymerization/polycondensation reactions, direct desolventizing of polymer solutions and process solutions for specific compounding and crafting processes providing possibilities for new polymers.

The company is particularly focusing on the direct devolatilization of elastomeric polymer solutions.

Over the past few years, List has progressed this technology to the commercial industrial level.

In addition to the pilot installation at the Technical Center in Arisdorf customers have access to a two – stage semi – commercial installation at the Institute for Applied Polymer Research (IAP, Golm) at the Merseburger Innovations – and Technology-Center in Schkopau (www.fraunhofer.de/fhg/press/pi/2007/07/Presseinformation18072007.jsp).

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The Perfect Plant

Savings Through Higher Productivity and Improved Capacity

Global competitiveness is placing tremendous pressure on cost, quality and responsiveness in manufacturing as nodes are being pushed out to distant locations leading to a loss of visibility and control. Asset efficiency is a premium, but effective comparative measures are difficult to achieve. Plants use copies of master data creating compliance and quality issues. Production personnel lack the decision support information to meet their targets. Business and financial impact of production asset exceptions cannot be monitored or controlled at the enterprise level.

John Harrison

As chemical companies struggle to deal with this environment, one of the tools being used is the concept of the perfect plant. The well known term "Perfect Order" refers to an order where everything is correct and reaction is quick. The term "Perfect Plant" is the operations version of the "Perfect Order" within the plant, success is defined by aligning corporate strategies and objectives with the plant's performance. However, to take ownership of these factors, plant personnel must have the visibility and control of key metrics.

The perfect plant concept from SAP gives a 360-degree view into all plant operations. It allows individuals to increase visibility, improve integration with business processes, and extend the investment in the SAP ERP application by integrating with plant operations.

It provides an environment in which manufacturing assets are optimized and production performance is increased - delivering critical visibility into all aspects of the manufacturing operations. Perfect plant processes offer capabilities that help to respond faster to changes in marketplace conditions and minimize the impact on the bottom line. The result is greater momentum, driving the company to increased yields, superior asset utilization, and streamlined order fulfillment.

This perfect plant concept has three major thrusts:

- **Asset Performance and Utilization:**

Assets are monitored so that events of concern are triggered automatically. Enterprise Asset Management (EAM) processes are optimized and all asset content is available in a single source. EAM processes are tightly linked to manufacturing processes.

- **Manufacturing Execution:**

Manufacturing execution is so effective that it is nearly event free due to proactive monitoring and automated event handling that is tightly coupled with EAM and the enterprise. Personnel have visibility across all critical processes that contribute to success of manufacturing execution.

- **Operational Scheduling / Planning:**

The Operations Schedule is such that changes are not driven primarily by unplanned events in manufacturing but rather by demand shifts and other factors. Manufacturing is able to manage & react to these changes more rapidly and reliably.

The perfect plant typically aligns and improves key performance indicators (KPI) across manufacturing. Here are some examples of typical KPI's for the Perfect Plant:

- Reduce manufacturing costs by 5% through manufacturing process monitoring and increased visibility
- Increase plant efficiencies by 25% through optimization of manufacturing processes and integration with the enterprise
- Increase production yields by 10% through proactive monitoring of manufacturing events
- Reduce maintenance costs by 10% – through streamlined maintenance processes and alignment with manufacturing metrics
- Reduce asset capital investments by 10% through improved asset performance from greater asset reliability
- Reduce inventory by 10% – manufacturing lean process enablement through streamlining and reducing variability of execution
- Increase value chain agility and customer responsiveness through Complete value chain integration and visibility

Example of a "Perfect Plant" Scenario

In a polyolefin plant, a customer order needs to be fulfilled in spite of a defective pump. With the integrated combination of SAP xAPP Manufacturing Integration and Intelligence (xMII), Pavilion's Manufacturing Process Optimization (MPO) and Meridium's Reliability Centered Maintenance and Optimization (RCMO) it is possible to avoid temporarily shutting down the production as well as being able to fulfill the customer order although the throughput was reduced (Pavilion and Meridium are both members of the SAP Industry Value Network for Chemicals). The production worker identifies that a pump has overheated and is running below optimal performance. He creates a maintenance order in SAP xMII and informs the production manager.

With Pavilion's MPO and the same process model which is used for the continuous regulation of the process, the production manager simulates the situation with the new parameters and optimizes the process anew. This guarantees that the customer order can be fulfilled in both quantity and quality and that the defective pump can safely continue even at a lower performance.

In SAP xMII the production manager can immediately and at all times see that the customer order is being produced without delays, interruptions or quality deviations. He can also see that although there are technical problems with the pump, the production is running at the theoretical maximum.

The maintainance engineer finds the source of the defective pump in the closure of the wheel blower. With Meridiums's fully integrated application RCMO, he analyses the risk of a complete breakage of the pump. He then creates a RCMO message automatically in SAP ERP detailing the required steps to minimize the risk. These steps are to monitor the rotation speed and temperature of the pump. SAP xMII obtains this data through the attached online systems.

Nova Chemicals

At Nova Chemicals, a manufacturer of plastics and chemicals in Calgary, Canada, the production manager and workers did not have any insight into fluctuations in performance and the financial repercussions resulting from them. In addition, the insufficient integration of the ERP and operating systems resulted in accuracy deficiencies.

Nova chemicals was able to implement the first part of their vision for the perfect plant by using xMII and Pavilion's application Manufacturing Process Optimization (MPO)
The benefits achieved by this were enormous:

- Million dollar savings through higher productivity and improved capacity
- Managers can quickly identify further areas to improve profitability
- Users can make better decisions based on real-time data

The line workers are motivated and empowered to maximize the efficiency of their equipment and to close the gap between theoretical possibilities and actual capacity utilization.

Eastman Chemical

At Eastman Chemical, a manufacturer of fibers and plastics in Kingsport, Tennessee, USA, the employees spent too much time manually collecting data from various systems. The company needed a company-wide, single version of the truth to support decision making.

The advantages were clear even after the first implementation steps of the perfect plant with SAP xApp Manufacturing Integration and Intelligence (SAP xMII) due to its high usability and complete integration into the SAP ERP system:

Through the better use of data for decision making purposes the company has the possibility to save more than US-$10 million on costs such as procurement, inventory, etc.

In the first month consignment stock was reduced by 8% and by May 2006 by 23%.

Thanks to an optimized visibility of inventory, Eastman was able to reduce expensive rush deliveries for consignment stock by 50%.

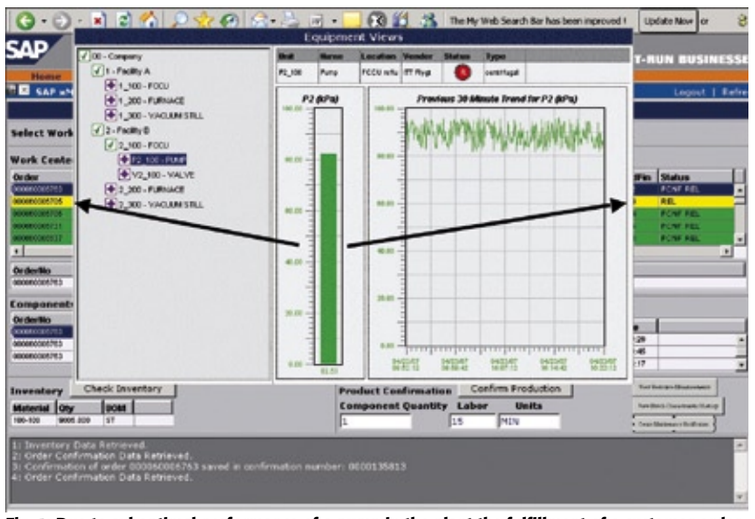

Fig. 1: Due to suboptimal performance of a pump in the plant the fulfillment of a customer order is at risk

The Road to the Perfect Plant

How can you go about making the concept of perfect plant a reality?
First, the areas requiring optimization need to be identified and defined within an overall plan, taking into account the individual characteristics of the company, its processes and production. As soon as a plan is in place the expected advantages of perfect plant need to be quantified and prioritized. Now it is time to begin the journey towards the perfect plant.

Every element and its realization is a stepping stone on the way to a company's ideal of the perfect plant. It is an ongoing journey – due to the ever changing environment between the creation of the vision and the realization of it. This leads to new challenges making perfect plant a continuous renewal and optimization process.

As overwhelming as the vision might seem, the journey to a perfect plant starts with a first step. With each problem that reality brings is an opportunity to refine the vision until what you have in the end is success.

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SAP-Solutions for the Chemical and Pharmaceutical Industry

From Nov 26 to Nov 27 the German Chemical Industry Association (VCI) and SAP conduct their traditional conference on SAP- and partner solutions for the chemical and pharmaceutical industry. During this conference, a series of lectures presents the latest developments and manifold applications related to SAP-technologies. CHEManager Europe and its German counterpart CHEManager will report intensively about this event in the upcoming issues.
For more information and registration, visit www.sap.com/germany/campaigns/vci-kongress/index.htm.

Glasslined Steel in Pharmaceutical Production

Universal Chemical Resistance Combined with Ideal Cleaning Properties

It is hard to imagine a pharmaceutical process plant without glasslined apparatus or components today. The universal chemical resistance of the glasslined compound material, combined with its optimum cleaning properties, are the main reasons why glasslined components have gained a firm position in this respect.

In the past, plant operators used to produce their active ingredients in commercially available standard apparatus and components which had been manufactured according to the comprehensive DIN standards applicable to glasslined apparatus and technology. In the past few years, however, manufacturers of glasslined equipment sparked off real fireworks of innovation in connection with glasslined components in pharmaceutical production.

Innovation

Innovation mainly focused on the following aspects:

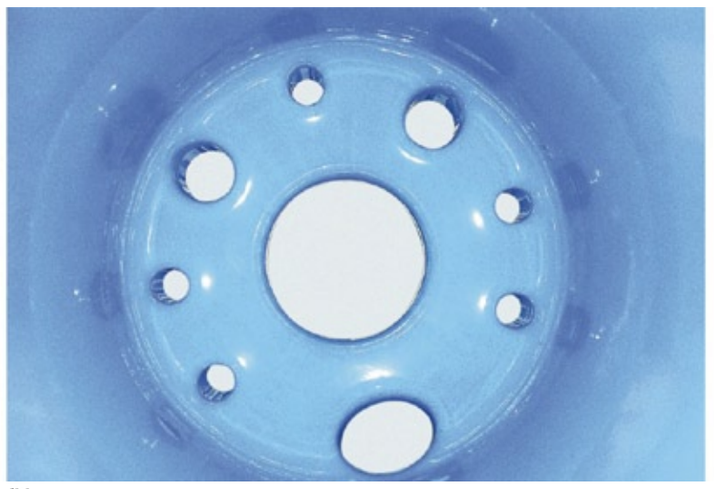
Optimized glasslining: Special glass qualities whose chemical resistance, composition and color even differed considerably in some cases from those of standard chemical glass.

Reduction of dead zones on glasslined nozzles and ports: For this purpose, structural solutions were developed such as special sterile mechanical seals in the area of the agitator nozzle, the reduction of nozzle radii of pipes, elimination of flange gaskets and their replacement with novel designs, optimization of bottom outlet fittings, etc.

Components for cleaning apparatus in compliance with pharmaceutical needs, such as quick-action lids, covers optimized for the installation of cleaning systems and spray lances, up to the validation of cleaning processes in the works of the apparatus manufacturer.

External cleanliness: Apparatus and component designs incorporating glasslined stainless steel, quick-action covers made of glasslined stainless steel, fully welded, tight apparatus insulation, housing of drives with external ventilation.

Some of the examples mentioned will be described in more detail below.



Various components, lined with pharma glass qualities

Glasslining Optimized for Pharmaceutical Needs

Some manufacturers of glasslined apparatus also offer glass qualities today that have been specifically optimized for the needs of pharmaceutical processes. In pharmaceutical applications, brightly colored glass is normally preferred, i.e. white and recently also light blue. Studies conducted prior to developing a special light-blue pharmaceutical glass arrived at the conclusion that light-blue products and media almost never occur in pharmaceutical processes, therefore, there is a good color contrast between the glass and the product. Besides, a bright color ensures that the reactor contents are well lighted, another factor that facilitates visual process control. In addition to the color, the most obvious feature, some modern pharmaceutical glass qualities are also characterized by improved surface properties and free from heavy metals. In order to avoid undesired glass corrosion when cleaning components with alkali media at elevated temperatures, the chemical resistance of the pharmaceutical glass was also optimized with respect to alkali media.

Reducing The Dead Zones

Being the main component of most chemical processes in active ingredient production, the glasslined reactor can be optimized for pharmaceutical needs in many respects. Since the sealing areas, as already described above in connection with the pipes, are most critical in regard to cleaning, dead zones, deposits of product residues and product remainders, they were naturally subject to the greatest optimization efforts. According to the principle that "the best gasket is the one you don't need", apparatus small low internal volumes were developed for which no main flange gasket was necessary. A typical example is the BE 630 reactor that complements the lower end of the BE series of reactors to DIN 28136. The largest opening of the BE reactor is the manhole, whose gasket is obviously shorter than the main flange connection of an AE reactor to DIN 28136 of the same size. Another possibility of shortening gasket lengths by doing without gaskets are the glasslined sight glass units of the type offered in several designs. With this option, a sight glass is fused into the glasslining of the manhole cover pressure-tight and without gaskets, and the result is a sight glass system without dead zones. In order to avoid cleaning difficulties in the area between the baffles installed in the reactor nozzle, glasslined reactors are offered today where the baffles have been welded to the reactor wall and fully coated with glass.

Another example to be described is the optimization of the agitator nozzle. While mechanical seals to DIN 28138-2 have many dead zones and undercuts which are difficult to access, the development of a pad type nozzle in connection with a sterile mechanical seal resulted in a much more convenient design in terms of cleaning ease. Due to the structural principle of the mechanical seal, undercuts can be safely avoided. Besides, by using gas-film lubricated mechanical seals, the risk of contaminating the product with abraded gasket material can be minimized.

Pharma-compliant Cleaning Ease

Cleaning of glasslined apparatus used for pharmaceutical production must be easy to accomplish and to reproduce. Based on its excellent surface properties, technical glass is probably the material of choice in order to obtain optimum cleaning results. Besides, a number of components are available to make cleaning the apparatus inside as simple and safe as possible. These include, for example, plug-in cleaning lances to be fitted to the quick-action covers, or cleaning lances in dedicated nozzles, which are preferably provided on the manhole cover.

External Cleanliness

And finally, "externally clean" components are also characteristic of ultramodern pharmaceutical plants. External cleanliness is not a value in itself, however, but should be combined with obvious benefits for the operator. For example, full insulation of glasslined apparatus characterizes state-of-the-art equipment today, which has been welded tight in the factory. For universal applications in a broad temperature range, the insulation will be made of cellular glass, whereas apparatus that is mainly operated at high temperatures will be insulated with glass wool. The insulation yields significant cost savings when operating the apparatus and also prevents external corrosion. Moreover it "looks nice". The same applies to a full drive casing. In addition to ensuring a homogeneous optical appearance, it prevents contamination of the workspace by abraded materials and worn components of the drive, or simply provides for the targeted dissipation of the electric motor's heat loss.

Glasslined apparatus in active ingredient production

Manhole cover with plug-in cleaning lance

Another alternative is to use components made of glasslined stainless steel. For example, manhole covers or the flat covers of smaller apparatus are made of glasslined stainless steel. The glasslined stainless steel material not only has an attractive appearance, it also efficiently prevents color particles from coming off and falling into the apparatus when opening and closing the manhole as a potential source of contamination of the product processed inside. In extreme cases, the entire apparatus may be made of glasslined stainless steel, a measure that is frequently not necessary, however, if full insulation for the apparatus is properly designed.

Conclusions

It must be mentioned at this point that most of the solutions described above have not been standardized by norms and guidelines, but by manufacturer-specific concepts at maximum. Therefore, some of the solutions shown may be manufacturer-specific and differ strongly, depending on the customer's express requirements. However, these examples demonstrate the flexibility of manufacturers of glasslined apparatus and components today when the optimum technical solutions to the specific requirements of producing pharmaceutical active ingredients have to be found and implemented. Today, customers have the choice among a wide variety of concepts and detailed solutions and may select the ones that optimally fit their GMP concept.

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New German Welding Technology

Up to 70% Reduction of Downtime in Petrochemical Plants

Operators of petrochemical and chemical plants, smelters and glass works have a new alternative. A patented welding method from Germany can reduce the forced downtime of the equipment by up to 70%. This could even affect fuel prices. The patented welding method, which is referred to as gierull welding, is available from SWS GmbH & Co. KG, Bottrop, Germany.

Now and then, crackers or steam reforming furnaces suffer damage due to power outage or unexpected events. Normally, repairs cost a lot of time and money. Damaged equipment made of temperature resistant high-alloy stainless steel is very difficult to repair. Often, the material is carburized and cannot be welded.

The scarcity of raw material and the corresponding long delivery times for replacement parts extend the downtime additionally. The damage due to loss of production, the cost of replacement equipment and the cost of repair affect the yield of the plant.

A solution: gierull welding, a patented welding technology. Gierull welding makes pipes and moldings of carburized, heat resistant steel weldable. Used pipes and moldings are repaired by gierull welding and welded in the furnace again. The benefits of the patented method are obvious: The time it takes to provide replacement parts can be saved; there are no time consuming inspections or crack tests with "new on old" welds; reduction of the cost of equipment and, of course, the reduction of downtime of up to 70%.

In June 2007, SWS signed a cooperation contract with H. Weber GmbH & Co. from Pulheim, Germany. The Weber Group is one of the largest players in industrial pipe and plant construction in Germany and throughout Europe. The cooperation focuses on services, remedy of faults, repairs and maintenance of furnaces and reactors.

More information on the company and the giuerull welding technology under: www.sws-online.eu

▶ www.sws-online.eu

Quick Disconnect Couplings

PRODUCT A new line of compact, non-spill quick disconnect couplings from Colder Products Company provides users with fast, safe and virtually leak-free fluid line connections. An excellent choice for printing and ink management, analytical instrumentation, electronic cooling, and many other applications, the patent-pending NS2 couplings provide high-flow fluid transfer in a small footprint.

"This NS2 Series of quick disconnect couplings builds on our platform of non-spill valves and reflects our commitment and ongoing investment in easy-to-use, high quality couplings," said Andy Hass, business unit manager, industrial markets, Colder Products Company. "For applications that require the safe transfer of fluids, the NS2 offers an easy, twist-to-connect locking mechanism and double-sided non-spill shutoff valves for added safety and convenience."

The NS2 meets the need for smaller, more cost-effective industrial couplings. The smaller couplings can replace larger ones, offering users a low-cost, space-saving option for a wide variety of coupling applications. The new couplings also offer very low air inclusion – air induced into the coupling upon connection – minimizing contaminants and reducing the need to purge fluid lines.

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Capitalise On Opportunities

Global Pharma Market to Double by 2020

The global pharmaceutical market will more than double in value to US-$ 1.3 trillion by 2020, according to a new report on the future of the pharmaceutical industry released by Pricewaterhousecoopers. The increase is driven by soaring worldwide demand for medicines and preventative treatments as the population grows, ages, becomes more obese and more prosperous.

By 2020 the E7 countries – Brazil, China, India, Indonesia, Mexico, Russia and Turkey – could account for as much as one fifth of global pharmaceutical sales. Further, the chronic conditions in the developing world will increasingly resemble those of the developed world. But the report indicates that the current pharmaceutical industry business model is both economically unsustainable and operationally incapable of acting quickly enough to produce the types of innovative treatments demanded by global markets. In order to make the most of these future growth opportunities, the industry must fundamentally change the way it operates.

Further, the report contends that despite unprecedented global demand for its product, the pharmaceutical industry is at a pivotal point in harnessing its ability to capitalise on these opportunities. Pharmaceutical companies are facing a dearth of new compounds in the pipeline, poor financial performance, rising sales and marketing expenditures, increased legal and regulatory constraints and challenges, and tarnished reputations. At the same time health care payers and providers everywhere have recognised that current health care expenditure levels are also unsustainable unless they deliver more demonstrable care and cost benefit over the long term.

Dr. Steve Arlington, global pharmaceutical research and development advisory leader, Pricewaterhousecoopers, and principal author of the report, commented:

"The pharma industry will not be in a strong position to capitalise on opportunities unless R&D productivity improves. The core challenge for the industry is a lack of innovation. The industry is investing twice as much in R&D as it was a decade ago to produce two-fifths of the new medicines it then produced. It is simply an unsustainable business model.

"Over the next decade, the industry must shift its investment focus more toward research and less on sales and marketing. Pharma's traditional strategy of placing big bets on a few small molecules, marketing them heavily into primary care with the aspiration of achieving blockbuster sales, will no longer suffice. It must focus on the development of medicines that prevent, treat or cure. These must demonstrate tangible benefits and tackle unmet medical needs. Governments and payers must play their part and ensure the industry is rewarded for these efforts."

Some of the major changes for the industry are:

Emphasis on outcomes to increase: The focus on outcomes and measurement of outcomes data will drive product development, pricing and reimbursement decisions and risk-sharing agreements between industry, health care payers and providers and regulators. Successful companies will prove that their products really work and add value. Companies will also be rewarded with a fair price for new therapies according to the level of improvement over existing medicines. Risk-sharing agreements will become more mainstream with drug manufacturers adjusting prices according to the results of outcomes analysis data that demonstrates drug efficacy.

Compliance monitoring becomes win-win for patients, payers and providers: Solutions to monitor and ensure that patients are fully compliant with their medications could generate more than US-$ 30 billion of revenue a year in new sales, and would improve outcome and patient safety. One U.S. study found that 20% of Americans never fill their original prescriptions, or use other people's medicines, and 60% of patients cannot identify the drugs they are taking. This not only affects safety and outcomes, it creates risk and revenue loss for pharmaceutical companies. Pharmaceutical companies will revise their proposition, employ new technologies and develop personalised compliance monitoring techniques as a value-added service to patients, payers and providers. Improved patient compliance would also help clinical studies and outcomes.

Focus will shift from treatment to prevention: Preventative health care represents a huge opportunity for both health care providers and the pharma industry. Currently only 3% of health care spending on OECD countries is used for prevention, yet the WHO says up to 80% of heart disease, stroke and diabetes and 40% of cancer could be prevented. Recognising the cost effectiveness of preventing diseases among healthy populations rather than treating sick populations, pharma will enter the realm of health management, with wellness programmes, compliance monitoring, vaccinations and other value-added services. There are currently 245 pure vaccines and 11 combination vaccines in clinical development, and the market is estimated to be worth as much as US-$ 42 billion by 2015.

New technologies will drive R&D: Transformational technological changes in the pharmaceutical industry will reshape the business strategies of pharmaceutical companies. The role of genetic-based diagnostics in the development of personalised medicines has already shortened the R&D cycle for those products. Further research into the human genome will open up a new world of opportunities in molecular science and new ways of looking at targets. These new technologies will be used to improve understanding of diseases and link genomic and clinical data. The development of molecular delivery platforms could speed the development of new products that leverage existing/approved platforms. The convergence of therapeutics and medical devices, which started in earnest with the drug releasing stent, will continue and they will become increasingly sophisticated, improving efficacy and reducing the risk profile of many existing therapeutic agents.

The current linear phase R&D process will give way to in-life testing and live licensing: The current R&D model, involving phase I, II III and IV clinical trials that typically end in submission for a drug licence and market approval, will be replaced by collaborative in-life testing and 'live licences' being issued contingent on the performance of the drug over its lifecycle. The industry will conduct smaller, more focused clinical trials, continuously sharing results with regulators. If testing confirms that a medicine is safe and effective, a live licence will be issued permitting the company to market the drug on a restricted basis. Further in-life testing will extend the licence to cover a larger number of patients or a different patient population.

Greater international regulatory cooperation: Already, several national and regional regulators have begun to collaborate by sharing safety and efficacy data. There may well be one global regulatory system by 2020, administered by national or federal agencies responsible for ensuring that new treatments meet the needs of the patient populations within their respective domains. Such a system would help to reduce the spiralling costs of regulatory compliance and reduce time to market.

The blockbuster sales model will disappear: It will be replaced by a smaller, smarter and more effective sales force, led by key account managers who will negotiate tender based contracts on therapeutic benefit and outcomes. The imperative will be who can add the most value, not who can sell the most pills. Under this model, most pharmaceutical companies will sell integrated packages of medicines and services, and some services, such as patient monitoring and disease management, may be more valuable than the medicines themselves.

The supply chain functions will become revenue generating: The future supply chain will be responsible not only for distribution of all products and services, it will also create new channels through which to market products, so becoming revenue generating rather than a cost centre. Furthermore, 2020 will likely give rise to 'made to order' therapies rather than 'made to forecast' using just-in-time manufacturing and delivery techniques learned from other industries such as the automotive sector.

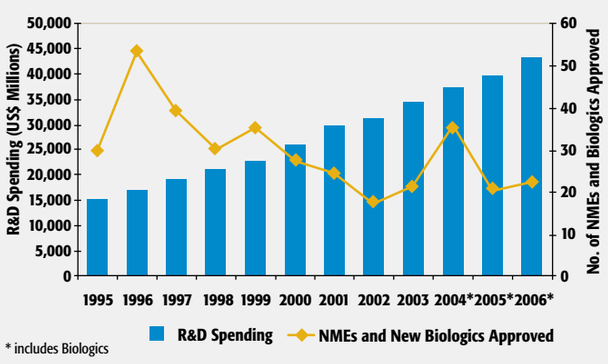
More sophisticated direct-to-consumer distribution channels will diminish the role of wholesalers: The industry's heavy reliance on wholesalers for distribution will be supplanted as the over-the-counter (OTC) self-medication sector grows and new technologies enable automated dispensing of medicines direct to consumers. Fulfilment of prescriptions for most primary-care medications will be fully automated, whereby doctors will write prescriptions, check reimbursement criteria, and download the script to the patients' smart health card or email account. Patients will be able to forward the script to an online pharmacy, which checks their identity using a web-based biometric device and mails the medication to their specified address.

Simon Friend, global pharmaceutical leader, PricewaterhouseCoopers, concluded:

"Increasingly pharmaceutical companies are no longer shaping their own destiny. The future will require the industry to take note of growing health care market dynamics involving the demands of payers, patients, physicians, regulators and politicians. For the industry to rise to these global challenges, the current business model needs to adapt, but cannot do so alone. It requires collaboration between all groups driving the delivery of future health care."

▶ www.pwc.com/pharma

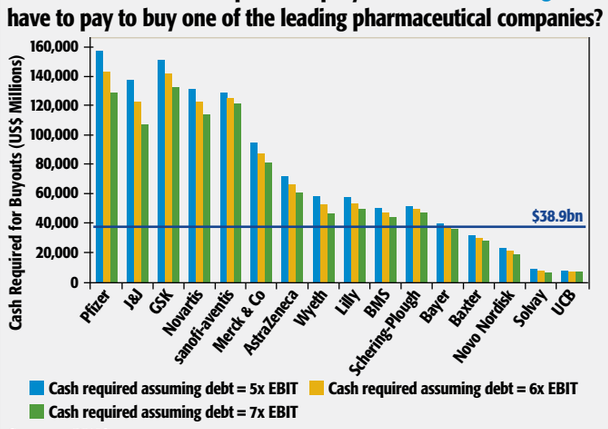
R&D spending has soared out but the number of NMEs and biologics approved by the FDA is down Figure 1



* includes Biologics

Source: PWC © GIT VERLAG

How much cash would a private equity consortium have to pay to buy one of the leading pharmaceutical companies? Figure 2



Source: PWC © GIT VERLAG

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A New Game Plan

Strategic Thinking for the Life Sciences Industry

Improved quality and reduced costs are two of the main driving forces behind the life sciences industry today. This is especially true for the biotechnology and pharmaceutical sectors. To a large extent, these forces are being driven by regulation, which is now one of the industry's major costs. However, regulators such as the U.S. Food and Drug Administration (FDA) and the Medicines Health Regulatory Agency (MHRA) are keen to reduce their cost burden by making manufacturers themselves focus more closely on improved product quality.

The idea behind such a self-regulating regime is that it would both improve product quality and reduce the need for – and therefore the cost of – intervention by a regulator. Although self-regulation has proved less than successful in some industries, in others it has led to substantial cost savings as a result of improved product quality and faster delivery. This should certainly be the case for the life sciences industry too.

However, it is important to remember that a regulator's first priority is patient health. So manufacturers have to demonstrate in the first instance that they thoroughly understand their manufacturing processes and that they know how to minimise the risk involved with them. The regulator is looking for terminology such as "risk-based approach" to demonstrate that company's quality systems embody forward thinking techniques for continuous improvement. A science-based approach founded on a total understanding of the science that underpins the manufacturing process supports manufacturer's claim to be in control of their risks and processes. It also shows that such understanding is being applied to quality systems by using standard procedures in risk management in order to achieve the very best product quality.

Many companies are now coming to realise that their level of regulation has increased over the years simply because, in the past, they have not been able to demonstrate this deep understanding of their processes to the regulator. On the other hand, companies that by sheer determination have achieved such understanding are finding that they can reduce the number or intensity of regulatory inspections and the number of quality systems they need – therefore reducing costs.

The New Approach

Most life science companies follow a classic product life cycle that starts with drug discovery and ends with plant decommissioning. They have been making products this way for many years. However, there is a growing emphasis on the need to better understand all aspects of new product development.

Firstly, manufacturers now learn as much as possible about the science of making a new drug. Although this stage still uses traditional analytical techniques, it is making far greater use of new technologies and instrumentation. This means that product manufacture can be understood right down to the atomic level. Importantly, it also helps scientists to understand the critical control points. These are routinely being used by both the oil and food industries to ensure that processes can be accurately repeated time after time.

Such critical control points are particularly relevant to the life sciences industry as you move from laboratory-scale production to full-scale production. The process dynamics change at each stage and in the past a procedural-based system was followed until the product was manufactured the same way three times. This was then adopted as the procedure for manufacturing that product.

A science-based approach ensures that when these critical control points are achieved, the manufacturer knows that it is in full control of its process. Success here depends to a large extent on data acquisition. The scientist knows what measurements to take and what variables to measure, so basically the laboratory is brought down to the production department to measure them in-line and also to do control in-line.

Once the in-line measurements have been taken, advanced process control tools and analysis tools can be used to understand correlations between process elements and interactions at the molecular or biological level. By understanding this and by looking for mathematical correlations, predictions can be made as to what happens during the process.

The software used here is based on statistical process control, and spectral analysis. It takes all the uni-variant data such as temperature, pressure and flow, along with the multivariant data such as frequency and mass spectrometry and puts them into a big mathematical engine that looks for correlations against set process points.

It is at this point that Eurotherm's technical expertise really comes into play. Its technology does two things – extremely accurate measurement and database manipulation. This is exactly the same procedure as carried out by the oil and food sectors for many years. However, it has not been adopted by the life sciences industry because traditionally the regulator has insisted on a procedural-based approach to manufacturing. This has now changed. Some would say the change is consumers lead and that they have pressured the regulator for lower costs and higher quality and they have accepted that its "stick to procedures" approach stifles innovation and promotes inefficiency whilst not necessarily guaranteeing quality.

Spend To Save

In one sense, cost savings are only marginal with this approach. Obviously, there is an increased cost at the front end, but you are achieving quality by design. By making sure of quality at the front end, however, it also ensures quality at the back end in terms of less wastage and less product variability. So companies do save money. Also, it is worth bearing in mind that with a new drug costing anything from £200 million to £1 billion to develop, the cost of this equipment and therefore the cost of understanding the process is a fraction of that. Of course the instruments and analysis tools can be reused for the development of many other new drugs, too.

The other important aspect to consider is the message that this approach sends out to the regulator. Effectively users are saying, "Look, I understand how to make my product, and I can reproduce it very accurately. There is also a risk-based approach to what I do in manufacturing, so you don't need to police me too much."

Nevertheless, such an approach does not signal the end of 21CFR Part 11: Companies will still adhere to good automation and manufacturing practices. It will be inherent in their quality systems. But what it does do is give them latitude to change the process without reference to the regulator.

In conclusion, therefore, Eurotherm helps with data acquisition at the drug development stage and with data analysis and therefore process understanding at the next stage. Once the process is understood, the loop can be closed by taking the same measurement and analysis technology from the laboratory and deploying it on the production line in order to do in-line control on new measurement techniques. This is a new and better method of control for the life sciences industry.

Eurotherm is a global supplier of control, measurement and data recording solutions and services to industrial and process customers. Eurotherm's product range includes distributed process automation systems and machine control incorporating single and multi-loop control, operator displays, data management and graphic recorders, power control and signal conditioning. It is an ISO 9000 approved company, and operates TickIT protocols for software management.

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GMP in the Centre of the European API Conference

The rapidly changing pharmaceuticals legislation entails worldwide challenges for Active Pharmaceutical Ingredients (API) manufacturers and manufacturing authorisation holders. Auditing, inspections by authorities, certification procedures and the requirements of ICH Q7A pose the key issues. In addition, products of European manufacturers have to compete with APIs produced outside of Europe that do not necessarily comply with European GMP and regulatory filings and are therefore less expensive.

These requirements and issues in mind, the Active Pharmaceutical Ingredients Committee (APIC) invites to the 10th European API Conference in Warsaw, Poland, from 24 to 26 October 2007 to discuss current developments and changes. Speakers from international authorities like FDA, EU, EMEA and EDQM will present updates on their recent and upcoming activities.

The conference comprises two parts: the GMP Conference will concentrate on European and US authorities' initiatives, activities, expectations and interpretations of regulations. Part of the conference will be an update on EMEA's activities related to API Compliance by Francois-Xavier Lery from EMEA in London. He will inform about the recent Guidances that have been published on API-related Inspections. Xavier Lery will also present the results of the evaluation of the API compliance situation as observed during recent dosage form manufacturer inspections. The inspection results will be entered in the newly launched EUDRA GMP Database.

The update on FDA's 21st Century Initiative on Pharmaceutical Quality Assessment will be presented by Moheb Nasr from FDA. The FDA is currently implementing this new approach across all product types. The new system encompasses several initiatives with the objective to allow rapid introduction of new technologies into pharmaceutical manufacturing and expedite review of applications without compromising the high quality of drugs. With this approach the FDA will focus on critical pharmaceutical quality attributes (chemistry, pharmaceutical formulation, manufacturing process, product performance) and their relevance to safety and efficacy. The system will rely more on the information provided by the applicant (e.g., the comprehensive quality overall summary (QOS) and the pharmaceutical development report) and less on the voluminous raw data currently being submitted (e.g., the executed batch records, raw stability data, methods validation package). An emphasis will be on quality by design in the evaluation of critical aspects of pharmaceutical quality.

Gerald Migliaccio, Pfizer's Vice President Quality Operation will report on the next steps regarding ICH Q10 "Pharmaceutical Quality Systems". This document was realised in May this year (Step 2). It will harmonise the requirements in the 3 regions (Europe, USA, Japan).

ICH Q10 is a model for a pharmaceutical quality system that can be implemented throughout the different stages of a product lifecycle. Much of the content of ICH Q10 applicable to manufacturing sites is currently specified by regional GMP requirements. ICH Q10 describes one comprehensive approach to an effective pharmaceutical quality system that is based on ISO concepts, includes applicable Good Manufacturing Practice (GMP) regulations and complements ICH Q8 "Pharmaceutical Development" and ICH Q9 "Quality Risk Management". The implementation of ICH Q10 and ICH Q 9 into daily operation will also be covered during one of the parallel sessions.

The European Commission launches a Public Consultation on the co-decision part of the revision of the Variations Regulations. Nicolas Rossignol from the European Commission in Belgium will inform about the background, reason and objective of the new revision which covers changes to the medicinal product. The proposal modifies the legal basis of the Variations Regulations, so that all medicinal products placed on the Community market – including those authorised at purely national level – are subject to the same criteria for the approval and administrative handling of changes, regardless of the procedure under which those medicines have been authorised. Hendrik de Jong, Chair of the European Pharmacopoeia Commission, will give a presentation on the impact of changes on API manufacturers and the manufacture of medicinal products. APIC´s view on the revision of the Variations Regulation will be presented by Hilde Vanneste from Janssen Pharmaceutica in Belgium.

The partly parallel Regulatory Affairs Conference will address major problems, e.g. regarding submission and implementation of changes. It will also highlight EDQM's latest activities on inspections and on the CEP procedure.

With this year's conference the committee will tie up to last year's meeting where attendees already discussed vibrantly latest requirements and hence demonstrated the importance of an ongoing exchange.

▶ www.api-conference.org

Chips and "Snips" for Personalized Medicine

Trend Report: Life Sciences and Diagnostics

From genetic testing for diagnostic purposes to protein analyses on chips – as in the past, the latest tools in molecular biology and bioanalysis will be the focus of Analytica 2008, in Munich from April 1 – 4, 2008. The international trade fair is a driving force behind developments in personalized medicine – medicine that takes the patient's genetic profile into account, which can reduce side effects and optimize treatment.

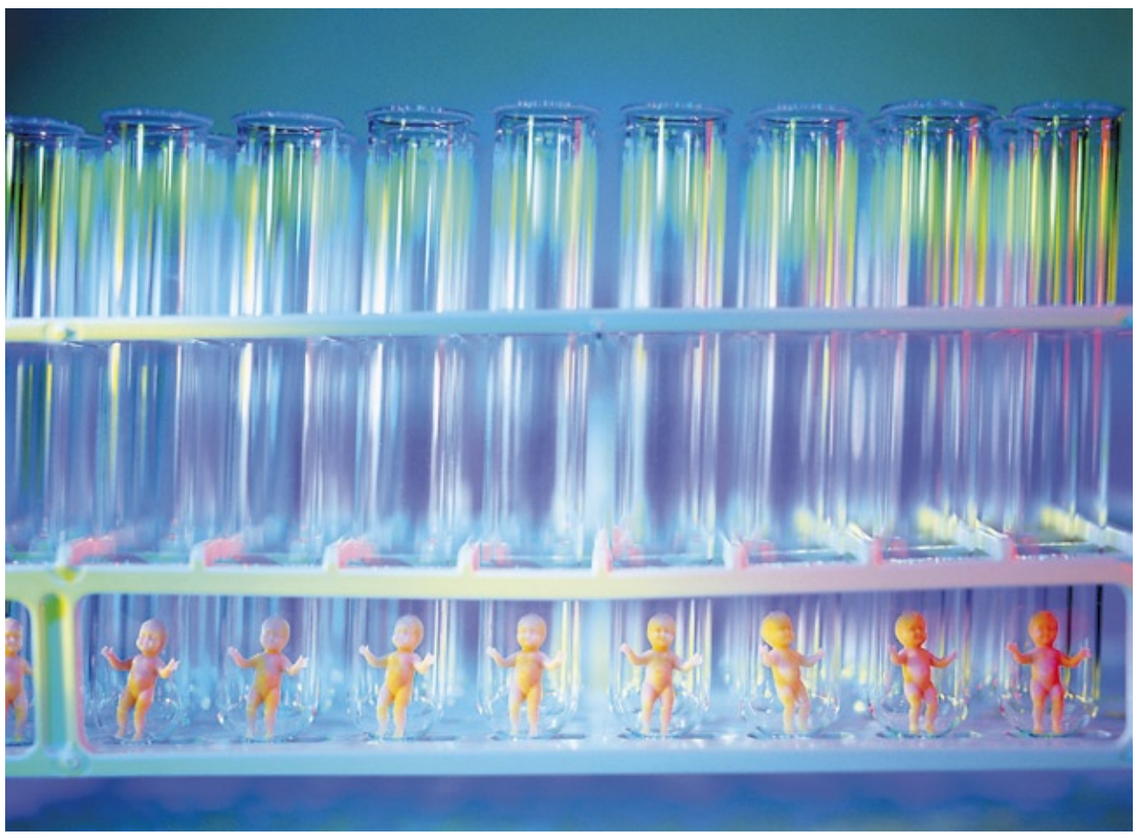

Photo: AlexSchelbert.de

The effect of medication varies from case to case. What works for one person does not necessarily work – or could even lead to serious side effects – for another. The reason: hardly any medication takes genetic differences between patients into account. Even the slightest deviations in a patient's genetic makeup can accelerate or delay the effect of medication and how they are broken down by the body. Molecular-biological diagnostics makes it possible to tailor therapies to patients' genetic profiles and modify medication dosages to suit their metabolisms. It is known as "personalized medicine". Analytica 2008 will focus on innovations in analysis, laboratory technology and biotechnology including the latest bioanalysis and diagnostics procedures that make customized therapies possible in the first place.

Biochips Increase Therapy Success

Personalized medicine revolves around DNA chips. Take breast cancer, for example: A microarray from Eppendorf will allow physicians to determine whether a patient should undergo radiation or chemotherapy following a lumpectomy – and which patients are considered cured and can skip this severe treatment altogether. The breast-cancer chip has more than 200 genes that identify the type and stage of a tumor.

Biochips can also be used to improve aids therapy. In this case, the virus' ability to change is problematic because it can make active ingredients less effective. Biochips identify these types of resistances by analyzing the virus' genome. Medications that would be ineffective are not even considered.

Roche also has a gene chip that makes it easier to choose the optimum medication in the right dose. The Amplichip CYP 450, which is already licensed for diagnostic purposes in the USA and Europe, recognizes deviations in two genes that are coded for liver enzymes in the Cytochrome P450 family. Patients with a deviation in these genes, for example, break down beta-blockers used to lower blood pressure too quickly or too slowly. Thanks to genetic testing, physicians can adapt medication treatment to their patients' metabolisms. Other Amplichips are also being developed: For example, the Amplichips p53, which detects defects in the tumor-suppressing gene p53, identifies how aggressive a tumor is, making it possible to customize the cancer therapy.

Genetic diagnostics is still reserved for specialized laboratories. However, as Analytica 2008 will show, chip technology is getting more and more user friendly. Detection kits with ready-to-use reagents, all-in-one concepts consisting of microarrays, hybridization stations, scanners and analysis software as well as ongoing advancements in automation are making it easier for chip technology to be incorporated into routine clinical applications. In an age of tight budgets in the health-care sector, costs also play a key role. There are already systems on the market that are an attractive alternative to common fluorescence scanners with regard to price: they detect hybridization electrochemically or by precipitating silver onto gold nanoparticles.

Identifying Minor Defects in Our Genetic Makeup

The fact that patients react differently to a given therapy despite a 99.9-percent genetic match is frequently due to single-nucleotide polymorphisms (SNPs, pronounced "snips"). A SNP is a minor defect in the script of the genetic mapping. Only a single letter, i.e. a base, is interchanged. Experts assume that there are ten million SNPs in the human genome. In many cases, SNPs are the cause of diseases.

The NGFN (Germany's National Genome Research Network), a group of researchers of various disciplines from throughout Germany, want to use DNA chips to examine 25,000 patients and control persons. Scientists want to identify the genetic causes of obesity, Alzheimer's, neurodermatitis, schizophrenia, tuberculosis and many other diseases. According to Peter Nürnberg, Professor of Genomics at Cologne University and coordinator of the genotyping platform at the NGFN, "We are delving into a new world of genetics that will help us to develop better treatment alternatives." He and his colleagues will collect more than 20,000 individual samples; the chips they use have more than a half-million SNPs and other gene variations.

Large-scale projects of this type are only possible using state-of-the-art bioanalysis, molecular-biology and information-technology tools. The latest systems – from online PCR devices and microarray scanners with integrated barcode readers to expanded bioinformatics software for analyzing and storing enormous quantities of data – will be on display at analytica. At the Innovations Area in Hall A3, start-ups in biotechnology, the life sciences and related disciplines will present their ideas and products that will give new impetus to the entire industry.

Cutting Costs In Healthcare

Because even a perfectly functioning gene is no guarantee for a correctly functioning protein, the big question is: which genetic products, i.e. which proteins, actually have an effect on the cell? Beside classical analysis techniques such as electrophoresis, chromatography and mass spectrometry, protein chips are increasingly being used to find the answer. Scientists use them to identify specific antibodies or proteins that can be used as biomarkers for more precise diagnostics.

Decoding proteins gives pharma-researchers a point of departure for new active ingredients. Biomarker tests, which filter out unsuitable active-ingredient candidates before they are tested on patients, also help companies to cut costs considerably.

Pharmaceutical companies also profit from the trend toward personalized medicine in another way: some blockbuster medications would still be on the market today if the patients who tend to have bad reactions for genetic reasons had been filtered out and treated using other alternatives.

Hans-Joachim Heusler, Managing Director at Munich International Trade Fairs, summed up the diverse program of events at the upcoming 21st European Trade Fair for Instrumental Analysis, Laboratory Technology and Biotechnology as follows: "Innovations in biotechnology, the life sciences and diagnostics are accelerating the development of custom therapies and offer a great deal of potential for cutting costs in the healthcare sector. Together, Analytica 2008 and the Analytica Conference not only give visitors a look at the latest equipment and techniques, they also give industry representatives a forum that promotes the active exchange of information between equipment developers and users and between international "cutting edge" researchers and decision-makers in the scientific and industrial sectors."

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Ultimate Time and Cost Savings

Outsourcing Drug Production

Pharmaceutical companies increasingly turn to Contract Manufacturing Organizations (CMOs) to improve cost-effectiveness, capacity and time-to-market. Outsourcing also allows pharmaceutical companies to take advantage of state-of-the-art process technology available from the OEMs that is perhaps not available in-house. In addition, outsourcing manufacturing allows pharmaceutical companies to concentrate more on their core competencies and on marketing their products. This article discusses specific guidelines for the successful outsourcing of drug manufacture.

Worldwide revenue for pharmaceutical contract manufacturing and research was estimated at $100 billion in 2004 and is expected to rise at an average annual growth rate of 10.8 % to reach $168 billion in 2009. More specifically, contract manufacturing of prescription drugs was reported as being worth $26.2 billion in 2004 and is estimated to grow to $43.9 billion by the end of 2009. Contract manufacturing of Over-The-Counter (OTC) and nutritional products is the largest and fastest growing segment, expected to rise at an average annual growth rate of 11.3 % to $102 billion by 2009.

Pharmaceutical contract manufacturing is growing at a considerable rate. Firstly, drug production costs incurred from building and maintaining plants is very high and constantly increasing. Pharmaceutical companies also face high costs to upgrade to new, advanced equipment and employing a workforce of highly competent professionals. In addition, drug production is very time consuming and a very expensive process requiring increased capital employment, Furthermore, price pressures in the pharmaceutical market are more intense than ever while pharmaceutical companies also need to comply with many strict regulatory requirements.

Consequently, pharmaceutical companies turn to CMOs who are capable of taking on the responsibilities for the whole drug production process including packaging, manufacturing and regulatory compliance and validation. Pharmaceutical companies can then focus on activities and other issues that are key to their sustained prosperity for example, marketing.

Identifying the Most Proficient Contractor

Identifying the most competent contract manufacturer can be a time-consuming and challenging procedure. Nevertheless, there are certain requirements that the contractor must fulfil and which can act as a useful guideline to making the most appropriate choice. Contract manufacturers must have an effective validation process in place which will help them achieve and maintain regulatory compliance. Other important issues to consider when choosing a contractor include the cost of the product, transfer costs and the time taken to complete the transfer. Pharmaceutical companies also need to ensure that the contractor is capable of producing high quality products, including the quality of the packaging, while also being reliable with regards to the timing of deliveries. Contractors need to set up a set of key performance indicators ensuring the measurement of delivery times against clear and demanding targets.

There are many small to medium size pharmaceutical contractors that are well positioned to meet all these requirements, but it is certainly far easier for large suppliers with sound and long-term financial backing and stability to do so. Contract pharmaceutical companies such as Cenexi that are backed by a financially strong company provide pharmaceutical organizations with important benefits over other contractors. The parent company provides the contractor with superior financial stability and security, which helps the contractor to keep pace with the latest market developments ensuring that the investment capital is always available for new equipment and services.

As well as satisfying the criteria mentioned above, pharmaceutical contractors need to fulfil four key criteria.

The Four Criteria

The first is to update and improve the pharmaceutical dossier making sure that the validation process is an integral part of the documentation. Details of formulations, raw material specifications, packaging details and information on the finished products should all be included in the new document. The availability of such a comprehensive pharmaceutical dossier will enable easier and more effective regulatory compliance, thus speeding up the validation process for new products.

The second criterion relates to stability studies associated with the improvements and expansion of analytical development. Processes

▶ Continues Page 28

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Ultimate Time and Cost Savings

Outsourcing Drug Production

Continued Page 27

never remain stable over the life cycle of pharmaceutical products. Changes are not only inevitable but they are often desirable, especially when they trigger stability enhancements or production efficiency gains. Nonetheless, whenever a process changes, stability trials need to be performed and thoroughly documented as part of the validation procedure.

The validation of new processes forms the third criterion. A team of six expert pharmacists and engineers are needed to facilitate and improve the validation process of new products and ensure compliance with the stringent GMP standards.

The fourth criterion is the continuous update of production processes in order to improve them, address and eliminate any problems while increasing efficiency with the aim to deliver products of the highest possible quality at the lowest possible cost.

Improving Processes

Some processes are easily and quickly improved. For example, production batch sizes can be increased without significant effort leading to substantial economies of scale. Further process improvements may include the installation of new equipment to improve productivity. However, such implementation may involve considerable investment, meaning that the potential benefits must be carefully evaluated in relation to the installation costs.

Achieving reductions in production plant downtime is an additional benefit associated with process improvements. Furthermore, having efficient maintenance procedures in place can eliminate costly and time-consuming production failures, therefore increasing productivity and reducing production costs.

In summary, contractors need to thoroughly apply their production expertise in order to offer an overall high quality service.

Transferring Production

The transfer of production from a pharmaceutical company's facility to that of the contractor can be a lengthy and difficult process taking from around 18 months up to two years to be completed. The process involves considerations such as the sourcing of raw materials, stability trialling, validation and traceability.

One of the most crucial requirements is for the contractor to have a high level of production processing expertise in order to be able to provide uninterrupted supply, since there are many people that are dependent on drug treatments on a continuous basis. Maintaining large stocks of those particular drugs is expensive, inconvenient and often impossible when it comes to short-lived products.

On the other hand, the transfer of production to a contractor ensures that the existing production line can continue operating while the contractor's facilities are being established and validated. As well as minimising the risk of disturbances in products supply, the transfer of production saves time, only six months to produce the first batches of product. Traditionally, such a short production period would have been completely impossible.

A further advantage of transferring production relates to regulatory compliance. It is certainly far more cost-effective to outsource production than to upgrade or replace an aged plant that has become incapable of meeting current regulatory requirements.

Conclusion

The pharmaceutical manufacturing arena is a highly competitive and challenging one. Companies face increasingly higher production costs and falling prices, making it a necessity to invest in and upgrade core capabilities to ensure future prosperity.

Outsourcing manufacturing to contractors is gaining momentum as a viable solution to address these challenges. A competent contract manufacturer needs to be innovative and forward-thinking, fully understanding the specific requirements of each pharmaceutical vendor and uniting the entire manufacturing operation to deliver high quality, competitive and profitable products. The long-term financial stability of the contractor is also a prerequisite to ensure uninterrupted supply throughout the product life cycle.

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Fine and Custom Chemistry without Boundaries

Ultimate Flexibility And Service

Being a researcher at a major pharmaceutical company, working on a potential new cancer drug, you need a specific intermediate molecule to be combined with other compounds to create the active ingredient in the test drug. Several suppliers can provide the compound but not the custom quality-control testing needed to understand how specific circumstances or foreign substances will affect it. You are faced with conducting the time-consuming analysis yourself. But as an alternative you can fall back on Thermo Fisher Scientific Fine and Custom Chemistry (FCC) services. They conduct the specific tests and provide you with the compound and quality control to your specifications. You can get back to work. That's "Service without Boundaries."

Stefan Verheyden, global business director of Fine and Custom Chemicals for Thermo Fisher Scientific, explains how this concept of Service without Boundaries is helping customers concentrate on their core activities.

The Fine and Custom Chemistry business became part of Thermo Fisher Scientific following the merger of Fisher and Thermo Electron last year. For decades, customers all over the world have turned to Fisher – and now Thermo Fisher – for our well-known chemical products. These include laboratory reagents, discovery chemicals and high-potential organic molecules in semi-bulk to bulk quantities. However, many people may not be aware of the unique capabilities of FCC. The company's standard chemical products can be tailored to meet special needs or provide custom synthesis as well as other services to help customers increase their efficiency and reduce costs.

'Service without Boundaries' is a message Thermo Fisher Scientific is communicating – through marketing activities – to customers who may not be aware of how they can be helped. Service without boundaries emphasizes broad capabilities, and it responds to a growing need in the market. The pharmaceutical customer, in particular, faces increasing pressure to cut costs and improve efficiency. They can be helped by providing the custom chemicals and services that will eliminate work and save them time in the lab.

The Fine and Custom Chemistry business brings together all of Thermo Fisher Scientifics internal and external capabilities to create a dedicated service provider for the customers. Their aim is to add value through expertise in sourcing and manufacturing custom products across a wide range of applications and technologies, from laboratory research and development to production. The dedicated service and intimate approach ensures the best and most cost-effective solution.

Products And Services

Thermo Fisher Scientific sells its chemical products through major catalogues representing the Acros Organics, Fisher Chemical and Maybridge product lines. Customers in many industries do their basic research with these reagents and chemicals. The Acros line includes fine chemicals, intermediate compounds and specialty chemical products. The Fisher Chemical range includes high-purity liquid-chromatography solvents, DNA synthesis solvents and electrophoresis-grade reagents; commercial grade BP, USP and EP chemicals, custom chemical blends and reagents. And, Maybridge represents a line of heterocyclic chemical building blocks for medicinal chemistry.

All of these products are sold in pre-packaged quantities. However, the Fine and Custom Chemistry business can provide individualized quantities of these products when customers scale up from research to development and production. They can also synthesize or source other compounds not found in the catalogues, and provide dedicated services such as special packaging, additional testing, re-packing of raw materials and more.

FCC's complete offering includes:

- Semi-bulk and bulk quantities of standard chemical products, including 20,000 different research chemicals sold under the Fisher Chemical, Acros Organics and Maybridge brands;
- Custom chemical synthesis and contract manufacturing to meet laboratory, kilo and pilot-scale needs;
- Production of pharmaceutical intermediates and organic building blocks;
- Private labeling for original-equipment manufacturers;
- Customized packaging;
- Specific quality-control fulfillments;
- Raw-materials handling and traceability.

These services also help customers eliminate legal red tape because in many cases they provide the regulatory and environmental clearance and documentation. A solution is delivered, not just a product.

Thermo Fisher Scientific is most active with customers involved in early-stage development – meaning from the research and development stage into pilot-phase production. For these customers, the same quality chemicals are delivered in both pre-pack (our catalogue business) and semi-bulk to bulk quantities. Also several dedicated products can be delivered in multiple (up to 100) ton quantities to meet the needs of later-stage development and production.

Another reason Thermo Fisher Scientific is different from their competitors is because of the people. Strong technical expertise gives a thorough understanding of their customers and their needs as well as the ability to envision the solutions. They have 100 experienced chemists on staff and superb sales, sourcing and technical support teams. Many of the people have strong chemistry and science backgrounds. They are also experts in service-related areas such as dedicated packaging, special mixtures, OEM business and complex quality-control requirements.

Secondly, the Fine and Custom Chemistry business combines strong global sourcing – from 3,000 suppliers all over the world – with their own manufacturing capabilities. Because of that, they offer a great buy available on the market without losing sight of local market demands, needs and expectations. The network of custom-synthesis and contract-manufacturing partners provide complete raw-material backward integration, and each partner specializes in a different area of chemistry so that they can meet almost any need of the customer – whether the compound developed by themselves or outsourced. And, they are continually expanding their offering. From a customers' perspective, working with the FCC business offers a good solution.

FCC's most important development and manufacturing facilities are located in the United Kingdom, Belgium and the United States. But of course, customers can be served all over the world: FCC commercial offices are based in Geel, Belgium; Loughborough, U.K.; and Morris Plains, New Jersey. Team members support customers across many continents, including Europe, North America, South America, Asia and Africa.

They have a dedicated back office, providing excellent service when it comes to quoting, order-entry and follow up, technical and scientific support and more. For FCC serving customers means exceeding expectations, not just meeting them.

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Low-cost Production of Ultra-pure Media

With the product lines Vapotron VT and Multitron MT, the pure-water specialist Christ Water Technology Group now presents the first ultra-pure steam generators and distillation units from their own production. The company can thus now offer technology and service for all sectors of water treatment – from Purified Water (PW) to Water for Injection (WFI). This simplifies the execution of overall projects and ensures a uniform documentation structure for complete water-treatment systems delivered in the form of turn-key plants. Furthermore, the new technology permits a reduction of up to 25% in the operating costs.

Fig. 1: The ultra-pure steam generator Vapotron VT produces 50 to 5,000 kg of sterile, pyrogen-free steam per hour.

Fig. 2: The Multitron MT series of distillation units guarantees the safe and economical production of WFI.

Economical Production of Pure Steam

The pure steam generator Vapotron VT generates sterile steam which is free of pyrogenic substances. It is particularly suitable for SIP sterilisation, the humidification of clean rooms and the operation of steam sterilisers. The system, which normally uses PW, delivers 50 to 5,000 kg of ultra-pure steam per hour. It differs from the previous versions in that it has short heat-exchanger tubes with floating integration of the exchanger elements. This reduces the thermal and mechanical stresses and considerably increases the operating lifetime of the units. In the case of problematical feed water, such as that containing large amounts of gas, a membrane degassing stage can be fitted before the generator in order to comply with EN 285 for non-condensable gases. The system is controlled fully automatically by a stored-program controller which complies with GAMP. Together with its easy to use touch-screen panel, it also complies with the requirements of 21 CFR Part 11.

New Distillation Technology Permits Savings

The Multitron MT distillation units also use a new technology which permits the cooling-water consumption to be reduced by up to 25% and the steam consumption to be reduced by 20%. This is made possible by the combical concept, a combined cooler and heater which pre-heats the incoming water and ensures optimal utilisation of the condensate. Furthermore, a triple drop separator guarantees the separation of small and large drops of water in ultra-pure quality.

Depending on the customer's requirements, the distillation units consist of up to nine columns and have an output of 100 to 15,000 kg of distillate per hour. The size of the first column can be adapted to the actual requirement for ultra-pure steam or WFI and this means, in many cases, that there is no need for a separate ultra-pure steam generator. Online TOC measurement is available as an option. The fully automatic control system ensures compliance with all relevant regulations and also keeps a record of all measured values. Integration into a comprehensive visualisation concept simultaneously permits a full, wet FAT test of the complete system, including the pre-treatment stages.

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Fit For The Future

Chemical Industrial Parks in China

Huge investments have flowed into China's chemical parks during the last few years. These investments have sparked off a high-performance chemical industry producing not only basic chemicals, but increasingly fine and special chemicals. In many cases the concepts have been inspired by European or American sites.

The Tianjin Economic and Technological Development Area (TEDA)

TEDA was founded in 1984 as one of the first national development zones. It is located 40 km from Tianjin and 120 km from Peking. 33 square km were originally reserved for the site, and most of this space is now being utilized. Permission was granted to TEDA in 2005 to develop an additional zone, TEDA West (48 square km). The principal industries in the zone are telecommunications (61%), machinery manufacturing and car production (25%), biopharmaceuticals (5%) and food (6%). The TEDA administration committee has set up three specialized industrial parks: the Microelectronics Industrial Park (4.6 square km), the Yat-sen Scientific and Industrial Park (10 square km) and the Chemical Industrial Park (27 square km). It is also responsible for the Tianjin Export Processing Zone (2.5 square km) and Tianjin University Scientific and Technological Park.

TEDA's GDP grew by 25% between 2004 and 2006 to 64.2 billion RMB. Value-added increased in the secondary manufacturing industry by 29% to 54.1 billion RMB and by 4.1% in the service sector to 10.1 billion RMB. The population in this area was 105,000 at the end of 2005. Total investment by 4,190 foreign companies was around US-$30 billion as of the end of May 2006.

By the end of 2005, 9,185 domestic companies had invested about 42 billion RMB. The high-tech sector and the service industry are the priorities in the site development strategy. The Tianjin Economic and Technological Development Area has excellent regional, national and international transportation links. Tianjin is one of the major rail centers in China, and it also has an international airport. It has a direct link to the national superhighway network and is only 5 km from the international seaport in Tianjin.

TEDA uses the "autonomous administration committee and development company model". TEDA Investment Holding Co. Ltd has responsibility for development. The company's activities include real estate and infrastructure development and operation of public utilities (water, waste water, electricity, steam and gas). The administration committee has achieved ISO 14001 certification, and an eco plan for special water and solid waste recycling was approved by the State Environmental Protection Administration (SEPA) in 2003.

The Chemical Industry Park was established as a TEDA satellite zone in 1996. Of the 27 square km which have been earmarked for development, 2.5 square km have been developed as of April 2006. TEDA CIP, a public company, has responsibility of park development. It takes care of investment incentives, provision of the environmental infrastructure and organization of the safety management program and it also carries out environmental and safety audits.

A favourable political framework provides support for investment incentives at three levels. TEDA CIP participates in the national "circular economy" initiative and has a program to attract recycling companies. General tax benefits also apply to the chemical industry park, and favourable land use rights are offered to attractive investment projects. TEDA CIP does not currently have its own infrastructure network. Instead, the park is connected to the public utilities networks (electricity, water and steam).

A water treatment plan for industrial users is currently under construction, and planning is underway for a dedicated district heating station. Waste disposal companies collect waste from industrial companies on the site. Each company currently operates its own emergency services, but that is likely to change in the future.

Development of the fine chemical industry is the priority at TEDA CIP. There were 20 investors at the site in April 2006. Five have already started production, and the other plants are still under construction. The list of domestic investors includes Tianjin Zhongwei Pharmaceutical (Vitamin B1), Tianjin DEK Chemical (dyes and pigments), Suanhuan Lucky New Materials (sintered magnets) and Cenway Technologies (herbal extracts and special chemicals).

The Japanese and Americans are the major foreign investors. They are engaged in joint ventures (JV) as well as direct investment (FDI). The list of American investors includes JV Cabot Chemical (Tianjin) which produces carbon black and has invested a total of US-$60 million, and the FDI PQ (Tianjin) Silicates Technology, which makes silicates. The Japanese are involved in the JVs Tokai Carbon Tianjin (US-$50 million), Tianjin Toho Lead Recycling (US-$4.75 million) and Tianjin Cosmo Polyurethane (258 million RMB). Tokai Carbon has a production capacity of 40,000 t/a of carbon black. Tianjin Toho can produce 12,000 tons of secondary lead mixtures a year and und Tianjin Cosmo specializes in polyether and polyurethane resins. Tianjin Sekisui Plastics Co. (US-$5.6 million) which makes Piocelan (a resin composite made of polyethylene and polystyrene) is a Japanese FDI. Taiding (Tianjin) Environment Technology is one of the recycling companies at the site. It can recycle 30,000 t/a of electrical and electronic waste.

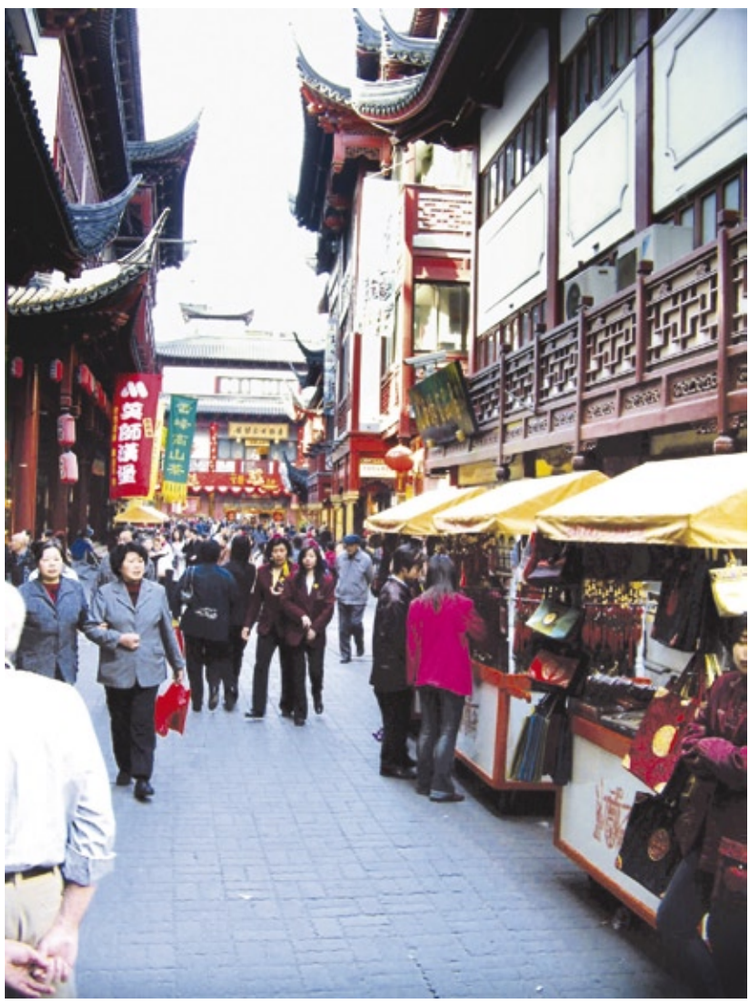
Industrial production at TEDA CIP increased to 263 million RMB in 2005. As of April 2006, there was little inter-company value-added at the site. TEDA CIP will target downstream producers in the future to increase the level of on-site vertical integration.

Shanghai Chemical Industry Park (SCIP)

Construction of the Shanghai Chemical Industry Park (SCIP), which focuses on petrochemicals, got underway in 2001. It is situated on Hangzhou Bay about 50 km from Shanghai. A total of 29.4 square km are available at the site. Development will take place in three phases. Because the Shanghai area is very crowded, land for the areas in phases 1 and 3 has to be reclaimed from the sea. Development has proceeded most quickly at the phase 1 site. Most of the plots are being leased by foreign investors, above all from Germany.

Phase 1 direct investments include BASF production facilities for 80,000 t/a of THF, 60,000 t/a of poly-THF and 8,000 t/a of polyisocyanate (total investment US-$335 million), Degussa production facilities for 9,000 t/a of polyester and 8,500 t/a of color-

Continues Page 31



Fit For The Future

Chemical Industrial Parks in China

Continued Page 30

ants (total investment US-$36 million), a future complex for 100,000 t/a of methylmethacrylate and special Plexiglas products and the British Lucite facility for 90,000 t/a of MMA at a total cost of US-$110 million.

Bayer is planning to invest a total of US-$1.8 billion at the integrated site. Bayer now has or is currently building production capacity for 10,000 t/a of polyisocyanate, 200,000 t/a of polycarbonate, 200,000 t/a of bisphenol A, 172,000 t/a of diphenyl carbonate, 230,000 t/a of methylendiisocyanate and 150,000 t/a of TDI. Construction of most of these production facilities got underway in 2003/04, and completion took place in 2005/06. Production is planned to start at the Degussa methylmethacrylate facility in 2009. Production at Bayer's MDI and TDI facilities will commence in 2008.

The list of Phase 1 joint ventures includes Shanghai SECCO Petrochemical cracker (joint venture between SINOPEC, SPCc and BP, capacity 900,000 t/a of ethylene) at a cost of US-$2.73 billion, the Shanghai Lianheng Isocyanates isocyanate facility (GPCd, SHYGe, SCACCf, BASF and Huntsman joint venture, US-$1.12 billion), the Shanghai SINOPEC Mitsui Chemicals (JV between SINOPEC and MGCg) bisphenol A facility (120,000 t/a) and the Shanghai Shenxing Chemical Industrial formaldehyde facility (80,000 t/a). Alongside the foreign investors, the domestic producers SCACC, GPC and SHYG have built their own plants for the production of PVC, acetone, ABS, SBR, PVDF and HFA. The 13.4 square km Phase 2 sector will be mainly used by downstream customers of the Phase 1 companies (fine chemicals and derivatives). Currently the sector is virtually empty, and SCIP Development Co. is searching for potential investors to increase the level of vertical integration at the site. The reagents plant built by TCI (Shanghai) Development of Japan at a cost of US-$70 million has now gone into operation. The land reclamation work for Phase 3 was completed in 2004, and the plots are already reserved for specific large investors. The list of facilities which will be constructed includes a cracker, a refinery, a gas-based power station and a port.

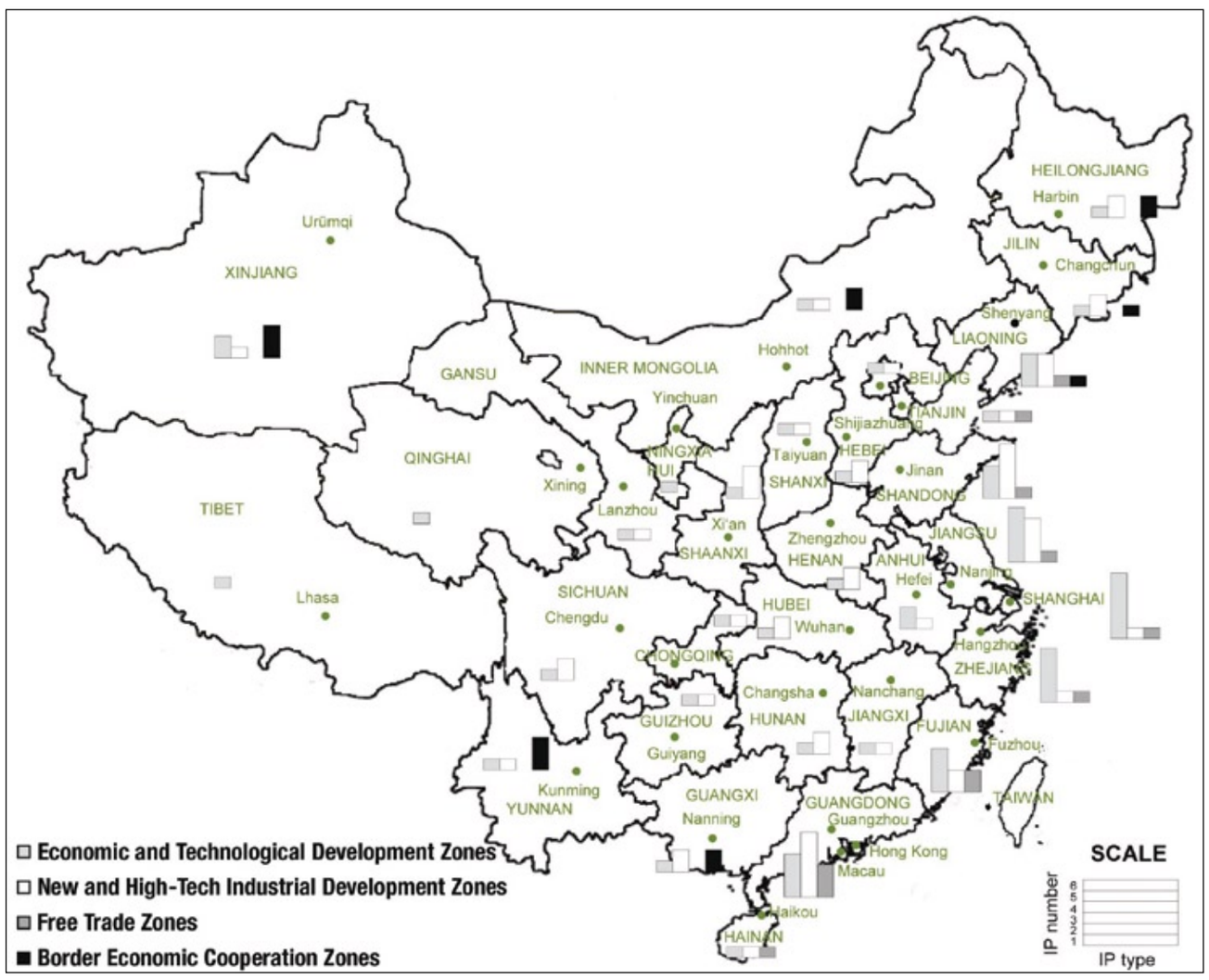


Fig. 1: Number and distribution of the different categories of industrial parks in China.

Table 1: Eco industrial parks including corporate groups and development zones in China

No.	Location	Industrial Focus	Approved
1	Guigang, Guangxi (Guitang Group)	sugar, alcohol, fertilizer and paper factory	2001
2	Nanhai Eco-Industrial Park, Guangdong	environmental S&T consulting, production of environmental protection technology, production of ecological products, recycling industry	2001
3	Baotou Aluminium (Group) Co. Ltd., Inner Mongolia	aluminum industry	2003
4	Changsha Huangxing Industrial Park, Hunan		2003
5	Lubei, Shandong (Lubei Group)	chemicals, construction materials and light industry	2003
6	TEDA, Tianjin	electronics, machinery, pharmaceuticals and foodstuffs, ISO 14001	2004
7	Fushun Mining Group, Liaoning	coal mining and methane recovery	2004
8	Dalian ETDZ, Liaoning	petrochemicals, electronics, telecommunications, etc. ISO 14001	2004
9	Suzhou High-Tech Development Zone, Jiangsu	telecommunications, fine chemicals, precision mechanics and new materials, ISO 14001	2004
10	Suzhou Industrial Park, Jiangsu	IT, automotive industry, logistics, ISO 14001	2004
11	Yantai ETDZ, Shandong	electronics, textile fiber, plastics food and biomedical, ISO 14001	2004
12	Guiyang Kaiyang Phosphorus Chemical Engineering Group, Guangxi	mining coal with high phosphor content	2004
13	Weifang Ocean Chemical High-tech Development Zone, Shandong	chemical and high-tech industry	2005
14	Zhengzhou Shangjie Industrial Park, Henan		2005
15	Baotou Iron and Steel (Group) Co. Ltd., Inner Mongolia	iron, steel and rare earth metal industry	2005
16	Shanxi Antai (Group) Co. Ltd., Shanxi	coal washing, coking plant, pig iron, construction materials and the electric power industry, ISO 14001	2006

Eco Industrial Parks (EIPs) Act as Pilot Projects for a Sustainable Economy

Sustainable development, "circular economy" and integrated production facilities play a strategic role in the Chinese economy. Numerous new laws have been introduced in order to implement what has long since been standard in western countries: conservation of resources, environmental protection and safety. The 7th AchemAsia from 14–18 May 2007 will bring together around 500 exhibitors from 25 countries and 20,000 visitors to discuss this topic.

Explosive economic growth, a higher standard of living, population growth and an unbalanced regional distribution of resources coupled with the lack of a strategy for sustained development have resulted in regional shortages of energy and water, significant pollution and damage to the environment. The government has recognized the problem, and in 2002 it adopted the "Circular Economy (CE)" as its new, far-reaching development strategy. It is hoped that this approach will provide a basis for continual economic growth by making more efficient use of natural resources and by increasing the ecological efficiency of production and consumer consumption.

The State Council gave an additional indication that the "Circular Economy" will play an important role in the country's future economic development when it transferred responsibility for driving the Circular Economy forward from the State Environmental Protection Administration (SEPA) to the National Development und Reform Commission (NDRC).

Since 2002, China has been phasing in the circular economy at three levels: at the micro and company level as cleaner production (Cleaner Production Promotion Law 2003), at the meso or industrial park level in the form of Eco Industrial Parks (EIPs) and at the macro level as eco cities and provinces.

At the industrial park level, an environmental research institute with support from the site management team develops an eco plan for the park, which takes regional constraints and opportunities into account. These plans are not limited to issues related to industrial production. They focus mainly on inner- and intra-company engineering issues, for example energy cascading, shared use of infrastructure, exchange of by-products and waste recycling, as well as on economic incentives such as subsidies for environmental protection investment and resource pricing strategies.

Once the eco plan has been approved by SEPA, the park is given "EIP" status. There were 16 Eco Industrial Parks in China in May 2006 (see table 1). SEPA published the Standards for EIPs in China, and it is expected to start assessing implementation of the eco plans in the near future.

Despite the success of some pilot projects (e.g. TEDA and Dalian development zone), progress has been slow because insufficient attention has been given to the economic aspects. In order to achieve more efficient implementation, a slow paradigm change is currently under way. Instead of being viewed as an incentive to recycle, "circular economy" will become a strategy for sustainable development evolving the industrial structure, developing new technology and reforming industrial policy. The draft Circular Economy Promotion Law is expected to go into effect in 2007 or 2008.

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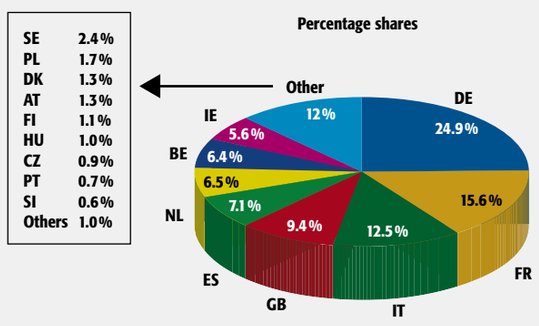
The EU Chemical Industry

Geographic breakdown of EU chemical industry sales
Sales 2005: € 613 billion



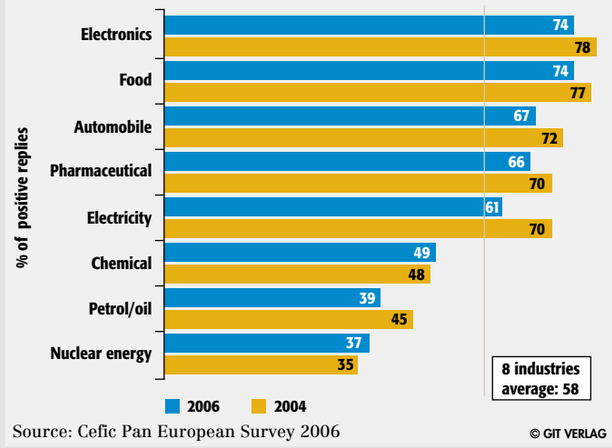
Note: Big 8: Germany, France, Italy, UK, Spain, Netherlands, Belgium and Ireland

Source: Cefic

Germany is still the largest chemicals producer in Europe, followed by France, Italy and the UK.

Together, those four countries generate almost two thirds of the EU's chemicals sales (€613 billion). Adding Spain, Netherlands, Belgium and Ireland raises the share to 88%. Poland is the biggest new EU country, representing 1.7% of total EU chemicals sales.

Public image of the EU chemical industry



Source: Cefic Pan European Survey 2006

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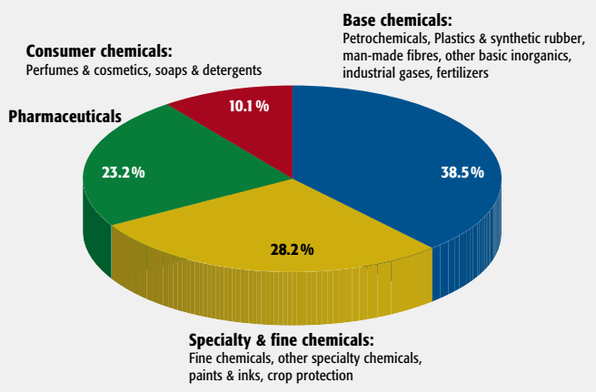
In a pan European poll on the image of the EU chemical industry, chemicals in 2006 were in sixth position out of eight benchmark industries and rank below the average. However, recent efforts to improve the reputation of the industry seem to work-ing. The image of the chemical industry in the last two years has developed far better than the average of all eight benchmark industries.

The EU Chemical Industry

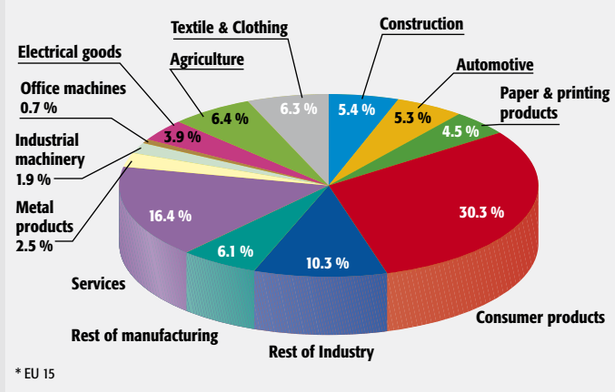
Sectoral breakdown of EU chemical industry sales



Source: Cefic

The output covers four wide ranges of products: base chemicals, speciality and fine chemicals, pharmaceuticals, and consumer chemicals. Base chemicals are produced in large volumes and are sold to the chemical industry itself or to other industries. Specialties cover the auxiliaries for industry, dyes & pigments, oleochemicals, crop protection, and paints & inks. Fine chemicals represent pharma-, agro-, and chemical intermediates. Pharmaceuticals represent both basic pharmaceutical products and pharmaceutical preparations but not pharmaceuticals intermediates. Finally, consumer chemicals are sold to final consumers: soaps and detergents, perfumes and cosmetics.

EU chemical industry consumption structure
% of chemical domestic consumption



* EU 15

Source: Cefic and Eurostat

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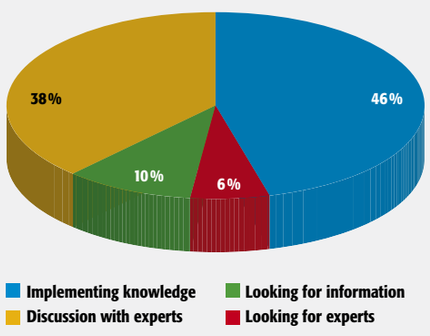
The chemical industry underpins virtually all sectors of the economy and its strategies impact directly on the downstream users of chemicals. The consumption structure of chemicals by downstream users gives the following picture:

- 30.3% of chemicals consumption is absorbed by consumer products, 16.4% goes to services, 6.4% to agriculture, 5.4% to construction, 6.1% to the rest of manufacturing and 10.3% to the rest of industry.
- The big industrial customers of chemicals are the metals, mechanical & electrical industries, textiles & clothing, the automotive industry and paper & printing products.

Knowledge Management

Time invested in knowledge work (%)



Source: Deutsche Bank Research

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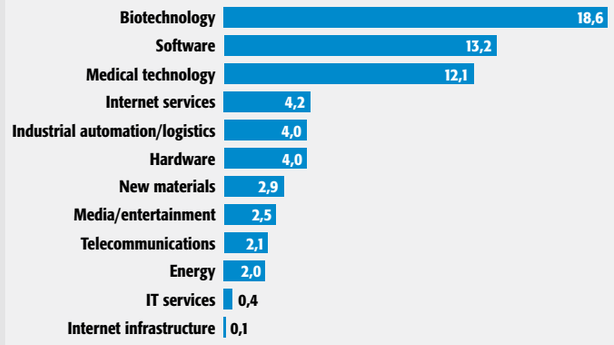
Thanks to improvements in technology, knowledge workers only have to use a small amount of their time in researching. More than 4/5 of their work time is used for discussions with local experts about finding feasible solutions and to put newly acquired know-how to use.

Quo Vadis, Venture Capital

Where are investments being made?
According to capital invested in venture capital panel participants in Q3 2006 in million €



Source: VDI

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In the third quarter of 2006, venture capitalists invested significantly less than in the past. Only €58 million was pumped into start ups by the 40 venture capital panel member German venture-capital investors. The most attractive sector for investment remains biotechnology: About €19 million was invested in the industry, mainly as follow-up financing of existing investments.

Latest Research in Organic Electronics

OEC-2007 in Frankfurt

Now in its fifth year, the Organic Electronics Conference and Exhibition 2007 (OEC-07) is the premier international gathering of scientists, engineers, manufacturers and investors for the discussion, demonstration and evaluation of organic semiconductor technologies and organic electronics. OEC-07 is held at the Sheraton Frankfurt Hotel & Towers in Frankfurt, Germany on 24 – 26 September 2007.

With all exhibition space sold out, nearly 100 speakers and a 100% increase in submissions of peer-review papers compared to 2006, all the indications are that OEC-07 is set to be the biggest and most exciting in the conference's history.

Hosted by cintelliq, the organic semiconductor industry specialist, and by its conference partner the Organic Electronics Association (OEA), the key industry association for organic electronics, OEC-07 aims to cover all aspects of organic electronics (encompassing plastic and printed electronics) and organic semiconductor technologies. OEC-07 will host the field testing of the first printed low cost organic tickets developed by the Prisma Project (Printed Smart Labels). The tickets will use first generation printed organic-tickets based on radio frequency technology produced by Bartsch and PolyIC in close collaboration with members of the Prisma -Project. During this first field trial, organic tickets will be used to collect statistical data. Four reader stations developed by PolyIC and about 1,000 organic tickets converted by Bartsch will be used to monitor the flow of attendees throughout the two day conference and exhibition. The field trial is expected to deliver valuable results and support the development of a wider range of pRFID applications.

The conference is divided into three themed tracks with invited speakers, and one peer-reviewed track. Conference delegates will benefit from focused presentations delivered by established multinational organisations such as BASF, Degussa, Dai Nippon Printing, DuPont, LG.Philips, Merck, Nokia, Siemens, Sony, and Samsung, as well as from organisations exclusively focused on organic electronics such as Cambridge Display Technology, Cenamps, E Ink, Konarka, Nanoident, Novaled, OLED-T, Plextronics, PolyIC, Polymer Vision, printed systems, Sumation and Thin Film Electronics.

Keynote speakers include:

- EC funding for organic electronics – Rosalie Zobel, Director European Commission
- Organic electronics roadmaps – Wolfgang Mildner, Chairman OE-A
- ePaper and eBooks in the newspaper industry – Allan Marshall, principal iMedia Advisory,
- Reducing carbon emissions through new technologies – Richard Guy, Research Manager Carbon Trust

Four pre-conference workshops on 24 September will help new entrants to the industry get up to speed with developments in technology, intellectual property, and commercial activities, while industry professionals will benefit from workshops providing more in-depth coverage of applications, standards, printing processes and manufacturing issues. Workshop participants will also be able to take part in visits to local companies MAN Roland Druckmaschinen and Merck KGaA.

The conference Gala Dinner on the evening of 25 September will host the presentation of the 2007 Organic Semiconductor Industry Awards (OSIA). Three awards will be presented: Start-up of the Year, Research and Development, and Best Peer-Review Paper.

Craig Cruickshank, cintelliq founder and CEO, said, "The continued and growing interest being shown in OEC-07 reflects the dynamism within the organic semiconductor and organic electronics industry as a whole, and we confidently expect to hear some exciting company announcements made during this year's event."

Wolfgang Mildner, chairman of the OE-A, said, "OEC-07 is the central forum and marketplace for this industry and consequently the place to inform the community about recent progress at OE-A: the expansion of our worldwide activities and the update of our roadmap for organic electronics."

More information can be found at www.oec-europe.com

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