9/2012
September

CHEManager EUROPE

THE NEWSPAPER FOR THE CHEMICAL AND LIFE SCIENCE MARKETS

Materials Solutions

Dow Corning's new Solar Energy Exploration and Development Research Center in Belgium.

Page 6

Locations

European Chemical Industry Parks and their Operators Face Great Challenges.

Pages 10, 11

Newsflow

Locations
European chemical industry parks and their operators are facing great challenges; increasing and complex demands of globally active chemical companies on the one hand, ongoing global competition among chemical industry parks on the other. In an overview on European chemical industry parks the pros and cons are discussed. Kokkola, one of Finland's Industrial Parks is Scandinavia's biggest chemical manufacturing site is presented in this issue.

More on **Pages 10, 11, 12** ▶

CPhI 2012
Madrid will be hosting this year's CPhI Worldwide Event, from October 9-11. The global pharmaceutical ingredients industry is meeting; trying to stay informed about the latest industry trends and remain one step ahead of a rapidly changing pharmaceutical market. We inquired opinions of some of the market players to hear the newest trends first hand.

More on **Pages 13, 14, 15** ▶

Pharma
Second quarter and first half reports of "Big Pharma" players showed that the crisis hit pharmaceuticals earlier than chemicals. While France's Sanofi a projected 2012 sales loss, UK's Glaxo SmithKline (GSK) has trimmed its outlook. Further companies presented in our pharmaceuticals overview are AstraZeneca, Novartis, Bayer, Pfizer, Merck & Co, Bristol-Myers Squibb.

More on **Pages 2, 11, 18** ▶

Chemicals
In July and August, second quarter and first half figures were presented. For the industry's majors in particular the numbers published so far this year have been on course or only slightly weaker. Even if chemical output in the European Union sank by 2.4% year-on-year from January to June, selling prices were 3.4% higher, Cefic reported. Companies presented in our chemicals overview are BASF, Dow Chemical, LyondellBasell, DuPont, Arkema, Solvay, Rhodia, Bayer.

More on **Pages 9, 20, 22, 24** ▶

Supply Chain Management Weighs Heavy

The Pharmaceutical Ingredients and Custom Synthesis Industry Prepares for Future Pharma Market Challenges

Jean-Luc Herbeaux
Head of Health Care Business, Evonik

Pharmaceutical companies today need an agile, reliable and empowering partner with global resources to increase efficiency and keep them on the cutting edge of technology.

Roger Laforce
CEO, Zach System

The pharma industry and its entire supply chain are undergoing a paradigm change considering the increasing importance of emerging countries now also seen as markets.

Marianne Späne
EVP Global Business Development, Marketing and Sales, Siegfried

Streamlined operations via lean manufacturing practices are today's standard which is increasing the demand for contract manufactured drugs.

Dr. Peter Pojarliev
Director, Business Development, Euticals

Among strategic partners open communication and common understanding of the project goals and expectations are key success factors.

Alexander R. Wessels
CEO, DSM Pharmaceutical Products

As global supply chains expand, the safety of ingredients and finished drugs, as well as the sustainability of these supply chains, become critical.

Elliott Berger
Vice President, Global Marketing and Strategy, Catalent Pharma Solutions

Partnering and open innovation models are clearly becoming more significant in the drug development and delivery space as well.

Hendrik Baumann
Commercial Director, CU Chemie Uetikon

As the custom synthesis market is extremely diversified, we will probably see a market consolidation in the next years.

David DeCuir
Director, Albemarle Fine Chemistry Services

Suppliers to the pharmaceutical industry will be required to make smaller campaigns of multiple drugs in their facilities rather than large campaigns or even dedicated lines.

Thomas D'Ambra
Chairman, CEO & President, AMRI

Recent issues in the pharma market coinciding with prolonged economic recession in Western countries are leading to changes in how pharma companies consider outsourcing.

Read the related article and the complete statements in the Pharma section on pages 14/15.

READER SERVICE

Don't have your own CHEManager Europe? Wrong address?

Send an e-mail to chemanager-europe@gitverlag.com

WILEY VCH · PF 11 05 64 · 69469 Weinheim · Pressepost · DPAG· Entgelt bezahlt · 78719

CONTENT

Lanxess Rises into German Stock Index DAX

Deutsche Boerse will include Lanxess in Germany's leading stock index DAX 30 effective September 24, 2012. On September 5, Lanxess shares closed at EUR 60.00. The DAX (Deutscher Aktien Index) consists of the 30 major German companies trading on the Frankfurt Stock Exchange. According to Deutsche Boerse DAX measures the performance of the 30 largest German companies in terms of trading volume and market capitalization. ■

Valeant to Acquire Medicis

Valeant Pharmaceuticals International agreed to buy Medicis Pharmaceutical for $2.6 billion in cash, in a deal that will add Botox competitor Dysport and other skin care drugs to its portfolio. Valeant, which is the largest publicly traded drug maker in Canada, has been on an acquisition spree since its 2010 takeover by Biovail Chief Executive Michael Pearson, a former McKinsey director, prefers growth through acquisitions to heavily spending on research. Valeant has been bulking up its skin care portfolio in the United States in recent months. ■

DuPont to Sell Car Paint Unit to Carlyle for $4.9 Billion

DuPont struck a deal to sell its slow-growing car paint business to private equity firm Carlyle Group for $4.9 billion cash as it seeks to focus on higher-growth areas such as agriculture and nutrition. The sale of DuPont Performance Coatings would remove the lowest-margin and slowest-growth business from the chemical company's portfolio, and allow DuPont to cut debt and make acquisitions in priority areas that also include advanced materials and biotechnology. ■

Warwick Reaches Agreement to Acquire IDC

Warwick Chemicals, a manufacturer of detergent chemicals for the laundry and home care market, has reached an agreement to purchase International Detergent Chemicals from Dubag Celtic Holdings. The terms of the proposed transaction were not disclosed. IDC is based in Cork, Ireland and manufactures tetraacetylethylenediamine (TAED), a bleach activator used in laundry and household product applications. The business was acquired by Dubag in February 2011 from Henkel, which began producing TAED for in-house use in 1984. The proposed transaction is expected to complete in 2012, subject to review by the relevant regulatory authorities. ■

Azelis to Represent Robinson Brothers in Rubber

Azelis has been appointed distributor for the Benelux region by Robinson Brothers, a leading UK based fine speciality chemical manufacturer. Azelis will be able to offer customers the ROBAC range of rubber accelerators and aims to work closely with Robinson Brothers to grow the market in Benelux with these products. ■

Rockwood Holdings to Buy Talison Lithium

Specialty chemicals producer Rockwood agreed to buy Talison Lithium for $729 million to boost its output of lithium used in batteries and smartphones. Demand for lithium batteries has risen in recent years as they are more efficient and help cut carbon emissions. Lithium business accounted for 14% of Rockwood's June quarter sales of $905.6 million. Talison Lithium exports over 350,000 tons of lithium products annually.

Rockwood, whose peers include Kronos Worldwide, Sensient Technologies, WR Grace and Co and Valhi, has said it expects battery-grade lithium products to show double-digit sales growth this year. ■

BASF Included in Three Indices

BASF was again included in the global Dow Jones Sustainability Index (DJSI World). The company has been recognized for its sustainability engagement in areas such as climate strategy, risk and crisis management as well as human capital development. The DJSI World is one of the most recognized sustainability indices and represents the top 10 percent of the largest 2,500 companies in each industry included in the Dow Jones Global Index. According to the international investor group Carbon Disclosure Project (CDP), BASF is among the ten leading companies in the world in climate protection. In the current ranking, the Carbon Disclosure Leadership Index (CDLI) listed BASF with an outstanding place for the eighth time and the company has been included in the Carbon Performance Leadership Index (CPLI). The CDLI contains 51 companies that disclose their data in a particularly transparent and comprehensive manner. The CPLI lists 33 companies based on their exemplary performance in climate protection activities – for example their climate strategy, their stakeholder communication or their management system. ■

F.I.S. Moves into Biotechnology with Areta Deal

After consolidating its presence in North America with the acquisition of Montreal-based Delmar Chemicals, a Canadian company engaged in the scale-up and cGMP manufacture of APIs, F.I.S. is positioning itself in the field of biotechnology. F.I.S. purchased a stake in Areta International, an Italian biotech company, which focuses on contract development and manufacturing of biotechnology and advanced therapy products. This deal creates new opportunities, broadening the Group's expertise and adding to the existing know-how the invaluable experience in research and development and manufacturing of biotechnological and innovative therapeutical products that Areta has built in more than ten years in the biotech domain. ■

Rockwood Completes Chemetall Split

Rockwood announced that its Frankfurt-based German subsidiary Chemetall has completed the formal legal split of its operations into two independent legal entities. Chemetall will remain the legal entity and brand name for the surface treatment business. The lithium and special metals business will be renamed Rockwood Lithium. The unit is already doing business under the brand name Rockwood Lithium. ■

DOW CORNING

all the options, at your fingertips

For efficiencies in silicones, point your browser to the XIAMETER® brand.

The XIAMETER brand from Dow Corning makes it faster and easier than ever to bring the performance benefits of silicones to your products. That's because we've expanded our lineup to include thousands of high-quality standard silicone products—all available online or with a quick call to your distributor. So you can make your products perform better. Cut the costs of manufacturing. And bring even more value to your customers.

See how at **xiameter.com**.

Silicones Simplified
XIAMETER®
from DOW CORNING

The Best of Both Worlds

Supply Chain Management Organizations Developing towards a Coordinated Network Model

SCM Development – The rise of new markets throughout the world means that all globally active companies must continuously adapt to the developing changes. Ultimately, change never comes to an end. This especially applies to the organization of supply chain management. A study which Camelot Management Consultants carried out together with a team from the University of Warwick, UK of the chemical, pharmaceutical and consumer goods industries, shows where SCM organizations in these industries stand at present. CHEManager Europe spoke to Michael Jarosch, Partner and Head of Pharmaceuticals & Life Sciences Practice at Camelot Management Consultants and Julian Amey, Principal Fellow, Warwick Manufacturing Group about the main findings of the study. The interviewer was Dr. Sonja Andres.

Michael Jarosch, Partner and Head of Pharmaceuticals & Life Sciences Practice, Camelot Management Consultants

Julian Amey, Principal Fellow, Warwick Manufacturing Group, University of Warwick/ UK

CHEManager Europe: Mr Jarosch, in the future, optimal organization of the supply chain will play an even more important role in the success of a company on the global market. What are the trends in the organization and management of the supply chain and which general external factors need to be taken into account?

M. Jarosch: Globalization and growth strategies of companies in emerging markets, increasingly volatile global demand as well as the trend to a virtualization of the supply chain and a geographical shift in sourcing are significantly changing the global footprint of companies and are having a dramatic effect on supply chain management (SCM). In addition there are increasing requirements with regard to compliance and supply chain security as well as the development towards a more sustainable "Green Supply Chain". These have all become a permanent challenge for the core activities of SCM: the reliable, agile and efficient supply of markets and customers with products. The organization and its necessary development and adaptation to these trends form the basis of successful SCM.

Together with the University of Warwick, UK, Camelot has carried out a study on the subject of "Supply Chain Management Organization" (SCMO). What was this study intended to discover or clarify and why were the chemical, pharmaceutical and consumer goods sectors singled out for investigation?

M. Jarosch: On the one hand, the chemical, pharmaceutical and consumer goods industries are primarily process industries with similar strategic and operative challenges and on the other hand they have the full spectrum of SC structures from local to globally integrated supply chains. We have seen that with regard to their general improvement initiatives there are differences between the sectors, for example with regard to their degree of maturity and their efforts concerning the standardization and harmonization of business processes. This is therefore a wide field in order to learn from each other, certainly taking into account the basic differences.

However, in all of these sectors, SCM is now an important element of company strategy and organization, which is continually developing. In spite of this, there is comparatively little information about how companies currently set up their SCM and their rationale.

The key question of the study was: Are SCM organizations prepared for and capable of successfully facing up to the apparent trends? In the study we developed a reference framework, which defines various SCM organization models and explains when these are successful with different strategies. The framework model also helps to examine the consequences of inconsistencies as well as the influencing and success factors for the structure and further development of the organization.

Mr Amey, what are the basic models for the organization of SCM in the three sectors which were investigated?

J.C. Amey: We were able to assign all the participating companies in all three sectors to three basic models: the local/regional decentralized, the centralized "Hub & Spoke" and the coordinated network SCM organization model.

Characteristic for the local/regional decentralized SCM organization model is the independence of the local units, i.e. their commercial freedom and authorization to make decisions in the local production and distribution units. Here, SCM is focused on local optimization. There is hardly any global standardization. The SC performance is not visible over the entire chain.

With the centralized "Hub & Spoke" SCM organization model we find a dependence of the local/regional units on the directives of a head office, with greater global end-to-end transparency of the SC, a high degree of standardization of processes, central control and a uniform SCM culture with aligned behaviors.

Finally, the coordinated network SCM organization model has strong interlinking, interdependence and collaboration between the local and central SCM units. It is based on jointly agreed objectives and commercial freedom of the local units within a defined framework. Special local circumstances are taken into account.

What advantages and disadvantages are there for chemical and pharmaceutical companies resulting from the different SCM structures?

J.C. Amey: The three basic organization models have very specific advantages and disadvantages. For the local/regional decentralized SCM model, the advantages lie in the entrepreneurial spirit, local SCM performance and consideration of the needs of local markets, e.g. on entry into emerging markets. The disadvantages are the poor end-to-end transparency of the SC, high stock levels and a less competitive cost structure. The central "Hub & Spoke" SCM has advantages with regard to costs, and efficient, harmonized SC and standardization. The disadvantages lie in the remoteness from customers, the weak "entrepreneurial spirit" and inflexibility. With the coordinated network SCM organization model, the advantages clearly lie in the balance between costs and service as well as between coordination and local agility. However, the prerequisite for this is an effective governance model.

The study revealed that some companies are converting their central, globally-oriented supply chain management into a local/regional organization. When does that make sense?

M. Jarosch: Many of the companies in all of the three sectors which we examined have developed towards a central SCM organization over the past years. This is due to the need for improved global transparency and control of the SC, together with a harmonization of SCM processes, especially planning. The fundamental prerequisite for this was that SCM IT systems continued to develop and could provide this global transparency.

Nevertheless, companies still face problems regarding the reliability of the supply chain. In particular, the agility of the SC tends to be restricted by excessively rigid central control. This often contradicts the requirement for speed and flexibility which is necessary for growth in emerging markets.

However, the companies are not "going back" to local independence. We are now seeing the first companies which are combining and developing the "best of both worlds" in the form of a coordinated network, with a high level of collaboration to achieve common objectives, agreed responsibilities and joint transparency. This is not a return to local independence but rather a further development towards a coordinated network.

What about the SCM basics such as simplification of processes, data management, IT structures, etc. in the industries?

M. Jarosch: Our view is very simple: "Fix the Basics!" The companies questioned did not consider themselves to be very good with regard to their degree of maturity in process standardization/harmonization, master data management and IT support. However these are essential prerequisites for both a centralized Hub & Spoke SCM organization model as well as for a coordinated SCM network.

There are very different successful models for the management and organization of the supply chain. How can a company find the optimum SCMO for its business concept?

J.C. Amey: There is no such thing as a "one size fits all" solution for SCM organization – even within a particular industry. Each of the organization models supports specific performance objectives.

M. Jarosch: For each company, with its specific, strategic and operational objectives, it is therefore necessary to individually examine how the market and competitive strategy, SC configuration and company culture and behaviours can be consistently coordinated, aligned and developed with the SCM organization. On the journey to this target organization, factors such as the history of the company (e.g. growth due to M&A), the degree of development of business processes, IT support of the SCM or the critical mass and skills of the SCM staff, both globally and locally must be taken into account.

Can the involvement of 3-PL (Third Party Logistics) providers be an option for the renewal, adaptation of change of the supply chain for the purpose of optimization?

M. Jarosch: The use of 3-PL service providers is common practice in all of the three sectors which were examined. Fundamental decisions, which have a considerable influence on the SCM organization relate to the degree of outsourcing of the SC. This concerns both the contract manufacturing as well as logistics and distribution. For a seamless flow in the SC, the company must integrate the external service provider as if it was one of its own units. Interfaces must be jointly standardized. Coordination of the SC does not end at the factory gate. The general objective for the sectors which were examined is to reduce complexity and remain agile. This is something which service providers must come to terms with.

What should e.g. a pharmaceutical company fundamentally take into account in the structural optimization of its SCMO?

M. Jarosch: Especially in the pharmaceutical industry, local optimization of the supply chain is now no longer sufficient, as a global "lean end-to-end SCM" goes far beyond the concept of "lean manufacturing". The need for improvement with regard to virtualization of the SC is especially pronounced in the pharmaceutical industry. On the other hand, a large proportion of growth is generated in emerging markets with special requirements. In future, a rigid centralism will prove to be too inflexible. In the pharmaceutical industry, the SCM must create a clear view of these developments and the resulting requirements, because only then a development path for the SCM organization can be defined on the basis of the current capabilities. We regard the skills of supply chain management staff to be a critical bottleneck in supply chain management, which in future will need to go far beyond analytical skills – both globally and locally. Here, the orchestration and decision-making process in SCM in optimization situations e.g. regarding inventories, production costs and customer service, will be exceedingly important in the future

The study can be ordered free of charge at: http://www.camelot-mc.com/en/about-us/insights/surveys/

Please direct inquiries for literature references used in this article to the authors.

- www.camelot-mc.com
- www.wmg.warwick.ac.uk

chemanager-online.com/en/tags/scm

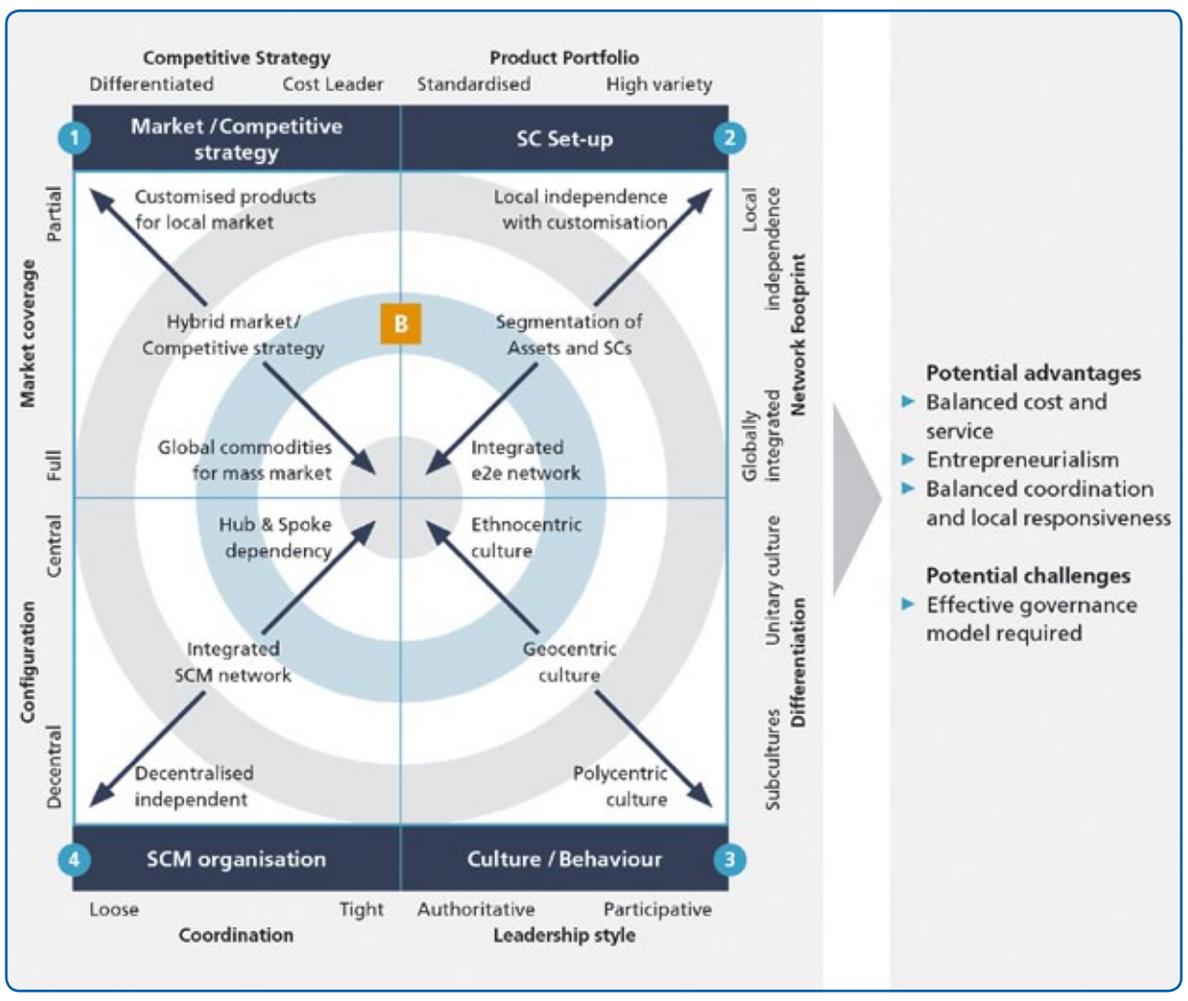


Fig. 1: Characteristics of the Coordinated Network Interdependence model.

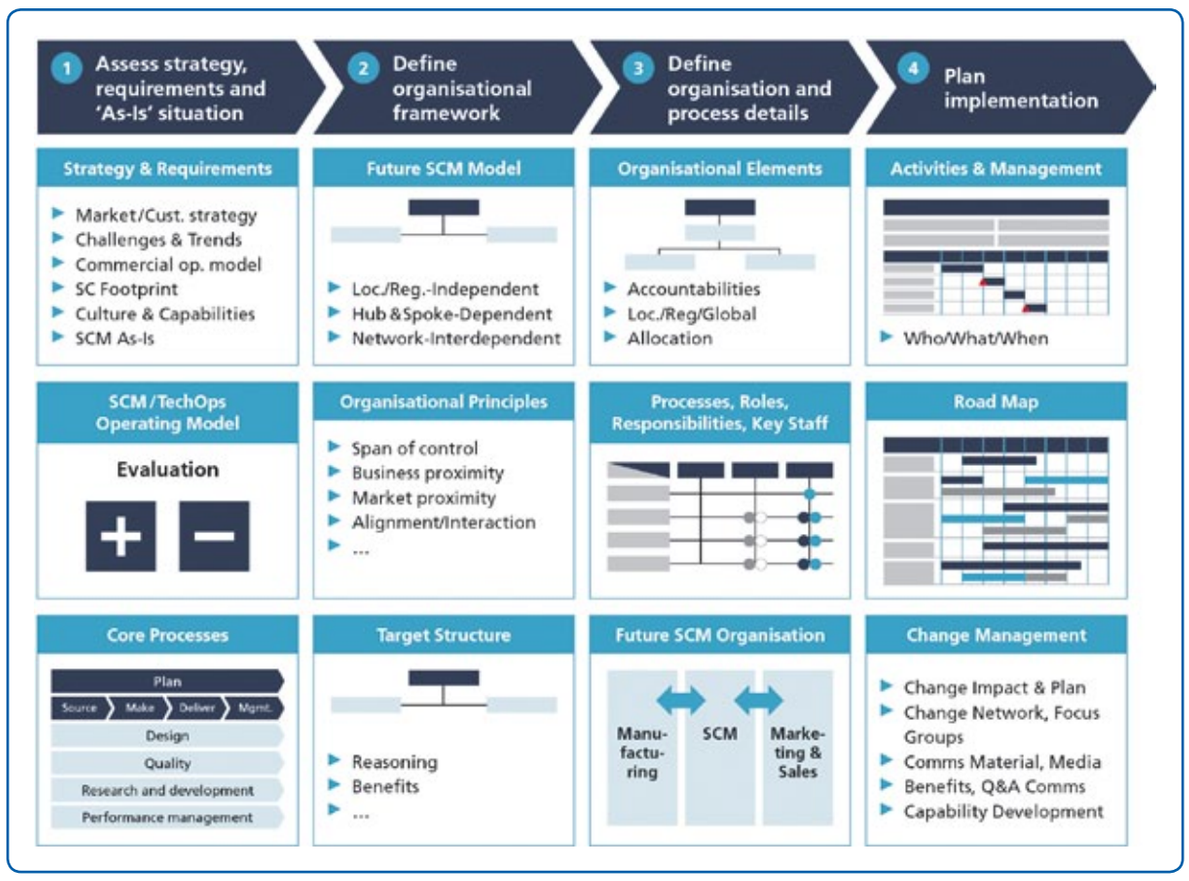


Fig. 2: 4 Step approach to SCM organisation design.

Contract Manufacturing in India and China

Government Policies Encourage Outsourcing

Outsourcing – Today's pharmaceutical industry is flooded with numerous CMOs, with Asian countries being the prime focus for big pharmaceutical companies looking to outsource. This is primarily due to the advantage of low production costs in Asia in comparison to other regions. Unlike the market for contract small-molecule manufacturing, the market for contract biologics manufacturing in China and India is still in its infancy. Western CMOs engaged in pharmaceutical chemical development, particularly early-stage intermediates and generic active pharmaceutical ingredients (APIs), face strong competition from suppliers in China and India and increased competition, particularly from Indian suppliers, in advanced intermediates and custom APIs.

Increasing Government Sanctions are Favoring CMOs

India and China represent the fastest-growing countries in the CMO services sector having witnessed drastic changes in their government and regulatory policies that encourage pharmaceutical outsourcing in order to increase business and attract foreign clients.

Regulatory Changes in India and China

In India the Biotechnology Policy in 2005 issued simplified procedures for regulatory clearance and exemptions from import duties and service taxes, encouraging foreign investments within the country. Furthermore, the introduction of the new patent regime in India during January 2005 encouraged multinational pharmaceutical companies looking to outsource their manufacturing of branded drugs with the protection of Intellectual Property Rights (IPRs). The amendment of the Schedule Y article allows parallel phase clinical trials to be conducted along with reductions in custom duties for clinical trial samples being imported.

In China the State Food and Drug Administration (SFDA) has clearly stated contract manufacturing as a long-term goal for the country's economic growth. In early 2001, Article 13 of the new edition of the "Drug Administration Law" was issued. According to this, a drug manufacturer may produce drugs only after getting approval of the drug regulatory department, which is under the State Council. The new law legalized pharmaceutical contract manufacturing in China. In August 2003, the SFDA clarified in the trial version of the "Regulations on Processing Drug for Export" that Chinese drug manufacturers' may conduct contract manufacturing for a pharmaceutical company outside China.

The Indian CMO Market

India is an important emerging CMO destination. A combination of factors such as the availability of low-cost skilled labor, low manufacturing costs, government and regulatory support, experience in generics manufacturing, strong financial condition of CMOs operating in India and the availability of adequate numbers of cGMP-compliant manufacturing sites in the region make India a popular outsourcing destination of choice for CMOs. According to GBI Research's analysis, the Indian CMO market was worth $1.3 billion in 2010 and is expected to grow at a CAGR of 21% to $6.0 billion by 2018.

Challenges and Key Concerns for the Indian CMO Market

A key concern over India's drive to become a major CMO hub is its poor IP protection and regulatory framework. Indian IP protection laws have undergone significant changes in recent years and are becoming increasingly favorable towards foreign investors, but there are still apprehensions over inadequate IP protection for Western companies. A notable example in this respect is the rejection of a patent application from Novartis for its anti-cancer drug Glivec (imatinib) by the Intellectual Property Appellate Board of India (IPAB). This drug was already patented in more than 40 countries around the world, including China.

Adding to these concerns is the increasing threat of counterfeit medicines originating from India. The World Health Organization (WHO) statistics show that up to 40% of drugs sold in India could be counterfeit. WHO also expressed concern over the manufacturing of such drugs and their export to other countries from India. WHO statistics show that counterfeit drugs from India constitute a significant proportion of worldwide seizures. The Organization for Economic Cooperation and Development (OECD) statistics show that 7.5% of fake drugs across the world have their origins in India. Such a high number of counterfeiting incidents makes the pharmaceutical companies wary of outsourcing to India.

Compliance with cGMP guidelines is quite varied across India due to the existence of many state drug regulatory authorities. A proposal to create a Central Drug Authority (CDA) that could regulate manufacturing on a national scale was shelved due to protests from small-scale manufacturers. The current regulatory framework is clearly inadequate for ensuring compliance with cGMP guidelines. A notable recent instance is the U.S. FDA's ban on imports from two of Ranbaxy's Indian manufacturing sites, citing violations of cGMP guidelines.

Effective tax rates in India are also very high and make it difficult to run businesses profitably. Total tax payments made by a business consist of a combination of profit tax (percentage of profits), labor tax (percentage of profits), and other taxes (percentage of profits). According to World Bank data, total tax payments as percentage of profits are as high as 64.7% in India. This is a point of concern for businesses operating there, as in Eastern Europe overall tax payments rates range between 37-59% of profit and for many attractive destinations the rates are in the range of the mid-40s.

The Chinese CMO Market

China is set to become the global hub for Contract Manufacturing Organizations. Production costs in China are among the lowest in the world and these low costs along with excellent infrastructure and facilities provide a competitive edge to Chinese CMOs. The direct and indirect personnel costs for the manufacturing of API in China are nearly 10% of those in Western countries and overall costs to produce a drug are 40% of that in the U.S.. Extremely low costs are one of the key reasons for production being outsourced to China.

The Chinese CMO market is currently generating revenues of $2.1 billion in 2010 and this market is expected to grow at a CAGR of 17.9% to reach $7.8 billion by 2018. The Chinese CMOs concentrate upon manufacturing generic APIs, bulk drugs and generics, but developments in the manufacturing of biologics are also taking place in China.

Challenges and Key Concerns for the Chinese CMO Market

One of the key challenges for Chinese CMOs is complying with the U.S. FDA and EMA's cGMP standards and getting large-scale contracts (especially for biologics manufacturing) from western pharmaceutical companies. As many of them are currently following national cGMP standards, the Chinese CMOs have to modify their facilities, improve their manufacturing processes, train their staff and implement IT systems to control their manufacturing processes in order to meet these challenges.

China does not have a great track record in IPR protection. Although the patent laws in China have recently been under revision to bring IPR protection more into line with global standards, there is still much to be done to improve IPR protection. Currently, China is on the priority watch list in the annual Special 301 report of the Office of the United States Trade Representative (USTR) for violations of IPR taking place in the nation.

Several Chinese drug manufacturers only follow national cGMP guidelines, which are below the accepted global standards (U.S. FDA cGMP, or EU cGMP) and this may create a regulatory risk for drugs originating from China. World Health Organization (WHO) estimates show that close to 20% of the world's counterfeit medicines seizures have originated from China. A noteworthy example is the major recalls of Heparin-based medicines made by the U.S. FDA in the U.S. in 2008 because of counterfeit Heparin API imported from China. Recently, China's leading internet search engine Baidu was accused of promoting counterfeit drug-selling websites. These examples show that drug regulation and IPR protection framework is still not effective in China.

Another challenge for CMOs from China is maintaining profitability while paying a high amount in taxes. Total tax payments made by a mid-sized business consist of a combination of profit tax (percent of profits), labor tax, and contributions to labor funds and other taxes. According to World Bank data, total tax payments as a percentage of profits are as high as 63.8% in China. This is just a little lower than India's 64.7% and still clearly higher than in Eastern Europe. The taxes there average out at the range of 45%.

Contact:
Kevin McHugh
Press Officer
GBI Research, Bolton, United Kingdom
Tel.: +44 1204 543 528
pr@gbiresearch.com
www.gbiresearch.com

chemanager-online.com/en/tags/markets

A Showcase for Energy Efficiency

Materials Solutions help make Solar Energy a Competitive Alternative to Traditional Energy Sources

Green Energy – As part of Dow Corning's global research network, the new €9 million Solar Energy Exploration and Development (SEED) research center in Belgium contributes to the development and discovery of new silicon-based materials that are advancing renewable energy and energy efficiency. Research activities within the SEED have recently started. Built with the latest technologies in energy efficiency, the research center also acts as a demonstration of what can be achieved in sustainable innovation using silicon-based materials in high performance building. Michael Reubold asked Eric Peeters, who served as vice president Solar Solutions & Wind Energy Solutions until recently and took on his new role as vice president Electronics Solutions for Dow Corning on September 1, about the strategy behind the investment in the SEED.

CHEManager Europe: Mr. Peeters, renewable energy and energy efficiency are key factors for a sustainable future. What does sustainability mean for Dow Corning?

E. Peeters: We see sustainability as essential to our future success. It will help us meet the needs of our customers, employees, and local communities. We are working hand-in-hand with our customers to develop materials and technologies that support their own sustainability goals and help them tackle some of the most pressing challenges of our society – from safer, more comfortable and more energy-efficient buildings to technologies that make renewable energy, including solar, more available and affordable. We also are seeking cost effective ways to extend the value of silicon-based technology to people in emerging economies.

What role does SEED play in this strategy?

Eric Peeters, Vice President, Solar Solutions & Wind Energy Solutions, Dow Corning

E. Peeters: Our new research facility SEED further enhances our ability to develop new silicon-based specialty materials which enable energy innovation to serve the needs of Dow Corning's European markets and customers, and bring additional expertise for global projects. It expands our research & development capabilities along the PV value chain as well as the next-generation of silicon-based technologies and applications, used to improve energy efficiency.

What is the strategic focus of your research portfolio for solar and wind energy solutions?

E. Peeters: Our entire portfolio focuses on improving performance and reducing the Levelized Cost of Energy. Everything Dow Corning develops and supplies to the PV industry addresses at least one of the following drivers: reduced cost per kilowatt hour, increased durability, improved performance, efficiency and reliability and global availability of large supply capabilities.

The SEED research complex was designed and built to showcase the possibilities of energy-efficient architecture enabled by silicones and silicon-based technology. Which energy efficiency features does the site display?

E. Peeters: Silicon-based technologies can significantly reduce the carbon footprint of products and applications. The Silicon Chemistry Carbon Balance study commissioned by the Global Silicones Council proved that the use of a relatively modest quantity of silicone and related products reduces the carbon footprint of many essential products and services. On average silicones, siloxanes and silanes can help save nine times the amount of greenhouse gases required to produce them. More specifically, sealants for window and insulating glass units can help save 27 times the amount of greenhouse gases required to manufacture them.

We are working with our customers to develop innovative solutions that help enable energy-efficient architecture and improve energy use, and have applied several of these technologies in our new SEED facility. For example, our new Vacuum Insulation Panels – VIP – cover the entire construction, providing high insulating value in materials up to five times thinner than conventional insulation products, and enabling maximal use of internal space. Building-integrated photovoltaics – BIPV -, a set of PV modules mounted as sun screens in front of the windows, reduce the need for cooling in the office area and simultaneously serve as power generators. Dow Corning's structural glazed facade technology allows the use of large, modern glass units, enabling more natural daylight in the building while improving energy efficiency and weather resistance.

Dow Corning's R&D group develops solutions for the PV industry.

Can materials solutions help make solar energy a competitive alternative to traditional energy sources?

E. Peeters: Absolutely. In solar, most research is happening in the areas where the biggest cost is. The highest cost is silicon, the semiconductor material used for crystalline PV. There is still a lot of research going on to making silicon cheaper, or making it better.

The second category of high cost is in materials used to assemble the module. Glass is quite expensive; a lot of research is going into this area to develop thinner, better glass. Wafers are becoming thinner as well.

Finally, the third category is installation. Today the installation of a solar module costs more than the purchase price of the module. There is huge improvement to be made, which can come partly from scale, but also from new, smarter materials and innovating with designs of structures, including how they are put together, which parts we assemble in the factory, which parts we assemble in the field, which kind of smart connection systems we use, et cetera.

Do you collaborate with industrial or institutional research partners on the development of innovative material technologies for solar and wind energy solutions?

E. Peeters: We need strong collaboration with customers, with our suppliers, and we definitely need collaboration with the academic world as well, whether that's directly with Universities or Research Institutes. At Dow Corning we have a combination of both. I share the view that industry and institutional research partners can work together on activities around pilot plants, and really implementing technology in the industry. Academia tends to focus on things that are quite far out whereas the industry tends to focus on the next quarter or the next government. That gap in between – the two to five year period of actually bringing a new idea into the market, and making it work – I think that is where the area of collaboration could be, that everybody would benefit a lot from.

Collaboration with partners along the value chain – either on a bilateral basis or in clusters – is becoming more and more important for chemical companies. Do you foster such partnerships?

E. Peeters: As a speciality chemicals company innovation with customers and research institutes is key to our success. We are working with several academic institutions on projects ranging from fundamental synthesis research to technology and applications for example the University of Cambridge, the International Solar Energy Research Center in Konstanz, Germany or Imec, the Interuniversity Microelectronics Center, in Leuven/Belgium, a world leading research center in nanoelectronics. By working with these centers of R&D excellence Dow Corning can leverage the expertise and resources of both industry and academia, accelerating key research breakthroughs and bringing innovative solutions that will benefit society.

> *We see sustainability as essential to our future success.*

Asian and U.S. solar panel manufacturers are top-ranked; the European photovoltaic industry continues to lose ground to overseas competitors. Why did you build the SEED research center in Europe and not in the U.S. or Asia?

E. Peeters: This investment demonstrates Europe's strategic importance for Dow Corning. The investment is one of several by Dow Corning aimed at further expanding the company's European network and supporting growth in the region. Between 2005 and 2010 Dow Corning has invested more than €140 million in our European infrastructures and in 2010 an additional €40 million in a new distribution center and in the SEED research facility. Europe has set the trend to enable energy innovation and we have the materials technology and applications expertise to address the specialized needs of our customers in these large and sustainable growth markets. The PV industry and companies like Dow Corning work in close partnership with the equipment industry, historically strong in the region, and many renowned research institutes that are located here to help making solar a competitive alternative energy option. Europe continues to play an important role in accelerating the development of new and innovative products and in pushing the PV roadmaps forward.

> *Europe has set the trend to enable energy innovation.*

What is your expectation for the growth of the global photovoltaic market?

E. Peeters: We are very optimistic about the future of PV and its potential to help address the world's enormous energy challenge. Relying on fossils fuels is simply not possible in long term. By increasing the solar energy capacity by 25-40 % year on year, the industry will continue to help increase the share of renewable, clean energy supply, securing the future of our children and our children's children.

What's your vision for the city of the future regarding energy generation, energy-efficient architecture and mobility?

E. Peeters: A city of the future will use clean and affordable energy, will have efficient and safe infrastructures and make sustainable construction reality. But to accomplish this goal we need technologies and applications that enable sustainable solutions. As a speciality chemicals company Dow Corning is working very closely with customers and research institutes leveraging our joint expertise to further advance silicon-based innovations that are enabling sustainable solutions especially in areas related to energy efficiency and energy generation.

chemanager-online.com/en/tags/photovoltaics

Solvay Acquires Sunshield Chemicals of India

To reinforcing its position in specialty surfactants market, Solvay announced that it has signed an agreement to acquire a controlling interest in Sunshield Chemicals, an Indian company specializing in surfactants, from Amit Choksey Group. This acquisition will enable Solvay's Novecare business to accelerate growth plans in India for the home and personal care, agrochemicals, coatings and industrial applications markets. Solvay is determined to double its sales in India by 2015.

Sunshield Chemicals generated net sales of €13.5 million in its most recent financial year ended March 31, 2012. This transaction enables Amit Choksey Group to focus more on their other activities in the field of pigments and other related products. This acquisition follows the opening of a major innovation center in Savli (Gujarat State) and further reinforces the Group's presence and commitment in India. ■

Cerbios and Xspray Establish Long-term Partnership

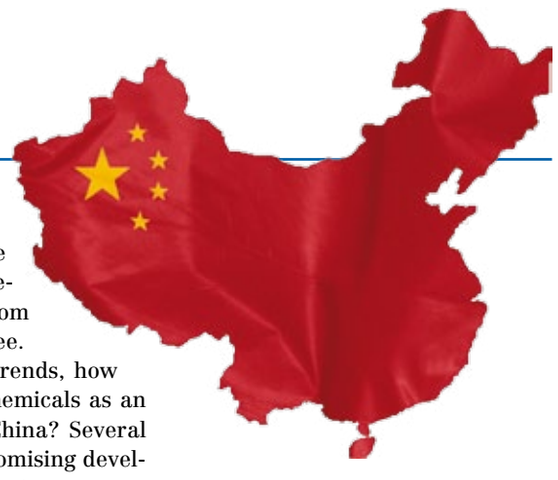
Cerbios-Pharma and Xspray Microparticles have signed a letter of intent to develop a long term, mutually beneficial collaboration whereby Xspray will be the preferred technology provider and Cerbios will be the preferred manufacturer for the joint development of HPAI (High Potency Active Ingredients) products with unique characteristics. The formulation and manufacturing abilities of Xspray's Rightsize technology offer the opportunity to improve drug substances through various strategies, enabling full control over particle design and production - simplifying drug formulation, extending delivery options and allowing the addition of innovative properties that truly benefit patients. The technology uses supercritical fluid as an antisolvent for controlled precipitation of an active pharmaceutical ingredient/drug substance. The development phases will be provided by Xspray in Stockholm , while the cGMP production for clinical and/or commercial at Cerbios in Lugano. ■

Bayer Sues Warner Chilcott for Patent Infringement

Warner Chilcott said German drugmaker Bayer filed a complaint against the U.S. pharmaceutical company, alleging that Warner's oral contraceptive drug Lo Loestrin FE infringes a Bayer patent. According to the complaint filed in a U.S. district court, Bayer is seeking an injunction on the product along with unspecified monetary damages, Warner said. New Jersey-based Warner said it would defend the litigation as it believes the complaint lacks merit. ■

Fine China

The Future of Fine Chemical Production



Production in Asia vs. the West – Fine chemicals are chemical substances that have a relatively high average price (similar to specialty chemicals), but they are sold based solely on a chemical specification, something they share with basic chemicals. Fig. 1 shows this classification along with some typical chemical examples for each segment.

Dr. Bernhard Hartmann
A.T. Kearney China

Dr. Kai Pflug
A.T. Kearney China

Fine chemicals broadly share a number of characteristics (Pollak, 2007):

- Fine chemicals are produced in small quantities and have an average price above about $10 U.S. per kg.
- Fine chemicals are single, pure chemical substances that can be fully characterized and specified.
- Fine chemicals are generally produced in multipurpose plants employing multistep batch processes.
- There is a huge variety of fine chemicals, though of the ten thousands of different molecules, each individual chemical company tends to produce only a small share.
- The number of applications for each fine chemical tends to be quite limited compared to that of more basic chemicals, and for each individual fine chemical, there is only a limited number of suppliers.

The pharma industry is by far the largest customer of fine chemicals, globally accounting for about two-thirds of demand. Related life science areas (agrochemicals and animal health) account for more than half of the remainder, while there is also a broad range of other applications, e.g., in catalysts, dyestuffs, electronic chemicals, flavors, food additives, etc.

Where To Produce

Is it preferable to select production sites in countries such as India and China or in countries with more mature economies? A number of contradictory factors influence the overall balance. Factors favoring production in Europe or the U.S. include:

- Raw materials costs (these are often higher in Asia because of added logistics costs).
- Stable energy supply (compared with the unstable supply particularly in India).
- Economic stability (as the sustainability of Asian economic growth is still questioned by some companies).
- Shorter supply chain and easier communication (as long as the majority of fine chemicals is still produced for Western markets).
- Easier monitoring of suppliers (for Western pharmaceutical companies).

On the other hand, the benefits of producing in Asia are getting more prominent:

- Salaries (though increasing faster than in the developed world) are still up to 90% lower, which leads to substantially lower overall labor costs even if adjusted for worker productivity. Salaries are quite relevant in fine chemicals production as the small amounts produced and the complex batch production process make it labor-intensive compared with basic chemicals.
- Lower investment costs per installed cubic meter of reactor capacity, with the difference ranging from a conservative estimate of 40% up to 60%.
- Lower costs to comply with local environmental regulation.
- Fast-growing local market (i.e., in China, recent growth of the pharmaceutical industry is about 15% p.a., and the low amount of medicine spent per head compared with the Western world makes further strong growth very likely).

Shifting Toward Asia

Examining these advantages and disadvantages of producing in Asia, it is difficult to come to a conclusion regarding the overall situation. However, it is telling that in the past few years, a number of fine chemicals units were sold and/or shifted to Asia. For example, in 2006 the pharma custom synthesis unit of Rhodia was bought by Shasun, an Indian API and intermediate producer. In the same year, the Chinese company Bluestar bought Adisseo, a producer of fine chemicals for animal nutrition. In 2008, two of the leading global chemical companies, Dow and BASF, sold some of their pharma production to the Indian pharma company Dr. Reddy's (the U.K. units of Dowpharma small molecules and U.S. pharma contract manufacturing, respectively). And at the end of 2010, DSM effectively sold half of its anti-infectives business to Sinochem by bringing the business into a joint venture.

Consolidation and Technology Upgrades

What can be expected for the near future? There are a number of trends. Among API producers, there is considerable consolidation.

Primarily, this takes place by the domestic market leaders acquiring secondary players — examples are the Sinopharma acquisition of China National Medicines or the Shanghai Pharma acquisition of Shanghai Zhongxi. At the same time, companies start focusing on marketing and sales rather than just on the production of active ingredients. This is particularly pronounced among generics producers such as Harbin Pharmaceutical, which has started experimenting with direct sales.

As in most segments of the Chinese chemical industry, improvement of ecological compliance is also a trend i, as seen in the implementation of a specific design code as well as the relocation of several major API producers.

Finally, fine chemicals producers in China are actively upgrading their technology and investing in creating and protecting their intellectual property. For example, Hengrui Medicine claims to have 300 researchers, half of whom have a doctoral degree.

In light of these trends, how attractive are fine chemicals as an investment area in China? Several aspects indicate a promising development for the segment.

As mentioned above, the domestic pharma industry is growing rapidly, generating similarly high demand increases for active pharmaceutical ingredients, a key subsegment of fine chemicals.

Apart from the domestic pharmaceutical companies, there is also a strong and increasing presence of global pharma players similarly generating demand for APIs. By now, all top 20 global pharmaceutical companies have production in China, and foreign direct investment increased by 34% from 2008 to 2009.

Costs are attractive as chemists in China still have comparatively low salaries. And the IP environment is indeed improving as Chinese companies more and more own their own intellectual property.

Finally, the competitive landscape of fine chemicals producers is improving. The industry is simultaneously consolidating, and the market share of SOEs is decreasing (from 29% in 2007 to 20% in 2009), leading to a more level playing field.

Domestic Advantage

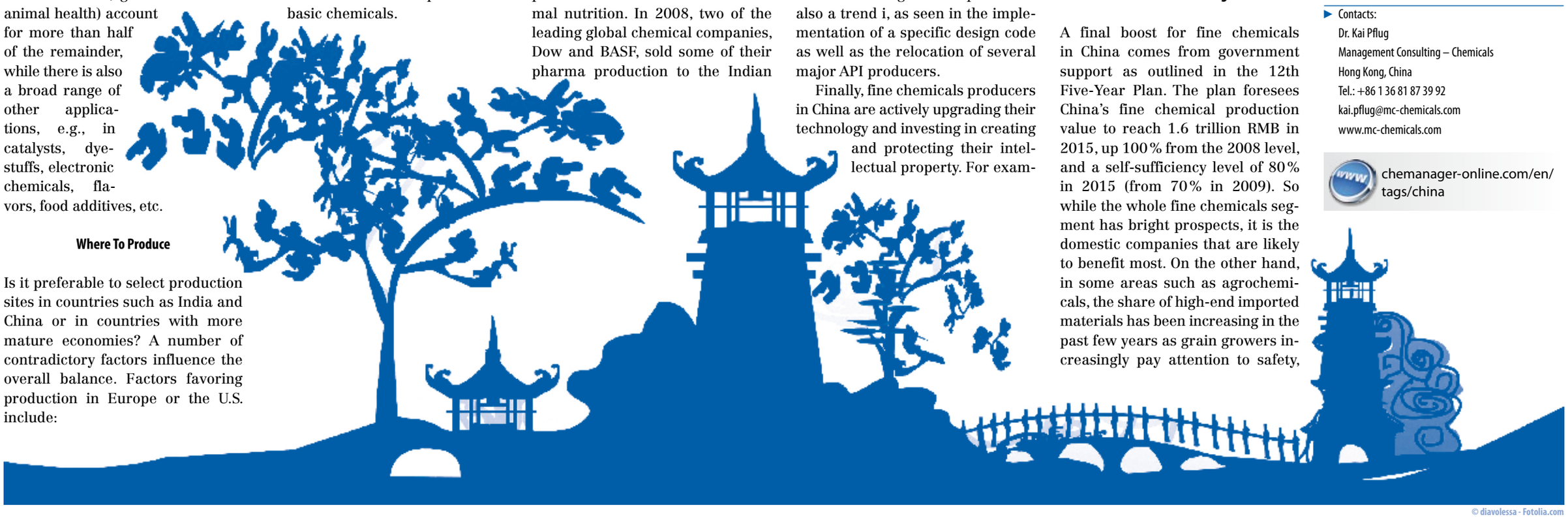
A final boost for fine chemicals in China comes from government support as outlined in the 12th Five-Year Plan. The plan foresees China's fine chemical production value to reach 1.6 trillion RMB in 2015, up 100% from the 2008 level, and a self-sufficiency level of 80% in 2015 (from 70% in 2009). So while the whole fine chemicals segment has bright prospects, it is the domestic companies that are likely to benefit most. On the other hand, in some areas such as agrochemicals, the share of high-end imported materials has been increasing in the past few years as grain growers increasingly pay attention to safety,

market for low-end fine chemicals (such as low-end pesticides) will shrink, allowing only those domestic companies that are capable of upgrading their technology in time to profit from the positive outlook for fine chemicals.

Authors: Dr. Kai Pflug, CEO, Management Consulting and Dr. Bernhard Hartmann, Managing Director, A.T. Kearney China

► Contacts:
Dr. Kai Pflug
Management Consulting – Chemicals
Hong Kong, China
Tel.: +86 1 36 81 87 39 92
kai.pflug@mc-chemicals.com
www.mc-chemicals.com

chemanager-online.com/en/tags/china



What's Up For Sale?

M&A in the Chemicals & Materials Sector

Mergers & Acquisitions – Recently, Squire Sanders commissioned a report from their partners at Mergermarket on mergers and acquisitions activity in the chemicals and industrials sector in 2011 and the first part of 2012. The results were very interesting, bearing out what had been seen by Carolyn Buller, a specialist lawyer in the chemicals sector at first hand over the past few years.

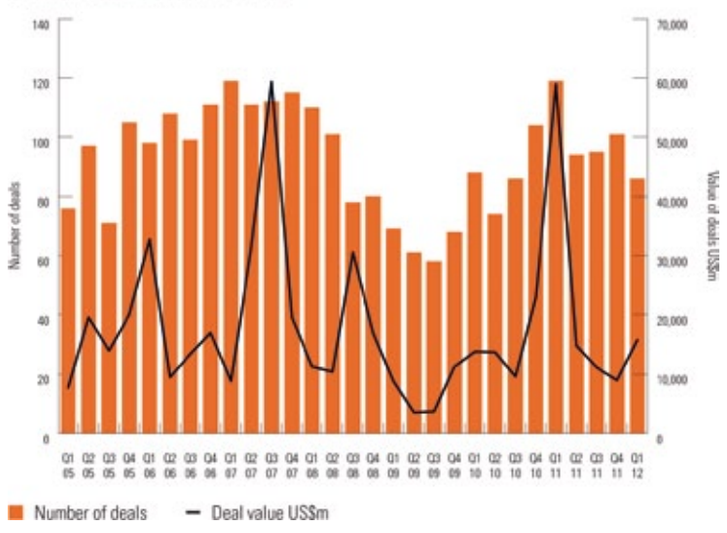
As industry-watchers will know, the chemicals and materials sector, which can be cyclical, was directly affected by the disintegration of the global credit markets three years ago. The withdrawal of investors

Carolyn Buller
Squire Sanders

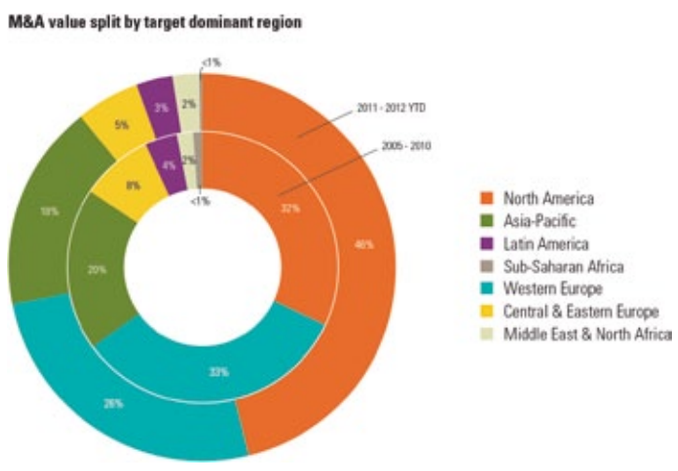
from the industry was inevitable and unsurprising. However, M&A activity did come to a virtual halt with both deal volumes and values falling dramatically – down 31% and 61% respectively on the previous year.

As the report demonstrates, there has been a slow and steady recovery underway since that time. In 2011 chemicals and materials M&A increased substantially from the previous year – with 409 deals completed, worth a combined $93.8 billion. That was a rise of 16% in volume and 56% in value on 2010. Private equity deals, which had slumped dramatically from 2008 to 2009, also saw an encouraging recovery. There were 55 private equity buyouts worth $6.7 billion in 2011, up 34% in volume and 56% in value from the previous year. And the evidence so far for 2012 shows this upward trend continuing.

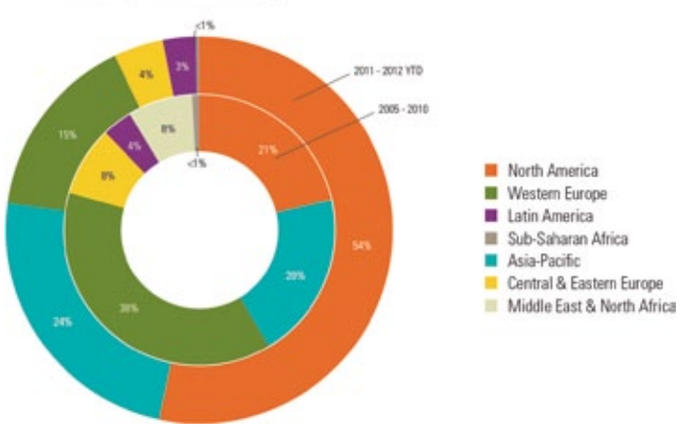
Chemicals and materials M&A trends



M&A value split by target dominant region



M&A value split by bidder dominant region



Chemicals and materials deal size split by year

Emerging Markets Attractive… But So Too Is North America

So, what is driving the recovery? An increasing interest in emerging markets for one thing - the desire to grow business in emerging economies has been a distinct characteristic of the chemicals and materials industry in the past few years. Some of 2011's largest deals showed this clearly. When Solvay of Belgium acquired France's Rhodia, part of the rationale was to strengthen the company's exposure to high-growth markets such as China and Brazil, where it generates 40% of sales. Eastman Chemical Company's $4.6 billion acquisition of Solutia will enable strategic expansion into the Asia-Pacific region, with the company anticipating a compound annual growth rate of up to 10% in the next few years. More than 30 % of Solutia's sales came from the Asia-Pacific region prior to the acquisition. Such big-ticket deals are not the norm in the sector but they reflect well the trend that is also affecting the main mid-market. (The biggest proportion of M&A deals, where values have been disclosed, have been taking place in $15- 100 million range – some 39% in 2011).

In addition, players from the emerging markets themselves have also been driving many of the M&A deals in the sector. Investors from the Asia-Pacific sphere played a role in the upswing in M&A in 2011, with state-backed entities from the region snapping up companies specialising in raw materials, technology and innovation. Take ChinaChem's acquisition (through its subsidiary China National Agrochemical Corp) of 60% of Israel's Makhteshim Agan Group (MAI). In turn MAI, a branded off-patent agrochemical producer, bought DuPont's non-mixture diruon herbicides business. While this deal illustrates the company's ambitious expansion plans, it also re-emphasises the central importance of the North America market to the global chemicals sector – the region is the most important target in terms of M&A value (46% in 2011-Q1 2012), and the second most important target in terms of deal volume (28% compared to 34% for Western Europe). As for bidders, North America again appears dominant in terms of M&A value (54% in 2011-Q1 2012), and neck-and-neck with Western Europe for deal volume (both at 32%).

Disposals and Exits are Key

The MAI-DuPont deal last year is a good example of a corporate disposal, and this highlights another big trend in the recovery of the chemicals and materials sector. Corporate disposals have produced approximately half of all M&A targets between 2005 and 2011, with spin-offs from major chemicals players such as Dow and DuPont hitting the market - and frequently going into the hands of overseas buyers: examples from the past year are Brazil's Braskem SA acquiring Dow's polypropylene business and India's Indofil Chemicals Company buying Dow's European dithane fungicide business.

Private equity exits were a significant feature in the market too last year. Stand-out deals were Clariant of Switzerland buying the majority of Germany's Sued-Chemie – owned by One Equity Partners of the US – for $2.6 billion, and China's Wanhua Industrials Group acquiring a 58% stake in Hungary's BorsodChem from UK-based buyout house Permira and Austria-based VCP Vienna for $1.7 billion. Strong secondary buyout (SBO) activity has also been lifting the sector. SBO volume totalled 15, worth $4.5 billion, in 2011 and two SBOs were among the top ten largest chemicals deals globally.

What Can We Expect

We can assume that corporate disposals and private equity exits will continue to drive chemicals and materials M&A through 2012, despite continued anxieties about the Eurozone. So far in 2012 we have seen some 200 chemicals and materials deals worth $22.3 billion globally, with still about 38% of total deal volume coming from the $15 -100 million range. So we are on track for a similar level of activity to 2011.

However there are issues particular to the industry and its various sub-sectors which are worth considering as we go forward. Opportunism has characterised much M&A activity in the agrochemicals sector. But for specialty chemicals we are very likely to see vigorous competition for increasing market share.

A decade ago, specialty chemicals presented the 'promised land' of higher margins and less capital investment. Many companies rushed to significantly increase their specialties investments. The result is no surprise: specialties are now seeing pressure on margins, as the competition to boost market share becomes more and more intense.

All businesses are exposed to rising costs, such as energy, but none more so than the petrochemical sector, where high and volatile commodity prices may reduce their attractiveness. On the other hand the development of unconventional sources such as shale gas should greatly contribute to the appeal of North American targets.

In fact, the shale phenomenon has been a major game-changer. In the past it has been taken for granted that the centre of the global chemical industry would be moving to the Middle East, and away from Europe and the US, driven by the abundance of relatively inexpensive oil feedstock in the Arab World. This idea has now been turned on its head. The shale gas phenomenon has created an abundance of ethylene and its derivatives, and set the stage for an abundance of inexpensive raw materials in the US.

It's not only the US that will benefit from shale discoveries. Argentina is on the cusp of large-scale production, and China's reserves could prove to be the world's largest. Both countries are actively looking for international partners.

We expect that this will translate directly into M&A opportunities for this year and especially in 2013. Indeed, energy independence a top priority for all major economies, after the volatility of commodity prices and the political turmoil in several oil-rich nations in the past few years.

Who would have predicted even two years ago, new refineries being built or old refineries reopening in the US? Now in 2012 that scenario is commonplace.

Author: Carolyn Buller, Partner, and Global Chemicals Industry Group Leader, Squire Sanders

Contact:
Carolyn Buller
Squire Sanders
London, UK
Tel.: +1 216 479 8528
carolyn.buller@squiresanders.com
www.squiresanders.com

chemanager-online.com/en/tags/ma

The Latest From SOCMA

DHS Secretary Says Permanent Reauthorization of CFATS a Priority

Despite recent challenges the U.S. Department of Homeland Security (DHS) has faced with implementation of its Chemical Facility Anti-Terrorism Standards (CFATS), a high-ranking agency official says it is a top priority to work toward permanent reauthorization of the program.

In his keynote address at the 2012 Chemical Sector Summit in Baltimore, MD, National Programs and Protection Directorate (NPPD) Under Secretary Rand Beers said DHS has made a lot of progress over the years and built up the CFATS framework in a short period of time. Despite an internal assessment that pointed out DHS's shortcomings in making progress with inspections and site security plan reviews under the program, Beers said his department is learning from its mistakes and moving forward to make substantive improvements. And while it is difficult to project the level of funding that will ultimately be approved by Congress for the next fiscal year, Beers said DHS will work toward permanent reauthorization of CFATS.

DHS Under Secretary Rand Beers told Chemical Sector Security Summit attendees that permanent reauthorization of CFATS is a top priority.

Currently, CFATS is authorized through Oct 4, 2012, and funded through fiscal year 2012 at $93.3 million. The U.S. House of Representatives-passed Homeland Security appropriations bill for 2013 provides $45.4 million for CFATS, $29.1 million below the amount requested by the administration and $47.9 million below the previous year's level. In an accompanying report to the bill, the Appropriations Committee said the reduction in funding is due to "significant managerial problems, program delays and poor budget execution."

The U.S. Senate Appropriations Committee approved its own homeland security appropriations bill in May, which preserves almost $87 million for the CFATS program - nearly double the amount of funding in the House bill. However, the full U.S. Senate has not voted on the bill.

With the fiscal year quickly coming to an end, it is expected that Congress will approve a short-term Continuing Resolution, extending funding for federal agencies across the board at 2012 levels through the November election and temporarily extending expiring authorizations for programs such as CFATS. When Congress reconvenes for a lame duck session, legislators could pass yet another Continuing Resolution or begin work on an omnibus appropriations bill for the remainder of fiscal year 2013 containing similar program extensions.

The internal audit of CFATS, which was widely publicized by the media in December, was a game changer in terms of long-term or permanent reauthorization of the program, according to congressional staff at the Summit.

As a result of the problems plaguing DHS's implementation of CFATS, Congress will likely maintain close oversight of the program by extending it on a year-by-year basis, the congressional staffers said. They also stressed that CFATS needs to be operating in a way that Congress can feel more confident about, and continuity in the program and its leadership is critical.

Beers and other DHS leaders, such as NPPD Deputy Under Secretary Suzanne Spaulding, also focused on the positive aspects of the CFATS program. Spaulding told Summit attendees that CFATS has already taken measurable steps toward a safer America, citing thousands of facilities that have removed high-risk chemicals so as not to require regulation, or made other changes to meet CFATS requirements.

SOCMA President Lawrence D. Sloan, who delivered opening remarks at the Summit, said that "while these challenges (to CFATS) are all serious, they are not insurmountable." Having a comprehensive set of security standards such as CFATS is in our nation's best interest, he said, and SOCMA still supports a long-term extension of the program to provide stability moving forward.

Contact:
Society of Chemical Manufacturers and Affiliates (SOCMA)
Washington, D.C., U.S
Tel.: +1 202 721 4100
www.socma.com

SOCMA is a U.S.-based trade association dedicated solely to the batch, custom and specialty chemical industry. Since 1921, SOCMA has represented a diverse membership of small, medium and large chemical companies and has now a global membership of more than 210 companies.

The Chemical Industry's Pulse at Half-time

Q2 Results of Major European and North American Chemicals Manufacturers, Business Confidence is Beginning to Wane

Market Overview – With the euro crisis biting ever harder, the US economy still staggering under a formidable debt burden and even the Chinese growth engine sputtering, the chief executives of European and North American chemical producers would have been forgiven for conjuring up a spectre of doom and gloom in presenting their respective business forecasts for the remainder of 2012.

But this largely did not happen when Q2 and H1 figures were presented in July and August, even if the company chieftains did exercise a reasonable degree of caution about the outlook, and surveys on both sides of the Atlantic saw business confidence starting to wane. Most chemical companies had nothing immediate to complain about. For the industry's majors in particular the numbers published so far this year have been on course or only slightly weaker.

Even if chemical output in the European Union sank by 2.4% year-on-year from January to June, selling prices were 3.4% higher, says the industry association Cefic in its Chemicals Trends Report. In the first five months of this year, the region's net trade surplus increased by €3.6 billion year-on-year to €19.9 billion. Up to May, chemical sales were nearly 6% higher than in pre-crisis 2008.

Export-oriented North American chemical players are increasingly worried that problems in the euro zone as well as in China and in other parts of Asia, as well as Latin America, could compound their homemade woes. First-quarter growth in the US was "mediocre" and the second quarter may have been even worse, says the American Chemistry Council. Chemical companies such as Dow and DuPont, however, continued to benefit from their presence in international markets.

The euro's weakening had positive and negative influences on European chemical business. A cheaper euro would increase feedstock prices in already volatile markets but it could also make regional producers more competitive internationally even as the lower valuation reduces euro-denominated sales revenue.

Major Chemical Companies Report Q2 Results

The world's largest chemical producer, **BASF**, increased sales revenue 5.5% to €19.5 billion in Q2, despite slackening global growth. The German group's euro-denominated income before special items (EBIT) rose 11% to €2.5 billion, even if EBIT of four business segments tumbled. Business drivers in the second quarter were the agricultural solutions and oil & gas segments, while chemicals, plastics, performance products and functional solutions deteriorated.

In his results presentation, CEO Kurt Bock said BASF is still targeting a year-on-year increase for sales and earnings in the second half of 2012, compared with the 2011 period. But as management does not expect an upturn in demand against the year's first six months, to achieve this goal a boost from cost-saving and the group's STEP excellence program -- designed to add €1 billion to earnings annually up to 2015 -- will be needed. The STEP scheme is being accelerated, Bock said.

World's number two and North America's number one chemical player **Dow Chemical** saw its sales turnover decline by nearly 10% to $14.5 billion in Q2, with volume sales down 5%. Pre-tax profit receded to $984m from $1.3 billion in the same period of 2011, while EBITDA hovered around $2 billion. CEO Andrew Liveris blamed sluggish demand in the euro zone and China for the earnings weakness. Prolonged maintenance turnarounds also pressured volumes. As at BASF, the plastics business was among the weakest.

Dow likewise does not expect the global business environment to recover substantially in the second half year. Liveris said the US group, too, will accelerate its cost-saving and efficiency programs. This will mean implementing disciplined price and volume management, further reducing costs and capital spending, while continuing to de-leverage the balance sheet and generating strong cash flow.

While based in The Netherlands, **LyondellBasell**, which was recently added to the US Standard & Poors 500 index, has a broad footprint on two continents. In Q2, the company benefited from its considerable upstream presence in petrochemical markets. Performing strongly in the US in particular, it also improved olefins margins in Europe. EBITDA rose 11% year-on-year to $1.77 billion, while sales fell by 15% to $11.2 billion. Amid global uncertainty, CEO Jim Gallogly said LyondellBasell will "continue efforts to improve its relative cost position" in Europe.

US-headquartered **DuPont**, also a giant in many international markets, saw Q2 net profit fall 3.3% year-on-year to $1.2 billion. A better performance by the company's life science and agriculture segments offset weakness in some industrial markets. Sales increased by 7% to $11 billion, with selling price 6% higher and volumes 1% lower. CEO Ellen Kullman said DuPont expects full-year earnings to be toward the lower end of its existing outlook range of $4.20-$4.40 per share.

© Joachim Wendler - Fotolia.com

Volatile feedstock markets plagued France's **Arkema** in Q2. While succeeding in lifting sales by 15.4% and EBITDA by more than 20%, the company booked a net loss of €12m. This was blamed on the divestment of its vinyls activities, however. In presenting quarterly results, CEO Thierry Le Henaff expressed concern about the "challenging economic environment," which he said was marred by the European sovereign debt crisis and volatile raw materials markets.

Belgium's **Solvay** reported flat sales revenue of €3.3 billion for the second quarter, despite a 6% rise in volumes. Selling prices were up 2% and the currency effect was 4% positive. EBITDA (recurring earnings before interests, taxes and amortization) rose 8% against Q1 2012 but were down 6% against the 2011 period. The specialty polymers and consumer chemicals businesses were driven by "strong pricing power." The integration of recently acquired **Rhodia** will help Solvay weather any storms on the horizon and hold REBITDA steady at the pro forma 2012 level, said CEO Jean-Pierre Clamadieu.

Along with Solvay, Germany's **Bayer** was among the more optimistic chemical players at Q2 reporting time. Following a better-than-expected first half, when currency effects pushed group sales forward by 10% and EBITDA pre-exceptionals rose by 6.7%, CEO Marijn Dekkers raised the full-year forecast. Management now expects a "high-single-digit percentage" rise in EBITDA for 2012 despite the fact that healthcare is likely to see grow only in emerging markets and storm clouds are forming on the Chinese horizon.

North American and European chemical companies will begin reporting Q3 results in late October.

Author: Dede Williams, Freelance Journalist

chemanager-online.com/en/tags/chemicals

Lanxess Acquires Germany's Bond-Laminates

Lanxess is strengthening its product portfolio of lightweight materials by acquiring German company Bond-Laminates. Financial details were not disclosed. Founded in 1997, Bond-Laminates, Brilon, North Rhine Westphalia, specializes in developing and producing custom-made plastic composite sheets that are reinforced with materials such as glass fibers. Lanxess has been working with Bond-Laminates since 2006 on several successful projects with the automotive industry. ■

Eckert & Ziegler to Buy Vitalea Science

Eckert & Ziegler Strahlen- und Medizintechnik has entered an agreement with Vitalea Science for the purchase of all of its stock and assets. Vitalea Science is a pioneering Bioanalytical Contract Research Organization that provides services to researchers and clinicians in drug development supported by validated Accelerator Mass Spectrometry (AMS) technologies. This method is used in pre-clinic and clinic studies for exploring the behavior of drug candidates in the organism. Due to the AMS device's ultra-sensitivity it is able to detect C14 tagged molecules in microdose levels. Vitalea also provides AMS services for the characterization and identification of non-medical carbon based compounds. ■

Ireland

Ireland is Currently Facing Significant Economic Challenges but is Open for Business

Page 12

Sites & Services

Online: German-language Quarterly Supplement on Industrial Parks and Technical Services

www.chemanager-online.com/themen/industriestandorte

Finland

The Kokkola Industrial Park is Scandinavia's Biggest Chemical Manufacturing Site

Page: 12

European Chemical Industry Parks 2.0

Insights from Global Benchmarking

No Walk in the Park – European chemical industry parks and their operators face great challenges. On the one hand, they have to meet increased and more complex demands of globally active chemical companies. On the other hand, ongoing globalization leads to intensified competition among chemical industry parks that try to attract international investors. Clear strategic positioning, synergy-targeted infrastructure, and comprehensive and customer-oriented site services portfolios are basic requirements for future competitiveness.

Strategic positioning based on investors' key criteria combined with operational excellence in site operations is decisive. Chemical park operators have to contribute added value to the competitiveness of the chemical companies at the chemical park and, at the same time, have to organize their site operations in a customer-oriented, flexible and cost effective manner, defining their core competencies while outsourcing non-core services.

This is valid for both the European chemical industry parks with a high degree of integration and long production history as well as for the developing chemical production clusters in Southeast Asia, China and the Middle East that were designed on the drawing board after decade-oriented master plans.

Chemical industry parks gain competitive advantages by continuously orienting themselves toward key investment criteria of global chemical producers.

Focusing on the European chemical park operator landscape, four core questions have to be addressed:

- How can European chemical industry parks successfully position themselves in global competition for future investors?
- How can competitiveness of existing chemical sites be increased, in particular by regional cooperatives generating further synergies?
- What are the key competitive advantages of the considered European parks compared with the global peer group; which Unique Selling Points (USPs) could be proactively developed and which weaknesses of the park should be addressed?
- How could chemical industry parks continuously measure the investors' confidence and satisfaction for an ongoing site development?

Christoph Behrendt
Scopein Management Consultants

© Tanja Bagusat - Fotolia.com

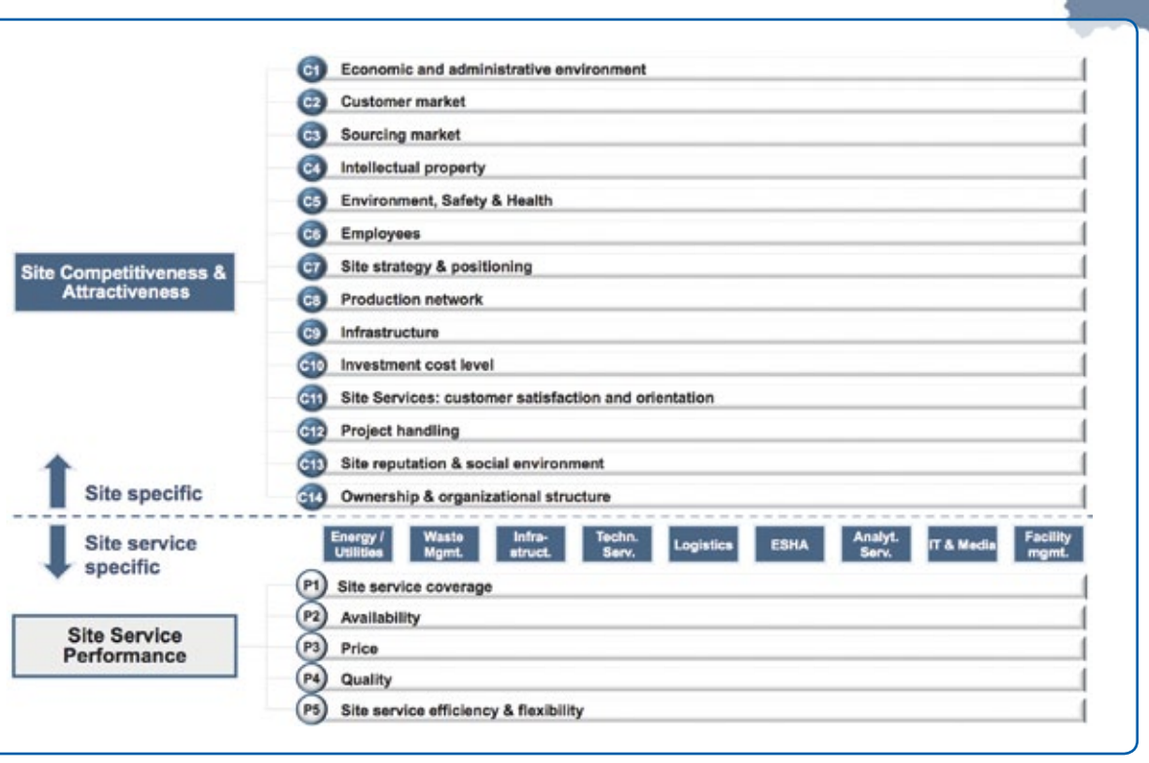


Fig. 1: Evaluation Framework for Global Site Benchmarking.

Global Site Benchmarking Approach

Comparison with the world's leading chemical industry parks shows the own competitive situation. This approach, however, creates a value-add beyond grasping the gap to best-in-class peers. It guides to new ways of goal-oriented and sustainable site development, based on an extensive site benchmarking database that provides best practices, role models, site benchmarks and other valuable inside views into analyzed chemical sites in Europe, the U.S., China, Southeast Asia and the Middle East.

The benchmarking approach functions as facilitator to optimally apply instruments like best-in-class analysis per site success factor, strengths and weaknesses profiles, site service performance evaluations, structured collection of investors' feedback as in investor confidence surveys or more quantified cost structure analyses related to Costs of Goods Sold (COGS) or industry cost curves for specific production set-ups. It helps site operators to make the most effective and efficient investment decisions to further develop relative competitive advantages and to close identified gaps.

Evaluation Framework for Global Site Benchmarking

Based on defined site-success factors for high site competitiveness and attractiveness, chemical industry parks could be objectively evaluated from an investor's or existing resident's perspective. These site-success factors and the more than 70 underlying benchmarks are derived from companies' investment decision processes for new production sites and represent the first part of SCOPEIN's Global Site Benchmarking evaluation framework.

The second part consists of an assessment of the Site Service Performance, i.e. the site infrastructure and services available within the battery limits or nearby the site (figure 1).

The Site Service Performance evaluation is based on a holistic function model for chemical industry parks. All required site services and energies by the producing chemical companies are evaluated and analyzed applying criteria such as site service coverage, availability, price and cost level, quality as well as site service efficiency and flexibility (figure 2).

Insights into Global Site Benchmarking

The most important and still valid conclusion drawn from benchmarking the worlds' leading chemical industry parks is that the "ideal chemical site for all kinds of investments with best-in-class chemical production conditions" does not exist. Instead, each site offers a portfolio of favorable and less favorable factors to be evaluated according to the projects' specific requirements. The challenge for globally operating chemical companies is to find the best-fit investment location facing the heterogeneity of chemical production locations. At the same time, it is an opportunity for chemical industry parks and their operators to present themselves at their best. The Global Site Benchmarking is key to both, identifying optimization levers for increased competitiveness for the own site and having a detailed and structured set of information regarding strengths and weaknesses of other worldwide leading chemical industry parks.

Figure 3 shows a global benchmarking comparison of chemical sites' success factors on top level.

Chemical Industry Parks in Europe

European chemical production sites provide very stable production conditions thanks to their long production history and highly professional site operators. Here, site service providers offer a very comprehensive site service portfolio and reliable infrastructure for chemical production companies according to the Plug & Play principle, leading to a high degree of customer satisfaction. A further main advantage of European sites is the availability of well-qualified personnel on all levels as well as reasonable Environment Safety and Health (ESH) regulations.

In general, investment cost levels are higher than at the Asian sites because of higher material, construction and engineering costs, but far lower than expected cost levels in the Middle East.

Chemical Industry Parks in the Middle East

Most Arabic states in the Middle East are actively looking for foreign

Continues Page 11 ▶

Fig. 2: Chemical Industry Park's Function Model.

◀ Continued **Page 10**

investment and technology partners following their economic development strategies, among others the settling of downstream chemistry. Most chemical industry parks in the Middle East region are centrally managed and developed by governmental institutions or state companies that are specifically responsible for the construction and operation of basic infrastructure facilities (land provision). Large investment programs in world-class chemical site infrastructure, such as in Qatar, generate very favorable conditions for investments and operations. Concerning the economic and administrative conditions, foreign companies need a local sponsor to establish joint ventures that are characterized by a statutorily fixed share distribution among the partners.

The favorable logistical location in the Middle East between Europe and Asia and the availability of deep-water port access at major chemical sites are prerequisites to optimally serve the export-oriented chemical production, especially because of a very small local customer market. Cheap feedstock, access to the world's largest crude oil and natural gas reserves, good raw materials availability and cost levels as well as very favorable electrical energy prices compared with all other global sites are key investment advantages for the region.

Major challenges for investing companies are the limited availability of skilled labor and high investment cost induced by extreme climatic conditions. Special materials, technologies and maintenance services are required to achieve global utilization rates of the plants.

Chemical Industry Parks in the U.S.

In general, American chemical industry parks offer a very favorable environment for investments and operations of chemical plants. The cost situation regarding all major utilities such as electrical energy, steam and especially natural gas are at a world-class level. In addition, labor costs are approximately on the same level as in Europe, whereas labor productivity is very high in comparison with the rest of the world. When considering the economic and administrative environment, a rather high income tax up to 39.5%, due to high federal tax, has to be considered.

Chemical Industry Parks in Southeast Asia

Investments in chemical industry parks in Southeast Asia, especially in Jurong Island in Singapore, benefit from a world-class administrational environment that offers very favorable tax incentives and shows a very effective site commercialization and clearly defined site development strategy. Tax holidays up to 10 years and reduced income taxes could be highlighted. Site service provision and project handling are considered as advanced as the Asian sites, but do not always meet high European levels. Located close to one of the world's largest seaports, the region's leading chemical site Jurong Island is well connected to the global customer and sourcing markets. Major disadvantages are the electrical energy prices that are as high as at several chemical sites in Europe, e.g., chemical cluster Antwerp, but double the price of other Southeast Asian chemical sites. Concerning qualified employees, comparable to the Middle East and China, there is a strong need for internal company training on the job, because of missing dual education system. The German education system still functions as a role model for several initiatives started in Asia and elsewhere.

Chemical Industry Parks in China

Especially the large and dynamic customer market for chemicals as well as low investment and labor costs put Chinese chemical industry parks in a favorable position when compared with other sites. Labor cost levels amount to less than 10% to 20% compared with European sites. Nevertheless, intellectual property protection remains an issue in China, although legislation has been adjusted to international standards. Furthermore, the low degree of production integration at the considered sites is not really addressed by a proactive intercompany production network planning and site commercialization by the Chinese site operators. In addition, there are monopolistic structures of site services supply, however, in total they have no influence on favorable production costs for electrical energy, wastewater treatment or maintenance services.

Especially when considering more rural chemical sites compared with a very developed and professionally managed park like the Shanghai Chemical Industry Park, the sites are at very early stages of development in becoming a chemical park. The heterogeneity in the Chinese chemical sites' landscape is still extensive concerning, among other things, site strategies, production network development plans, availability of qualified labor, satisfying labor productivity level and site services as well as infrastructure provision.

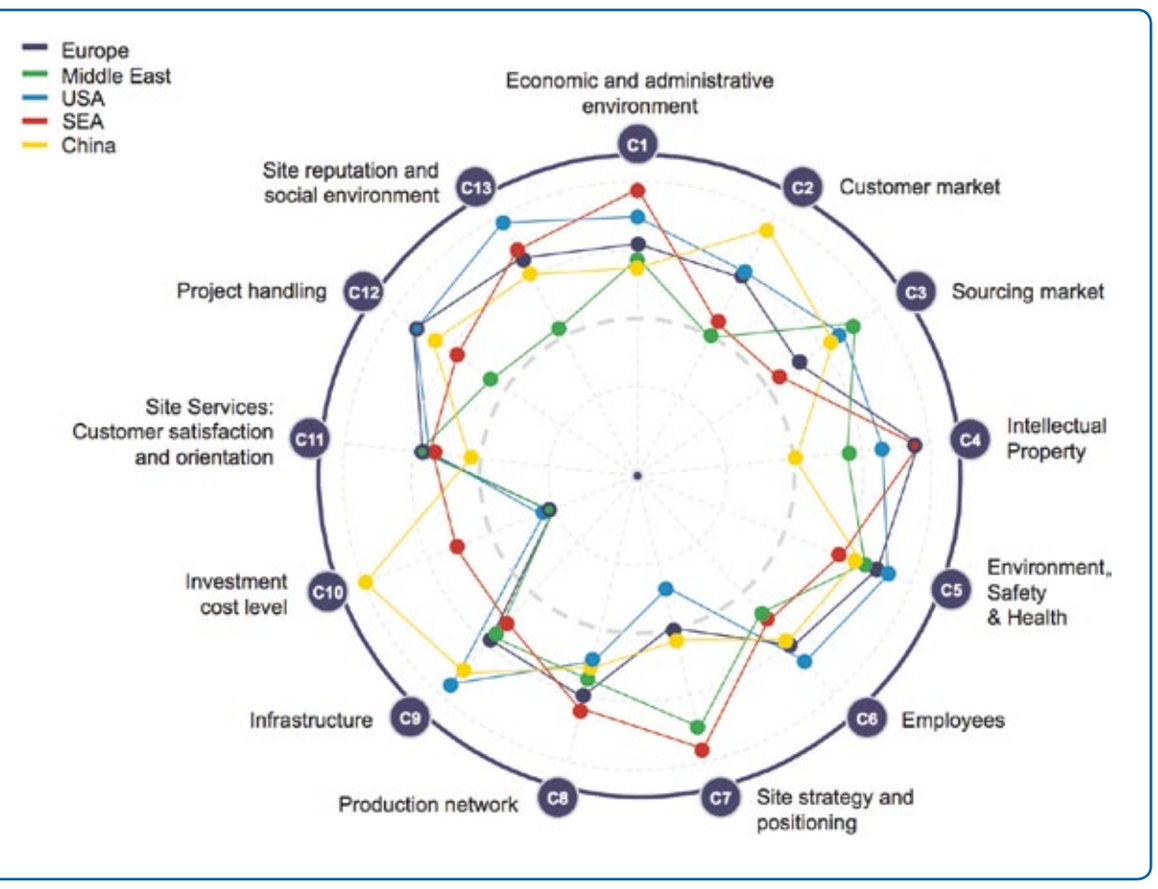


Fig. 3: Competitiveness assessment of worlds' leading chemical industry parks

Outlook

Continuous improvement of sites' competitiveness and attractiveness enable European chemical industry parks to be best prepared for increased competition for potential investors from investment locations in China, Southeast Asia and the Middle East. The identification of improvement and development potentials based on the defined site-success-factors model supports a targeted development of the individual park and the achievement of sustainable European sites' competitiveness.

Author: Christoph Behrendt, Scopein Management Consultants

▶ Contact:
Christoph Behrendt
Scopein Management Consultants
Duesseldorf, Germany
Tel.: +49 211 730 6220
christoph.behrendt@scopein.de
www.scopein.de

chemanager-online.com/en/tags/locations

Leading in Sustainable Ibuprofen Production

BASF in a celebration honored twenty years of operations in the manufacturing of Ibuprofen. In Bishop, Texas, BASF operates a world class production plant for manufacturing ibuprofen, deploying an award-winning, environmentally friendly production technique that avoids the use of chromium salts and minimizes waste. The BASF facility at the Bishop, Texas, site was built in 1991 and began operations on September, 1992. Since then, it has become one of the world's most significant Ibuprofen plants. The FDA-audited and GMP-compliant production site is part of the OSHA (U.S. Department of Labor's Occupational Safety and Health Administration) Voluntary Protection Program (VPP) and is recognized with the "VPP Star site" status. The VPP recognizes employers and workers in the private industry and federal agencies who have implemented effective safety and health management systems. ■

Aveva Extends Global Reach

Aveva and Infosys have signed a partnership to deliver engineering information management solutions to support the operation and maintenance of process plant and power facilities. Through this partnership, Infosys will provide global scale and reach to advance the delivery of Aveva's suite of information management solutions to clients across the world.

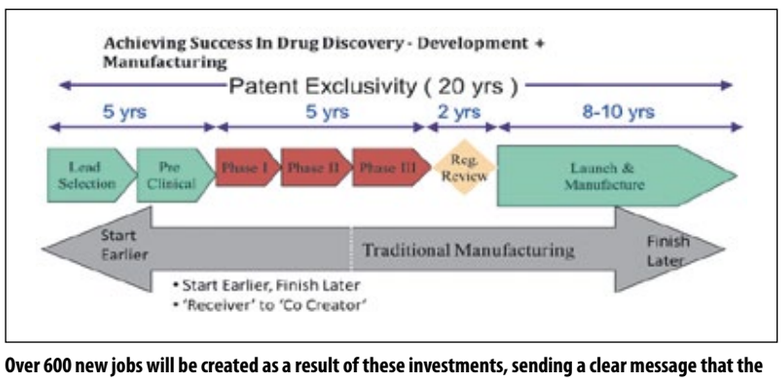
Aveva Net has been selected by Organika-Sarzyna, one of Poland's largest chemical producers, to provide a data integrity management program for a new MCPA (phenoxy herbicide) production plant installation. Aveva Net will enhance the quality of management and maintenance data. The PDMS Gateway has been acquired and made available to subcontractors, including the Polish EPC Prochem, who is working on the MCPA installation design. ■

Pharma Chemical Ireland Strategy on Track

Long Term Solutions Counteract Wide Range of Challenges

Ireland – PharmaChemical Ireland (PCI), representative of the chemical and pharmaceutical industry in Ireland, have launched two strategy documents to date. The first, "Innovation and Excellence- PharmaChemical Ireland Strategic Plan" was launched in New York at DCAT in March 2010. It was followed by "Ireland- the Location of Choice for Scientific Investment" launched in Washington DC last year. PCI's mission is ambitious: Bringing together all relevant stakeholders in the state, namely industry, the Government, the research community and the public at large to effectively communicate the unique attractiveness of this country as a leading location for the supply and development of such products. "It has been well documented that Ireland is currently facing very significant economic challenges. However, my message is clear – Ireland is open for business. We have many unique strengths and our economy will return to growth this year." Enda Kenny T.D. (Taoiseach) said.

Company	Investment in €	Type of Investment
Pfizer Pharmaceuticals	200 million	Biopharmaceutical
MSD Ireland Ballydine	100 million	Development Facility
Allergan	330 million	Biopharmaceutical
Genzyme/Sanofi Aventis	150 million	Biopharmaceutical
Amgen	150 million	Biopharmaceutical
Eli Lilly	300 million	Biopharmaceutical
MSD Ireland Brinny	29 million	Biopharmaceutical



Over 600 new jobs will be created as a result of these investments, sending a clear message that the sector remains committed to Ireland for the long term.

Matt Moran
PharmaChemical Ireland

Awareness of Problems is Key to Solutions

Recent media coverage points to the penny having finally dropped with regard to the impending patent cliff. Though it may be news to the public at large it comes as no surprise to the sector in Ireland. PCI has established a standing committee on strategy and this committee continues to oversee the implementation phase. This committee brings together the industry, Government and its agencies and the research community. The industry continues to hold the view that the only way that the sector will meet the challenges presented by the patent cliff is to embrace the development plus manufacturing model thereby expanding the mandate of existing companies in this country (see below). The industry recognises the fact that it needs to work closely with the research community to assist in this process and also to uncover new opportunities for commercialisation of research. The industry also needs to try and access the health system to help the development of an effective clinical research base resulting in translational research and the evolution of a clinical trials infrastructure.

Meanwhile companies continue to drive down the cost of supply through smart application of lean manufacturing techniques. There are many examples of Irish sites significantly reducing their cost of goods via operational excellence. The industry continues to attract investment in development and high end manufacture including biopharmaceuticals vindicating the strategy adopted by PCI. In fact if you total the recent announcements it amounts to well over €1 billion. (see table below)

In keeping with the theme that the sector needs to innovate to stay competitive, PCI hosted their Third Biennial Conference in collaboration with The International Society for Pharmaceutical Engineering (ISPE) and the Parenteral Drugs Association (PDA), titled "Transforming Ireland Through Innovation". A wide range of speakers explored in detail how the industry can apply innovation practically. High level speakers from the regulatory word- including Irish Medicines Board Chief Executive- Pat O'Mahony and Christine Moore from the FDA – outlined how industry can embrace regulatory change to its advantage and to the benefit of the patient. The high level of compliance by the sector here remains a key strength and an ongoing reason why companies continue to invest in Ireland.

Common thematics were explored via key note addresses and focussed workshops. Topics such as operational excellence, Quality by Design and Process Analytical Technology (PAT), Supply Chain and new business models were discussed in detail. There was an extensive range of speakers drawn from the industry, regulatory bodies and service providers from as far afield as India. This coming together of expertise underpinned the valuable critical mass of knowledge and experience that resides in this country supporting a strong and vibrant life sciences sector.

Finally, the pharmaceutical sector is undergoing a sea change at the moment as major companies seek to stay in the market. An inevitable consequence of this has been a series of mergers and acquisitions resulting in global overcapacity in the sector. Now more than ever it is critical that Ireland sends a positive message to the industry. Our healthcare policy supports access to innovative medicines and medical technologies that are developed in Ireland. It is vital that Government continues to take a long term view of the overall cost of healthcare. Medical treatment funding is regarded as investment in the nation's health and economic prosperity. Such an approach will send a positive signal to pharmaceutical companies. It is critical that Government policy is well aligned in this regard, if companies are been asked to support the sector by investing in innovation in manufacturing they would expect the Irish citizen to be able to avail of these innovations in the marketplace.

In conclusion it is fair to say that the sector here does face a range of challenges however it is also fair to say that the industry is well aware of these and that through PharmaChemical Ireland is responding to these challenges strategically. All evidence points towards this strategy being firmly on track.

Author: Matt Moran, Director, Pharma Chemical Ireland

Contact:
Matt Moran
Pharma Chemical Ireland
Dublin, Ireland
Tel.: +353 1 605 1567
matt.moran@ibec.ie
www.pharmachemicalireland.ie

chemanager-online.com/en/tags/locations

Nordic Clustering

The Kokkola Industrial Park is Scandinavia's biggest chemical manufacturing site

Finland – Germany and other Central European countries are pioneers in "clustering" their chemical production sites, but the Scandinavians already showed their will to catch up. In Finland the Kokkola Industrial Park (KIP) is the largest centralization of inorganic chemistry in the Nordic countries. Infrastructure and geographical location offer various advantages for investors and chemical manufacturers – Kokkola's biggest plus.

The Kokkola Industrial Park covers an area of 600 ha and therefore ranks among the ten biggest European Chemical Clusters.

For over 100 years Europe has been world leader in manufacturing and exporting chemicals, but during the last decade a shift is noticeable. Asia is attracting new investors with double-digit growth rates and is about to claim the throne of worldwide chemical manufacturing. Even though Asian production sites are becoming more and more established, there are still some advantages for the European chemical sector. With a highly skilled labor force, many decades of experience and state-of-the-art production sites Europe managed to defend its position among the most successful chemical-producing regions in the world. Especially modern production plants, which are often centered in clusters, strengthen Europe's position.

Kokkola Industrial Park – Scandinavia's figurehead

Approximately 20 companies run plants in Kokkola, another ten support them for key activities. The reasons for their investments are manifold and range from logistical advantages to legislation issues. "In Finland, research results derived from joint efforts with research organisations will become the property of the company. For this reason, we have centralized a significant proportion of our R&D operations in Kokkola," says Jöran Sopo, Managing Director OMG Kokkola Chemicals. With 375 employees the OM Group is the second biggest employer in the Industrial Park, manufacturing mainly cobalt products. In total 2000 employees are based in Kokkola. Research and development indeed plays a very important role for the Kokkola site. The new € 500.000 chemical test plant, Chemplant, offers a wide field of functions from the preparation of solid raw materials to gas cleaning and various extractions of solid and liquid materials. Companies can also link their own research departments to the technology center Ketek, which is especially designed as a R&D environment, to work on polymer applications, chemical processes or laser and material technology.

Alongside their focus on R&D facilities, the Kokkola Industrial Park benefits from its long tradition in chemical manufacturing. The chemical industry is a reputable employer in the region and the supply of committed labor is good. Due to this long tradition, the given infrastructure is well developed and meets the requirements of a modern and globally orientated production site. The airport is just 15 minutes away from the plant, offering the opportunity to ship chemicals flexible to all parts in the world. Not as flexible as the air route, but much more cost-efficient is Kokkola's outstanding railway connection. In goods traffic, the same track gauge is used all the way to China, which makes delivery to the Russian and Asian market possible.

Top 10 Products

- Sulphuric acid
- Calcium chloride
- Hydrochloric acid
- Potassium sulphate
- Phosphoric acid
- Limestone
- Ammonia
- Potassium salt
- Cobalt products
- Zinc

Kokkola's harbor can be seen as a link in trade between east and west. It offers quick connections to Russia, and from there to the rest of the world. Cargo to be shipped to Russia is loaded in the harbor directly into railway carriages which will cross the border between Russia and Finland ten hours later. Several large-scale international industrial establishments have operations in the immediate vicinity of the harbor. But it is not only the advantageous geographical location that makes Kokkola harbor an important transfer site. The port is home to the only All Weather Terminal (AWT) in the Nordic countries, which is at the same time the largest in Europe. In the terminal, ships can be loaded and unloaded in a covered space, which means that the cargo will never be left to the mercy of weather.

The inorganic chemical industry sees the benefits of Kokkola's Industrial Park and started investing a couple of years ago. "In Kokkola things move very fast. The speed at which we had our new plant up and running was amazing. The cooperation between Kosek and Woikowski and the city of Kokkola was seamless," says Clas Palmberg, Managing Director Oy Woikoski AB, Finland's oldest specialized gas producer and distributor. The internal connections between the companies at KIP are interlaced in a way that leads to a cost efficient value chain. The broad product portfolio, ranging from cobalt and zinc products to calcium chloride, limestone or ammonia, speaks a clear language and illustrates the optimized value chain.

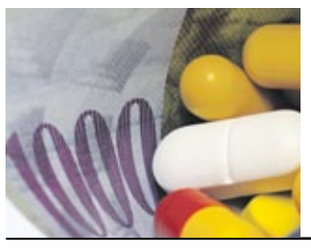
The European Chemicals Agency is also situated in Finland and, as part of the EU's Subsidy Area 2, there is guaranteed potential for financial support. Another important partner for Kokkola Industrial Park is the European Chemical Site Promotion Platform (ECSPP). The organization was founded in 2005 and since then supports chemical clusters all over Europe. Currently the ecspp operates in ten countries, with 30 members and 70 chemical sites. The Kokkola site is among the ten biggest clusters in Europe, covering an area of 600 ha. The only chemical sites with a larger scale are either located in Germany or in the Netherlands and range from 650 to 2000 ha.

Outlook

In the future it will be crucial for the European chemical Industry to focus on clusters like Kokkola Industrial Park. In terms of costs the Asian competitors are nearly unbeatable and the one big thing that keeps European companies competitive is their level of connectivity. The chemical production in Europe is predominantly organized in clusters and investments in this area need to be intensified to face the challenges of this changing market.

Contact:
Ville Honkala
Project Manager
Kokkola Industrial Park
Kokkola, Finland
Tel.: +358 44 7809098
ville.honkala@kip.fi, www.kip.fi

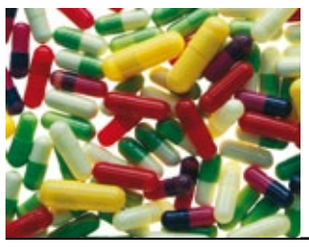
chemanager-online.com/en/tags/locations



Opinions

Pharma Supply Chain Experts Discuss Challenges arising from a Changing Business Model.

Pages 14, 15



Strategy

Siegfried Adds More Pieces to its Puzzle of Offerings for the Pharmaceutical Industry.

Page 17

Synthesis

Manufacturing Challenges for the Targeted and Potent Drugs of Tomorrow.

Page 18

¡Bienvenidos a la Feria!

CPhI Worldwide, the Leading Annual Networking Event of the Global Pharmaceutical Ingredients Industry, Returns to Madrid

Face Time – More than 29,000 attendees from over 140 countries visited the CPhI Worldwide in Frankfurt, Germany, last year and met face-to-face with staff from almost 2,000 international exhibitors. There's no doubt that CPhI allows attendees to stay informed about the latest industry trends and remain one step ahead of a constantly changing pharmaceutical market. However, while the show has grown and grown since its inception in 1990, it has also faced its fair share of criticism from the industry regarding its size — something the show says reflects industry growth. The show's brand director Andrew Pert is therefore always on the lookout for new ways to better connect with the industry's needs and tailoring the show accordingly. CHEManager Europe asked him about the organizer's efforts ahead of this year's 23rd edition at the Feria de Madrid, Spain, to take place October 9-11.

Andrew Pert, Brand Director CPhI Worldwide, ICSE, P-MEC Europe, InnoPack, UBM Live

CHEManager Europe: The CPhI has continued to gain international interest and attendance. Tell us a little bit about that, as well as why attendees should be excited for Madrid.

A. Pert: Not only is Madrid a popular venue with exhibitors and visitors, but we are also going into 2012 with many records already broken. It is a great time to be a part of CPhI, ISCE, P-MEC Europe and InnoPack and we are looking forward to being onsite at the Feria! We have more exhibitors than any previous year, many of them returning, and 108 new companies have joined us. Event attendance retention is the highest ever this year at 84 % and our zones have also seen growth with 9 new exhibitors in the biopharmaceuticals zone and doubling of exhibitors in the ICSE logistics and supply chain zone.

Bigger is not always better: What is more important than exhibitor space when developing future CPhI Worldwide events?

A. Pert: The most important thing to us as an event organizer is our exhibitor and attendee return on investment (ROI). Throughout the years the events have grown, which has allowed us to continuously shape them based on feedback from our visitors and the experiences we have had. We recognize that it is no small undertaking for our visitors to participate in an event of this magnitude, so we need to be sure that they are more than worthwhile to our visitors.

Which new services for visitors and exhibitors do you offer prior to the Madrid event?

A. Pert: As we prepare for Madrid in 2012, we are taking many concepts live through new technologies and improvements in existing features. Leading into the show, UBM is offering webinars to help exhibitors and attendees prepare for the event, as well as offering a new CPhI Global Meetings programme that acts as a matchmaker for scheduling customized meetings into your diary. The Pre-Connect series will return a day before the full event goes live and will feature information on the top industry trends and regulations, including ways to enter new markets.

We are also very excited to introduce the CPhI mobile app in Madrid! It will make searching for suppliers easier by offering real-time navigation and pointers for guests who are on site at the event, as well as functionality to connect and network with other attendees via social media. Also on the navigation front, we have put a great amount of research and effort into expanding the zoning format to include new zones that better match exhibitor profiles and make locating products and services easier for guests. The new zone offering includes:

- CPhI Worldwide: APIs; Generic APIs; Custom Manufacturing; Fine Chemicals; Intermediates; Excipients/Formulations; Biopharmaceuticals; General;
- ICSE: Logistics & Supply Chain; BioServices; Analytical & Lab Services; (Pre) Clinical Trials, CRO & Clinical Data Management Zone; New Exhibitors; North America Zone; General Floor;
- P-MEC Europe: LABWorld;
- Innopack: Labelling.

> *We are always open to exhibitor and visitor input for future planning.*

Will CPhI become even more international regarding exhibitors and visitors?

A. Pert: We are very excited to talk about how the events continue to expand internationally. We have fifteen Global Pavilions this year that highlight suppliers from specific regions. This is also a record for us, due to the fact that we are introducing global Pavilions for Russia and Malaysia, two regions that have been experiencing rapid growth in the pharmaceutical industry. They will be complemented by the return of Pavilions for Argentina, Brazil, China, Egypt, France, India, Ireland, Korea, Morocco, Portugal, Scotland, UK and North America, which now features SOCMA. The North American Pavilion is also having a record year with a 10 % increase in participating exhibitors.

What does that mean for your global expansion plans?

A. Pert: In order to support our global expansion we have put a great amount of time into creating strategic partnerships with key international organizations. This includes an extended partnership with the India Brand Equity Foundation (IBEF) and Pharmexcil to promote the progress in the Indian Pharma market. UBM Live is also pleased to partner with Scottish Enterprise, PharmaChemical Ireland, Egypt Expo &Convention Authority, Pharma Portugal, Matrade in Malaysia, Ministry of Industry and Trade of the Russian Federation, and the CCPIT Sub-council of Chemical Industry and CCCMHPIE in China to name a few.

What other items are notable this year?

A. Pert: The CPhI Innovations Awards return with a twist this year. The line-up has been rebranded as the CPhI Pharma Awards and features an additional category, for a total of three award categories: two returning and one new. The rebranding reflects the diversification in the industry, which has been evident through the changes in the types of entries over the past nine years in which the awards have taken place.

The returning Best Innovation in Pharma Awards category will feature five finalists competing for gold, silver and bronze. This category has expanded over the years to include not only chemistry innovations, but also to showcase exhibitors with groundbreaking innovations in formulation, drug delivery, chemical manufacturing of APIs and intermediates, and biomanufacturing of biopharmaceuticals and intermediates. The Sustainable Stand Design Award returns to celebrate one exhibitor that has minimized their environmental impact through the materials, labor, and resources used in their stand at the events. Finally, the Best Sustainable Packaging Design Award has been introduced to recognize one exhibitor that offered a specific material, machine, or supply during 2011 that facilitated sustainable packaging and processes.

> *We have put a great amount of research into expanding the zoning format to include new zones that better match exhibitor profiles.*

In terms of the search for the perfect location, CPhI Worldwide has recently moved between the European cities of Frankfurt, Milan, Madrid and Paris with plans to return to Frankfurt in 2013. Do you think about other cities that might provide a good location for a global pharmaceutical show like CPhI?

A. Pert: Location choice is really about staying focused on making the event valuable to attendees. Even as we continue to grow, we do everything we can to ensure that the events are accessible and easy to participate in. Part of that involves working with venues that meet the needs of our attendees. We do continuously review new venue ideas throughout Europe, but many have insufficient space or do not meet other requirements, such as having availability during October.

As a global event, a very important key factor in venue selection is the feasibility for overseas visitors to reach the city. Among other considerations, we need to be sure that convenient flights are available, that we can work within the dates we have identified, consider visa requirements for people travelling outside of Europe, ensure there are a sufficient number of hotel rooms in a particular city, and look into public transportation connections between the airport and the venue. In addition to these practical points, we also survey our exhibitor and visitor attendance regularly, and these cities continually receive positive feedback.

Of course, as time goes on, new venues will be built, existing ones will be expanded and flight patterns will change, so we keep a live eye out for new venue possibilities at all times. We are always open to exhibitor and visitor input for future planning.

chemanager-online.com/en/tags/cphi

Changing Times

Pharmaceutical Supply Chain Experts Discuss Challenges Arising from a Changing Pharma Business Model

CPhI – As a transforming model of healthcare in countries around the world could make its way to the core of the pharmaceutical industry, pharma supply chain partners like CROs, CMOs, and CRAMs have to be prepared to adjust their business models.

Technology has changed many industries over the past decades. The biopharma and healthcare industry is also currently preparing for some massive changes, which could lead to an era of 'connected health'. McKinsey recently published a report titled „How the new connected era is reshaping biopharma", which made clear that due to better connectivity via the internet, improved diagnostic tools and the dissatisfaction of patients, healthcare and biopharma are now facing a transformation from centralized medical distribution to a more personalized approach. The ambition of this 'connected health' approach is simple: Identify the right treatment for the right patient at the right time.

The current model for healthcare around the globe is characterized by inflexibility, centralized distribution and high costs. Medical mass production generates standardized drugs with variable quality and the outcome monitoring is at least questionable. Often data are monopolized by the suppliers, which leads to an unsustainable imbalance between supply and demand. Since the world population is growing constantly many countries are observing an aging population. As a consequence, the demands toward the pharmaceutical industry change and the pharma companies need to react. The idea of 'connected health' was born out of this challenging situation, trying to revolutionize the model for healthcare. „Connected health will give rise to a number of new business models that have the potential to transform healthcare," says Kristin Peck, Pfizer's executive vice president for worldwide business development and innovation, in an.

'Connected health' offers a wide variety of advantages, especially for consumers and physicians. The biopharma industry on the other hand is not yet ready to serve this new market. Even though the industry's commercial model already started to change, there is much to be done to face the upcoming challenges. „Pharma companies will need to be able to overcome the commercial and market-access risks that could accompany this shift," guesses Kristin Peck. „The Implication is a shift away from highly innovative treatments toward highly effective solutions, especially solutions that shift accountability toward the consumer." If 'connected health' becomes reality, the biopharma industry and all its suppliers need to reposition themselves within the market.

Even though the situation for biopharma companies is challenging, there are also lots of opportunities for improvements. Especially R&D can profit from a better connected pharmaceutical industry. Virtual workplaces, set up via the internet, offer the chance for open collaboration among biopharma companies, academics, clinical-research organizations and contract manufacturers. It is crucial for long-established companies to see new business models as a chance and not as a threat for the status quo. The model of healthcare is adapting to the needs of the consumers and pharma companies should do exactly the same.

CHEManager Europe asked experts from the pharmaceutical ingredients and custom synthesis industry to share their opinions on this topic prior to the industry global networking event, CPhI Worldwide in Madrid, Oct. 9-11, 2012. Read what they think about the prospects for their businesses given the challenges – and opportunities – ahead.

Jean-Luc Herbeaux,
Head of Health Care Business, Evonik

Roger Laforce,
CEO, Zach System

Marianne Späne, EVP Global Business Development, Marketing and Sales, Siegfried

Alexander R. Wessels,
CEO, DSM Pharmaceutical Products

Hendrik Baumann,
Commercial Director, CU Chemie Uetikon

J.-L. Herbeaux (Evonik): The pharmaceutical industry has undergone significant changes in the last years, which call for large-scale revisions in business models. Several overlapping factors have made this necessary, including increased cost pressure due to tightened health care policies and higher competition, more stringent regulatory requirements and lower blockbuster potential arising from weaker development pipelines. All this is compounded by the so-called patent cliff, which threatens originators with sudden and significant loss of revenues and prompts further acceleration of change.

Increased efficiency is the trend that has evolved out of this challenge among pharmaceutical companies as well as their suppliers and partners. To that end, businesses are looking toward outsourcing and leveraging a few select partners that are both flexible and provide enabling technologies.

Evonik offers the strength and breadth that comes with working with one of the world's largest specialty chemical companies. We cover a large part of the value chain, from manufacturing of API's (including HPAPI) and functional excipients to development of drug formulations and specialty manufacturing of drug products.

Thanks to our strong global R&D laboratory and production network, we support pharmaceutical companies in developing better manufacturing routes for their high value APIs. We ensure their successful and economic scale-up and secure supply through clinical trials all the way to commercial launch and beyond.

Thanks to the recent acquisition of Birmingham Laboratories in Alabama (USA), Evonik now also has the competencies and facilities to offer full development and manufacturing services in the area of injectable controlled release formulations. This, combined with our oral drug formulation development services carried out of our global technical laboratory network, means that we can now assist our customers in developing and launching more effective drug formulations for both oral and injectable applications.

Our Eudragit and Resomer functional polymer systems complete the offering. These two leading excipient platforms are used safely by customers the world over to impart controlled release functionality to sophisticated oral and parenteral dosage forms.

Our broad competencies in APIs and drug delivery systems combine to support clients in new ways. For example, Evonik is now active in the design and production of antibody drug conjugates (ADCs). This is a new type of targeted therapy where the antibody binds directly to, for example, specific markers at the surface of cancer cells. The ADC is then internalized within the cancer cell and the active ingredient released exactly where it is needed, thus reducing side effects and widening the therapeutic window.

Evonik has extensive experience and knowledge covering a broad spectrum of solutions for the pharmaceutical industry. Companies today need an agile, reliable and empowering partner with global resources to increase efficiency and keep them on the cutting edge of technology. That's exactly what Evonik does.

R. Laforce (Zach System): No doubt, the pharma industry and its entire supply chain are undergoing a paradigm change considering the increasing importance of emerging countries now also seen as markets. Countries with large populations like the entire Asian-Pacific Rim are profiling themselves for regulatory, IP and access to their markets. Such markets show different characteristics. Rich and medium class people can afford more expensive drugs, but a large part of their population needs ultra-low cost drugs with totally different distribution systems (buy a pill a day). These patients have the same right for the same quality as better situated ones.

Does this mean that the European API industry is doomed with the ever increasing regulatory framework within the EU and in single countries such as Italy?

The triad markets USA, Europe and Japan show a trend towards personalized medicine and new treatment areas for its ageing populations. Cancer treatment, geriatric drugs treatments against metabolic diseases like antidiabetics, antiobesity or neurodegenerative drugs. Growth for many anticancer will be more linear and not exponential like blockbusters, quantities lower, the chemistry more sophisticated. The combination of synthetic APIs with biomolecules and protein based drugs will increase. These changes need to be captured by the pharmaceutical chemical companies and will lead to a change of their strategies.

The collaboration of US, European and Japanese companies with industries in emerging markets needs to further strengthen, since the major innovation drivers are still in the USA, Europe and Japan, where more solutions are needed in emerging countries. Interestingly, multinational pharma companies are still underrepresented in China. The production of low-cost APIs at large volumes and high quality is one of the major challenges of our part of the supply chain in the next decade. It will open new business opportunities if we take this challenge. Such innovations will feed back to our markets.

The bulk part of pharmaceutical-chemical production today is still batch operated. The API factory of the future will be more modular and more processes and entire production units tend to become continuous. Sophisticated manufacturing systems using continuous or semi-continuous techniques are only the beginning.

Data streams on a global level demand more stable and higher performing lines to manage global level supply chains.

The European Fine Chemical is obviously not doomed but has still a lot to offer to the pharmaceutical world. It will contribute with a wealth of know-how grown for more than a century of chemical culture.

M. Späne (Siegfried): Today, the pharmaceutical industry faces multiple challenges, such as a marked decline in bringing NCEs to market, coupled with generic competition, regulatory and health system payer pressures combined with continued weak economic growth, especially in the largest market the US. Pharmaceutical companies in future will have to be willing to change current business models which apply innovative marketing, R&D & supply chain practices to mitigate & replace revenue losses from patent expiration and lack of blockbuster medicines.

The model shift will rely more on outsourcing service partnerships to solve technical problems, improve efficiency and productivity, and ultimately to streamline the value chain. We foresee companies de-risking their R&D efforts through increased product in-licensing and partnerships together with outsourcing of activities previously largely kept in-house such as manufacturing of regulated intermediates, APIs and finished products. Streamlined operations via lean manufacturing practices are today's standard which is increasing the demand for contract manufactured drugs.

To bridge these gaps, CMO's will need to demonstrate long-standing track record(s) coupled with extensive technical know-how, to gain customer confidence. Siegfried has done so by strengthening its position as a well experienced drug substance and drug product development and manufacturing company with superb compliance record. We offer a fully integrated service, and we are continuing to invest in additional capabilities that our clients require including: high potency and bridging technologies such as spray-drying & micronization.

Under Siegfried's 'transform' strategy, we fully forward integrated our drug product service offering through acquiring 'AMP', who offers a full range of aseptic fill services which complements our solid oral dosage capabilities. Also, we have begun to backward integrate manufacturing with investment in Nantong, China to offer both non-GMP substances and GMP substances as a secondary cost structure strategy for our clients.

Pharma companies both innovative and generic, realize that outsourcing combined with creative partnership models will create greater value. Pharma preferred partner relationships will allow both organizations to fully contribute their core strengths such as R&D, manufacturing and marketing. Many clients we work with operate under the 'preferred supplier program umbrella' which manages their outsourcing choices. Finding these ideal outsourcing relationships, are what will make the key difference for most pharmaceutical companies.

Recently, Siegfried re-established its corporate logo as 'expect more'. We believe we are that innovative, flexible, integrated partner a pharmaceutical company seeks, to reduce costs and enhance technologies, to streamline their supply chain needs.

A. R. Wessels (DSM Pharmaceutical Products): DSM's stake in the pharma outsourcing market is based on a

Continues Page 14 ▶

◀ Continued **Page 15**

global portfolio of resources to continuously serve changing customer needs and bring real value as the pharma industry shifts business models. There is a need for substantive, long-term partnerships between pharma and outsource partners.

As a contract manufacturer and technology provider, we make a commitment to employ expertise across our organization to achieve success for our customers. DSM offers an integrated approach to sustainable manufacturing using biotechnology, chemistry, and pro¬cess technology. With its biotechnology and (bio)chemistry capabilities DSM has an extensive toolbox for developing the most economic and sustainable solutions. And DSM has extensive expertise in technology, IP and operations developed over a period of many, many years.

While there is great discussion around the concept and practice of sustainability, the quest for sustainable development will certainly be a key theme in the coming years. The world will soon be faced with the challenge of accommodating nine billion people who all want to live healthy and prosperous lives. It is therefore essential to find solutions to scarcity, security and other constraints – it is the only way to maintain stability and prosperity.

For pharma there is the opportunity to achieve sustainability with an outsourcing partner and manufacturing expert like DSM, whether they are licensing technologies to optimize their own biomanufacturing or leveraging our green chemistry to extend the life cycle of proven drug compounds.

In the biopharma space growth is still high and opportunities are all around. However, consolidation in the small molecule API sector particularly in the western countries is something that we see happening. Consolidation is being forced not only from a capacity perspective, but also for reasons of quality and safety. As global supply chains expand, the safety and traceability of ingredients and finished drugs, as well as the sustainability of these supply chains, become critical. The almost doubling of the number of warning letters that the FDA has issued this year seems to indicate and address growing concerns from a regulatory perspective.

The DSM "Quality for Life" seal is at the heart of what we do in demonstrating our systematic quality program. Quality for Life assures customers that the ingredients they are buying from us are safe in terms of quality, reliability and traceability. Moreover, they are manufactured in a safe and sustainable way.

H. Baumann (CU Chemie Uetikon): The limited number of new chemical entities (NCE's) in the pipelines of the big pharma companies on the one hand and the decreasing investments/fundings of small and venture pharma companies on the other hand, will change the custom manufacturing and fine chemicals business significantly. As a result the outsourcing volumes of those pharma companies will decrease, while CRO's and CMO's fighting for the same limited numbers of products and projects. This will have an influence to the profitability of the contract manufacturers and last but not least to the supply chain. From our point of view, it is a global and not a "western" problem.

In addition some of the largest pharmaceutical markets – for example Germany or Japan – are under heavy price pressure from the public health insurance system. The goal is to have a fixed price system for any medicine which is controlled by the government or fixed annual price reductions are requested (irrespective whether it is a new drug or a generic). As a result, pharma companies may lose their interest to launch new API's in such markets as they cannot keep their profitability.

A look into the pipelines of the leading pharma companies shows another interesting trend: The major API development direction is cancer, diabetes and CNS. The landscape is scattered and only few NCE's are or will be successful, most of them in small dosages or as individualised medicine, which means small volumes for the API producers.

Last but not least many of the CMO's will face dramatic changes in the legal environment, which will finally increase their costs of goods, key words here are GDUFA (US FDA fees) and FMD (EU directive). As the custom synthesis market is extremely diversified, where no single company has more than 3 % market share, we will probably see a market consolidation in the next years.

The above mentioned scenarios will influence the business model of each single CRO and CMO. We still believe that a diversified product and project portfolio including "bread and butter" products in combination with operational excellence will be key for future success. Also we are convinced that the right small-midsized capacity, excellent customer service and high flexibility are the success criteria for the future.

E. Berger (Catalent Pharma Solutions): Partnering and open innovation models are clearly becoming more significant in the drug development and delivery space as well. Resource constraints, a need to focus scarce talent on core competencies and priority areas, as well as increasingly challenging molecules in pharma pipelines, are driving large and small companies to partner with specialized technology and expert services providers. Catalent has seen a significant increase in cooperation at earlier stages of drug development, particularly in complex oral dose forms with challenging bioavailability, release, or targeted delivery profiles as well as in method development, scale up and manufacture of complex products. We can also see this trend in biopharmaceuticals and biosimilars, as well as in clinical trial supply solutions.

Larger companies are looking to supplement their capabilities with specific niche expertise, while mid-size and smaller companies are looking to partner for integrated solutions. Catalent has focused on developing a broad range of expert solutions and new drug delivery technologies as well as global supply capabilities explicitly to meet these needs. Our recent investments in drug development expertise and talent, OptiForm API optimization technology, OptiMelt hot melt extrusion capabilities and OptiDose flexible oral delivery technology, combined with global capability improvements in oral and biomanufacturing, are expressly designed to meet this demand for tailored partnership solutions.

D. DeCuir (Albemarle Fine Chemistry Services): Increased efficacy in the design, manufacture and distribution of pharmaceutical products will likely mean that dosages of new products will decrease as the products become more effective, but also, older effective products will stay on the market longer. This means that new "designer drugs" will require increasingly smaller campaign sizes due to increased efficacy and that effective generic drugs will be longer lived, and will compete for time in manufacturers' facilities. Consequently, the suppliers to the pharmaceutical industry will be required to make smaller campaigns of multiple drugs in their facilities rather than large campaigns or even dedicated lines.

Increased complexity of drug products will mean more opportunity for CMOs since these products will be more difficult to make and require additional steps manufactured under cGMP; even as large pharmaceutical companies increasingly outsource production in order to concentrate on core activities. Companies who can do process development and manufacturing, instead of either of these steps, will receive a disproportionate share of the outsourcing revenue in the future. As always, reliability in supply will be a key differentiator.

Aging populations with growing prosperity and access to information about pharmaceuticals will inevitably mean a larger pharmaceutical market in the future. This alone bodes well for pharma custom manufacturing companies. However, it will be increasingly difficult to bring new products to the market since those new products will increasingly have to prove that they are better and more cost effective compared to existing products. This means that while new products will be fewer, they will be longer lived. The most exciting aspect to this new supply chain is the customer's increasing ability to compare medications on efficacy, price and quality metrics that will necessitate positive changes for high quality producers of APIs. Lower cost but lower quality products will not be tolerated by the increased scrutiny of both regulatory agencies as well as a better informed patient population. This bodes well for reliable Western producers of high quality API with flexible assets.

T. D'Ambra (AMRI): Recent issues within the global pharma market, including failure to fill pipelines to compensate for a number of key patent expiries, coinciding with prolonged economic recession in Western countries, are leading to changes in how pharma companies consider outsourcing. As a result, CROs and CMOs are under increasing pressure to reconsider their own business models, to ensure they provide the most appropriate service offerings for the changing industry.

Pharma companies have invested considerable effort into evaluating R&D strategies and programs over the past couple of years, which has led to massive layoffs of scientific R&D staff and many facility closures, particularly within Europe and the USA. On the one hand, this could mean fewer overall opportunities for CROs and CMOs, compounded by an increasing focus on biopharmaceuticals that means even less budget is available for traditional small-molecular discovery and development. However, I believe these changes could lead to greater demand for outsourcing: many pharma companies are now focusing on increased outsourcing to accomplish many of their R&D objectives, having eliminated key functions, staff and facilities.

Furthermore, these eliminated staff and resources are available to outsourcing companies. We are seeing experienced discovery and development scientists from large pharma taking positions in the CRO industry, providing a valuable pool of talent that outsourcing providers can use to meet the evolving needs of customers. Significantly, this means that the balance of expertise is beginning to shift from customers to suppliers.

In recent years, the lowest priced offering was often a key deciding factor when awarding contracts to outsourcing companies. However, pharma customers' changing needs are driving the development of new business models, including increasing focus on services being delivered on time and within budget; the need for collaborative advice and more strategic partnerships; the need to ease the burdens of project management; and the need for more flexibility, adaptability and quality. The ability of providers to adapt and respond to these industry changes will play a vital role in improving the success rate and outcomes at all stages of the drug discovery and development pipeline.

At AMRI, we have specifically developed our new service offering in response to the changing industry. AMRI Smartsourcing is designed to provide customers with the ability to customize our resources, technologies, geographic footprint and record of accountability and accomplishment. Our customers can create an ideal offering to meet the needs of their research programs, without the need to compromise on quality, productivity or timeliness.

P. Pojarliev (Euticals): For a second consecutive quarter, overall sales and earnings for many pharmaceutical companies have declined. The impact is a result of the healthcare reforms in most of the European countries in the last 4-5 years, the increasing generic competition and loss of revenues of expired top-selling products. Companies hit from the economic environment and its repercussions are using everything possible ankle from acquisition of businesses to geographic diversification to shore up their businesses. Cost reduction programs affecting their labor forces are spreading through the western world.

The industry is changing or is forced to change to maintain the pace of growth. Our customers are looking for establishing low risk supply chain with strategic partners in the sourcing area and manage a pool of few and reliable suppliers who can offer specialties and comprehensive services meeting their needs. Open communication and common understanding of the project goals and expectations are key success factors. Suppliers in their turn are in a need to diversify in terms of geography, products and services.

Euticals Group acts as a fully-fledged API, fine chemicals and contact manufacturing organization. We are a major player globally based with 11 facilities located in Italy, France, Germany, UK and the US. Our core business is and will remain the manufacturing and process development. We are also aiming at the forward vertical integration in dosage forms.

With our diversity in services, production facilities and our philosophy – customers come first; we are an ideal partner in a constantly changing market environment. Achieving what we promised and meeting customers' needs in timely manner help us build strong relationships and help our customers overcome an increasingly challenging market environment

Elliott Berger, Vice President, Global Marketing and Strategy, Catalent Pharma Solutions

David DeCuir, Director, Albemarle Fine Chemistry Services

Thomas D'Ambra, Chairman, CEO & President, AMRI

Dr. Peter Pojarliev, Director, Business Development, Euticals

chemanager-online.com/en/tags/cphi

Thriving Generics

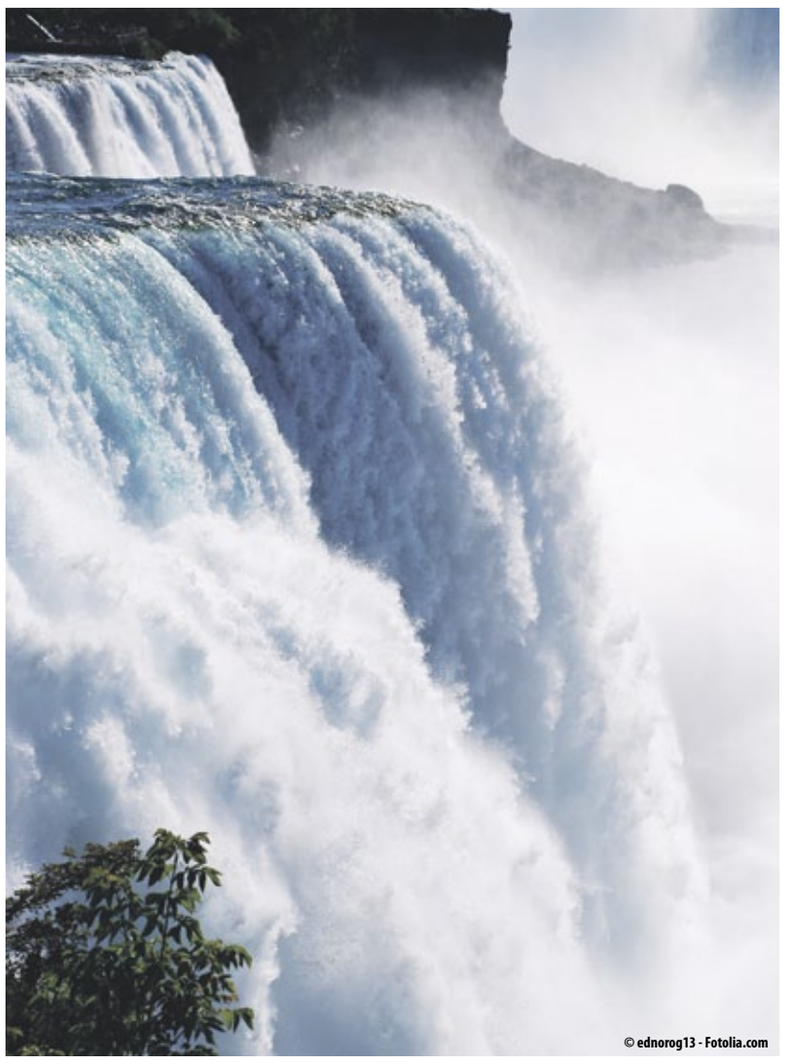
Patent Cliff Revenues Fertilize Generics Companies

Market Transition – When we think about the patent cliff, an image along the lines of a massive waterfall, with companies' revenues in free fall comes to mind. What we usually forget to consider, though, is that the waterfall is nourishing a fertile, green valley below. While big pharmaceutical companies are scrambling to bolt-on smaller biotechs with marketed drugs to protect themselves, generics manufacturers are reaping windfall profits.

While the industry has been nervous about the patent cliff for years, it is turning out to be a blessing in disguise. Patients are benefitting the most by gaining access to the innovative drugs of the past few decades at generic prices. Biotech companies are benefitting from a frenzied M&A environment, and generics companies are reporting record profits. Big pharmaceutical companies, meanwhile, have been forced to respond to the challenge by refocusing their attention and honing their business strategies.

Pfizer vs. Watson

As an example of this phenomenon, it's worth looking at the biggest loss of the edge of the cliff, Pfizer's cholesterol drug Lipitor. The company recently released its first quarter earnings, and reported Lipitor sales of $1.4 billion, a 42% plunge from the same period in 2011. The drugmaker can hardly complain, though, as the drug recorded cumulative sales of $128 billion for Pfizer through the end of 2011. Meanwhile, Watson Pharmaceuticals was the first to begin selling generic Lipitor in November, 2011. As a result of strong generic Lipitor sales, as well as other generic launches including generic versions of Concerta and Lovenox, Watson's first quarter revenue increased 74% to $1.5 billion, compared to $877 million for the corresponding period in 2011. Increased sales drove an 87% increase in net income, from $112 million in Q1 2011 to $209 million in 2012. As a result of its newfound financial heft, Watson was able to expand its geographic reach with the purchase of the European generics firm Actavis. Watson announced the €4.25 billion ($5.6 billion) acquisition on April 25, and should lead to 2012 pro forma revenue of $8 billion for the combined company in 2012, compared to $4.6 billion for Watson in 2011 and $6 billion in 2012 based on annualized first quarter revenue. Mylan, another major generics company, reported an 18% increase in earnings for the first quarter compared to 2011, to $0.52/share from $0.44/share. This gain was due to a 9% increase in revenue from $1.45 billion in Q1 2011 to $1.58 billion in 2012.


© ednorog13 - Fotolia.com

New Strategy

Pfizer and other big pharmaceutical companies, meanwhile, appear to be on course to successfully navigate the rapids. Although Pfizer saw its earnings drop 19% in the first quarter compared to 2011, there are bright lights on the horizon. The FDA is set to decide on its rheumatoid arthritis drug tofacitinib by August 20, and the drug has the potential to eventually generate up to $1.5 billion in revenue per year. The company has another drug before the FDA for review, with a decision expected by June 28. Eliquis was co-developed with Bristol-Myers Squibb for the prevention of strokes in patients with arterial fibrillation, and also has blockbuster potential. Finally, Pfizer is flush with cash after selling its infant nutrition unit to Nestle for $11.9 billion, and ready for another round of acquisitions that could range from small, bolt-on biotech purchases to another pharmaceutical mega-merger.

Rising Stars

Through a continuing wave of lucrative biotech buyouts, two small companies with approved drugs are now the focus of major pharmaceutical M&A efforts. Human Genome Sciences Inc. (HGSI) received approval for its first drug, Benlysta, last year. The drug was the first new therapy approved by the FDA for lupus in almost 50 years, but so far the launch has been much weaker than many had expected or hoped. Despite three promising, late-stage pipeline programs for treating infectious diseases, cardiovascular disease, and diabetes, HGSI's share price has suffered since the March, 2011 approval of Benlysta. On April 19, HGSI disclosed a rejected take-over bid from GlaxoSmithKline of $13/share, or about $2.6 billion, causing the company's shares to rocket to an 81% single-day increase. Although the bid was rejected, we believe that GlaxoSmithKline will eventually acquire its target. The company has gone hostile with a $13/share bid with the belief that their partnership with HGSI, which covers Benlysta and two of HGSI's late-stage clinical assets, will deter other potential bidders.

Another company on the pharmaceutical auction block is Amylin Pharmaceuticals, which possesses a series of lucrative diabetes drugs, most notably two drugs related to the exenatide franchise. Exenatide, sold in a twice-daily version as Byetta and a once-weekly version as Bydureon, is an incretin mimetic, GLP-1 receptor agonist that helps type 2 diabetics control their blood sugar. The other approved drug is Symlin (pramlintide), an analogue of the human hormone amylin (the company's namesake) that helps type 2 diabetics control glucose with the potential for weight loss. Amylin had been involved in a long-term partnership with Eli Lilly for the promotion and sale of the exenatide franchise, but that agreement ended in a messy divorce last year after Lilly began co-promoting a competing portfolio of diabetes products along with partner Boehringer Ingelheim.

As a result of the break-up between the two companies, Amylin found itself with complete ownership of its approved drugs, making it an attractive takeover target. The company went public with its intention to be acquired after rejecting a $22/share, $3.5 billion buyout bid from Bristol-Myers Squibb in February. Amylin shares jumped more than 50% the day it announced the rejected acquisition. It has since begun an auction-type process to sell itself, and it has reportedly drawn bids from Sanofi and Merck & Co., as well as potential interest from Merck, Pfizer, Roche, AstraZeneca, Takeda, and Bristol-Myers Squibb. AstraZeneca, with a weak portfolio of diabetes products and a dire need to bring in new sources of revenue, is an obvious candidate to purchase Amylin. While any of these companies would likely benefit from the blockbuster exenatide franchise, Takeda and Sanofi are other drug makers who we believe might go after Amylin with intensity. When the process is completed, we will not be surprised to see Amylin sell for well over $4 billion, perhaps approaching $5 billion.

Outlook

With deals like these on the horizon, the biggest development regarding the patent cliff will be watching large pharmaceutical companies' attempts to maintain growth in the face of expiring patents. But regardless of how or whether Big Pharma stays atop its mountain or goes over the cliff, generics firms will continue to reap the profits of major pharmaceutical patent expirations.

Author: Dr. Jerry Isaacson, Head of Global Data Healthcare Industry Dynamics

Contact:
Alice Robinson
Global Data
Bolton, UK
Tel.: +44 1204 543 537
arobinson@globaldata.com
www.globaldata.com

chemanager-online.com/en/tags/generics

No Experimenting

Stick to Your Strengths with Biosimilars

Pharmaceuticals – Of the many challenges inherent with biosimilar development, the inability to predict market expectations may top the list for decision makers. While uncertainty is a function of all nascent markets, in the biosimilars world, it has almost seemed to become the norm. In the US, although biosimilar legislation was approved as part of the Patient Protection and Affordable Care Act in March of 2010, it wasn't until the Supreme Court of the United States upheld the law this past June that biosimilar developers knew for certain the abbreviated pathway would remain.

Setting aside uncertainty, many other challenges exist for potential competitors looking to enter the biosimilar market. Regulated markets require expensive, complex regulatory dossiers to gain approval, and in markets void of automatic substitution, additional costs for marketing and sales may be necessary to drive uptake. Provided companies have in-house capabilities to develop and commercialize biosimilars, prior experience working with large molecules may be lacking.

But despite these challenges, over the past few years opportunity within the attractive biosimilars market has continued to grow, giving way to over 200 companies investing in development activities. Regulatory bodies across the globe have established abbreviated approval pathways for biologic products providing both increased competition and cost containment for health systems. Additionally, steps towards regulatory harmonization through the use of a global reference product could reduce the high costs of major clinical programs. Cost-effective manufacturing opportunities such as single-use technologies may provide further relief from cost barriers associated with entering the market.

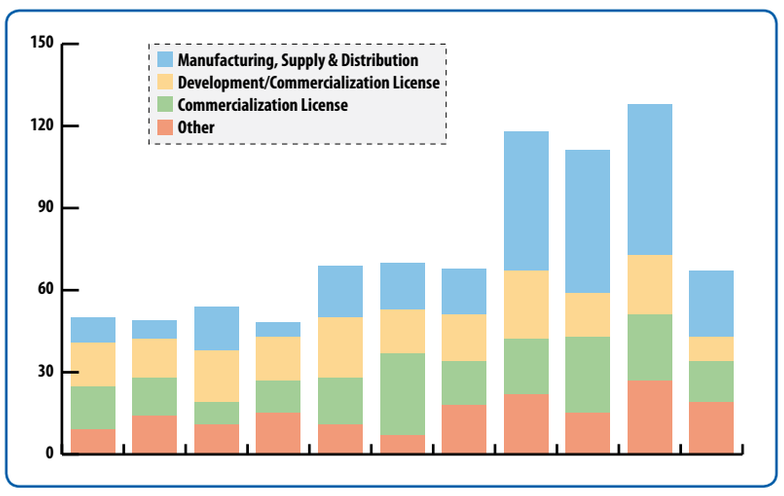


Fig. 1: Since 2009 there has been a spike in biologic product based deals, specifically those focusing on manufacturing, supply and distriction.
© Thomson Reuters Newport Premium

Thus far, the term "buy or build" has aptly characterized the decision companies looking to invest in the biologics market must make. Very few companies are without gaps in one of many important aspects of biologic development including experience, capacity and commercialization know-how resulting in having to either "buy" into partnerships to help fit needs, or "build" in-house capability. Looking at the deal activity from over the past ten years, manufacturing, supply and distribution deals since 2008 have seen significant growth (see figure 1). Also, many companies are focusing deals on complex monoclonal antibody products (see figure 2).

Although many partnerships have focused on providing experience, technology or capacity, a few recent deals have focused specifically on a specific biosimilar candidate. In June of 2011, Merck paid $720 million to license HD203, a biosimilar etanercept developed by the South Korean company Hanwha. In a similar deal, Watson Pharmaceuticals entered into a licensing agreement with Synthon focusing on the Dutch company's biosimilar trastuzumab. Watson will work in collaboration with Amgen on future development of the product from phase III studies through commercialization.

Investing resources or "building" in-house capabilities has been common among some of the more established companies in the pharmaceutical industry. Dong-A of South Korea and Meiji Seika of Japan are investing in a new facility located in Songdo, South Korea that will focus on the development of biosimilar antibodies. Another South Korean

Continues Page 17 ▶

API	Companies Involved	Deal Type	Detail	Year
adalimumab	PharmaPraxis, Ministry of Health, Brazil	Manufacturing, Supply & Distribution	Pharma Praxis to Develop Biosimilars and Supply to Domestic Market	2011
denosumab	Daiichi Sankyo Co Ltd, AstraZeneca plc	Commercialization License	Copromotion agreement in Japan for denosumab for the treatment of bone disorders stemming from bone metastasis.	2011
infliximab	Hospira Inc, Janssen Biotech Inc	Manufacturing, Supply & Distribution	Hospira was involved in the manufacturing of Centocor Ortho Biotech's Remicade (infliximab) injection	2011
rituximab	Coherus BioSciences Inc, Daiichi Sankyo Co Ltd	Development/Commercialization License	Exclusive agreement to develop, manufacture and commercialize biosimilar forms of etanercept and rituximab in certain Asian countries.	2012
rituximab	Gedeon Richter Ltd, Stada Arzneimittel AG	Commercialization License	STADA acquired non exclusive distribution rights for Europe and the CIS area (excluding Russia) for the biopharmaceutical active ingredient rituximab from Gedeon Richter.	2011
rituximab	Spectrum Pharmaceuticals Inc, Viropro Inc	Development/Commercialization License	Spectrum Pharmaceuticals signed a binding letter of agreement with Viropro for the development of its proprietary biosimilar formulation of the monoclonal antibody drug rituximab	2011
rituximab, trastuzumab	Emcure Pharmaceuticals Ltd, Roche Holding AG	Manufacturing, Supply & Distribution	Roche had signed a manufacturing contract with Emcure for Herceptin (trastuzumab) and MabThera (rituximab).	2012

Fig. 2: Companies continue to partner around monoclonal antibody products, a trend that will continue.
© Thomson Reuters Newport Premium

Expect More

Siegfried Promises to Deliver on its Slogan as the Company Keeps Adding Pieces to its Puzzle of Offerings

Dedicated Investments – One year ago, Siegfried launched its new slogan, 'Expect more, create more value as an integrated supplier'. Since then, a lot of things have happened. For instance, the Swiss pharma outsourcing partner completed upgrading the Zofingen, Switzerland facility for high containment drug products and acquired Alliance Medical Products in Irvine, CA. Birgit Megges asked Marianne Spaene, the company's Executive Vice President, Global Business Development, Sales and Marketing, how these pieces fit into Siegfried's puzzle of offerings to meet and even exceed their customers' expectations.

Marianne Spaene, Executive Vice President, Global Business Development, Sales and Marketing, Siegfried

CHEManager Europe: How would you judge the response your new slogan created in the markets you are serving?

M. Spaene: We are pleased with the slogan 'expect more', as it represents Siegfried as a broad and full-fledged service partner. Combined with our redesigned website and exhibition booth, the slogan has been very well received by our customers. Our message is clear, and everyone understands Siegfried's position. When a company makes a statement as strong as 'expect more' to reflect its primary corporate message, then expectations will be nothing short of the competition. As we combined the slogan with concrete promises for expansion in 2012, we had to underline the commitment with actions. I have to thank my team, because they walked that "extra mile" to meet and exceed customer expectations wherever possible.

What actions are you referring to?

M. Spaene: We strengthened our position as an integrated supplier through investment in supporting technologies for our business. Recently, we completed upgrading the Zofingen, Switzerland facility for high containment drug products, and mid-year we obtained approval for development and production of highly potent drug compounds from "Swissmedic", the Swiss agency for authorization and supervision of therapeutic products. Thanks to this piece of the high-potency puzzle we can offer our customers a fully integrated continuous supply chain for high-containment products starting with API development through to commercial manufacturing of drug products.

In addition, we now offer micronization technology at both our global headquarters in Zofingen and at our U.S. site in Pennsville, NJ, which further supports our promise to customers. Moreover, we are expanding our warehousing, packaging and tableting capabilities to enhance oral applications production in Malta.

Didn't your stakeholders and customers expect more, a bigger step forward?

M. Spaene: Naturally, they expect more, and I am pleased to say that they will receive more. At the end of June we acquired Alliance Medical Products, a sterile filling facility in Irvine, CA. This acquisition clearly demonstrates our commitment as an integrated service provider.

In addition to our existing oral formulation and manufacturing capabilities in Malta, we now offer sterile/aseptic development and manufacturing competencies in the USA. Combined with our current chemical facilities in Pennsville and in Zofingen, this additional site allows us to provide fully integrated services both in the US and in Europe.

Do AMP and Siegfried fit together?

M. Spaene: AMP works with unique and interesting customers that ideally complement Siegfried's current customer portfolio. Essentially, this provides us with a great potential for new business opportunities. Our customers have expressed interest in forward integration, and we are convinced that AMP's customers will appreciate backward integration into API for some of their products.

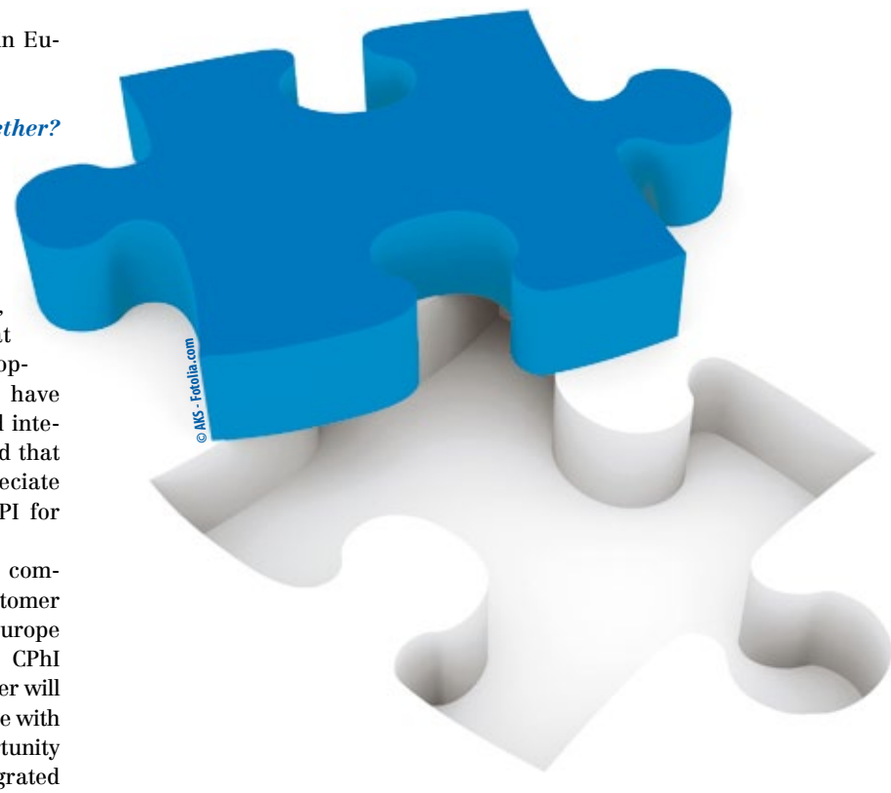
Siegfried and AMP as one company provide a US-focused customer the possibility to expand into Europe and other regions. The 2012 CPhI convention coming up in October will be a great format for us to share with customers the unique opportunity they now have with our integrated sterile filling facility. In addition, we are planning a combined customer road show with AMP experts within the next months. It is great to see that AMP and Siegfried have a common desire for doing business together, and both sides collectively enjoy the forthcoming opportunities.

What, in particular, makes AMP such a good fit?

M. Spaene: AMP is a unique fit for Siegfried because they are true specialists in producing sterile drug products, including sophisticated ophthalmics, and they offer a full range of aseptic-fill services for pharmaceutical, biotechnological and medical device companies. In addition to automated filling, they provide small-run manual filling for special cartridges, bottles, vials and syringes. We plan to expand and augment their existing development and contract manufacturing focus. We intend to do this by developing a portfolio to include our own IP combined with co-development and other creative business models customized to our customers' requirements.

AMP reports sales of about US-$ 20 million. Do you expect significant short-term growth potential?

M. Spaene: Absolutely! With some interesting phase-3 projects in the pipeline there is real growth potential. At the same time we recognize that there is no guarantee that a phase-3 development will become commercial. Currently, there are many promising opportunities at the evaluation stage: we are assessing our customers' interest in the forward integrated opiate business and in sterile high-containment drug products. Market analysis tells us that around 80% of cytotoxic products are applied in sterile form. We therefore have sufficient opportunities on our plate.



Other Siegfried business segments are also developing positively. How do you view their growth potential?

M. Spaene: We are growing our opiate portfolio via new products and improving and sustaining our existing overall portfolio with optimized processes. We naturally have to stay competitive and constantly offer lifecycle improvements. Also, we see an increasing interest in our oral formulation and manufacturing capabilities, either in terms of co-development, lifecycle management or contract manufacturing. As mentioned, we have expanded our Malta capacity in tableting, packaging and warehousing to cater for this growth.

You mentioned cost optimization. Is this possible with a purely Western-hemisphere dominated company?

M. Spaene: It is an incredible challenge and we actively consider all opportunities to lower our costs at all times. For sure, we are not in a position to compete on costs alone. Therefore, we try to offset the competition by working with our Asian partner and our USP as an integrated supplier with an effective supply chain and great quality practices. Unfortunately, this is not always enough to obtain new business.

Based on these circumstances, we have chosen to invest in our own factory in Nantong, China – about two hours outside Shanghai – which will mirror our Zofingen site. We plan to offer non-GMP substances beginning in 2014 and GMP substances from 2015 onward. We are very excited about this opportunity, as we can offer a secondary cost structure strategy and we will gain access to new markets such as China, India and others.

How can Siegfried manage all of these projects simultaneously?

M. Spaene: The key is a good team that shares the same strategy and is enthusiastic to be part of the growth and success of the organization. We recognize that it is not an easy path to follow. However, we have demonstrated that our talented team is strong enough to overcome such hurdles. Our people continue to be focused, very dependable and self-motivated. With a team like Siegfried, you can expect more.

chemanager-online.com/en/tags/siegfried

No Experimenting

◀ Continued Page 16

company, Samsung, has also invested in building a plant for biologic manufacturing. Samsung partnered with US based Quintiles and has formed a joint venture with Biogen Idec to enter the biosimilars market with plans to construct a facility in Incheon, South Korea.

Which Way to Go?

But which strategy will provide the lowest amount of risk? The answer, of course, is uncertain. While both strategies can help companies meet the challenges inherent with biologic development, the path to success will most likely not be the same for each competitor. Indeed, perhaps the most important element of strategy design when investing in the biosimilars market is to not drift from proven in-house success. In other words, stick with what you know best.

Boehringer Ingelheim (BI) is one of the most well known contract manufacturers globally. As early as 1997, BI was contracted to do development on biologic products, when it reached an agreement with MedImmune to manufacture the monoclonal antibody palivizumab (Synagis). Over the next decade BI was contracted to develop and manufacture large-molecule products for Novartis, Amgen, and Genzyme, among others. Over years working on different products at a large scale, the company gained valuable experience few companies can claim to share. In 2009, BI leveraged this experience through a strategic alliance with Indian manufacturer Kemwell. Under the terms of the agreement, Kemwell built a new biologics facility which would include BI's Hex technology platform for cell line development. The agreement provides opportunity for BI to drive business through scaling up potential production from the smaller Kemwell plant.

One of the pioneers in the biosimilars market is Novartis' generic arm, Sandoz. Known for developing and commercializing the first biosimilar in multiple regulated markets (Omnitrope), Sandoz has also been a leader in developing other biosimilars, including versions of filgrastim and epoeitin alpha. But where other major generic companies such as Teva and Hospira have turned to partnering for development opportunity, Sandoz has remained dedicated to in-house talent and capabilities. In 2010, Sandoz subsidiary LEK opened a new protein manufacturing facility to help supply the global market for biosimilar epoetin alpha. Sandoz currently has three biosimilar candidates in late stage trials including a version of the monoclonal antibody rituximab.

Moving forward the trend towards deal making in the global follow-on biologic market is not expected to change. Companies will continue to partner and jockey for position in both regulated and less regulated markets, hoping to see a return on whatever investment was made. At the time when uncertainties are no longer and norms have been established, the competitive landscape may look very different than it does now. But which path will provide enough stability to navigate the immediate challenges? The most effective strategy to ensure a long term stake in the biosimilars market may be the one that has already brought success to your company.

▶ Contact:
Andrew Bourgoin
Thomson Reuters
Portland, ME, USA
Tel.: +1 207 871 9700 33
andrew.bourgoin@thomsonreuters.com
www.thomsonreuters.com

chemanager-online.com/en/tags/biosimilars

HPAPIs and ADC Toxins

Manufacturing Challenges for the Targeted Drugs of Tomorrow

A Spoonful of Safety – Demand in the pharmaceutical industry has sharply increased for the manufacture of targeted and potent drugs that improve efficacy and reduce side effects, such as antibody-drug conjugates (ADCs). By combining a monoclonal antibody (mAb) and a highly potent small molecule toxin (usually a cytotoxic compound), ADCs directly target cancerous cells.

In the body, the mAb specifically binds to an antigen on the outer surface of cancerous cells and the ADC is absorbed inside the cell via endocytosis; the cleavage of the linker (that is designed to be labile within the cell medium) releases the toxic substance, leading to cellular death. This therapy is very promising because of its high selectivity and significantly reduced side effects. Indeed, theoretically, healthy cells should not be affected by the treatment, and that is of upmost importance for the patient. Lower dosage can be used since the treatment is delivered only where needed. In standard (nontargeted) chemotherapy treatment, an acceptable therapeutic window has to be found for the medication to affect malign cells with a minimal impact on healthy cells; hence molecules exhibiting particularly high cytotoxicity have to be discarded. Targeted therapies enable a safe use of these same molecules as toxins or ADC "payloads." However, from a manufacturing point of view, these ADC toxins require higher containment levels than typical highly potent active pharmaceutical ingredients (HPAPIs) to ensure a safe production environment for the operators while preventing product contamination and protecting the environment.

The main challenge in HPAPI manufacturing resides in the ability of the producer to operate safely and adapt to the constraints of innovative and ever more potent molecules. It implies using an appropriate confinement strategy based on engineering controls, collective and personal protection equipment, continuous training for all personnel on site, establishment of standard operating procedures (SOP), monitoring occupational hygiene, and implementing medical surveillance of the employees.

Safely Manufacturing Highly Potent Compounds

There are no official guidelines for the control and monitoring of safe handling of HPAPIs, which is left to the companies' appreciation. Therefore, this mastery can be obtained only through an extensive and long-lasting experience in the area and only a few manufacturers hold the appropriate expertise to handle these compounds. External assessment of HPAPI production safety is provided by specialized companies such as SafeBridge Consultants Inc. The company's certification is the only independent evaluation system to date and assesses the management, the evaluation, the containment, the control, and the communication elements of HPAPI operations.

When it comes to HPAPI manufacturing, finding a partner operating SafeBridge certified facilities ensures that a high level of mastery of such manufacturing constraints has been demonstrated. To date, only 11 companies have met the consultants' current industrial standards (source: SafeBridge Consultants Inc., February 2012). SafeBridge has established a potency rating system in which compounds are classified into four categories depending on their Occupational Exposure Limit (OEL), the maximal exposure acceptable for employees over an eight-hour work shift. For each compound, an exhaustive potency assessment has to be carried out before any work starts, and the highly potent compounds are classified in category 3 (OEL< 10 µg.m-3.8h-1) and category 4 (OEL< 30 ng.m-3.8h-1).

As the development of ADCs enables the therapeutic use of more potent molecules, a shift to lower OEL is currently observed for several new molecules of interest, and ever-higher levels of containment have to be met. While the certification applies to specific areas within a factory, these usually include a broad range of facilities such as R&D laboratories, kilo labs, and high containment manufacturing areas and their associated quality control laboratories. Indeed, all areas where HPAPIs are handled, including QC laboratories, have to comply with the appropriate confinement level. The outsourcing of HPAPI analysis is not common, and most analyses should preferably be performed in house. In addition, the high level of purity requires adequate detection and rejection of highly potent impurities, which requires the manufacturer to operate highly effective analytical equipment and measurement methods. Frequent hygiene monitoring is adequate to ensure that the necessary containment is achieved at all times, and all operators involved in HPAPI manufacturing undergo regular health checks.

Reaching High Purity in Confined Environment

Advanced purification methods are required to deliver active ingredients at the desired level of purity. Efficient purification at large scale is often key in getting cost-efficient access to semi-synthetic starting materials from various sources including fermentation broths and natural extracts. Two factors imply the use of advanced purification technologies for the production of HPAPIs: 1) their intrinsic complexity (whether these molecules are extracted from biomass or synthesized from scratch) resulting in mixtures containing very closely related impurities, and 2) the very high level of purity typically required. Preparative chromatography is almost a must and, from an economical point of view, preparative HPLC is particularly well adapted to reaching high purity for moderate scale productions (rarely exceeding a few hundred kilograms per year at production scale for HPAPIs, with even smaller volumes for ADC toxins). The main advantage of preparative HPLC is the very predictive assessment of the results on large scale, based on automated screening results obtained from just a few experiments and sub-gram amounts of material, due to a direct scalability. As a consequence, an accurate estimation of productivity and costs at large scale is obtained very early in the process development phase, while minimizing the handling of the highly potent compound. In addition, advanced computer simulation tools allow for a rapid, reliable development and straightforward validation of the process. Furthermore, compared with traditional low-pressure chromatography, preparative HPLC offers considerably improved unit productivity and therefore a smaller system and much less stationary phase are required. As a consequence, the column can be easily located in a confined area and the handling of the packing material and the cleaning of the system are much easier. Preparative HPLC has proven to be robust and reliable at commercial scale. It constitutes the purification method of choice for the production of commercial HPAPIs and ADC toxins in particular.

Antibody-drug conjugates and other types of vectorization of toxins and HPAPIs require specific technologies depending on the type of payload (maytansinoids, auristatins, anthracyclins, pyrrolobenzodiazepines, calicheamicins, taxanes, etc.) and linker/vector used (amino acids and peptides, pegylated and polymeric chains, other complex side chains). Innovative and tailored solutions for downstream purification and isolation may involve low-pressure chromatography (affinity chromatography, ion exchange, gel permeation, etc.), tangential flow (ultrafiltration) technologies that have to be operated according to biopharmaceutical and HPAPI standards. Since the cytotoxic payloads are usually complex and fragile molecules presenting several chiral centers, they require mild and efficient technologies. Tangential flow filtration (TFF) is well suited for small molecules isolation, concentration and for formulation of large molecule APIs. As for HPLC, the limited size of TFF equipment is well adapted to implementation in confined areas.

Conclusion

In a world where molecules reaching the market are ever more complex and need to meet very stringent purity standards, the right combination of technologies is more important than ever. The manufacturing of new targeted drugs, such as ADCs, fully benefits from the mastery of synthesis and purification technologies. Since these molecules lay at the interface of chemical and biological domains, their development and manufacturing fully benefit from the cross-fertilization occurring only in CMOs with expertise in both areas. When it comes to ADC toxins, a careful choice of the manufacturing partner is key to success.

Authors: Aline Devoille, marketing manager – synthetic molecules and Jean-François Marcoux, technical business development manager, Novasep

▶ Contact:
Dr. Aline Devoille
Novasep
Pompey, France
Tel.: + 33 383 496 497
aline.devoille@novasep.com
www.novasep.com

chemanager-online.com/en/tags/apis

Austerity Measures Bite

The European Pharmaceuticals Economy

A Pill a Day – Unlike chemicals, the pharmaceuticals sector does not have cycles. Even in a sluggish economy, sick people will still need medicine. But the widening European debt and currency crisis seems to prove that a sick economy can indeed infect an otherwise healthy industry. Drug makers traditionally spoiled by success are now facing unprecedented hurdles as governments rein in healthcare spending and many of the region's southern countries cannot pay at all.

The crisis hit pharmaceuticals earlier than chemicals, and quarterly reports of Europe's "Big Pharma" players showed that some were better able than others to absorb the resulting income shortfall. While for France's Sanofi a projected 2012 sales loss of €300m from European austerity measures will be balanced by growth elsewhere, the UK's Glaxo SmithKline (GSK) has trimmed its outlook.

The problems already visible at the beginning of the year, worsened as 2012 progressed. Greek hospitals have faced drug shortages for months as some international suppliers have pulled the plug after unpaid bills piled up. The misery has spread to Portugal, where missed payments from January and July were said to total €1.5 billion. In Spain, the pharmaceutical industry believes it is owed a similar sum.

The Spanish industry association Farmaindustria has predicts that the country's consumption of pharmaceuticals will fall 15-20% in 2012 against 2011. It adds that the industry has borne the brunt of government austerity measures. Many drug producers are reported to be in a very difficult financial situation and are taking steps to restructure and reduce staff, says Farmaindustria.

Drug Pricing Issues Compound Industry's Problems

Company executives say drug pricing is becoming an equally important issue. "It's been a higher level than we had expected," Tony Zook, head of AstraZeneca's commercial organization, told the press in July. Novartis pharmaceuticals head David Epstein told financial analysts that Europe has become the toughest pricing market "anywhere in the world."

Italy's national health budget has been slashed by €11 billion over the past five years, and leaks of a recent government plan suggest further cuts of €1billion. The pharmaceutical industry association Farmindustria fears that 10,000 industry jobs could be lost in the next five years. Some 61% of drug manufacturers in Italy are foreign-owned, and the European pharmaceutical business association EFPIA says the budget cuts will make it harder for them to stay in business there.

This month, the government of France will reveal details of its new healthcare budget, which is expected to call for cuts of around €2 billion in 2013. In 2012, the French drug market is forecast to shrink for the first time.

The European pharmaceutical industry says the impact of price reductions is magnified because governments across the continent peg their reimbursement prices to southern Europe's level. This exacerbates any shortages as products are sucked out of the south and re-exported north to countries such as Germany, where prices are higher.

European Drug Companies Feel the Pressure

In Q2, **Glaxo SmithKline** saw turnover recede by 4%, to pounds 6.5 billionn, while per-share core profit declined 5% to 26.4 pence. The earnings tally thus fell short of analysts' expectations for the second consecutive quarter. GSK's sales in Europe fell by 8%, reflecting a 1% decline in volume and a 7% slip in selling prices. Due to the disappointing performance, CEO Andrew Witty has revised the full-year outlook downward. He now expects the operating margin in 2012 to be flat at the 2011 level of 32.1%.

Swiss pharmaceutical giant **Novartis** saw net sales fall 4% to $14.3 billion in Q2. Sales growth in recently launched products – which contributed 29% to the group total – more than offset lost income from a patent expiration. Core operating profit fell 3% to $3.9 billion. But Novartis' 2012 performance is still on track and the outlook for the full-year unchanged, said CEO Joseph Jimenez.

Bayer's healthcare sub-group, Germany's largest pharmaceuticals player, saw Q2 sales revenue rise 10% year-on-year to €4.6 billion, with volume sales up 3.3% and prices up 0.8% Currency effects accounted for 6.2% of the rise. The pharmaceuticals segment lifted turnover 10.5% to €2.7 billion boosted by portfolio changes and foreign exchange shifts. North American sales added 24%, Asian sales 22%, while European revenues sank by 2.4%. Pharmaceuticals EBITDA before special items rose 12% to € 809 million.

With forward visibility unclear, Bayer CEO Marijn Dekkers now expects revenue growth in pharmaceuticals to be "only in the low single-digit range." While demand in emerging markets, especially China, is seen to continue robust, US growth could sink into the low single-digits. In Europe, negative growth is likely in some markets.

AstraZeneca reported Q2 revenue down 21% to $6.7 billion. Loss of exclusivity on several key brands accounted for 15% of the decline, the company said. Operating profit slipped 37% to $1.9 million, due to negative foreign exchange parities. Core earnings per share (EPS) were down 6% to $1.53. For the full year, interim CEO Simon Lowth is maintaining core earnings guidance at $5.85 to $6.15 per share.

In the 2012 first half, **Sanofi** reported a year-on-year net sales increase of nearly 8% to €17.4 million. Operating profit rose 55% to €3.8 billion, EPS to €2.26 from €1.70. For the full year, CEO Christopher Viehbacher said EPS may be 12% to 15% below 2011 at constant exchange rates. The guidance takes into account, among other things, the expiration of two US patents, the performance of key drug platforms, cost control measures and national healthcare reimbursement policies.

Strong Dollar Hits U.S. Pharma Profits

U.S. drug makers do not face pricing constraints on a national level as a public healthcare system is still a "foreign" concept. However, a sluggish economy hurts companies in their home market and abroad. Most recently, the stronger dollar has also been a hindrance. For Q2, U.S. giant **Pfizer** reported higher-than-expected earnings, thanks in part to research budget cuts. Net quarterly income was $3.25 bn, or $0.43/diluted common share, compared to a net profit of $2.61 billion or $0.33 per diluted common share a year earlier. Global sales revenue fell 9% year-on-year to $15 million. U.S. revenue decreased by 15% to $5.7 billion, due to a patent expiration, international revenue by 5% to $9.3 billion, reflecting unfavorable foreign exchange parities. U.S. number two, **Merck & Co**, reported better-than-expected earnings in Q2, thanks to strong revenue from vaccines and treatments for diabetes and HIV. As sales rose 1% to $12.3 billion, net profit totalled $1.8 billion, or 58 cents per share, compared with $2 billion or 65 cents per share in the 2011 quarter. Despite the negative foreign exchange impact, Merck is holding its full-year earnings forecast at a flat $3.8 billion. At Bristol-Myers Squibb, second-quarter net sales fell 18% to $4.4 billion due to a patent expiration. U.S. sales dropped back 27% to $2.6 billion for the same reason, with pre-tax earnings down 41% to $1.06 million. Quarterly EPS declined 27% to $.038.

Author: Dede Williams, Freelance Journalist

The Most Trusted Advisor

Emerson's Steve Sonnenberg on the Importance of Trust in Business Relations

Customer Is King – For Steve Sonnenberg, Vice President of Emerson and President of Emerson Process Management, the word "trust" plays an important role for the company's strategic direction. CHEManager's Dr. Volker Oestreich visited the Emerson Global User's Exchange in Dusseldorf from 29th to 30thMay and talked with Steve Sonnenberg about Emerson's ambitious goal to become their customer's "most trusted advisor".

Steve Sonnenberg, Vice President of Emerson and President of Emerson Process Management

CHEManager Europe: In the US, the Emerson Exchange has grown over the past couple of decades to an important event with thousands of participants. The first Emerson Global Users Exchange dedicated to Europe and the Middle East here in Dusseldorf has attracted about 1,000 participants. Are you satisfied with this event?

S. Sonnenberg: Yes we are, everybody here at Emerson did a great job and I would like to thank our Emerson Exchange Board of Directors. They have volunteered countless hours, weeks and months to make this event a reality. Like all of us, they already have full-time jobs, so their work was a labour of love to bring a world-class conference to all visitors, by users, for users.

And since this event has such a personal character, we want to provide our customers and business partners, who are our shareholders in a manner of speaking, with an update on our company's performance and strategic direction. I believe it is important for our shareholders to know the things our company is focused on, not out of arrogance, but instead out of a sense of stewardship. Because our customers don't simply buy products, they are placing their trust in our company.

What exactly is Emerson focused on?

S. Sonnenberg: Two years ago, during our Emerson Global Users Exchange in the United States, I committed that Emerson would focus on two important things in the future: First, that Emerson would continue to invest in areas that we believe will bring our investors value and secondly, that Emerson would strive to be an organisation that listens and acts on what we hear. It's only by listening and understanding our customer's problems that we can work to provide a solution.

Can you give an example for this "listening & understanding" philosophy?

S. Sonnenberg: Well, you can't listen if you don't ask, so we asked our customers. One thing that came out clearly was that Emerson offers great technology and has very good people, but our response times are sometimes too slow. This is one reason Emerson is investing so extensively in manufacturing and service facilities around the world. So we can respond faster and better. My leadership team and I are also identifying other areas we can improve on, ranging from our quoting process to delivery.

Alongside your "listening & understanding" philosophy you said investments play an important role in the company's strategy. How much courage is necessary to make investments in such nervous times, with an ongoing financial crisis not only in Europe?

S. Sonnenberg: After the downturn of 2009 and now the European debt crisis, it is clear that the world is indeed a very small place economically. Markets around the world can affect each other in profound ways and very quickly. With a nervous economy, it is common for companies to become fiscally conservative.

Emerson's position on investment takes a very long-term view. In fact, it has been our policy to invest, even in the darkest of times, to ensure we come out of those downturns in a position of strength. We challenged ourselves to do this in 2009 and 2010 and as you will see, it has helped us to do just that – recover from a position of strength. Emerson is not being timid when it comes to investment in this industry; in fact, we are investing at unprecedented levels.

Which markets are you focusing on?

S. Sonnenberg: Emerson is very much a global company, but in the past few years, we have placed an even bigger emphasis on becoming more local. We have added manufacturing facilities in Russia, Sweden, Turkey, Germany, Saudi Arabia, Mexico, Brazil and Dubai. We have also added regional service centres in multiple locations in Europe, as well as Abu Dhabi, Qatar and three in China. 2012 will continue to see major investments in regional manufacturing and customer support centres, including new or upgraded facilities in cities all over the world. Regardless of the location, they all share a common theme –position Emerson to be the most responsive, supportive local partner to customers.

Just a few days before your last Emerson Exchange event in the U.S. in October, the tragic flood in Thailand occurred. Emerson and its customers were directly affected by the flooding, since shipments were delayed. How did your react to this tragedy?

S. Sonnenberg: There was much we did not know at that time, as the flooding had just happened days before. But we did know that our production shipments would be affected due to the supply of electronic boards. So in the spirit of transparency, I announced this delay during the opening of our Emerson Exchange event, in front of 3,000 people. Not exactly the way you want to open a conference with your customers.

We are now receiving full shipments of almost all of our boards and we plan to reduce our overdue backlog in the next several months. I am proud of the 1000's of Emerson employees that worked tirelessly through these many months to minimize the negative impact to our customers. Implementation of risk mitigation plans, started prior to the flooding, have been significantly expedited since to ensure that we will have one of the most robust supply chains in the industry.

You announced the delay "in the spirit of transparency". A new Emerson guideline?

S. Sonnenberg: Well, it's pretty simple. Emerson has one, very clear goal: To be our customer's most trusted advisor. We don't want to just supply cool technologies and services and give a positive spin. We want to be transparent and genuinely desire to be part of the inner circle of all of our stakeholders: We want to be the people you turn to with your toughest challenges, with the confidence that you will get our best, each and every day. And to achieve this, we have to earn our customer's trust each and every day.

Companies normally try to earn revenue, not trust.

S. Sonnenberg: The thing about trust is that it's not a milestone. It's not a static position you strive for and then once you get it, you keep it. Trust is a daily commitment. It's earned each day and it's at risk of being lost. It's true each day in our personal relationships and it's true each day in our business relationships.

It's actually become a pretty common word, which many of us use in everyday speech. Like a lot of things today, you could argue that the word trust has become overused. But if you look at what's happening in politics, the news or financial sectors, is trust still alive and well? I'm not so sure.

Being trustworthy includes the small things as well as the big ones. It can be as small as being on time to a meeting, or following up on a task from that meeting or as big as delivering on time a very large, complex order. It means only committing to a product delivery date that we are confident we can hit. This is why we are adding production and support locations all around the world – to give us the ability to meet the schedules you demand and do it with the confidence of knowing we will keep our promises.

Does this philosophy influence your products as well?

S. Sonnenberg: Our customers are in everyday contact with our products, so of course we are focused on earning trust through satisfaction. We try to satisfy our customers by using our Human Centered Design approach. In 2009, we introduced the idea of "Conquering Complexity" and applying the science of Human Centered Design to every product we develop. I'm proud to say that no automation supplier puts greater focus on ease-of-use and improved usability than Emerson.

But creating great technologies and products by themselves is not enough. To get the full value, they need to be integrated with existing assets and often this involves many different types of technologies working together. That's why we are placing even greater emphasis on integrated application packages in which we pre-bundle solutions across multiple product groups to minimise the work our customers have to do.

What are your personal highlight technologies presented here at Emerson Exchange in Dusseldorf?

S. Sonnenberg: Among lots of new technologies, let me just mention two of them: Our Combustion Control System with True-Energy technology and our recently introduced Rosemount Wireless Acoustic Transmitter, which allows the operator to monitor steam trap leakage. Both innovations can help customers, who want to improve their energy management. The creation of energy – steam and electricity to run plants – can account for 30 %, even 40 % of the operating budget. That's enormous! Imagine putting a percentage point or two to the bottom line just by not wasting energy or being smarter about how to create it. A plant may be wasting millions of dollars every year in energy management and these two technologies can put it back on the bottom line.

▶ www.emersonprocess.com

chemanager-online.com/en/tags/emerson

Sartorius Opens Production Facility for Bioreactors

Sartorius opened its new plant for the manufacture of bioreactors in Guxhagen, northern Hesse, Germany. After one year of construction and approx. €18 million invested in the plant, Sartorius now manufactures bioreactors and further production equipment for customers in the biopharmaceutical industry. Covering a total area of nearly 10,000 square feet, the new building complex provides space for a high-tech manufacturing hall and offices for around 240 employees. With this new site in Guxhagen, Sartorius has moved from its former bioreactor production facility in Melsungen, where it had reached maximum capacity limits. ■

BASF to Invest €20 Million in Technology Upgrade

BASF will modernize and service its acetylene facility at the Ludwigshafen Verbund site, Germany. In the course of these efforts the company will also perform routine maintenance at its facility producing 1,4-butanediol (BDO), which is based on acetylene. BASF will make use of this period to upgrade its plant technology. In 2012 alone, the company is investing more than €20 million for this purpose. ■

Scrum in the Regulated Environment

Opportunity or Risk for Computer Systems Validation?

Sabine Komus
Koblenz University of Applied Sciences

Ayelt Komus
Koblenz University of Applied Sciences

Paul Noble
IQC Group

Sprint to the Finish – Agile methods such as Scrum are beginning to dominate in software development over the classical "waterfall" approaches, to which computer validation has been oriented. Basic features of agile methods, such as short internal and independent development cycles, are often viewed as contrary to or problematic for computer validation principles. Is the concern justified? An analysis of the basic features and potentials of the Scrum method with regard to computer validation sheds light on this question.

Basic Features of Scrum

The goal of Scrum is to respond fast and flexibly to changes in requirements during the project, without sacrificing quality, cost control, motivation or especially user needs. Instead of orientation upon high-level and extensive planning, as well as their documentation, there is a heavy emphasis upon interaction with the users during incremental practical and focused development cycles.

The basic principle of Scrum is to divide the development process into short development cycles, so-called sprints, which have pre-defined tasks to address pre-selected goals of the project. Sprints are limited to no more than 30 days, and the sprint team manages itself. A "Daily Scrum," lasting 15 minutes, is used to compare current results with the tasks and its difficulties or problems. At the closing of the sprint, the results are presented, which should be potentially deliverable.

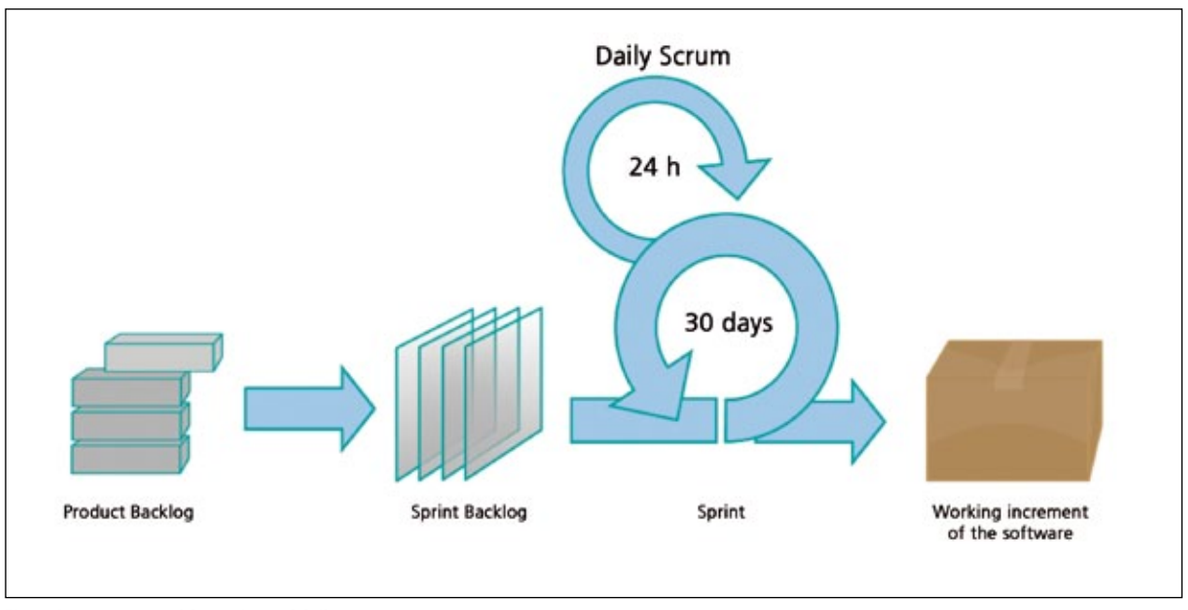


Fig. 1: Scrum process with a sprint and daily scrum.

Advantages over "Waterfall" Approaches

Disappointing practical experience with "waterfall" or top-down approaches is commonly raised as justification for agile development methods. "Waterfall" methods follow a basic principle of sequential, non-iterative development phases encompassing a software release, as displayed in the common V model of software development. Problematic characteristics of these approaches include the assumption that problems and goals can be thoroughly analyzed to yield detailed, documented development plans up front. Scrum circumvents many of the typical problems of these methods:

- **Lack of Prioritization**

With "waterfall" approaches, requirements generally all have the same or similar priorities, whereas priorities of tasks are reassigned with every sprint in Scrum. Lack of focus upon priorities often results in implementation of required functionalities relatively late in the project. If time and money become limited near the project closing, then important functions can suffer more from lack of resources than less important features.

- **False Precision**

All requirements are expected to be known at the beginning of a project so that accurate and detailed project estimates and plans can be made. This leads often to detailed and extensive product specifications, which are based upon unrealistic assumptions from lack of practical experience, and thereby deliver a false sense of precision. There is a danger of creating very detailed but outdated documentation. The same applies to tests, which can be based upon an outdated design and not reflect the actual risks. This is an especially critical concern for regulated products. Scrum does not start with the premise that all requirements are known.

- **Inflexibility**

Progression through sequential project phases is inflexible when responding to changes. This leads to situations where changes needed for new requirements, which are recognized during later project phases, are not implemented, and the product is already obsolete upon release. Another consequence of this inflexibility is that lessons learned during the project cannot be applied. By comparison, Scrum is via sprints inherently flexible for learning effects and changes.

Possible Reasons Against Using Scrum in Regulated Industries

It is commonly argued that using the Scrum method inhibits achieving the requirements for validation in regulated industries. This reasoning is analyzed in the following paragraphs.

- **V Models are Needed for Validation**

In GAMP 5, the industrial guideline increasingly relied upon as the standard for computer validation, the classical V model is no longer exclusively specified. Rather, according to GAMP 5, "it is now recognized that other models and approaches are equally acceptable." Risk-based approaches and economy are the focus of the new GAMP version, and agile models are not excluded. User requirements must no longer be finalized before functional and technical specifications are written (already a common practice).

- **Complete Documentation**

It is sometimes argued that Scrum does not require or need documentation. One of the ground rules of the Agile Manifesto, upon which Scrum is based, is that a complete product has priority over complete documentation. That doesn't imply that no documentation is needed.

Sprints should start with requirements, user roles and concrete uses, which are specified in the form of User Stories. It is expected with the Scrum method that a processed work package is included when closing a sprint. Complete processing is indicated by DoD ("Definition of Done"), which includes a detailed description. The method can be adapted to include documentation requirements for validation and their approval with the DoD. It should be recognized that the Scrum method can mitigate a typical problem with "waterfall" approaches: An uncontrolled accumulation of incomplete documentation is inhibited via short development cycles and their approvals.

- **Extensive Test Documentation**

Because requirements can frequently change during a Scrum development, a complete documentation of testing is a valid concern. Here, adaptation of the method to validation requirements needs consideration.

In the many sprint cycles to be expected, specification, implementation and testing activities are needed to meet good manufacturing practice (GMP) expectations. Of special importance are the acceptance tests for a cycle. Formally documented tests are demanding, and changes to requirements demand retesting. It is therefore important, especially for agile methods, to determine when the product design has achieved relative stability. At this point (and in later iterations), a sprint cycle should be conducted with the goal of obtaining formal test documentation and validation compliance. Such special sprints need to focus on formal aspects only. It has to be assured that the perspective of a formal test documentation later on is not used as an excuse for not substantially finishing, documenting and testing products at the end of each sprint.

Further Reasons for Using Scrum in Regulated Industries

Close contact between developers and users, as well as the emphasis upon refactoring, are further good arguments for using Scrum, also in regulated industries.

- **Close Contact in Scrum**

Agile requirements management anticipates direct user input for the formulation and prioritization of user requirements. The customer tries using the product at the end of a sprint cycle and can give feedback quickly. These trials can be interpreted as User Acceptance Tests, and ensure that the users are included at an early stage and obtain extensive knowledge of the product.

- **Emphasis upon Refactoring**

Refactoring is an important element of agile methods to improve software structure. Its aim is to improve readability, simplify code maintenance, and improve flexibility of program code without altering its function. Via refactoring it is possible to continually improve the quality, which is certainly central to the goals of computer validation.

Conclusions

Regulators do not prescribe specific validation methods. GAMP 5 accepts other methods besides the classical V model, a "waterfall" approach, to development. Agile software development methods, such as Scrum, are therefore not excluded from GMP. By the evaluation of the risks and opportunities with agile methods, it should be recognized that in reality, software development is not practiced optimally on either a technical, economical or regulatory basis.

Agile methods strive to achieve results and quality with the help of simple rules and less bureaucracy. They must be integrated into the Quality Management System when used in regulated industries. It is recommended to add special sprints for covering formal documentation requirements, without changing the basics. A combination of agile with conventional methods (hybrid models) can also be considered.

Scrum appears to be a relevant option for regulated industries. In several aspects its focus upon results, clarity and transparency correspond better with the basic goals of computer validation than conventional methods, as they are often practiced.

Authors: Ayelt Komus, Professor, Koblenz University of Applied Sciences;
Sabine Komus, consultant with IDS Scheer Consulting and lecturer at the Koblenz University of Applied Sciences;
Paul Noble, consultant, IQC Group

Contact:
Prof. Dr. Ayelt Komus
Sabine Komus
Fachhochschule Koblenz
Koblenz, Germany
komus@hs-koblenz.de
skomus@hs-koblenz.de
www.komus.de

Dr. Paul Noble
IQC Group
Reinheim, Germany
paul.noble@iqc-group.com
www.iqc-group.com

chemanager-online.com/en/tags/scrum

Huntsman to Expand MDI Plant

Huntsman announced it has commissioned engineering design studies to increase its global capacity for the manufacture of methylene diphenyl diisocyanate (MDI) through investment at its Geismar, Louisiana site. Anthony P. Hankins, President of Huntsman Polyurethanes, said: "We are studying several options for expansion of the Geismar facility to ensure we can satisfy the strong demand in residential and commercial insulation. With the benefits of US shale gas,

the economics of investing in our US facilities has improved significantly. The global market for MDI Urethanes is expected to continue to grow strongly well into the next decade, and the proposed investment in the United States will complement our previously announced planned expansion in China". Huntsman Polyurethanes operates worldscale MDI facilities in Geismar, Louisiana; Caojing, Shanghai; and Rozenburg, Rotterdam.

Optimization of Product Protection

Implementation of Improved Hygiene Zones at Swiss DSM Site in Sisseln

GMP in View – Within two years, Chemgineering – as general planner and contractor – converted a bottling plant at DSM to comply with current standards. The efficient collaboration of the project team and client guaranteed success of the ambitious multi-million-euro project.

Royal DSM, a global science-based company active in health, nutrition and materials, delivers innovative solutions that nourish, protect and improve performance in global markets such as food and dietary supplements, personal care, feed, pharmaceuticals, medical devices, automotive, paints, electrical and electronics, life protection, alternative energy and bio-based materials. DSM's 22,000 employees deliver annual net sales of around € 9 billion.

With about 900 staff members and an annual production volume of 40,000 tons, the plant in Sisseln (Switzerland) as a branch of DSM Nutritional Products AG is one of the most important production facilities of DSM's life sciences division.

From Planner to General Contractor

Planning activities with DSM began with a conceptual design phase in 2009. In Building 320 of the DSM plant in Sisseln an existing process was to be optimized during ongoing production: The solid and liquid intermediate products, delivered as bulkware, were to be packaged in commercially available packages in a GMP-compliant environment using the existing filling technology.

Chemgineering was initially assigned to develop various versions of the GUPAS+ project both technically and commercially. This involved, in addition to a range of remodeling work, setting up new and optimizing existing hygiene zones (clean rooms).

Following the conceptual design phase in 2010, Chemgineering was appointed as the general planner for the entire project to produce the basic design; in 2011, to be entrusted with the implementation of the project as the general contractor with full responsibility for costs, scheduling and quality.

The implementation involved the fulfillment of numerous and diverse requirements as well as compliance with statutory regulations. The primary objectives of the project included:

- cGMP-compliant implementation of DSM's internal guidelines for the filling of powder and liquid products in Building 320
- assessment and comparison of different process versions
- planning and implementation of a hygiene concept according to DSM's internal guidelines for personnel, material and production units
- planning and implementation of a pressure rating system for room ventilation
- adaptation of the new apparatus technologies (e.g. material handling) as well as the infrastructure to the existing process and safety requirements
- timely implementation of the project without affecting other projects, departments or the ongoing production in Building 320

Conversion During Ongoing Operations

Because all measures had to be implemented during ongoing production with only a few exceptions for complete stoppages, the remodeling and new construction had to be done in several phases.

Thus, existing building sections and systems were dismantled in multiple phases in order to facilitate the installation of a pallet transfer system with vertical pallet handling technology. The existing bottling system was also converted.

New clean rooms (hygiene zones) were integrated on three floors of the building. During this process, 1800 m2 of new clean room flooring was laid. To create space for a new ventilation system, old ventilation components (ducts, monoblocks, etc.) were dismantled.

Moreover, a new infrastructure and power supply system (e.g. heat recovery system, cold sink) was installed and connected. Finally, the new systems and hygiene zones were put into operation and qualified.

During planning, compliance with the current cGMP standards was taken into account and implemented jointly with the client. During the implementation and construction phase, elements including process optimization, automation and EMSR technology, building site management, ventilation technology, clean room installation and qualification support were implemented and optimized in close collaboration with DSM.

The complete conversion of the bottling plant was successfully accomplished during ongoing production. The tough requirements for product quality and occupational health and safety (accident-free construction site) were met to the fullest satisfaction of the client.

After a two year planning and remodeling phase, Chemgineering successfully completed the project in January 2012 and handed the building over to the DSM operators.

Author: Dr. Wolfgang Müller, Managing Director, Chemgineering

▶ Contact:
Dr. Wolfgang Müller
Chemgineering
Pratelln, Switzerland
Tel.: +41 61 467 54 54
wolfgang.mueller@chemgineering.com
www.chemgineering.com

chemanager-online.com/en/tags/gmp

On a Sound Basis in Line with the Current Trends

Sepawa 2012: On a Growth Course with Numerous Innovations

Business and Science Meet – The attendants of the Sepawa/EDC Congress in Fulda Oct. 23-25 can look forward to a diversified, well-filled program. During the congress, the cooperation of the major specialist associations, the Sepawa and the GDCh, with the collaboration of the DGK, stands for the latest state of the art in of beauty care and cleaning. With 184 booths, plus ceremonial addresses and high-level scientific lectures, participants can expect the right balance of business, information, scientific discussion and networking.

Hygienic and clean, neat and beautiful, pleasant and glamorous — these attributes will be in focus at the Sepawa/EDC Congress 2012. Scientific fundamentals will be considered as well as sustainability. This will enable attendants to gain a comprehensive survey of the state of the branch. The combination of exhibition and a diversified lecture program offers an inspiring atmosphere.

Foam — A Dazzling Phenomenon

Opinions differ on the issue of foam, the focus topic of the eighth EDC. On the one hand, abundant foam formation is essential for certain products, particularly in the field of care and wellness. On the other hand, it compromises efficiency considerably, e.g., that of automatic cleaning procedures. Dr. Horst-Dieter Speckmann, chairman of the GDCh specialist group "Chemistry of Washing" is looking forward to intensive discussions about the issues, such as how foams can be created, stabilized and then destroyed, if necessary.

"Though the addressed issues are of particular importance, there are crucial details about foams and their properties which have not been understood yet," Speckmann said. "This is why, in many cases, it is impossible to control the foam properties."

He points out that many operating processes are based on empirical values. In his opinion, innovations often fail because engineers are afraid that they would not cope with the foam. The initial lecture "Foam — A Blessing and a Curse" indicates the ambivalence and up-to-dateness of this issue.

Sustainable — More Than Green

The lecture block "Sustainability and Product Safety" is organized by both the Sepawa specialist group LUV (Legislative-Umwelt-Verbraucher — Legislative-Environment-Consumers) and the GDCh. For a long time, the detergents industry solely focused on environmental issues — various renewable raw materials resulted in "green products." Intensive research and development were carried out on their biodegradation and their environmental fate. Meanwhile, both the industry and consumers have recognized that just the ecological point of view is considered too narrowly. Moreover, the life cycle of a product should be looked at in its entirety. Dr. Roland Schroeder, chairman of the Sepawa specialist group LUV, explains: "A green product is not necessarily a sustainable product. In every case, a sustainable product should have an appropriate performance in addition to its ecological compatibility."

If one further takes into account the total supply chain, one arrives at more intricate assessment criteria. To assess the sustainability of a product, the behavior of the consumers must also be taken into consideration, e.g., when dosing and adjusting the temperature.

The latest innovations for detergents, the low temperature detergents and the supercompactates, enable the consumers to make their own decision on this part of the value-chain.

The novel ingredients and additives of the sustainable detergents and cleansing agents, such as enzymes, chelating agents and cosurfactants, will be subjects of many contributions to the "Forum for Innovations." Here, some of these products will be presented for the first time.

Precepts of sustainability for the internal courses of business are often regarded somewhat skeptically, and sometimes it is difficult to convey this idea. One of the surprises of the event will be to detect the connection between these tendencies and the internal dynamics of a team of an expedition. Keynote speaker Arved Fuchs in 1989 was the first to reach both poles by foot within a single year. He will talk about his experience with leadership in extreme situations.

Just Sunshine And Roses?

Applicative sun protection is widely accepted by consumers and is in the bag for holidays and leisure time. The effect of the UV light, however, has not yet been understood by far. In a special section of the event, which is organized by the DGK (Deutsche Gesellschaft für wissenschaftliche und angewandte Kosmetik – German Society for Scientific and Applied Cosmetics), these fundamental issues will be addressed. To give an example, sub-erythemal sun exposure will be a topic, as it may have a negative effect on the skin well before any erythema is visible. Will organic components replace the inorganic ZnO and TiO2-particles? The latest results on the undoubted interactions between the immune system and the effect of light will be presented. Finally, the conference will explore whether the sun protection factor, which has been generally accepted so far, will be reliably conclusive on a global basis. The second field of topics of the DGK, "Hair Care from Root to Tip," will also attract wide interest.

All Set for Novel Trends in Cosmetics

The sustainable growth in the field of beauty care, which was 1.4 % from 2010 to 2011 according to the IKW (Industrieverband Körperpflege und Waschmittel – Industrial Association for Body Care and Detergents), is also reflected in the presentations of the "Forum for Innovations," the use-oriented part of the event. Forty-four of 90 contributions in total deal with the field of personal care. For natural cosmetics, the IKW even stated a growth rate of 10 %. This tendency is also observed in many contributions, dealing with the latest active agents and additives on a natural basis, such as sea buckthorn and oat. With increasing customer reach for cosmetic products in those 60 and older, anti-aging agents and specialty products for mature skin are further fields of attention. Until today, close experience has played an important role in the purchase of cosmetics, but recently a considerable amount of online sales has emerged. The online trade for perfumes and cosmetics has increased more than any category except clothing. Surely, Christian Baudis, former CEO of Google-Germany and now manager of the German branch of a video-marketing network, will impart important insight to the auditorium with his lecture "Society 2.0 – How the Internet is Changing Us."

"The demand for more and more better and innovative products is a tremendous challenge," underlines Prof. Dr. Klaus-Peter Wittern, first chairman of the Sepawa e.V. "This is why we need highly qualified and motivated personnel, further on. It is, therefore, important for the Sepawa e.V. to promote our junior scientific staff. Thus we can maintain the successful course of our branch."

▶ Contact:
Monique Senicky
Sepawa
Thannhausen, Germany
Tel.: +49 8281 79940 24
senicky@sofw.com
www.sepawa.com

chemanager-online.com/en/tags/sepawa

Hard Wood with a Soft Core

Wood is one of the most flexible materials our planet has to offer. It is used for sturdy constructions or simply for decorative items, as winter fuel or as a musical instrument. Aside from its manifold range of use, wood offers another invaluable advantage: It is the world's only naturally renewable construction material. Especially the slow growing hardwoods are popular when it comes to massive woodworks, also for industrial structures. The faster growing softwoods, on the other hand, are not suitable for bigger constructions, since their surface is not hard enough to resist bad weather conditions.

Accoya wood combines the advantages of both sources. The material is manufactured from New Zealand grown Radiata Pine, which has been chemically modified through a proprietary acetylation process. Accsys Technologies developed the treatment to give the fast-growing timber exceptional dimensional stability and Class I durability. "Traditionally, only endangered tropical hardwoods or other environmentally compromised alternatives were suitable for use in harsh external environments, but Accoya now allows the use of wood which does not compromise in either performance or sustainability," says Bryan Crennell, Head of Marketing, Accsys Technologies.

The sustainably produced Accoya wood won numerous prizes for its ecological benefits. Due to its environmentally friendly production and its good characteristics, Accoya wood is seen as one of the most seminal construction materials. "It is very encouraging that as greater focus has been put on sustainable building in recent years, wood is playing an increasing role," says Crennell.

To distribute the new material in Europe, Accsys entered into a license agreement with Rhodia Acetow. The license grants Rhodia the exclusive rights for a 15 year period to produce and sell Accoya to over 40 European countries except the UK, Ireland and Benelux. The agreement also allows the construction of multiple Accoya production plants in various locations over a period of 25 years.

The cooperation between Accsys and Rhodia is only the newest partnership in a wide network. BP, one of Europe's major manufacturers of acetyls-based chemicals, also supports the Accoya wood production by supplying acetyls products. Paul Clegg, CEO of Accsys Technologies, commented: "The long term objective of Accsys is to license its proprietary acetylation technology for the manufacture and sale of Accoya and Tricoya to third parties around the world. " Tricoya is Accsys' latest brand, including acetylated wood elements like chips, fibers and particles – of course sustainably produced and with all typical Accoya characteristics.

▶ Contact:
Bryan Crennell
Accsys Technologies
Windsor, UK
Tel.: +44 1753 757500
www.accsysplc.com

chemanager-online.com/en/tags/materials

Eastman Announces Partnership with North Carolina State University

The Eastman Chemical Company has entered into a multiyear agreement with North Carolina State University to conduct joint research in chemistry, materials science and other scientific disciplines. As part of the agreement, Eastman will provide $10 million over six years in support of the Eastman Chemical Company Center of Excellence (ECCE) partnership. It also establishes the Eastman Innovation Center (EIC) laboratory. The lab will be located on Centennial Campus, NC State's nationally recognized research campus. "We're excited about the possibilities the Eastman Innovation Center being established at NC State brings," said Dr. Greg Nelson, senior vice president and chief technology officer at Eastman Chemical Company." Our partnership launches a world-class, open innovation collaboration with a leading university. That relationship will help us bring differentiated new ideas, technologies, and materials from early stage research to the market more quickly than traditional approaches." ■

Oxea Expands Production Capacities for Carboxylic Acids

Oxea has further expanded its production capacity for carboxylic acids. Oxea now serves the continuously rising global demand for carboxylic acids with this increased capacity. Carboxylic acids can be used for manufacturing energy-efficient lubricant esters for environmentally friendly refrigeration units such as air conditioners and refrigerators or specialty plasticizers, among others. Oxea currently operates four production plants for carboxylic acids world-wide and additionally plans to bring on-stream another new carboxylic acid plant in Oberhausen, Germany, at the end of 2012. ■

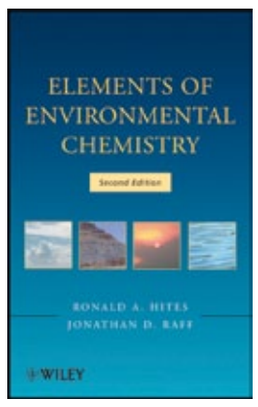
EVENTS

Maintain 2012, October 16 to 18, Munich From October 16 – 18 service providers representing various branches of industry, potential customers and experts will meet at the leading European trade fair for maintenance. Maintain is the industry gathering for strategies, methods and tools in industrial maintenance. It showcases service concepts as well as products and components. Specialists in nearly all manufacturing and processing industries go to gather information about industrial services, repair, maintenance, and after-sales strategies for industrial plants and machinery. Maintain is being held at the MOC Veranstaltungscenter Munich.

ADIPEC 2012, November 11 to 14, Abu Dhabi ADIPEC, short for "Abu Dhabi International Petroleum Exhibition and Conference" is the largest exhibition for the Middle East oil and gas industry. Supported by Abu Dhabi National Oil Company (ADNOC) and the UAE's Ministry of Energy, it hosts over 1,600 exhibitors and attracts more than 45,000 attendees and is considered the event where oil and gas industry professionals get together to experience, discover, network, discuss and debate core industry issues. ADIPEC began as a biennial event in 1984 and has grown in stature, significance and size with every exhibition since. From 2013 the show will become an annual event.

SPS/IPC/Drives, November 27 to 29, Nuremberg Suppliers of electric automation technology from around the world meet in Nuremberg, Germany. SPS IPC Drives is the exhibition for electric automation technology. It covers all components down to complete systems and integrated automation solutions. Products, trends and innovations within the industry are presented from November 27 to 29. The trade fair and adjoining conference offer a good platform to search for the right solutions for automation tasks.

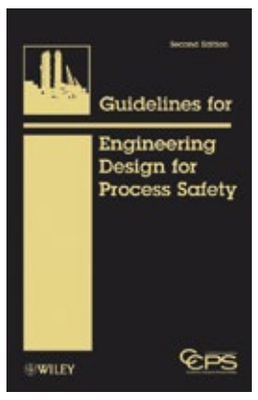
Elements of Environmental Chemistry



Providing readers with the fundamentals of environmental chemistry and a toolbox for putting them into practice, this book is a concise, accessible, and hands-on volume designed for students and professionals working in the chemical and environmental sciences. Tutorial in style, this book fully incorporates real-world problems and extensive end-of-chapter problem sets to immerse the reader in the field. Chapters cover mass balance, chemical kinetics, carbon dioxide equilibria, pesticide structures and much more. This Second Edition includes new chapters on atmospheric chemistry, climate change, and polychlorinated biphenyls and dioxins, and brominated flame retardants. In addition, new practice problems and a helpful tutorial on organic chemistry names and structures have been added to improve both the scope and accessibility of the book.

► Elements of Environmental Chemistry
Hites, Ronald A. / Raff, Jonathan D.
Wiley-VCH, 2012
ISBN: 978-1-118-04155-0

Engineering Design for Process Safety



This updated version of one of the most popular and widely used books from the Center for Chemical Process Safety (CCPS) provides plant design engineers, facility operators, and safety professionals with key information on designing chemical, petrochemical, and hydrocarbon processing facilities, while addressing process safety concerns. The book discusses how to select designs that can prevent or mitigate the release of flammable or toxic materials, which could lead to a fire, explosion, or environmental damage, with key information on failure modes and potential design solutions. New topics covered include inherently safer design, safety instrumented systems, and layer of protection analysis.

► Guidelines for Engineering Design for Process Safety
Center for Chemical Process Safety (CCPS)
Wiley-VCH, 2012, ISBN: 978-0-470-76772-6

PEOPLE


Pascal Soriot

Pascal Soriot has been appointed CEO of AstraZeneca. He will join the AstraZeneca Board as an Executive Director on 1st October. A French national, Soriot (53) has served as Chief Operating Officer of Roche's pharmaceuticals division since 2010. Prior to that Soriot was CEO of Genentech. Pascal Soriot joined the pharmaceutical industry in 1986 and has worked in senior management roles in the US, Asia and Europe.


Eric W. Norris

Eric W. Norris has been appointed as manager for FMC Corporation's Lithium Division. Norris joined FMC in 2001 as director of Investor Relations. He was named director of Corporate Development in 2005, and a year later was appointed director of FMC's Healthcare Ventures unit. Norris began his career in 1989 at Rohm and Haas Company in technical sales and held roles in strategic planning, marketing, business development and commercial management before being named Investor Relations manager in 1998.

Dr. Mike Ironside has been appointed as General Manager of Hovione's Technology Transfer Center (TTC) in New Jersey/USA. Dr. Ironside was previously with GSK in the UK and with AMRI and most recently with Anacor Pharmaceuticals, both in the USA. At Anacor he held the position of Vice President of Chemical Manufacture and Development.


Guillermo Novo

Guillermo Novo joins Air Products as senior vice president, Electronics, Performance Materials, Strategy and Technology. Novo will be responsible for the company's Electronics and Performance Materials businesses, Technology organization, and corporate strategy and marketing. He will report to the chairman and CEO and serve on the company's Corporate Executive Committee. Novo joins Air Products from Dow Chemical where he has most recently served as group vice president, Dow Coating Materials, a large specialty chemicals business. Guillermo Novo _Air Products_CMI0912

Jennifer Stewart has become new Vice President and Managing Director in the Europe, Middle East, and Africa (EMEA) region for Eastman Chemical. Jennifer's predecessors Godefroy Motte and Joost Berting have been assigned other responsibilities at Eastman Chemical: Godefroy Motte is Eastman's Senior VP Integrated Supply Chain and Chief Regional & Sustainability Officer, Joost Berting is Regional Business Director EMEA for the Specialty Fluids and Intermediates Business, and responsible for coordinating the integration process of the recently acquired Solutia organization in EMEA, Asia Pacific and Latin America.


David Faghani

David Faghani, who served CU Chemie Uetikon as a Director of North America for over 14 years, will now continue his cooperation with CU as an independent representative for Specialty Fine Chemicals, Pharmaceutical Intermediates, and New Chemical Entities (NCEs). As of April of 2012, David Faghani Incorporated "DFI" is a legal entity registered and based in New Jersey. CU's new representative office's main focus will be to provide direct commercial support to CU's customers in collaboration with CU's agents and distributors and to further develop new business opportunities.

Dr. May Shana'a has been named group vice president, Technology and Growth Strategy, for Ashland Specialty Ingredients. Shana'a will be responsible for leading Ashland Specialty Ingredients' global R&D and applications capabilities, with direct operational responsibility for the unit's global research and technical centers. In addition, Shana'a will be in charge of business development, including leading the strategic growth plan for the business.

CINF Scholarship for Scientific Excellence goes to Christin Schärfer, Tu C. Le und Rodolpho C. Braga

At the 244th ACS National Meeting in Philadelphia, Pennsylvania, Christin Schärfer, Tu C. Le and Rodolpho C. Braga were announced the winners of this year´s "CINF Scholarship for Scientific Excellence" sponsored by the German Chemistry information centre FIZ Chemie. The scholarship program of the Division of Chemical Information (CINF) of the American Chemical Society (ACS) promotes advancements in the field of computer-aided chemical information. It is given to junior scientists who deliver exceptional research contributions to support computer-aided chemical preparation, research collaboration and the use of specialized knowledge.

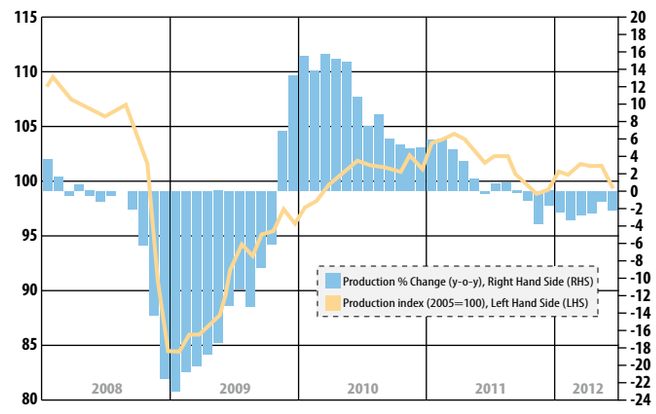
Sandra E. Peterson to Leave Bayer CropScience

Sandra E. Peterson, Chairman of the Executive Committee and Chief Executive Officer (CEO) of the subgroup Bayer CropScience, has asked for her contract, which runs until summer 2013, to be terminated effective November 30, 2012. The Supervisory Board of Bayer CropScience agreed to her request. Born in 1959 in New York, N.Y., Peterson became CEO of Bayer CropScience on October 1, 2010. Before moving to Bayer CropScience, she was a member of the Executive Committee of Bayer HealthCare from May 2005, heading up the Medical Care Division from January 2009. Prior to that she was in charge of the Diabetes Care Division.

European Chemicals Sector: Production Down, Prices Up

EU Chemicals: Production

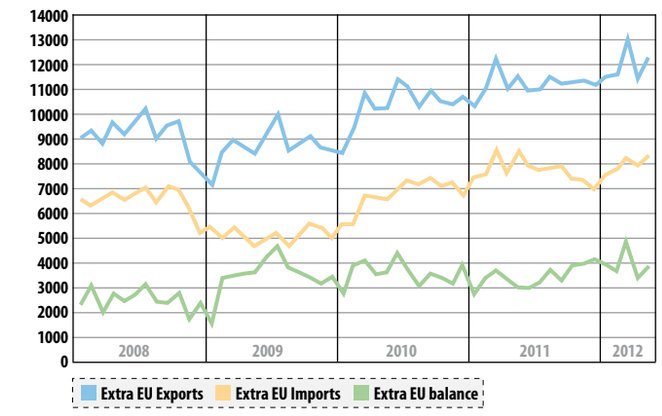
Production index (2005=100)



Source: Cefic Chemdata International © CHEManager Europe

Extra-EU Trade Flows: Chemicals

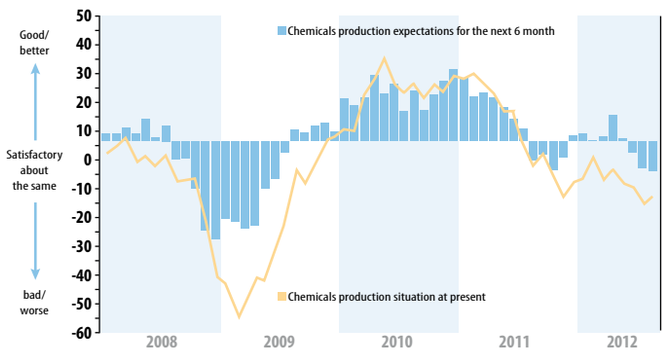
Trade Flows (euro millions)



Source: Cefic Chemdata International © CHEManager Europe

EU Chemicals Business Climate

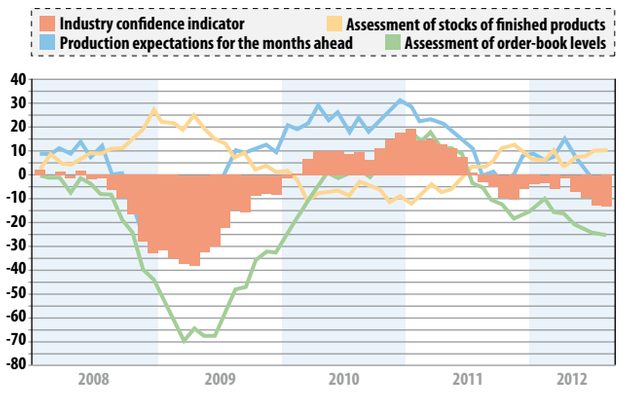
Production trend today versus expectations



Source: EU Commission and Cefic analysis © CHEManager Europe

EU Chemicals Confidence Indicator (CCI)

Net balances of replay to the questionaire (in % points)



Source: European Commission © CHEManager Europe

Ups and downs - The European Chemical Industry Council (Cefic) reports that EU chemicals production recorded a 2.4% decrease in the first six months of 2012 compared with the same period in 2011, according to the latest Cefic Chemicals Trends Report. Monthly data for June 2012 showed a 2.2% decline compared with June the year prior. First-half 2012 data point to EU chemicals production levels remaining 5.8% below the peak in 2007.

Prices for chemicals in the European Union climbed on a year-on-year basis in June, up 1.6% during the month against the comparable month in 2011. The price increase was led yet again by the overall price increase in basic inorganics. However, month on month price data for June 2012 indicate a 1.2% decrease compared with May. Despite a monthly break in the upward price trend, overall prices for chemicals climbed by 3.4% during the first half of 2012 against the comparable period in 2011.

Latest trade data show the EU chemicals net trade surplus increased further through the first five months of 2012 by €3.6 billion compared with the same period of last year, reaching €19.9 billion. According to the latest EU Commission survey from August 30, 2012, confidence in the EU chemicals industry declined slightly in August 2012, and gradually continued the downward trend reported since April 2012. This is in line with the EU industry as a whole where confidence continued to decline since March 2012.

Year-on-year June Chemicals Output Lower

Monthly data for June 2012 showed a 2.2% output decline for the EU chemicals industry compared with June the previous year. Polymers production was down in June 2012 by 8.4% against the comparable period the year prior. Petrochemicals and specialty chemicals experienced a similar fall of 2.5%in June 2012. Basic inorganics and consumer chemicals, however, were the only two sectors where production increased in June, up 1.7% and 1.2% respectively on a year-on-year basis.

EU Trade Surplus up by €3.6 Billion

An EU net trade surplus with the NAFTA region contributed significantly to the bump in the January-May overall surplus, reaching €4.9 billion, up €1.5 billion compared with the same period in 2011. The EU net trade surplus with the Rest of Europe was €5.9 billion in the first five months of 2012, up €0.9 billion compared with the same period of last year. A €2.3 billion surplus occurred with Asia, excluding Japan and China, which fell €0.4 billion compared with the first five months of 2011. May 2012 trade data indicate a €19.9 billion overall EU chemicals net trade surplus.

Prices for Basic Inorganics Climbed

Year-on-year EU chemicals prices rose in June by 1.6%, driven by the price for basic inorganics, which increased by 3.7% during the one-month period. Prices for consumer chemicals rose by 1.1%, while petrochemicals and pharmaceuticals prices edged down respectively by 1.6% and 1.5% in June as compared with the year prior.

EU Sales in Jan.-May 2012 5.8% Higher

EU chemicals sales for May 2012 were 1.9% lower compared with May the year prior. EU chemicals sales recorded a 1.0% decrease in the first five months of 2012 compared with the same period in 2011. Compared to full-year sales levels in 2008, the pre-crisis peak, the total value of sales through the first five months of 2012 was 5.8% higher. The full report can be read at www.cefic.org

Game Changer – BASF has made a game-changing breakthrough towards sustainable snack packaging that can help companies and communities everywhere get closer to their goal of zero-waste. The chemical company partners with the Seattle Mariners, one of the greenest teams in Major League Baseball a and a member of the Green Sports Alliance. BASF uses the iconic snack of the American pastime, peanuts, to debut prototype packaging developed with its advanced biopolymer technology. The 100% compostable snack bag delivers needed shelf-life at a competitive price point, with a more sustainable 'end-of-life' solution than with conventional packaging materials.

Visions in Plastics

Sustainability – In the 21st century, climate change, limited natural resources and the increasing demand for energy throughout the world are making sustainable production and consumption more urgent than ever. These challenges are also of central importance to the plastics industry. However, meeting these challenges also offers opportunities for the industry, as plastic products open up many possibilities, from conserving resources and energy to protection of the climate, consumers and the environment.

Products made from plastics are important solutions to the problems: for example, lightweight car components and building insulation materials make an important contribution to energy savings and reduction of CO_2 emissions. However, plastics are not just essential for energy savings: solar cells, fuel cells and wind energy generators contain polymer materials and exploit infinite CO_2-free sources of energy. Packaging made from plastics protects goods and helps to keep food fresh for longer and make it easier to transport. Further fields of application, in which plastic products save energy during their usage phase include the automobile, the construction and the electrical and electronics sector.

In addition to its sustainable products, the plastics industry is continually researching into new, more efficient process and products, which save energy and resources and therefore reduce their impact on the environment during production and use.

VIP – Visions in Plastics 2012 documents the creativity and innovation of the plastics industry by a wide variety of topics. The special supplement will be distributed with the October issues of CHEManager and CHEManager Europe. ■

Index

Imprint

Publisher:
Wiley-VCH Verlag
GmbH & Co. KGaA
GIT VERLAG
A Company of
John Wiley & Sons, Inc.

Geschäftsführer
Jon Walmsley,
Bijan Ghawami

Director
Roy Opie

Product Management
Dr. Michael Reubold
Tel.: +49 6201 606 745
michael.reubold@wiley.com

Editor-in-Chief
Brandi Schuster
(on maternity leave)
Tel.: +49 6201 606 755
brandi.schuster@wiley.com

Managing Editor
Dr. Roy Fox
Tel.: +49 6201 606 714
roy.fox@wiley.com

Media Consultants
Corinna Matz-Grund
Tel.: +49 6201 606 735
corinna.matz-grund@wiley.com

Thorsten Kritzer
Tel.: +49 6201 606 730
thorsten.kritzer@wiley.com

Ronny Schumann
Tel.: +49 6201 606 754
ronny.schumann@wiley.com

Roland Thomé
Tel.: +49 6201 606 757
roland.thome@wiley.com

Team Assistants
Lisa Rausch
Tel.: +49 6201 606 742
lisa.rausch@wiley.com

Beate Zimmermann
Tel.: +49 6201 606 764
beate.zimmermann@wiley.com

Freelancers
Dr. Sonja Andres
Dede Williams
Miranda Kennedy
Dr. Volker Oestreich
Philipp Praet

Production Managers
Christiane Potthast
Claudia Vogel (Advertising)
Oliver Haja (Layout)
Ramona Rehbein, Elke Palzer
(Litho)

Reprints
Dr. Katja Habermüller
Tel.: +49 6201 606 719
katja-carola.habermueller@
wiley.com

Subscription/Reader Service:
Silvia Amend
Fax: +49 6201 606 700
silvia.amend@wiley.com

Bank Account
Commerzbank AG Darmstadt,
Germany
Account No. 01715501/00,
Routing No. 50880050
The current price list is valid
from 1st October 2011

CHEManager Europe
appears 10 times in 2012.

Print run: 20,000
(IVW Report
Q2 2012: 19366 tvA)
Eighth year 2012
Subscriptions
10 issues €84
incl. postage
single copy €13.50
plus postage

Students receive a discount of 50 % upon presentation of a valid certificate. Subscription orders can be canceled within 1 week in writing. Dispatch complaints are possible only within 4 weeks after publishing date. Subscripti-on cancellations are accepted 6 weeks before end of year.

Orginal Articles
Specially identified contributions are the responsibility of the author. Manuscripts should be addressed to the editorial office. Instructions for authors may be requested from the publishing company. We assume no liability for unsolicited, submitted manuscripts. Reproduction, including excerpts, is permitted only with the permission of the editorial office and with citation of the source.The publishing company is granted the exclusive, space and content restricted right to arbitrarily use the unmodified work/editorial contribution for all purposes for itself and for businesses that have an interest in the publishing company as defined by company law as well as to transfer the right of use to third parties. This right of use applies to both print and electronic media including the internet and data banks/data media of all types.

Printed by
Druckzentrum Rhein-Main
GmbH & Co. KG
Alexander-Fleming-Ring 2
65248 Rüsselsheim

GIT VERLAG
Printed in Germany
ISSN 1861-0404