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CHEManager EUROPE

THE NEWSPAPER FOR THE CHEMICAL AND LIFE SCIENCE MARKETS

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Facing 2012

Saltigo Examines the State of Custom Manufacturing in the New Year

Optimism Springs Eternal – 2011 was a year fraught with uncertainties, and many industries are wearily eyeing the year to come. The state of the worldwide economy as well as the health of the 10-year-old euro has many concerned about what the next months will bring. However, reports from mainstream media seem to differ from the mood within the chemical industry. Here, the outlook is overwhelmingly positive; the sector went through a lot of changes after the crisis that began at the end of 2008, and most in the industry are ready to face any challenges ahead. Brandi Schuster spoke to Saltigo CEO Wolfgang Schmitz; Andreas Stolle, Pharma business head; and Dirk Sandri, head of Marketing & Sales in the Agro & Fine Chemicals business line, about the year ahead in pharma, agro and custom manufacturing in general.

Wolfgang Schmitz
CEO, Saltigo

Dr. Andreas Stolle
Head of the Pharma business line, Saltigo

Dirk Sandri
Head of Marketing & Sales in the Agro & Fine Chemicals business line

CHEManager Europe: What is Saltigo's outlook for the coming year?

W. Schmitz: We are expecting positive perspectives for our agro business this year, and this is where we plan on sharpening our focus. In fact, we have already booked orders for the first half of the year. The majority of our agro customers – and among them the major players – have positive expectations for the coming year. The positivity is also underscored by prices on the commodity bourses in Chicago and Kansas – we're looking at prices that are similar to those in 2008, which clearly shows that the long-term dynamic is intact.

Mr. Sandri, what trends have you been seeing in the agricultural sector?

D. Sandri: The agrochemical sector has been very bullish in comparison to many other industries lately. Forecasts show that the end market will have grown by 16–18% in dollar terms in 2011, which is a very positive signal. And the first signals for 2012, at least for the first half, also look very promising. Our customers are optimistic about developments in various markets, particularly in Eastern Europe, Asia and Brazil.

Mr. Stolle, what about pharma?

A. Stolle: Within pharma, we expect to continue to face hard competition. Compared to agro, it's a more difficult business environment, so we are more cautious. We've been observing ongoing consolidation on the demand side, which is leading to an impressive amount of price pressure in the industry. For our part, Saltigo has been successful in improving its pipeline with drugs in late stage of development where we are now preparing for production of launch quantities.

Has the euro crisis affected your parent company Lanxess?

W. Schmitz: The construction and electronics sectors have been affected in the second half of 2011, but Lanxess is overall on track to achieve record results for 2011 of €1.1 billion EBITDA pre exceptionals.

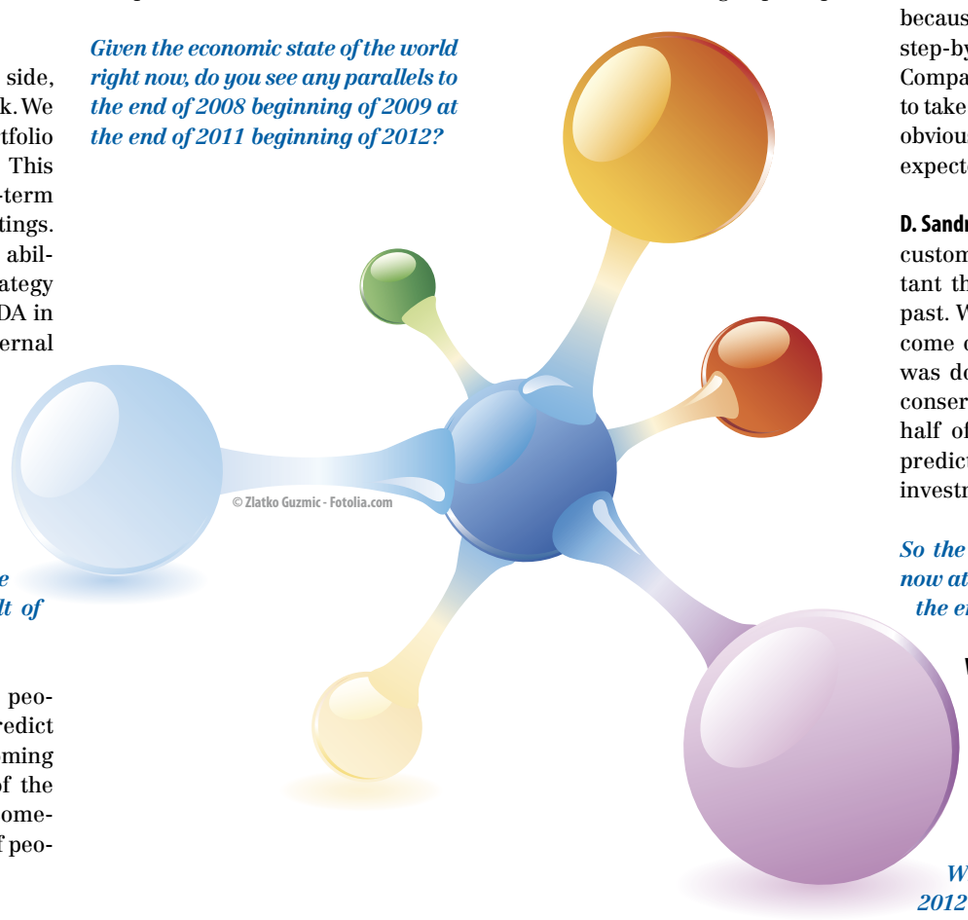
Many companies have come up with a contingency plan should the euro fail.

W. Schmitz: On our financial side, Lanxess has done its homework. We have a balanced financing portfolio and a good maturity profile. This is also reflected by solid long-term investment-grade credit ratings. All this means, we have the ability to pursue our growth strategy of achieving €1.4 billion EBITDA in 2015 through organic and external growth measures.

Many chemical companies have a positive outlook for 2012, despite gloomy economic reports. Is the euro collapse really as possible as it seems, or is a lot of the debate around the currency the result of media hype?

W. Schmitz: In fine chemicals, people are quite optimistic and predict strong performance for the coming year. As far as the stability of the euro is concerned, it's also something of a psychological issue. If people talk and talk about the dangers and what to do when it collapses, this inevitably leads to more and more people thinking that it will indeed collapse. This is not something any of us want. We see quite positive chances for us to grow further, and this is what we're primarily concentrating on. And we shouldn't forget how many advantages the euro has brought to German, export-oriented companies like Lanxess.

Given the economic state of the world right now, do you see any parallels to the end of 2008 beginning of 2009 at the end of 2011 beginning of 2012?



W. Schmitz: In 2008, the entire industry was taken by surprise. Orders practically ceased overnight, and this was after the entire supply chain was underway full blast, expecting a good year. It was as if a reset button had been set, and this forced everyone to reconsider the way they do business. In 2009–10, industries thoroughly investigated their supply chains and dramatically reduced the money they had bound as working capital, particularly on the raw material side. This means customers are now much more cautious about the amount of product they order. In the past, customers wanted the security of knowing that they had enough material on hand. Now, many have redefined the level of inventory they need to keep.

What does this mean for the current economic situation? If demand were to go down now, the effect will not be as abrasive as it was in 2008 because everyone has now prepared, step-by-step, for such a situation. Companies are now better prepared to take on any uncertainties, although obviously no one knows what is to be expected in the coming months.

D. Sandri: In agro, we have seen that customers are much more hesitant than they have been in years past. We had a lot of new capacity come on stream when the demand was down, so people are naturally conservative nowadays. If the first half of 2012 develops better than predicted, then we can expect new investments to follow.

So the industry is better positioned now at the beginning of 2012 than at the end of 2008?

W. Schmitz: I would definitely say so, but we still don't know if the turbulences in the financial market will fully make their way into the real economy.

What will be setting the tone in 2012 in custom manufacturing?

A. Stolle: The euro crisis and the patent cliff in pharmaceuticals will move pharma companies to consider further cost savings. Some of these savings will need to come from their procurement organizations, which means suppliers will be expected to be even more creative and innovative when it comes to supply-chain simplification and cost cutting. This means there is a fierce competition between all custom manufacturers to stay in the game and protect the business. With our portfolio and pipeline, we focus on innovative processes to stay competitive.

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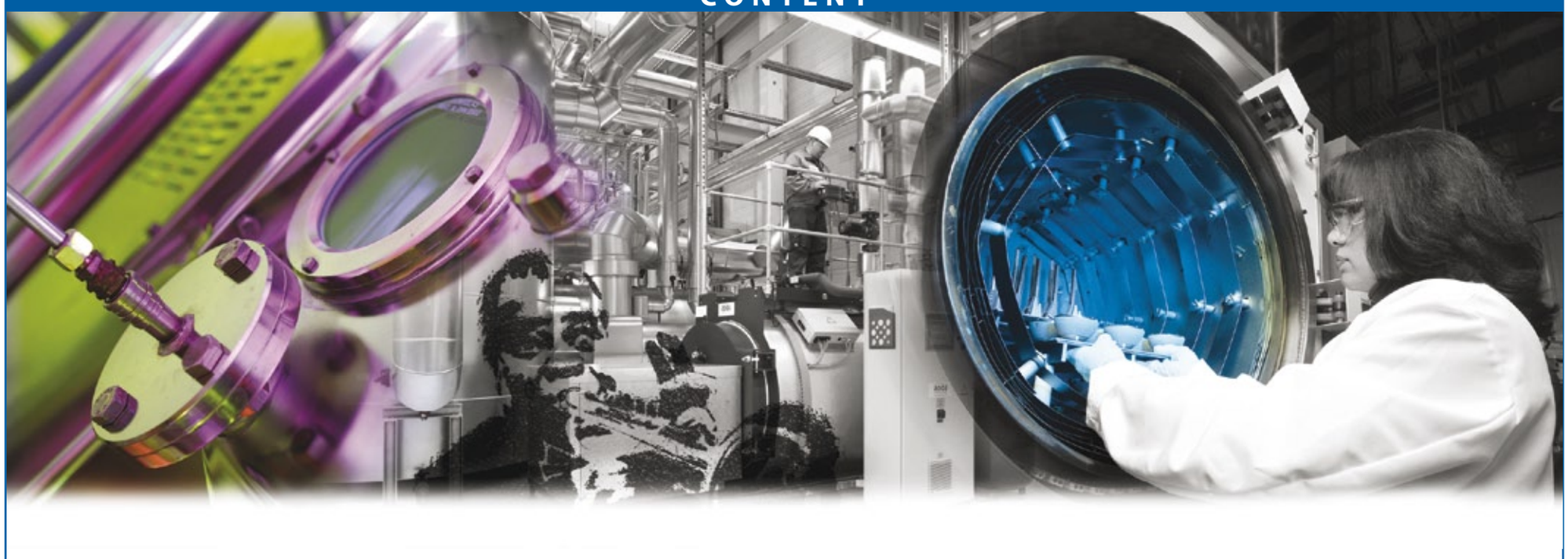


ThyssenKrupp Affirms Outlook for Q1

ThyssenKrupp, Germany's largest steelmaker, denied market speculation it would issue a profit warning and reiterated guidance for the first quarter.

"We deny the profit warning speculation," a spokesman told Reuters on Wednesday after several traders said there was talk that ThyssenKrupp might issue a warning.

"We are reiterating our guidance for the first quarter that Materials would be difficult and Technologies would be stable," the spokesman said.

ThyssenKrupp, which also makes submarines, elevators, automotive components and chemical plants, said last month it sees operating profit for the whole group to be significantly lower in the first quarter to December 2011 than in the same period last year.

ThyssenKrupp has not provided an outlook for its full fiscal year, citing uncertainty over how the debt crisis in Europe may affect the real economy. ■

Saltigo: Joerg Schneider Succeeds Uwe Brunk

Dr. Uwe Brunk
Saltigo

Joerg Schneider
Saltigo

Saltigo, a subsidiary of German chemical company Lanxess, has appointed Joerg Schneider as head of its Agro and Fine Chemicals business unit. He succeeds Dr. Uwe Brunk, who is leaving the company at his own request, according to a press release. The change is effective Feb. 1. Schneider is currently managing director of Lanxess Elastômeros do Brasil. ■

Ex-Innospec Director Pleads Guilty

A man who used to work for Innospec has pleaded guilty to conspiracy to corrupt, including making corrupt payments to Iraqi officials, the UK's Serious Fraud Office said.Dr. David Turner pleaded guilty in a London court to three counts of that charge. These included conspiracy to give corrupt payments to public officials and other agents of the Indonesian and Iraqi governments between 2002 and 2008 in order to secure contracts for Innospec.

The sentencing of Turner was adjourned. ■

Novozymes Shares Drop After Q4 Profit Misses Forecast

Novozymes , the world's biggest industrial enzymes producer, posted earnings at the low end of expectations and warned of uncertainties in the global economic outlook, sending its shares to a near two-month low.

The Danish company, whose enzymes are used to produce consumer goods from detergent to biofuel, said its profits were held back by higher raw material costs, currency conversion effects and slack sales of bioenergy enzymes.

Earnings before interest and tax (EBIT) rose 19% to 496 million crowns ($85.5 million) in October-December from 417 million a year earlier, falling short of an average expectation of 515 million in a Reuters poll of 10 analysts.

Jyske Bank kept a "reduce" recommendation on the stock, saying that growth in the bioenergy enzymes segment was disappointing even though the results overall looked in line with its expectations.

Novozymes said it expected full-year 2012 EBIT growth of between 9

Steen Riisgaard
CEO, Novozymes

and 12% and sales growth in Danish crowns of 7 to 11% -- noting the wide ranges reflected difficulties in anticipating global economic trends.

"The full-year 2012 expectations reflect uncertainty about the global economy, expressed by relatively wide intervals for sales and earnings growth guidance," it said in a statement.

Chief Executive Steen Riisgaard said in the statement Novozymes' products had been fairly resilient in earlier downturns but added: "We currently see scenarios at both the high and low end of the guidance."

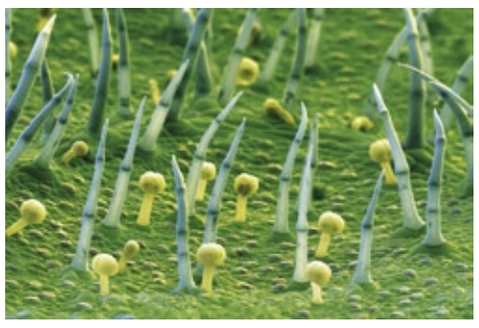
Fourth-quarter revenue grew 8% year-on-year to 2.59 billion crowns, roughly matching analysts' average estimate of a rise to 2.60 million in the Reuters poll. ■

AkzoNobel Selects Tebodin for Chlorine Plant Conversion

AkzoNobel Industrial Chemicals said has selected consulting and engineering company Tebodin for the engineering, procurement and construction management of a new chlorine plant in Frankfurt into state-of-the-art membrane electrolysis technology. The new plant will increase current annual production in Frankfurt by approximately 50%, to 250 kilotons of chlorine and 275 kilotons of caustic lye. The energy consumption per ton of product will be improved by nearly 30%. Construction will start in August 2012. Expectations are that the new chlorine production facility in Frankfurt will come on stream in the fourth quarter of 2013. ■

German Farm Group Regrets BASF's GMO Move To U.S.

Germany's giant association of farming cooperatives said it regretted the decision by BASF to transfer its research into crops with genetically modified organisms (GMOs) from Germany to the United States and other countries.



BASF had received European Union permission in 2010 for commercial cultivation of its GMO potato Amflora

"The announcement by BASF to transfer its (German) domestic plant biotechnology research and development activities to the United States is disastrous for Europe as a location for agricultural industries," Manfred Nuessel, president of cooperatives association DRV, said in a statement on Tuesday.

The German chemical company said on Monday the headquarters of BASF Plant Science, its biotech unit, would be moved from Limburgerhof in Germany, to Raleigh, North Carolina.

BASF said its biotech research and development activities would be concentrated mainly in Raleigh and also in Ghent in Belgium and Berlin. Development and commercialization of all products targeted solely at cultivation in the European market will be halted, the company said.

"Because of this development, I believe it is essential that a political and social climate is created in which biotech companies are not forced to transfer their activities abroad," Nuessel said.

Constant protests by opponents of GMOs over the years, including repeated destruction of fields with GMO crops in Germany, have caused great uncertainty about the future of GMO crops, Nuessel added.

BASF had received European Union permission in 2010 for commercial cultivation of its GMO potato Amflora, which is used for industrial starch production, not food, and has been approved as safe for commercial production by the EU.

But in 2011, BASF said it planned to cultivate just two hectares of the GMO potato Amflora in Germany and 15 hectares in Sweden.

EU policy on GM crops has long been politically fraught, with a majority of consumers opposed to modified foods, but the bloc relies on imports of about 30 million tons of GM animal feed each year.

In October 2011, Europe's biotechnology industry warned the European Commission that agricultural imports vital to EU food security were increasingly being put at risk due to the slow pace of the bloc's approval system for GM crops.

Several countries, including France and Germany, are imposing bans on cultivating GM crops despite EU safety approval. ■

Facing 2012

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In the end, though, it's all about how a company can bring cost cutting to the table while improving the service at the same time. This is a trend that's here to stay in 2012.

How can a company cut costs while improving products?

A. Stolle: Saltigo has its strengths in chemistry, technology and engineering. We are continuously improving our processes and coming up with new engineering solutions. It is not just continue what we do. We are targeting step changes and focus on our key strength. That is driving down cost in the processes that we have established in the plants and, of course, looking at different supply chain options.

Do you see that a lot of your customers are looking to Asia as an alternative to save money?

A. Stolle: It depends on the customer. Some have a dual supply strategy of going to Asia while also staying in Europe. Then there are companies who will go where ever the best prices can be found – and it should be said that there are good Asian companies out there who are very competitive. Others will only source very early intermediates in Asia while preferring to do the high-value adding steps in Europe. Again, it all depends on the customer, the company philosophy and perhaps even individual experiences in different regions.

How do you sell Europe to companies who are seemingly only concerned about the bottom line?

A. Stolle: We make them aware of the need to look at the total cost of supply. It could be that companies can save money on production in Asia, but this is without taking the overall cost and security of supply as well as total value for money into consideration.

W. Schmitz: I think this is also especially valid for a project up to the launch phase where safety and speed of supply are very important. This is where many customers prefer to rely on Western suppliers.

D. Sandri: In agrochemicals, we have seen a significant takeoff for products in Asia last year. In some cases where we have supplied Asian customers with raw materials, we have seen these demands shift partly back to Europe.

Why?

D. Sandri: It is definitely a quality issue; price isn't everything. You can have a nice low price, but you need a material in the right quality, in the right quantity, in the right packaging, at the right moment. And since there is a high volatility in demand planning of our customers, and because their main production units are in Europe and in the U.S., they don't have time to wait for weeks for materials from China or from India to Europe back and forth. So this is definitely an advantage also for European suppliers that we can offer a short-notice supply.

Mr. Stolle, it's no secret that the pharma industry is booming in Asia. How do you accommodate customers who want to expand into this region?

A. Stolle: In this case, we help customers indirectly. We are constantly analyzing how to stay competitive and how to support the costs of goods needed in the Asia market. We can do that either through our technology or we can investigate sourcing from countries with less intensive labor costs in order to keep the overall cost down.

Many pharma companies want to build a physical presence in Asia, but they have difficulties going it alone and look to contract manufacturers to help them get a foot in the door. How do you assist these customers?

"We've been observing ongoing consolidation on the demand side, which is leading to an impressive amount of price pressure in the industry," Dr. Andreas Stolle, Head of the Pharma business Line of Saltigo, said.

A. Stolle: Some customers ask directly, "Why should I use Saltigo to do this?" In some cases, we take care of all of the sourcing and supply chains, which means we can reach out through our Saltigo and Lanxess procurement departments in Asia. This helps customers to manufacture on a global basis.

Is this something that has been gaining in popularity?

A. Stolle: I would say yes. However, there are a few companies who go into these regions directly.

W. Schmitz: It's a case-by-case situation. In companies that have been reorganized, procurement departments have also become smaller. This means they end up concentrating on their first-tier suppliers and expect them to organize the entire supply chain instead of doing it themselves.

Your customers expect Saltigo, as a contract manufacturer, to be an all-round service provider.

A. Stolle: That is absolutely right. It's not just about manufacturing anymore; it's also about the entire service package.

As a custom manufacturer, do you see that the pharma companies regard you as a partner in the collaboration?

A. Stolle: It depends on how intimate we are with the customer. The smaller the company, the more intimate the collaboration usually is. This is particularly true with emerging pharma companies; there we are really a part of their team, and innovation in the pharmaceutical sector is coming out of these emerging companies. Some Big Pharma companies just give us an order and we deliver accordingly. That being said, I have seen a clear trend that many pharma companies are beginning to see the value customer manufacturers have to offer, particularly when it comes to innovation.

Do you see that Big Pharma is having a kind of problem making this change in mindset?

A. Stolle: It is indeed a change in mindset, and that is something that many people need years or even generations to do.

The much-prophesized patent cliff is upon us – do you think that will be the real catalyst for getting Big Pharma to change the way they do business?

A. Stolle: I think it is more than that. Of course the patent cliff plays its part, but a weakening euro and the international debt crisis – as well as the crisis that began at the end of 2008 – are also making people think. Also, the drug prices to be achieved in emerging markets are typically lower than in Western countries. This all drives Big Pharma to change the way they do business, and it's a process that starts from the top down. A lot of CEOs have already recognized the need for change. This line of thinking flows down to the procurement level, where they realize they need partnering in order to get more value out of collaborations.

▶ www.saltigo.com

chemanager-online.com/en/tags/custom-manufacturing

Weak Euro Cold Comfort for European Exporters

Currency hedging, dollar costs and the potential for a deeper economic crisis stand between European exporters and any easy win from weakness in the euro currency. The euro has lost 10% of its value against the dollar since late October and is close to a 16-month low at around 1.28, hit by mounting concerns over Europe's debt crisis and two interest rate cuts by the European Central Bank.

In theory, this should be good news for exporters to the U.S,which benefit from a production cost base in euros and selling prices in dollars. In fact, there are three reasons why a dollar upswing may not feed into extra profits for exporters.

Currency Hedging

Most companies that report earnings in euros but have sales in dollars take euro positions to protect themselves against any adverse move in the exchange rate. While forex positions can be adjusted if the euro weakens, existing hedges mean that it takes time for currency benefits to show in corporate earnings.

German carmaker Daimler, which generated around 25% of its revenue in the United States in 2010, has hedged two thirds of its dollar sales exposure for this year and one third of its exposure for 2013.

"Almost 80% of companies are hedged so the sensitivity on profits is very small, unless you have a very big swing," said Claudia Panseri, an equity strategist at Societe Generale.

Dollar Cost Base

The second factor is that many companies that have a significant portion of their sales in the United States increasingly have large dollar cost bases too.

Among industrials, Siemens generated 20% of its top line in the U.S. in the 12 months to end-Sept., making the country its largest market by revenues. However, the Munich-based conglomerate employs 16% of its workforce in the United States and has a number of other dollar-based costs, such as raw materials and components.

"Most European industrials used to have a much more export-heavy business model 10 years ago, but many of them by now have an almost complete match," with high dollar costs swallowing up a large portion of the benefits of a weak euro, said Andreas Willi, head of European capital goods research at JPMorgan.

Global Growth

Boasting the highest net revenue exposure to the dollar in the automotive sector, German auto groups Daimler and BMW should be key beneficiaries of a weak euro if consumer demand holds, Deutsche Bank autos analyst Jochen Gehrke said.

"But how high are the chances of demand not weakening and the euro staying where it is now?," Gehrke wondered.

The euro zone's economy barely grew in the third quarter, with collapsing business confidence and slowing industry pointing to a recession in the coming months. If the euro bloc slips into protracted contraction, the impact on global growth would more than offset any beneficial currency effect on exporters' profitability. Corporate earnings among European exporters declined along with demand when the euro dropped to 1.23 versus the dollar during the 2008 recession.

Beneficiaries

Nevertheless, some stocks should still do well from a weak euro.

Pharmaceutical stocks and consumer-related sectors historically showed the greatest share price sensitivity to dollar appreciation versus the euro, along with some aerospace and defense names, according to SocGen data.

"This share price behavior has to do with the fact that some companies are perceived as more protected in a weak euro environment," SocGen's Panseri, said.

Exporters of luxury goods and other discretionary items benefit from the exposure to a healthier economy in the United States when macro conditions on this side of the Atlantic are depressed.

As for pharma stocks and consumer staples retailers, their defensive profile helps them outperform in tandem with the safe-haven dollar at times of economic uncertainty in the euro zone.

Ahold, a Dutch grocer that generates around 60% of its sales in the United States, would be a likely winner in this scenario, Anthony Sleeman, sector analyst at Bernstein Research, said. ■

THOMSON REUTERS

GDUFA: Who Will Benefit?

The pharmaceutical supply chain is increasingly globalized. It is estimated that 80 % of the active ingredients used in generic medicines marketed in the U.S. are manufactured in foreign countries with half of this volume originating from China and India. The U.S. FDA has struggled to conduct inspections of foreign facilities, especially in emerging markets, due to a lack of appropriate resources and funding. Currently, the review time for the average ANDA amounts to 31 months and more than 400 ANDAs are estimated to be otherwise approvable but require an outstanding FDA inspection.

GDUFA Overview

In September 2011, the FDA announced the ratification of a proposed Generic Drug User Fee Act (GDUFA) to collect fees from finished dose and API manufacturers and use them for the review of ANDAs, referenced DMFs and conducting associated facility inspections for fiscal years 2012–2017. The program would provide the FDA with adequate resources to review ANDAs in a timely manner, provide transparency within the complex pharmaceutical supply chain, and improve the safety of generic medicines. Additionally, the new regulations will require the identification of facilities involved in manufacturing both finished dose and active ingredients and, by 2017, ensure parity of inspections between US and overseas manufacturers, with a goal of biennial inspections of both finished dose and API manufacturers.

The annual funding from GDUFA user fees is set at $299 million in fiscal year 2013 and will come from application fees (ANDAs, prior approval supplements ((PASs)) and DMFs) and facility fees. Funding for fiscal years 2014–2017 will remain at $299 million plus an annual adjustment. Approximately half of the fees are expected to come from finished dosage form facilities, with the remaining half divided among fees from ANDA filings, API facility fees and DMF first reference fees (figures online). During fiscal year 2013, 17 % (~ $50 million) of the total GDUFA user fees will come from ANDAs remaining in the backlog as of Oct. 1, 2012.

Currently there are more than 2,000 ANDAs waiting in the approval backlog. By the end of 2017, FDA has vowed to review 90 % of the backlog ANDAs and reduce the primary review time for ANDAs submitted after Oct. 1, 2012 to 10 months.

The agreement still needs to be reviewed by the Department of Health and Human Services as well as the Office of Management and Budget. FDA indicated in September that it was anticipating providing a generic drug user fee package to Congress in January 2012. At the GPhA Fall Technical Congress in Washington, D.C. last October, Keith Webber, the Acting Director of the Office of Generic Drugs at FDA, expressed hope that the new user fees will be implemented in October 2012.

Impact On The Industry

While the FDA has publicized information about the proposed user fee structure, the actual fee amounts are not yet known. The author had an opportunity to gather speculative feedback regarding possible user fee amounts from several industry experts at CPhI Worldwide last October and learned that fees may fall in the following ranges: $40,000–50,000 for DMFs, $75,000–100,000 for facilities and $100,000–200,00 for ANDAs. Non-payment of annual facility fees from API and/or finished dose manufacturers will result in all products from those facilities being classified as misbranded and banned from sale in the U.S. market.

The creation of a DMF database with "available for reference" status is a possible outcome of GDUFA. For those companies who pay the fee, the FDA will perform an administrative review of the DMF at submission time and will add it to the list of DMFs that are available for reference. The FDA will refuse to review an ANDA application which cites a DMF for which this fee has not been paid. This change may reduce the number of incomplete and/or substandard DMF submissions (so called "marketing DMFs") received by the FDA in the future.

Smaller companies seem to be quite concerned that they will be priced out of the market. Meanwhile, some companies with multiple manufacturing sites are worried that they will get hit hard by annual facility fees. It is possible that some companies may choose to consolidate manufacturing sites to avoid paying multiple fees. Some manufacturers view the proposed user fees as anticompetitive due to the barrier of entry which it creates while others argue that faster and more predictable review times will speed up product launches thus benefiting the manufacturers. It is also possible that, at least initially, the increased number of global surveillance inspections will lead to additional warning letters and import bans which may prevent certain companies from selling their products into the U.S. market.

Therefore, the creation of additional drug shortages is another possible unintended consequence of GDUFA. Going forward, companies will likely be selective about which active ingredients and finished dose forms they manufacture and may choose to stop production of some low margin products in light of having to pay user fees. Because the budget for GDUFA is fixed and based on a set amount of regulatory filings per year, a decrease in the number of DMF and ANDA submissions would result in higher user fees the following year, further contributing to the drug shortage problem. On the plus side, the quicker review times should make it possible for new players to enter the market if shortages loom.

To date, there is a general lack of certainty regarding the final implementation of GDUFA but it is being viewed as a significant game changer within the industry. So whom will GDUFA benefit? The new legislation will likely favor the generic giants and those smaller players who possess excellent quality systems. The increased frequency with which FDA inspects facilities will lead to improved and more consistent quality generic medicines which ultimately benefit U.S. consumers, although in the short term we should be prepared for additional drug shortages.

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Fierce Competition

Cefic: Business Uncertainty to Affect Industry in 2012

Chemicals in 2012 – Growth in European chemicals output will be weaker than expected on 2012 because of heightened business uncertainty and inventory trimming, industry group Cefic said. The group's summary forecast of chemicals sector economists predicts year-on-year growth of chemicals output for 2011 is likely to be 2 %, in line with the historical trend growth rate and against 4.5 % expected in June. Expansion in 2012 will probably reach 1.5 %.

Giorgio Squinzi, Cefic President and Mapei CEO, discusses EU policy at the Cefic Economic Outlook press conference in Brussels.

"The continuing debt crises in the Eurozone and high U.S. government debt level have undermined macroeconomic sentiment since the summer," Cefic President Giorgio Squinzi said. "Companies are hoarding cash. The uptrend in oil prices has halted, reducing the incentive to buy ahead. Added to this is increased business uncertainty, which is encouraging reductions in inventories. Lower output growth is the inevitable result."

Slow Growth In 2012

Following on from a strong demand recovery with double-digit growth in 2010, much of 2011's rise in chemicals output took place in the first quarter. Since then, output has been relatively flat. Cefic said it believes chemical industry growth will resume during 2012, however, strengthening slowly through the year. Its forecasters expect underlying EU gross domestic product growth of 1 % in 2012, down sharply from the 1.8 % they predicted in June.

But risks remain, mostly on the downside. Growth in most developed economies remains perilously slow, and austerity measures are provoking political protest. Developing Asian economies continue to grow, but asset bubbles there could deflate suddenly.

Consumer chemicals were the star of the European industry in 2011, with growth of 6.6 %. They remain the top growth sector in 2012, at 2.5 %. Other chemicals sub-sectors are near the average, although pharmaceuticals were expected to attain 3 % growth in 2011 and 2.0 % in 2012.

External Demand

EU output continued to be driven by external demand. The EU external trade surplus narrowed slightly during the first three quarters of 2011 from the record level reached in 2010. In 2012, the surplus is expected to be roughly stable, and inventories are also expected to cease falling. Construction stabilized in 2011, after prolonged contraction, and may grow a little in 2012.

"Companies have reported relatively strong global results for the third quarter and are in good financial health," Squinzi said. "If the Eurozone can finally establish an effective solution to the debt crisis, and deliver credible actions to stabilize markets and confidence, the European chemical industry can look forward to renewed growth through 2012."

But he warned that European chemical producers continue to suffer from high regulatory and social costs and high energy prices. Yet in the U.S,. shale gas development is attracting a new round of investment in basic petrochemicals, and the Middle Eastern capacity build-up continues.

"Global competition remains fierce," he said.

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Linde Expands Homecare Ops with $750 Million Buy

Linde is acquiring the European homecare business of U.S. rival Air Products and Products in a $750 million deal that will thrust the German industrial gases maker into No. 2 position in the homecare respiratory market.

The business being bought – which generated sales of €210 million ($267 million) in the year through September 2011 – provides care for patients who suffer chronic ailments requiring oxygen, ventilation or nebulization therapy at home.

An industry observer who declined to be named said the acquisition – one of Linde's biggest since it bought UK-based BOC for €12 billion ($15.3 billion) five years ago – would make Linde a strong No. 2 in the homecare business after French group Air Liquide.

Linde, already the world's second-biggest supplier of medical gases and industrial gases, declined to comment on its market share, but said its healthcare operations were more profitable than industrial gases. Air Products said it was selling the business because it was no longer a natural fit with its core gases business.

Linde counts the steel and chemical sectors as its main customers but also supplies gases used to produce solar cells, make LCD flat screens and lift the giant helium character balloons of Macy's Thanksgiving Day Parade. Prior to the BOC buy it bought Swedish industrial gas supplier Aga in 2000.

Linde's healthcare business posted total sales of €1.1 billion in 2010, with around 280 million generated in the homecare segment. The group says its operating profit margin in healthcare is wider than in industrial gases, where it achieved a margin of 27.3 % in the first nine months of 2011, though it would not give a figure for healthcare profitability.

Linde is scheduled to release 2011 results in March. ■

Sinopec Group says Plans to Double Overseas Equity Oil Output

Sinopec said it aims to more than double its equity oil output from overseas projects to over one million barrels per day (bpd) by 2015 from 2011, the largest Chinese oil company by sales said.

Sinopec International Petroleum Exploration and Production Corp (SIPC), its investment and operation unit for overseas upstream projects, gained 22.88 million tons or 457,600bpd of oil from overseas projects last year, Sinopec Group said.

SIPC will get 27 million tons of equity oil – output it is entitled to according to production sharing contracts – from overseas projects in 2012, Sinopec Group said. As of the end of 2011, SIPC owned 47 overseas projects in 23 countries. ■

Sinofert Buys China Phosphate Mining Firm for $219 Million

Chinese fertilizer producer Sinofert Holdings said it will buy a phosphate mining company for 1.38 billion yuan ($218.72 million), looking to tap abundant phosphate reserves and develop its phosphorus chemical business in southwest China.

Sinofert said it would buy the entire equity interest in Xundian Lomon Phosphorus Chemical, which owns phosphate mines in Yunnan province, in a deal funded by internal resources and bank loans.

The fertilizer maker will buy acquire the company from Sichuan Lomon Corp and Tibet Longsheng Investment Management. ■

Huntsman Acquires Turkish Polyurethanes Systems Company

Huntsman has acquired EMA Kimya Sistemleri Sanayi ve Ticaret, an MDI-based polyurethanes systems house in Istanbul, Turkey. As a result of the deal, EMA will become part of Huntsman's Polyurethanes division and will be known as Huntsman-EMA. EMAs' two major shareholders, Gulum Kabil and Engin Tataroğlu, will continue to manage the business operations of the new venture.

EMA's plant was built in 2006 to produce polyurethane blends for Turkey's fast-growing MDI systems market. Today, the facilities have capacity for system blending, polyester polyols manufacture and bulk MDI and base polyols storage. Financial details of the purchase were not disclosed. ■

Obama Asks Chemical Companies, Other U.S. Firms to Keep Jobs At Home

President Barack Obama recently pressed U.S. business leaders to expand their industries at home rather than outsourcing jobs abroad, extending an election-year push to fight high unemployment.

The White House sees an increasing trend of companies deciding to "insource" jobs and invest in U.S.-based plants and factories, according to a White House official. It wants to encourage more businesses to follow that trend, the official said.

The emphasis on keeping U.S. jobs at home is in line with a populist economic message that Obama has championed that could play well with union workers, whose support the Democratic president will need to win re-election in November.

More than a dozen large and small businesses attended the event, including padlock maker Master Lock, furniture company Lincolnton Furniture, software application developer GalaxE Solutions, and chemicals company DuPont.

The practice of U.S. firms moving jobs to foreign countries such as India and China, where labor is cheaper, is a source of concern to many U.S. workers, especially in the manufacturing sector, which was hit hard by the economic downturn.

Persistently high U.S. unemployment is the top concern of voters in the 2012 election. The White House was encouraged by the December jobs report, which showed a drop in the jobless rate to 8.5 %, its lowest level in nearly three years. ■

Brenntag Says It Made No Mistakes in Silicon Delivery to PIP

German chemical distributor Brenntag said its deliveries of industrial silicon to the now-defunct French breast implant manufacturer PIP were properly executed. "We confirmed in our order acknowledgements the exclusive industrial use of the products (including Personal Care)," the company wrote in a press release. Rather than using comparatively expensive medical-grade silicon, Poly Implant Prothese (PIP) filled its implants with industrial-grade, allegedly saving the company millions of euros. Many of the implants have ripped, causing the possibly carcinogenic substance to leak into the bodies of the affected women. About 300,000 women worldwide are reported to have such implants.

According to Brenntag, customers are provided with safety data sheets and specifications on all necessary information. Inquiries from the French authorities were fully answered in April 2010, the company said. The company said it has since not received any further inquiries, but will continue to cooperate should new information be necessary. ■

Sibur: Weak China Demand Weighs On Chemicals Prices

Sibur, Eastern Europe and Russia's largest petrochemical company, is feeling the pinch from a sharp decline in global prices for its synthetic rubber and polymers, brought about by cautious Chinese customers.

Sibur is more concerned about inventory levels at its Chinese customers than the European debt crisis, the head of Sibur's export organization, Ilya Gushchin, said.

That is even though it channels about two thirds of its exports to Europe and just a quarter to Asia.

"The main factor here is not Europe but China, where monetary policy is being tightened. Companies there are reacting by decreasing their working capital," he said.

It generates almost half of its $6.2 billion in annual sales outside Russia.

"During the last three to four months, (China) has been the main driver behind the drop in global prices," which mostly affected its rubber business but also polymers and some liquid chemicals such as alcohols, Gushchin said.

Russia's Sibur is looking to dispose of ist non-core businesses, which includes tires and fertilizers.

Negative Trend Also in LPG Prices

Sibur mainly refines associated petroleum gas (APG) that emerges as a by-product of Russia's oil industry.

This is sold as fuel for cars in the form of liquefied petroleum gas (LPG) or processed further into synthetic rubber or building blocks for plastics.

"In LPG prices, we also see a negative trend but fortunately it is not so dramatic," Gushchin said.

But the company, which competes with Germany's Lanxess in rubber chemicals, remains confident about its long-term growth prospects and is sticking with its major investment projects.

It is spending $1.8 billion on a polypropylene plant in the western-Siberian town of Tobolsk and is also building a Baltic sea port in Ust-Luga, near Saint-Petersburg, both due to be fully operational in early 2013.

IPO Planned For 2013

Sibur was built on the foundation of the former Soviet petrochemical industry and was recently bought by Leonid Mikhelson, the chief executive of independent gas producer Novatek.

The group's Chief Executive Dmitry Konov told the Reuters Russia Investment summit in September that Sibur's long-planned initial public offering will likely not happen until 2013.

Sibur is banking on Russia's bid to build up a manufacturing sector to reduce its dependence on the energy sector and is also keen to tap one of the country's major unused resources: the wasteful burning of associated gas at oil fields situated far from the state-controlled gas pipeline network. Russia is the world's biggest flarer of associated gas, but in early 2009, the government passed the resolution titled "On the Measures Stimulating Reduction of Atmospheric Pollution by Products of Associated Gas Flaring." The document set a target for 2012 and beyond, limiting flaring levels to only 5% of the entire APG output. Since the beginning of the year, producers are now liable to paying increased fees for excessive flaring. The fees will be hiked by 4.5 times.

"This is one of the cornerstones of our strategy. Governmental regulations are in line with Sibur's strategy in APG processing," Sibur export chief Gushchin said.

Sales Of Non-core Assets

The company also recently announced the sale of its OAO Sibur-Russian Tyres (SRT) to a group of investors including the management of SRT and Vadim Gurinov, former CEO of Russia's largest tire manufacturer. The disposal follows the restructuring of SRT with the sale of two of its non-core plants: OAO Sibur-Volzhskiy, a manufacturer of synthetic fibers, which was acquired by CJSC Gazprom Stroy TEK Salavat and OAO Volzhkiy Nitrogen and Oxygen Plant, which specializes in commercial grade gas production and was sold to the ROEL Group.

"The sale of our non-core assets for the production of tires and fertilizers has been very efficient and we look forward to maintaining a mutually beneficial partnership with the new owners on feedstock supply," CEO Konov said. "The new structure of Sibur will allow us to focus on developing our core petrochemical business of gas processing and the production of polymers, organic synthesis products and synthetic rubbers."

chemanager-online.com/en/tags/sibur

In Oil Boom, Petroleum Engineers Hottest Commodity

While millions of college grads look forlornly into the worst U.S. job market in decades, Emily Woner pretty much guaranteed herself one of America's best-paid post-graduate jobs before she ever set foot on campus. Spurred by an early interest in following her father's footsteps into the oil sector, Woner secured a post-high school internship with Oklahoma City-based Devon Energy Corp.

After summers spent riding seismic trucks in the Barnett shale, designing water pipelines in east Texas and helping model oil reservoirs in Wyoming, she's now a 22-year-old senior at the University of Tulsa waiting to take a job in one the country's most sought-after professions: petroleum engineering.

Energy companies are racing to exploit America's vast shale gas and oil fields, the increasing discoveries of which has upended markets and sparked the biggest drilling boom in generations. While Wall Street slashes the kind of banking and trading positions that were once the most coveted for top graduates, energy firms can't hire fast enough for the technical jobs that have been all but overlooked for a generation.

The shale boom has run into many obstacles: environmental concerns from earthquakes to water safety, a lack of needed materials, and logistical bottlenecks. But the shortage of specialty engineers may prove one of the most vexing. Poaching is rife and supplies are short, putting a premium on industry veterans who know how to get the most value out of wells that can cost tens of millions of dollars to drill.

Oil companies have seen the squeeze coming for years and – to a degree – the job market has responded. Bachelor's degrees in petroleum engineering tripled to over 750 since 2001.

But industry officials and analysts say it is likely still not enough for companies to maintain their ambitious growth in North American shale oil plays, Canada's oil sands, deepwater offshore Brazil, post-war Iraq and other frontiers.

At least 40% of the globe's petroleum engineers are expected to retire in the coming decade, according to top industry recruiters. A generation lost to the 1980s oil bust leaves a thin cadre of mid-career professionals to take up the slack until incoming 20-somethings get up to speed.

Half of the world's energy companies say they will delay projects if they can't get the right people, according to a 2011 Schlumberger Business Consulting survey of 37 global firms.

And competition is fiercer than ever, said Dane Groeneveld, regional director of NES Global Talent, a worldwide oil and gas industry recruiter.

"It's at the front end where you're creating the value and really finding those assets, which really underpin the share price," he said. "It's just at the foundation of the future of the business where you tend to find that people are fighting more tooth and nail for people in that space."

Key To Future Supply

Petroleum engineers seek out oil and gas reservoirs, whether tens of thousands of feet beneath the sea or locked tight in thick shale far underground. They also design methods, equipment and processes to coax as much oil and gas as possible from those unforgiving recesses. Demand has intensified once again as oil firms rush to tap into the vast oil and gas reserves trapped in U.S. shale rocks, a process that requires far more wells than the big-ticket offshore fields that were the mainstay in recent decades.

U.S. shale oil plays – most of which produced almost no oil just a few years ago – now pump nearly one million barrels per day, with potential to jump to three million barrels per day by 2035 as more reservoirs in more plays are found, according to the National Petroleum Council. Canadian production is also booming, while Brazil's offshore output also is poised to surge.

Under Construction

BASF, Sinopec Complete Second Nanjing Phase
BASF and Sinopec inaugurated the $1.4 billion second phase of their integrated petrochemical site in Nanjing, the companies announced. The existing steam cracker has been expanded to a total of 740,000 metric tons per year of ethylene, along with the expansion of the existing ethylene oxide (EO) plant to 330,000 metric tons per year, and the construction of a new EO purification unit with a capacity of 150,000 metric tons per year. New plants in the expanded EO derivatives value chain include a new non-ionic surfactants plant with a capacity of 60,000 metric tons per year; a new amines complex with a capacity of 130,000 metric tons per year for the production of ethanolamines, ethyleneamines, and dimethylethanolamine; and the construction of a new DMA3 plant with a capacity of 25,000 Construction of a superabsorbent polymer (SAP) plant with a capacity of 60,000 metric tons per year will begin in mid-2012. Commercial production is planned for the beginning of 2014. New projects to strengthen the C3 and C4 value chains include the construction of a new acrylic acid facility with a capacity of 160,000 tons per year, a new butyl acrylate plant, as well as a capacity increase at the 2-propyl-heptanol plant.

AkzoNobel Doubles Dimethylether Production
AkzoNobel Industrial Chemicals is to increase dimethylether (DME) production capacity at its Rotterdam/Europoort plant in the Netherlands to 45,000 tons a year. The DME plant in Rotterdam/Europoort, which is capable of producing 20,000 tons a year, opened in the 1990s. The recently announced expansion in capacity will become available in Q4 2012 and is based on existing technology.

Bayer MaterialScience Commissions New Hydrogenation Technical Center
Bayer MaterialScience has commissioned a new technical center for the development of isocyanate production processes at Chempark Dormagen. The research center was erected in just under a year with an investment of €5 million. The state-of-the-art facility is focused on hydrogenation technology for the production of precursors to diphenylmethane diisocyanate (MDI) and toluene diisocyanate (TDI). The researchers plan to concentrate on the further optimization of both process variants at the new technical center. Other focal points will be researching and improving the hydrogenation of dinitrotoluene to obtain toluene diamine, the direct precursor to TDI, and also the Deacon process for the oxidation of hydrogen chloride.

Dow Corning Completes R&D Facility In Belgium
Dow Corning said it has completed its new state-of-the-art research and development facility in Seneffe, Belgium. The Solar Energy Exploration and Development (SEED) center includes a Solar Application Center and a Silicone Synthesis Technology Center. The €9 million addition to Dow Corning's global innovation capacity aims to advance research in new silicon-based materials and solar cell efficiency, the company said in a press release. Installation of lab equipment in the facilities has started, and research activities within the SEED are expected to start in the first half of 2012.

'Best-in-Class' For Vaccine Production

Building Automation System for the Pharmaceutical Industry

Special Requirements – The production of pharmaceutical products requires strict compliance with specified ambient conditions – room temperature, humidity and air quality are decisive factors influencing product quality and process reliability. Since the building automation systems (BAS) must meet very special requirements and increasingly stringent official regulations, conventional "off the peg" solutions are frequently unable to meet these demands.

A maximum degree of reliability and safety: Pharmaceutical production takes place mainly in Category C and D cleanrooms. Consequently, high standards apply for compliance with the specified ambient conditions.

Helmut Schmidt
Siemens, Industrial Automation Systems

Dr.-Ing. Joachim Schillgalies
Stadler + Schaaf Mess- und Regeltechnik

In pharmaceutical production plants, the building infrastructure must meet the highest standards from the initial spatial layout to the carrying out of the construction work and the management system. In biotechnology plants in particular, including those used for vaccine production, these requirements are especially high on account of the staff and material flows within the building. The objective is to ensure product purity at all times. Heating, ventilation and air-conditioning technology (HVAC) ensure controlled conditions around the clock. No errors are permitted in the control, monitoring and the recording and archiving of all production-relevant ambient conditions according to official regulations – a challenge that the building automation system has to be able to meet. Particular focus is on the operation of cleanrooms. These rooms are subject to strict regulations of German and European supervisory authorities, but also to regulations imposed by the U.S. Food and Drug Administration (FDA).

For the operation of cleanrooms, it is not permitted to exceed the limits set for airborne particles and for microbial contamination of air or surfaces. Compliance with the ambient parameters must be certified. As part of this certification process, special guidelines for cleanrooms apply, such as Annex 1 of the EU GMP (Good Manufacturing Practice) guidelines, the "Aseptic Guide" of the FDA, ISO Standards 14644 and 1340-1, as well as the provisions of VDI 2083.

Operation of Biotechnology and Pharmaceutical Plants

A reputable international pharmaceutical company has built a new production plant for vaccines – consisting of warehouse buildings for outgoing products, production building, quality control building and central energy station – at a location in Germany in record time for a European showcase project. The aseptic production has to meet the highest requirements for the sterility of the preparations. Two active viral strains can be processed simultaneously on two production lines within a production operation thanks to a core process that is largely identical. This also ensures that highly complex handling requirements are met: The ventilation and air-conditioning technology has to prevent effectively and with 100 % reliability an exchange of air between the respective cleanroom areas. During the feed in of media and seed viruses via the supply corridor, open- and closed-loop control parameters have to be adapted extensively to the situation in the event that individual HVAC fail.

In addition to reliably detecting and recording dangerous states, the extensive modification of the parameters is an automation control challenge that previously seemed insurmountable, especially taking into account the need for certification. In the certification process, special focus has been paid to the building automation system (BAS), especially with regarding to the handling of "new" pathogens or pathogens whose biological risk is classified as high for the production of vaccines (such as in the case of pandemics or the SARS virus). The BAS must meet the requirements for higher biological safety, by switching from overpressure to underpressure, for example. These challenges were tackled in this project.

The BAS used for the project, which was based on Simatic PCS 7, is designed to meet the criteria as center of excellence for the production of vaccines – not only with regard to the above mentioned requirements. The objective was also to include all of the new plant's buildings, from the production to the warehouse, test laboratories and the connected combined heat and power station, in an integrated system. The client's requirements for the BAS, such as continuity, uniform engineering, advanced control functions and high-performance communication, could only be met with requisite automation and control systems of the highest industrial standard. The Siemens process control system was therefore the first choice of the experts and was able to convince from the start thanks to its excellent integration capability and open interfaces.

Engineering Partner

The project planners searched for a partner that was able to translate the innovative approach into specifications and to further refine this, and who had proven experience in the pharmaceutical sector and with Simatic PCS 7 area in order to be able to even meet the ambitious deadlines set for the project. The decision fell on Stadler + Schaaf Mess- und Regeltechnik, a company whose roots lie less in building automation and more in process automation with more than 25 years' experience ranging from concept to engineering, installation, and service for automation in the process and production industry. Stadler + Schaaf is a certified "Process Control System Simatic PCS 7 Specialist."

Stadler + Schaaf were commissioned with the project's detailed planning, programming, delivery, assembly, cabling and commissioning of the entire building and automation system with measuring and control equipment, approximately 2,700 field devices, 180 control cabinets for Motor Control Center (MCC) and automation components. The BAS is used in various areas: It ensures the required ambient conditions in the laboratories, in the warehouse and in the production facility and is used as management system for the central energy supply.

Electrical energy and heat: Efficient power-heat coupling in the plant's own combined power and heat station ensure a power supply that meets its requirements and can operate independently of the regional power provider in case of emergency.

Combined Heat and Power Station

The central energy station not only supplies the plant with electrical power around the clock, but also supplies steam, compressed air and refrigeration as required. The functioning of the entire plant depends on a reliable supply of media; the sensitive cleanroom conditions, in particular, can only be maintained if the infrastructure is right. Over a dozen sub-plants with separate control systems (package units) such as turbines, generators etc. are connected to the BAS and can thus be centrally monitored and controlled. Two high-availability Simatic S 7-417H automation systems ensure trouble-free operation. An integrated load management prevents peaks when production requirements change.

A graduated concept for starting and shutting down consumers also contributes to maintaining even loads and to an operation that is "gentle" on the machinery. All essential drives are frequency controlled. A special challenge was posed by the implementation of the "Island operation" with which critical areas of the plant can be operated autonomously from the regional power supply, e.g. in the event of a failure in the provider's high-voltage power system, an interruption of the supply to the plant, a transformer breakdown or similar occurrence. The installed M-bus system allows the consumer values of the energy supply to be integrated into the monitoring and visualization of the building automation system.

Validation, Archiving And Maintenance

Since the validation requires proof that all systems that have an influence on the product quality are capable of fulfilling the specified requirements when in operation, this applies also to the BAS. The use of the Siemens process control system make the otherwise laborious official approval process much easier, because this system and the standards implemented in it are already designed for use in production plants that require validation. Accordingly, it can be classified as an already tested standard manufacturer software.

If one calculates the hardware costs alone, the realized solution is admittedly more expensive than others. However, as soon as the project and its life cycle as a whole is considered, it quickly becomes clear that substantial time and cost savings can be reached alone on the basis of the qualifiable interfaces or the central engineering. Simatic PCS 7 also meets future documentation, archiving and maintenance requirements, both from the official authorities and from the user.

As a special element, the building automation system underlines the innovative approach of the client's project team in building the plant. The award granted to this new construction project in one category of the renowned "Facility of the Year Award" shows, for example, that this client's requirements were completely met. The BAS design implemented by Stadler + Schaaf has created a standard that can also be used in other applications. In future, other locations and clients can also profit from the continuity, the uniform monitoring and the uncomplicated qualification of the BAS on the basis of Simatic PCS 7.

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About Sensors And Systems

Global Users Exchange Coming to Europe

Customer Support – From specific technologies and services to comprehensive solutions: A broad family of brands represents the myriad ways Emerson Process Management can support their customers in chemical industries, life sciences, in oil and gas, power, pulp and paper and much more industrial branches. CHEManager Europe's Dr. Volker Oestreich asked Gertjan van der Ven, General Manager Sales & Marketing Germany, about current trends in process automation.

CHEManager Europe: Mr. van der Ven, you've been responsible for Emerson Process Management's sales and marketing for a year now. How do your German customers differ from those from other countries around the world?

G. van der Ven: Most of the German customer base has been around for a long time, and we are seeing very few newly built facilities in Germany. German customers in general have a deep knowledge of technology and have a wealth of experience. As Emerson Germany, we are strongly represented in the chemical industry but less in oil and gas and power compared to other countries. Our portfolio for the power industry for example is very strong and it is one of my goals to make this better known to the major German power players. We also see that the world is getting more global so the differences are becoming smaller and smaller.

In fieldbus communication, Emerson Process Management was committed to Hart and Foundation Fieldbus for years. Nowadays, the company also supports Profibus PA. Is this a response to the German market?

G. van der Ven: We believe the FF-H1 is the best solution for PID Control as their communications are scheduled and synchronized and therefore deterministic. This is not the case with Profibus. DeviceNet/Profibus are better solutions for discretes and drives. Our DeltaV system is specifically designed to support all of these solutions. Our field equipment portfolio has been designed to support most of the protocols. This is a worldwide strategy that for Germany has most effects on the Profibus side.

20mA with and without Hart, fieldbuses, wireless – when does Emerson think the different transfer matrix methods will be ready for use? What does the future hold?

G. van der Ven: Our goal is to provide our users with easy-to-use equipment that provides maximum flexibility, security and availability tailored to specific application and user requirements. New technologies like wireless and our IO on Demand (CHARMS) are specifically designed to give the user maximum flexibility in their IO configuration during project execution. With the CHARMS technology, a user can roughly plan their IO in a certain area and at the latest moment put in the required I/O types and quantities. This late binding provides enormous advantages in dealing with the usual changes in projects. Wireless of course is the most flexible in this perspective and delivers the highest value. We continue to support a wide range of IO systems to serve our customers in extensions to existing plants, upgrades, migrations and building new facilities. Emerson provides all the consultancy services to plan and design complete control and safety systems to all customer requirements.

Process control these days shouldn't just reliably regulate and control the process, rather also play a role in the efficient use of resources – often in conjunction with MES or PLM systems …

G. van der Ven: … Absolutely. Emerson has always offered a wide range of traditional process control equipment with top brands like Rosemount, MicroMotion, Fisher Valves and DeltaV. True value is only delivered if the entire production system is taken into the equation. Emerson has a wide range of layered solutions to offer. Productized solutions that are designed, implemented and services by our worldwide project services teams. With AMS, Emerson has provided tremendous value in the management of field equipment that when rightly integrated in the maintenance regime of plants is a huge contributor to resource optimization and safety. Emerson has integrated most of its MES offerings integrated in the Syncade Platform. Good examples of these can be found in the pharmaceutical and bulk storage industries. The first installations in Germany have been ordered and will be installed in the next few months.

Gertjan van der Ven
General Manager Sale & Marketing Germany, Emerson Process Management

This also means more complexity – which presents new challenges to plant operators. How can the human-machine interface be designed so that the operator has a clear overview? What tasks can be taken over by the control system in order to lighten the operator's load?

G. van der Ven: This is probably the best question you could ask! Today, automation users face twin challenges. The task of building and running a safe, efficient operation is more complex than ever. At the same time, many of the experienced workers needed to deal with such complexity are nearing retirement or simply not available. Emerson understands these challenges and is investing not only to make our products easier to use, but also to make customers' jobs easier to do. This investment includes Emerson's work in applying human centered design to process automation. Understanding customers' roles, tasks, and interactions with others has become part of our product-development culture.

Emerson's Smart Wireless is an excellent example of how the company is using technology to overcome the challenge for running plants – reducing the complexity of adding "eyes and ears" in the process so that maintenance and operations can be more effective.

Recently, Emerson Process announced the first Global Users Exchange in Europe.

G. van der Ven: Yes, and it will be held just in front of our German offices. The three-day event, themed "Exchanging Ideas. Creating Solutions," runs from May 29–31 at the Hotel Maritim in Duesseldorf, close to the airport. We are proud to have this event here in Germany for the very first time.

▶ www.emersonprocess.de

chemanager-online.com/en/tags/automation

First Global Users Exchange in Europe

Bob Sharp
President, Emerson Process Management Europe

Emerson announces the first Global Users Exchange in Europe. Themed "Exchanging Ideas. Creating Solutions," the three-day event will run from May 29–31 at the Hotel Maritim, Duesseldorf, Germany. Tailored to meet the needs of users in Europe, the Middle East and Africa, delegates will learn about best practices and see how colleagues are meeting new regulatory requirements, increasing yields, improving efficiency and reducing costs with enhanced automation.

The event will include workshops, presentations, industry forums, short courses, technology exhibits and product roadmaps. Delegates will be able to choose from themed presentations in English, German and Russian.

"We are delighted to announce the details of the first Global Users Exchange for our many users across Europe and others who will join us from other regions," said Bob Sharp, president, Emerson Process Management Europe. "The Emerson Global Users Exchange is much more than an industry-leading technical conference. It is a community of manufacturing leaders committed to extracting the most from their automation investment and sharing their learning with each other."

The Emerson Global Users Exchange organization is offering users the possibility to share their experiences and expertise with their process automation peers by giving a presentation, workshop or short course at the event. Presenting at the Global Users Exchange provides a unique opportunity for users to showcase their company and its successful operational practices.

▶ www.emersonexchange.org/emea

Petronas in Talks With Oil Majors For Petchem Tie-Up

Petronas is in talks with several global oil majors including Shell and Exxon Mobil to develop petrochemical plants within its $20 billion refinery complex in southern Malaysia, two sources with direct knowledge of the matter said. Malaysia's national oil company is also talking to Japanese firms Itochu Corp and Mitsubishi as well as to Dow Chemical as it seeks to tap surging Asian demand and diversify its earnings, the sources told Reuters.

Petronas is expected to make a decision on the partnerships by mid-2012, which signals it is quickly moving beyond the feasibility stage of the project.

"Petronas is getting a lot of interest for the joint venture undertakings," said one source who declined to be identified as the talks are ongoing.

"They have moved to the basic engineering and design stage and after this the tendering process for building the complex will start," the source added.

Petronas, Shell and Mitsubishi officials in Malaysia declined to comment. Itochu, Dow Chemical and Exxon Mobil were not immediately available to comment.

Petronas first unveiled the Refinery and Petrochemicals Integrated Development (RAPID) project in May and has said the complex will be commissioned by end-2016, which both sources said was on track.

The $20 billion complex is to be built in southern Johor state which borders Singapore – the largest oil trading hub in Asia.

The project is key to Petronas' plan to join the likes of India's Reliance Industries in grabbing a larger share in the $395 billion global market for specialty chemicals – high value raw materials used in products from diapers to higher performance tires and LCD televisions.

"In terms of markets for petrochemicals coming from RAPID, Petronas is aiming for Myanmar, Bangladesh and parts of the subcontinent," said a second source.

"The potential is there as these are huge markets or in the case of Myanmar, just opening up."

Rapid Reach

The RAPID project will include a 300,000 barrel-per-day refinery that produces naphtha, gasoline, jet fuel, diesel and fuel oil.

The first source said the crude feedstock would come mostly from Petronas' equity projects in Sudan, Chad and eventually Venezuela instead of Malaysia's own higher quality and expensive crude, domestic production of which is slowing.

The crude feedstock from Petronas equity projects will also be channeled into the petrochemicals and polymer complex, including a three million tons-per-year naphtha cracker and petrochemical derivatives facility focusing on synthetic rubber.

"Over one million tons will be for ethylene and propylene and the rest for high grade specialty chemicals," said the first source.

"Synthetic rubber is a big thing. Nearly 90 % of a tire is made of synthetic rubber because natural rubber production is declining in Asia, so there is an opportunity for Petronas," the source added.

Struggle Or Survive

The RAPID project gives Petronas' downstream operations a better chance of staying afloat in times of economic downturns and poor margins as it allows Malaysia's only Fortune 500 company to tap into its global feedstock sources, analysts say.

"From a Petronas perspective, there is vertical integration opportunity," said Andrew Wong, lead analyst covering Petronas at Standard & Poor's in Singapore.

"I think the expectation for a recovery in the petrochemical sector in 2011 did not quite happen due to the external factors and there is concern whether the project will come on-stream at a good point in time of the global economic cycle," he added.

Industry players have said Malaysia and Petronas' ramp-up of oil infrastructure in the southernmost tip of the country will create a "Greater Singapore" trading hub that allows the region to keep up with competitors like China.

Petronas is counting on interest from Japanese firms which are looking to relocate their plants or re-invest outside their home base after the March tsunami and earthquake triggered uncertainty over future energy supply, the second source said.

"The interest has particularly been strong from the usual Japanese players in the petrochemical market. This project has started at the right time," the source added. ■

Alternative Feedstocks, Reducing Costs

Strategic Opportunities for Specialty Chemical Plants

Challenges Ahead – This year will bring many challenges and opportunities for the chemical industry. There will be opportunities with alternative feedstocks and challenges to reduce costs while sustaining asset performance in order to capitalize on favorable markets as they occur.

John Gilbert, managing director of a $4 billion line of business for a global chemical company, sees bright spots of opportunity for the customer-centered specialty chemical firms, despite the predicted gloom of global growth slowing to 2.2% this year.

"Overall, there is a confidence and a resurgence for the chemical industry to invest," Gilbert said.

However, due to volatile petrochemical prices in recent months, leading groups in this value-driven sector have been approaching innovation and investment cautiously and this has been having a knock-on effect within the financial markets.

Rethinking Feedstock

According to Gilbert, some chemical groups are radically rethinking their business in terms of feedstock. The boom of shale gas and the quest to commercialize bio-based succinic acid have garnered interest as future petroleum alternatives. The potential rewards from these feedstock alternatives lies in the usefulness of both producing the building blocks for a plethora of secondary chemicals cheaply. More importantly, these alternatives offer long-term, low-cost feedstocks, particularly in North America and Europe.

As specialty chemicals is an asset, intensive industry overall equipment effectiveness is essential and maintenance is critical to the operation.

"In my 26 years in this industry, the challenges to changes in feedstock availability and price as well as labor cost, energy cost, differential rates of economic growth and environmental pressures never change," he said. Fundamentally, what has changed in more than a quarter of a century in the chemical industry is the increased focus on the margin. Each year, I've noticed a new level of competitive intensity that is driving not just the commodity field but fine chemicals, too.

"What is critical these days, in view of long-term sustainability, is to increase production and on-stream time in a plant; while, at the same time, looking for cost-cutting potential and pushing for operational efficiency."

Philip Morel from asset management firm T.A. Cook Consultants has seen the difficulties of putting these profitability strategies into action on a plant which was not organized efficiently.

"One of our clients has a global footprint worldwide in specialty chemicals but was receiving inaccurate data from its new South American site," Morel said. "Our analysis uncovered short-comings in both the planning and scheduling of maintenance jobs. As a result the maintenance technicians worked too often on their own initiative without adequate supervision. Due to the lack of management control and a reporting system this situation was not detected and therefore not being dealt with appropriately."

Any profitability strategy relies on asset availability. Gilbert concured: "When it comes to the bottom line, every second your maintenance can't fix a piece of equipment, and there is no production, you're losing enormous potential. Effective asset management brings dollars to the bottom line."

Taking Control

But what are the areas of influences that can help you strategically control and manage the maintenance process within your factory?

"Asset managers and planned maintenance were unheard of concepts 25 years ago," Gilbert said. "As this is an asset-intensive industry, overall equipment effectiveness is essential and maintenance is critical to the operation. Predictive maintenance was not considered a major drive to profitability a quarter of a century ago."

T.A. Cook Consultants work side-by-side with companies to assess business practices and develop solutions which, when implemented, drive the required behaviors to make sustainable improvements.

"An overall picture begins with an analysis of the maintenance data supplied and the maintenance practices we see," Morel said. "This involves scrutinizing the frequency and quality of maintenance, the gate keeping management and the data collected from the practices of regular planning and scheduling.

In our experience, after an analysis we can help design and implement a stronger structure and a sustainable operation tailored to a client's business needs that will enable them to better manage attainment of their business targets. In the case of our South American assignment we created a 25% increase in efficiency during the execution of maintenance jobs, leading to a reduction of maintenance costs."

Success Through Coaching

"The people involved in planning, scheduling and supervising all needed coaching in properly conducting a management review of the existing reporting," Morel said. "It was a new way for them to look at their own production reporting but they soon saw the value. The client greatly benefitted from T.A. Cook's hands-on guidance during the implementation. Our coaching helped ensure there was proactive management and supervision on the shop floor directing people's activities in the proper direction."

Another challenge to effective asset management is the communication gap between production and maintenance.

"From my experience," Morel said, "it is more common than not to find that the working relationship is one of adversity instead of a relationship of cooperation."

The root cause of the problem is often a conflicting set of priorities between operations and maintenance when deciding how to operate the equipment and how to best look after it. T.A. Cook's approach is to implement best practices and management reporting system through a facilitated series of workshops to have operations and maintenance collectively look at ways of improving this relationship and turn it into a working partnership. With roles and responsibilities established and reinforced through on-the-floor coaching.

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Fortune Oil Declines $2.2 Billion Sinopec/ENN Bid

Fortune Oil, a key shareholder in takeover target China Gas Holdings, will not accept the unsolicited $2.2 billion bid from Sinopec and ENN Energy Holdings, a top executive at Fortune told Reuters.

"We will not sell the stock," Fortune Oil Chief Financial Officer Bill Mok said when asked whether Fortune would consider accepting the HK$3.50 per share bid from China Petroleum & Chemical Corp (Sinopec) and ENN. Fortune's decision was a blow to the Sinopec/ENN consortium's effort to gain control of China Gas after the piped gas distributor said the offer was opportunistic and failed to reflect the fundamental value of the company.

Fortune Oil's sway over the success of the deal was amplified after the London-listed company teamed up with the biggest single shareholder of China Gas Holdings, Liu Minghui. The venture with Liu, a Chinese businessman with experience in the gas distribution industry, and his personal shareholding will emerge as the single largest stakeholder in the target company, Fortune Oil said in a statement.

In December, China Gas hired Macquarie Group to advise on the deal after receiving the HK$3.50 per share cash offer from state energy giant Sinopec and ENN. The potential offer is conditional on more than 50% shareholder acceptance.

Fortune Oil also recently revealed that it had accumulated a 2.15% stake in China Gas, putting it among the company's top shareholders after individual shareholder Liu Minghui and some foreign shareholders such as South Korea's SK Group.

Liu held 8.06% of China Gas at the end of March 2011, China Gas annual report showed.

Buying China Gas would give Sinopec and ENN access to China's largest portfolio of natural gas projects. The company has piped gas operations in 151 cities and more than 100 compressed natural gas stations. Its gross profit in the six months ended September jumped 32% to HK$1.62 billion ($208 million).

China-focused Fortune Oil said the 50/50 joint venture with Liu would tap the boom in the country's gas consumption. The venture will own about 6.7% stake in China Gas as Liu contributed part of his stake, based on Reuters calculation. ■

France's Total in $2.3 Billion U.S. Shale Gas Deal

French oil group Total is plowing $2.3 billion into the development of U.S. shale gas reserves in Ohio in the latest example of global energy companies piling into burgeoning new energy sources. In a deal with Chesapeake Energy, which the U.S. group announced in November without identifying its partners, Total will take a 25% stake in a joint venture covering the Utica Shale area of eastern Ohio.

North America has seen a boom in investment in energy resources such as shale gas in recent years, raising the prospect of the United States reducing its dependence on imported energy. But the process used to access these resources – commonly known as fracking – has become controversial because of environmental concerns.

Under the terms of the deal, Total paid $610 million to Chesapeake and $290 million to a U.S.-based group called EnerVest, the other partner in the venture. Chesapeake will receive another $1.42 billion contribution to drilling and well-completion costs, expected by the end of 2014, it said.

Total, which previously had a joint venture with Chesapeake in the Barnett Shale area in Texas, has said it is looking to boost its position in U.S. shale basins that have crude oil or natural gas with a high liquids content, making them more valuable than dry gas.

Contents of the latest joint venture were disclosed in November, but at the time Chesapeake, the second-biggest U.S. producer of natural gas, did not reveal the identity of its partners.

Chesapeake is an aggressive buyer of land in the new U.S. shale formations, believed to hold massive reserves of natural gas and oil. But its appetite for new property has left the company too debt-laden to pay for drilling and forced it to attract joint venture partners to help fund development costs. ■

Shenzhen Raises Minimum Wages

Shenzhen, a boomtown in China's southern manufacturing hub, will increase the minimum wage by 13.6% in February, the local government said, adding further pressure to exporters who are grappling with falling demand from the West. The wage hike, following rounds of increases over the past few years, came after a series of major strikes at factories across China's export power houses in the Pearl River Delta in recent months, demanding better wages and benefits.

Minimum monthly wage will rise to 1,500 yuan ($240) in the city next to Hong Kong on Feb. 1, the Shenzhen municipal human resources and social security bureau said in a statement on its website.

Some factory owners in Shenzhen expressed disappointment at the decision, saying Chinese authorities have ignored their lobbying for a one-year freeze on plans for wage hikes, the South China Morning Post reported Wednesday.

"We are disappointed at the sudden pay increase, which came at a very inappropriate time and hit badly our confidence in the prospect of the manufacturing sector," Jimmy Kwok Chun-wah, who runs Rambo Chemicals, a petrochemical plant in Shenzhen, was quoted as saying in the newspaper.

China's export-oriented manufacturing industry is already struggling with falling orders amid the eurozone debt crisis and rising labor and raw material costs. The Federation of Hong Kong Industries expects orders to fall between 5–30% in the first half of 2012. ■

Reach

Thought your Reach worries ended in 2010? Think again.

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How to handle global legal obligations.

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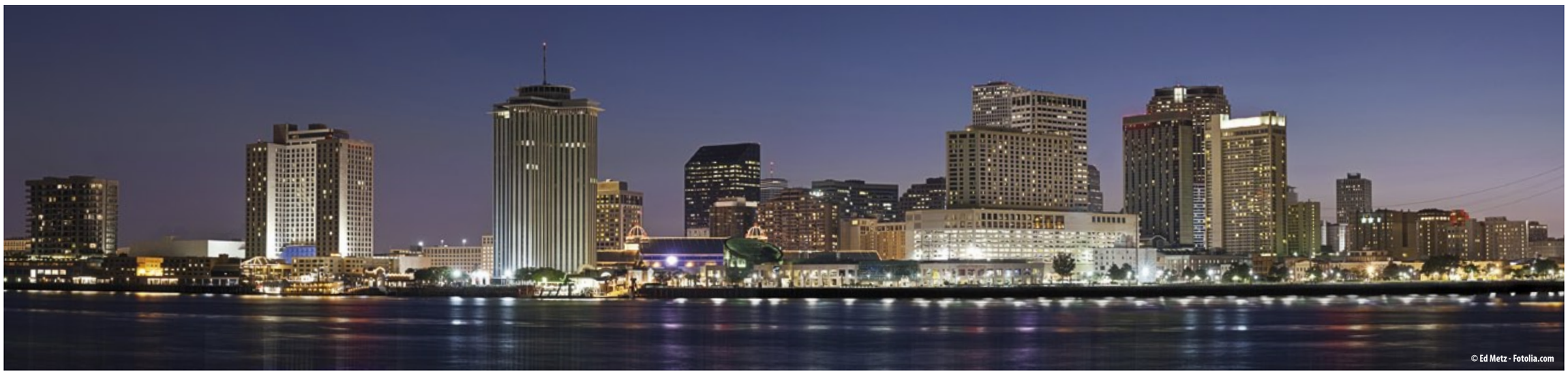

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Informex USA Goes Global

Show to Open Doors with New Name, New Features

New Year, New Name – Like every year, the 2012 trade show season will kick off with the Informex in the States. But this year, a few things will be different: The show is being launched Feb. 14–17 in New Orleans with a new name and new features. What was once known as Informex USA is now being called Informex Global, which organizers say reflects the fact that the event is no-longer limited to the U.S. Brandi Schuster spoke to Caitlin Devlin, UBM's marketing manager for the Informex, about her ambitions for the future of the show, what's new in 2012 and how she sees the competition from the Chemspec USA.

Caitlin Devlin
Marketing Manager, Informex Global

CHEManager Europe: This year's Informex will be in New Orleans for the first time since 2008. What brings the show back to the Big Easy?

C. Devlin: New Orleans has often been called the "spiritual home" of Informex, and we are excited to return for the 2012 event. The event is being hosted in New Orleans as part of our scheduled rotation of the show, which we have expanded. Where it was once a rotating East and West Coast event, we will now offer venues going through the East, Middle and West of the U.S. moving forward. The first step in this expansion was seen last year when we hosted Informex in Charlotte, NC, for the first time. The ultimate goal of the rotation is to offer exhibitors and visitors with access to new markets and to facilitate business relationships in specialty industries across the country.

What are your expectations for the 2012 show?

C. Devlin: We are pleased that Informex Global 2012 is looking very positive and numbers are up across the board. As of early December, we had an 11% increase in attendee registration, 30 new exhibitors and more than 24 countries represented.

Our event program has been tailored to provide a plethora of resources for each unique visitor's needs and will once again kick off with a welcome reception hosted by Dixie Chemical Company. From there, Informex Global will feature a full line-up of both new and returning educational and networking events to complement the exhibition throughout the four days onsite. Particularly, the breakfast briefing format will come back with a new focus on popular buyer markets within the show. And the Speed Networking Sessions, which debuted to exceptional feedback last year, will also return in an expanded format for 2012.

New educational introductions include Tech Talks, hosted by Elsevier, which will feature Informex Global exhibitors highlighting the most cutting edge technologies in the industry. Global quality consortium Rx-360 will also host a new morning session on how to address risks in the supply chain. On the networking side, an invite-only Buyer's Reception has been introduced on Wednesday, Feb. 15, and on Monday, Feb. 14, a culinary walking tour of New Orleans has been added to the line-up as a unique networking opportunity offsite from the event.

The Informex Asia, which was to take place in November, was canceled. What do you consider to be the main hurdles when trying to establish a show in new markets?

C. Devlin: Any time you approach a new market, you are taking a risk. The Informex Asia offering was a very new one for us, and many factors contributed to the cancellation of the event. Overall, as a brand we prefer to take the action of calling off an event if we do not feel that we will be delivering a top-line program to our attendees. We believe that our exhibitors and visitors can appreciate that approach because it shows that we really do have their experience and ROI for each event in mind as our first priority.

Will there be another attempt to launch the show in Asia? What other regions are of interest?

C. Devlin: Of course we are still looking at expanding into the Asia market, as well as other areas across the globe, but it will be key for us to continue researching in order to make strategic event introductions. Each market has different requirements, and it is important to learn how to most effectively work within them. As we move forward, South East Asia has become a prime target because of the strong chemicals market seen there; however, we are still in planning mode and will proceed with caution as we look to expand the brand globally.

The Informex brand is also branching out into conferences, such as the Global Pharma Sourcing in December and Specialty and Performance Chemical Forum. What was the inspiration behind this?

C. Devlin: The Global Pharma Sourcing and Specialty Chemicals Conference are both part of the extended Informex Conference portfolio that was introduced in order to continue to offer educational content across the various sectors throughout the whole year. The introduction of the conference program was based on demand for events that provide players in unique sectors within the wider fine and specialty chemical and pharma industry with a targeted platform to learn and network around focused subject areas. The conferences complement the Informex Global offering and have received positive feedback from attendees to date.

The Global Pharma Sourcing conference topics were similar to ones that can be found at the Pharma Chem-Outsourcing. Are you looking to compete with that show?

C. Devlin: There is bound to be cross over between the various shows and events in the chemical and pharma industries, but we do not introduce events to specifically compete with another event. The Global Pharma Sourcing event was added to the Informex and UBM conference portfolios in order to offer a unique platform for guests to address key issues within the changing global chemical and pharmaceutical markets. It was held in a two day conference format in early December in Philadelphia, Pa., and had an exceptional line-up of top-level players in the industry including SAFC, Eli Lilly, Aptuit, PwC, Teva, Arch and Catalent. The event went very well.

The show is facing competition from Chemspec USA, which will be taking place in Philadelphia in May. Has this had any impact on your exhibitor numbers? Is it possible for both shows to co-exist in the U.S.?

C. Devlin: Based on how Informex Global 2012 has been tracking so far, it is safe to say that we have not had any impact on our numbers. In fact, we are pleased to report that our show is growing. Our registration is tracking solidly and the addition of 30 new exhibitors is encouraging to us as we move into another year of Informex. All markets thrive based on competition, and it is definitely possible for us to co-exist in the same market.

How would you describe the evolution of the Informex brand? In other words, what are your ambitions for the brand?

C. Devlin: Exhibitors and attendees may notice that Informex has had as "soft rebrand" from Informex-USA to Informex Global for 2012. This reflects the event's expansion from serving just the fine and specialty chemicals markets into serving the global chemical marketplace as a whole. It also reflects the fact that this is not a United States only event. Informex Global is a full-scale chemical spectrum event with an ever-increasing amount of global attendees. Our ambitions are simply to tailor each event in the Informex portfolio to what the industry needs and offer exceptional experiences and return on investment to our guests.

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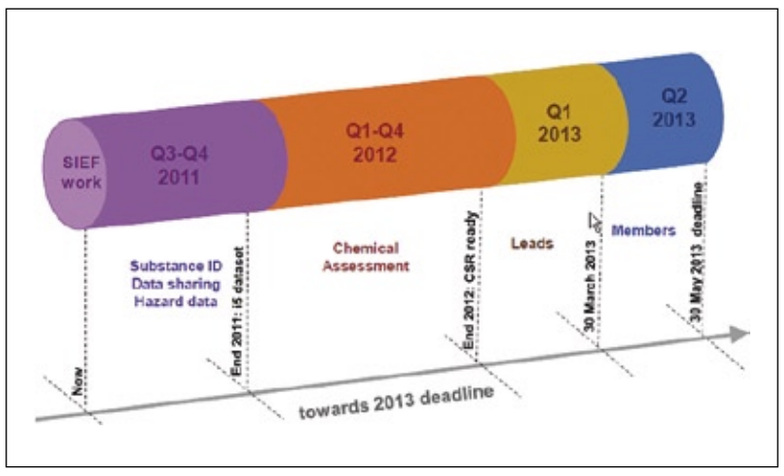
Looking To 2013

What Reach Challenges Can Be Avoided in the Next Registration Wave?

First Round – By Dec. 1, 2010, the European Chemical Agency (ECHA) had received approximately 25,000 registration dossiers for about 4,700 different chemical substances that are produced in or imported into the European Union, mainly in the tonnage band of over 1,000t/y. Furthermore, it received more than 3.1 million notifications from approximately 110,000 different substances where basic classification data were communicated. It has been estimated that this huge effort has cost the European chemical industry already more than €1.2 billion.



The optimal timeline for the upcoming registration (Picture: ECHA (http://echa.europe.eu)

Was this a success? How have the companies managed to get there?

Preparing For Reach:

Four months before the first registration deadline, the EU's Directors' Contact Group on Reach Feedback Advocacy summarized the main difficulties of the process like this:

- SIEF problems
- Completeness of dossiers
- Dependency on the Lead Registrant
- Uses not covered by a registration
- Legal entity change
- Confidentiality of substance name for classification and labeling inventory
- Stability of guidance

For the next registration wave (for substances in the 100–1,000t/y tonnage band), it is very likely that these challenges will occur again if we do not succeed in transferring the experiences of the first wave in an appropriate way. The crucial step for this success is an efficient and streamlined cooperation in the Substance Information Exchange Forum (SIEFs). But to come to this level, each company has to prepare itself according to a number of basic rules to be ready to contribute to the SIEFs:

5 Golden Rules For Basic Reach Preparation:

- 1. Close cooperation through industry associations is strongly recommended as they are aware of all basic aspects of Reach and Classification, Labeling and Packaging (CLP).
- 2. Budgeting is the financial prerequisite for a change. Estimation of costs as a result of Reach and CLP is difficult and continuously changing, but there is good guidance available via Cefic and ECHA as well as through associations and consultancies. Budget adequately and on time.
- 3. Use the full time frame. Concentrate on substances with the highest priority; develop an in-house Reach/CLP strategy; allocate resources accordingly.
- 4. Communication is crucial. Internally, create awareness for all affected departments such as marketing, sales, procurement. Externally, create transparency for your customers and suppliers. For example, create a company-specific homepage for Reach.
- 5. Start on time (and check your schedule regularly.). Adopt your IT/ERP systems and implement the changes in the production process.

Efficient Cooperation In SIEFs:

Which tasks are expected from a SIEF – and which are out of scope?

In Reach legislation there are very clear descriptions of the expected achievements of a SIEF:

- Substance Sameness ("OSOR," one substance, one registration.)
- Classification and labeling
- Data availability – data gap analysis
- Lead registrant (LR) vote
- Regular progress status report
- Joint/separate chemical safety report (CSR)
- Joint dossier submission

The members of a SIEF can freely decide whether or not they will create a consortium, where the more active members are grouped and transfer these obligations accordingly. A consortium is by no means a legal requirement. In practice, it has turned out that the consortium is the most powerful force in the registration process. Where ever applicable, it is strongly recommended that a consortium be created. Here again are some hints to be considered:

- SIEF communication needs to be consistent and efficient.
- Use existing reference documents and contract templates (e.g. CEFIC, other trade associations). Don't re-invent the wheel.
- SIEF management can be done by LR or outsourced to service providers.
- An appropriate SIEF communication platform is the key. Depending on the size of the SIEF, it is sufficient to communicate on just an email-level (avoid cumbersome and expensive IT tools.)

Main Issue: The Costs

The regulation states: "Cost should be transparent, fair and non-discriminatory." This is not very helpful. Nonetheless, the main cost drivers of a working SIEF/Consortium are well known:

- SIEF management
- Preparation of IUCLID dossiers, exposure scenarios, chemical safety reports, risk management measures, etc.
- Generation of invoices, letters of access (LoA), etc.
- Provision for reimbursement (limits should be agreed in the contracts.)

The more transparent the costs and the sooner they are communicated within a SIEF, the less misunderstandings will occur. For active SIEF members and for the LR in particular, some basic rules regarding costs apply:

- Pay only for the data you need (tonnage band, intermediate …).
- Explain the cost sharing system in an easily understandable way.
- Give an early cost-estimate if possible.
- Communicate clearly at which point in time SIEF members will get the data, the LoA, the invoice, etc.

Details should be regulated in the SIEF agreement as mandatory basis for cooperation. Cefic published notes on transparency and fair cost sharing.

What Can Happen During the Cooperation in SIEFs?

Even though the publically available standard contract templates (consortium agreement, SIEF agreement, LoA, etc.) that were prepared by the legal experts of Cefic to cover most scenarios, lots of unpredictable things can happen when SIEFs work together:

- Member opts out and blames the consortium for unfair or discriminatory costs
- Member becomes bankrupt after having signed the SIEF agreement
- Member doesn't communicate CSR-requiring uses due to company owned IP
- Member doesn't handle data confidentially
- Member acts in a non-compliant manner with regard to competition laws

Experience shows that also the LR is not on the safe side:

- LR becomes bankrupt after having agreed his role
- LR does not submit a registration dossier in time
- LR submits his dossier, but subsequently fails technical completeness check
- Legal entity/owner change (also for members)

Not every possible scenario can be regulated. In these cases SIEFs have to decide individually what to do – ideally in a unanimous way.

What Will Be Different in 2013?

On the one hand, the European industry has had a lot of experiences during the first registration wave. Provided these can be communicated effectively to new registrants, the second and third registration waves should be accomplished much more smoothly.

On the other hand, there are clear indications that the upcoming registrations will be more difficult:

- Average number of SIEF members will decrease (fewer companies per substance)
- Expect fewer substances to be handled in consortia
- More small and medium-sized enterprises will require registrations
- SIEF management challenges will become even more important
- Substances are likely to be data poor
- Less experienced LRs will be managing SIEFs

Conclusion

Most of the European chemical manufacturers/importers will be obliged to register their substances in future – many of them for the first time.

The first registration wave in 2010 demonstrated that this process is manageable when a few basic hints are followed:

- Start your registration process now.
- Check if the substance was already registered in 2010 and contact LR/consortium.
- If not registered yet, consider forming consortium/SIEF leadership team.
- Do the necessary basic SIEF steps ASA.
- Use documents and tools available via CEFIC website.
- … and finally: make use of existing experience.

Good luck for 2013!

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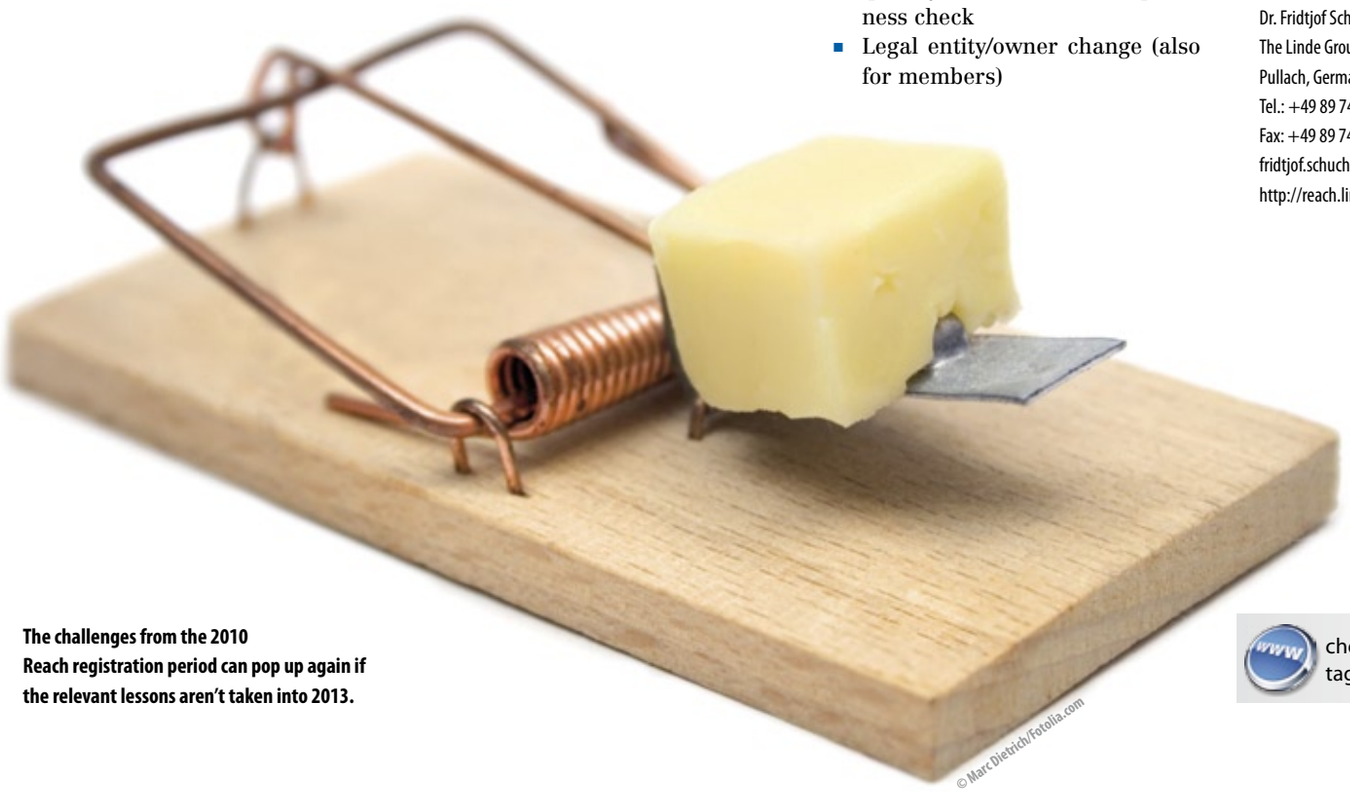

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The challenges from the 2010 Reach registration period can pop up again if the relevant lessons aren't taken into 2013.

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AstraZeneca, Novartis and Sanofi Douse Hopes for New Drugs Three of Europe's biggest drugmakers – AstraZeneca, Novartis and Sanofi – reported product setbacks, underlining the difficulties of developing new medicines to make up for those going off patent.

With the weakest pipeline of its European peers, AstraZeneca was hit hardest by a double blow to treatments for cancer and depression, which triggered $381.5 million in charges and will push 2011 profits to the lower end of its forecast range.

Novartis, meanwhile, faces plunging sales of blood pressure pill Rasilez after patients taking it actually did worse in a clinical trial, and Sanofi's hopes of competing in the new market for oral multiple sclerosis (MS) drugs were dented by failure in a head-to-head study.

While AstraZeneca's and Sanofi's experimental medicines were known to be risky projects, the setback for Rasilez – an established treatment – caught analysts by surprise.

Kepler's Martin Voegtli said the fact there were more adverse events when the Novartis drug was added to standard blood pressure pills was a "major setback" and was likely to lead to the drug being pulled from the market, wiping out an estimated $1.7 billion in peak annual sales.

Novartis Wins Backing in China for Lucentis, Galvus Novartis said eye drug Lucentis and diabetes drug Galvus have won approval in China, giving the Swiss drugmaker a boost in a one of the fastest-growing economies in the world. China's State Food and Drug Administration is backing use of Lucentis in wet age-related macular degeneration (AMD) and Galvus to treat type 2 diabetes as an add-on to metformin, the standard treatment, Novartis said. Novartis is currently scaling back costs to help it protect its bottom-line and profitability as key drugs like blood pressure treatment Diovan lose patent exclusivity. Like most other pharmaceutical companies, Novartis is banking on growing demand from emerging markets to shore up its top line.

U.S. Pharma Pays up for Scarce Assets Drug companies have been forced to pay massive premiums on acquisitions as the selection of target companies with viable prospects narrows and the need to fill out their portfolio of medicines intensifies, industry executives and bankers said at the JPMorgan Healthcare Conference in San Francisco.

"There's always been a steady wave of health care M&A. The only difference now is there is a panicky quality to deals as companies appear to be playing musical chairs and they are grabbing at things to avoid being left alone when the music stops," said an investment banker, who declined to be named because he was not authorized to speak to the media.

Over the past five years, the average takeover premium for biotechnology firms has been 44%, above the average premium across all industries of 26%, according to data from Thomson Reuters. Worldwide, the healthcare industry broadly attracted a higher premium than any other industry over the past two years, the data showed. Last year, the average premium for any health care deal was 35.2%, compared with an average premium of 30.0% across all industries, Thomson Reuters data showed.

Buyers in this industry may need to accept those rates will go higher, even if that means raising the risks as well.

Emerging markets would get more interest as companies need local representation and local branding to succeed in those markets, bankers and executives said. Pfizer Chief Executive Ian Read told investors at the JP Morgan conference that the company would consider small deals in China, India and Turkey if the prices were attractive.

Pfizer Says on Track for Strategic Decisions Pfizer remains on track to decide this year whether to sell or spin off its animal health and nutrition businesses, company Chief Executive Ian Read said. Wall Street analysts have speculated the two businesses together could fetch more than $16 billion, much of which could be funneled back to shareholders in the form of share buybacks and dividend increases. The company's animal health sales jumped 21% to $1.04 billion in the third quarter, boosted by Pfizer's acquisition of King Pharmaceuticals and its Alpharma brands. Sales of nutritional products, such as baby formula and maternity supplements, jumped 31% to $577 million on increased demand, primarily in China and the Middle East. Pfizer named Read last month to the additional post of chairman and approved a new stock-repurchase program for up to $10 billion worth of shares, including $5 billion in buybacks this year. It bought back more than $9 billion in stock last year. Read said the buybacks are warranted because company shares are "undervalued" and do not reflect the worth of Pfizer's pipeline of experimental prescription drugs. He said Pfizer, which paid $67 billion to acquire U.S. rival Wyeth in late 2009, is "disinclined" to make any major acquisitions and instead favors smaller "bolt-on" deals.

Carbogen Amcis Acquires Creapharm Parenterals Carbogen Amcis has acquired Creapharm Parenterals, a subsidiary of France-based Creapharm Group. Creapharm Parenteral, for an undisclosed sum. The company has been renamed Carbogen Amcis SAS. According to a press release, the acquisition will extend Carbogen Amcis' range of development and manufacturing services by adding complementary formulation, lyophilisation services and sterile GMP capabilities for the rapid supply of drug products, including highly potents for preclinical studies and clinical trials.

Teva Looks to Asian Expansion Israeli generics giant Teva said has announced plans to extend its footprint into Asia, a market where generic use is expected to increase rapidly over the coming years. Specifically, the company is examining markets in China, India, Vietnam, Korea and the Philippines.

"The key is very local businesses," Teva CFO Eyal Desheh said at the JP Morgan Global Healthcare Conference in San Francisco. "There won't be deals the size of Cephalon, Ratiopharm and Barr, but it's possible to expect smaller acquisitions and acquisitions of products." Like most pharma companies, Teva will also be affected by the looming patent cliff: Its patent for the multiple sclerosis blockbuster Copaxone is set to expire in May 2014. The company is also looking to expand its branded business to compensate for the expiration.

Genuine And Safe

Combating Counterfeiting In Pharmaceuticals

The War Continues – The European Union's Falsified Medicines directive, ratified in 2011, was arguably the most significant landmark to date in the war on fake drugs. The law will require (from around 2016) a traceable safety feature and tamper evident closure on almost all prescription medical products sold in the EU. Mark Davison, CEO of Blue Sphere Health, examines some of the approaches his customers are using to comply with the directive and other legal obligations around the world.

Mark Davison
CEO, Blue Sphere Health

The Big Picture: Safe and Authentic Medicines

Discussion of the impact of new legal initiatives in the EU, U.S., Argentina, Brazil, China, India and elsewhere has tended to focus on digital issues: the codes, readers and databases that will be needed for traceability. Less attention has been paid to the physical authentication of the package and product. A successful anti-counterfeiting strategy should incorporate both coding and physical verification in an integrated approach. Blue Sphere Health spends a lot of time helping drug and medical device companies to develop product security approaches that are appropriate to their specific risk profile, manufacturing environment, budget and legal obligations.

Strategy

Anti-counterfeiting should be a planned and ongoing activity driven by top executives, not a reactive tactical response by low-level managers to each reported incident. By treating counterfeiting like any other corporate risk and taking appropriate mitigating precautions, best-in-class corporations are reducing their liability and minimizing their total cost of ownership of product security technologies. Modifications to manufacturing equipment and production processes – necessary for serialization and ePedigree – are complex and time-consuming. These activities need the collaboration of many departments. Mistakes can be very costly so planning is vital – as the old carpenter's saying goes, "measure twice and cut once."

Digital Traceability

Uniquely coded (serialized) packs are a central component of many national and regional security systems for pharmaceuticals and healthcare products. The theory is that by identifying and tracing each pack in the supply chain, we remove the opportunity for counterfeiters to insert large quantities of illicit goods undetected into the legitimate commercial channels since the improperly coded products will be rapidly detected. The data format that has been chosen for most of these systems is the globally compatible GS1 numbering system. Interoperability between different systems is the key to the effectiveness of serialization, so common standards are critical. After a few false starts, this seems now to have been achieved.

Creating and printing a unique number for each of the billions of individual packs of medicines which circulate in the global supply chain creates practical challenges. To avoid time-consuming and error-prone manual input, machine-readable codes are strongly preferred. However, the linear bar codes familiar from retail environments are not suited to the task as they need to be impracticably large to encode the necessary information – many packs simply do not have sufficient space. The most cost-effective carrier is the data matrix, a two-dimensional code with a much higher data capacity per unit area than a standard barcode. These are cheap and relatively easy to print (although initial technical issues need to be solved) but many existing laser-based bar code scanners cannot read data matrix codes. Some pharmacies will therefore need to upgrade their point-of-sale equipment to camera-based readers which can handle both linear and 2D codes.

> *"Anti-counterfeiting should be a planned and ongoing activity driven by top executives, not a reactive tactical response by low-level managers to each reported incident."*

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Coding and verifying every drug pack will be complex and will certainly add some costs, although these have frequently been exaggerated. Traceability on its own it will not prevent counterfeiting but it will be a large step towards a more secure supply chain.

Tamper-Evident Closure

Another key security enhancement proposed by the directive is the requirement for sealed packs, to discourage removal or replacement of the product on its journey from manufacturer to patient. Authorized repackagers, such as international distributors, must replace the original packaging with an equivalent, securely closed box or container. In the European supply chain, where unit-of-use formats such as blister packs are more common, this relatively simple action of sealing packs is an effective deterrent. In some other countries, most notably the U.S., this measure may not be as useful as medicines are typically manufactured and transported in bulk and then dispensed into smaller containers by the pharmacist. The types of secure closure commonly used include: glued and perforated end flaps, adhesive seals, shrink wrap and tear tape. Vials and bottles can be protected with snap-off caps, induction seals etc. All of these technologies are designed to be single use (tamper-evident) rather than impregnable (tamper-proof) so that they are easy to remove but hard to replace.

Physical Authentication

Anti-counterfeiting technologies that give a yes-no answer to the question "Is this pack genuine or not?" are very useful. These may be visible features such as colorshift inks and holograms or covert features such as micro and nano structures, chemical markers and taggants. Serial numbers and codes – the key components of digital traceability – are easily duplicated so having another authentication feature which is difficult to copy is a wise safeguard. These features can even be incorporated into the code printing step to give a "one-pass" solution with multiple layers of security.

Processes

Many companies have focused on technology "solutions" to their anti-counterfeiting needs, but the improvement or elimination of insecure processes should not be overlooked. Security is only as strong as the weakest link. Look for data disconnects and local "workarounds." Often, local managers solve local problems without realizing that they may be introducing system vulnerabilities. Gap analysis projects for large companies have uncovered some surprising vulnerabilities in their handling of sensitive traceability and anti-counterfeiting information.

Conclusions

Anti-counterfeiting is an ongoing process, not a discrete project. Individual elements have compliance deadlines but the overall mindset needs to be one of continuous vigilance. By addressing strategy, processes, physical security and digital traceability in a planned and integrated way, drug companies can reap genuine business benefits from new legal obligations, as well as playing their part in keeping patients safe. We are all customers for the pharmaceutical industry at some time in our lives, so we owe it to ourselves to ensure that medicines continue to be genuine and safe.

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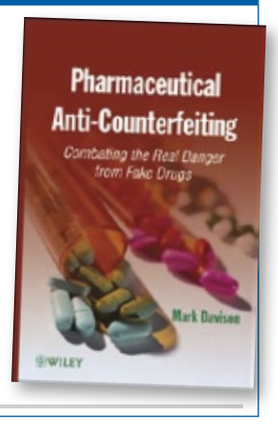
Win a Copy of Mark Davison's Book!

"Pharmaceutical Anti-Counterfeiting" covers the key concepts and explains the available options in pharmaceutical anti-counterfeiting including a mix of policy, strategy, tactics and practical implementation tips. A must-read for those determined to do something about counterfeit pharmaceutical and healthcare products, and will prove useful to brand protection professionals in other industries. To register to win a free copy, send an email with your business mailing address to CHEManager-Europe@gitverlag.com by Monday, Feb. 27!



See page 15 for more on the book.

Is It Worth It?

Cost Considerations of Switching API Sources

Costs of Switching – Competitive bidding has historically been used to reduce the cost of purchased materials. In the case of active pharmaceutical ingredients, it is not always clear that lower ingredient prices will generate a satisfactory return on the effort to qualify an additional source of supply. Steven Harvey of PL Developments examines the costs of a switch.

Steven Harvey
Strategic Sourcing Manager,
PL Developments

Drivers And Impediments

There is more than one reason to change or add new API suppliers. Drivers of change may include quality or performance improvements, better assurance of GMP and regulatory compliance, increase reliability of supply or to reduce costs, lead time and/or working capital.

On the other hand, there are several impediments to changing or adding new API sources. Whenever making a change from one source to another, pharmaceutical regulations require a stringent process be undertaken to qualify the new source. This process must be repeated in part for each product form or SKU utilizing that ingredient. This effort may involve additional opportunity costs if resources are borrowed from other value adding activities to carry it out. The benefits from the change must justify the cost.

The change effort requires resources. Research and development; quality control; quality assurance; production; and purchasing all play key roles in qualifying ingredient sources. In this case, "source" means the actual manufacturer of the API. But how do we estimate the cost of applying the necessary resources? Traditional financial accounting does not routinely quantify and report such costs of supplier qualification by ingredient.

Estimating Costs

One approach well-suited for estimating costs not tracked by traditional account is activity-based costing. The approach works like this: 1. Determine the activities that drive work for each cost center; 2. interview the people who do the work or supervise it and estimate resource requirements; and 3. convert man-hours to cost and total the costs by activity.

For example, key activities for research and development will involve clarifying ingredient specifications, requesting and testing preliminary samples, requisitioning and testing larger quantities in process characterization batches and production trials, assisting in validation runs and setting up stability testing. Purchasing will assist R&D in the early stages by identifying potential sources and prescreening based on information collected from published sources, requests for information and meetings with suppliers.

Quality Control must develop any needed analytical procedures, test pre-formulation lots from R&D, approve protocols for the testing of process characterization runs, validate test methods for validation lots, set up protocol for product stability testing, package samples and initiate testing, monitor all and report on findings. Quality assurance will likely send out questionnaires to the new source to survey them on their manufacturing and quality processes, review the responses and prescreen (eliminate) sources that are suspect. Next, QA will conduct a physical Q7A audit of the manufacturing site and related support activities/infrastructure.

Assuming a potential source passes initial hurdles, material is purchased for validation trials (normally three separate lots), those trials are conducted in production, the results analyzed and product produced is packaged for stability testing. After successful stability results, purchasing will negotiate a supply agreement, QA will negotiate a quality agreement, finance will accredit the supplier and the process will be complete.

Total Cost

The total cost will vary by technical complexity of the ingredient, the cost of the ingredient, the process used to produce it, the number of SKUs that incorporate the API, by the cost per kilogramn of the API and by the location of the manufacturer relative to the buyer. Typically, the costs of the R&D and quality control efforts make up 60% or more of the total qualification effort, followed by validation and quality assurance activities. Costs of purchasing effort are normally less and the finance effort is minimal, relatively speaking.

In PL Developments' experience, (experience of a private label pharmaceutical manufacturer), costs of switching API sources generally ranges from $50,000 to $500,000. Abbreviated new drug application (ANDA) drugs tend to fall at the high end and monograph products in the middle to lower end of the cost range. Excipient sources can normally be qualified at less expense that APIs. However, it is difficult to generalize. Each project is different.

If the objective is to improve quality or assure supply reliability, then qualification efforts may be a necessity. If the objective of switching is to reduce costs, then the savings need to justify the effort and generate a suitable return on resource investment.

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Up In Smoke

What Pharma Can Learn from the Tobacco Industry

Billion-Dollar Industry – The illicit trade in counterfeit pharmaceuticals is worth an estimated $200 billion a year and has obvious implications for public health. A range of anti-counterfeiting measures are currently underway or under consideration. These measures include, at country level, reimbursement initiatives, e-pedigree and covert authentication, and, at EU level, co-operation agreements and the directive on Falsified Medicines.

For pharmaceutical companies, combating counterfeiting is a complex issue, and the coexistence of different approaches by governments and private companies can compound that complexity. As countries and regions move at different speeds with different solutions, manufacturers have to adapt supply chains to cope, losing operational efficiency and agility.

In addition, some of the approaches have unanticipated side effects – for example, if governments mandate particular technology solutions, they may create a de facto monopoly for the technology providers.

Why Consider Tobacco?

To resolve the complexities facing the pharmaceutical industry in dealing with counterfeiting, it can be helpful to compare the experience of other industries that face comparable issues. These include the logging and beverage industries, but in this article we'll focus on the tobacco industry, where we estimate that anti-counterfeiting is up to five years ahead of pharma.

Though counterfeiting takes a slightly different form in the tobacco industry (with smuggling being an important factor), it faces many of the same complexities as pharma. For example, there are once again conflicting pressures in tackling illicit trade: the Framework Convention on Tobacco Control, EU agreements and individual countries' legislation all make different and sometimes contradictory demands.

10 Lessons the Pharma Industry Can Learn from Tobacco

Given the similarity of the challenge, there are salutary and highly relevant lessons to be learned from the tobacco industry's experience. Here are 10 of the most important:

- 1 Focus on the problem, not the technology. Too many proposed solutions are "technology push," not "problem pull." Invariably, these miss the mark and require additional complexity and cost that do not add value.
- 2 Formulate a strategy early on. Decide whether your organization should be a leader, a fast-follower or a late adopter. What resources are you going to apply? Is there competitive advantage to be had?
- 3 Find industry-wide solutions for industry-wide problems. Initiatives from industry bodies and joined-up responses from the industry are much more powerful than anything that an individual company can do.
- 4 Balance policy, enforcement and technology. The most successful solutions put in place so far have come from enhanced policy and increased enforcement supplemented by technology. For example, California's tax stamp implementation increased tax revenues by around $150 million: This achievement is attributable to increased enforcement and duty levels in addition to technology which enabled the enforcers to detect illicit trade and provided evidence for prosecution.
- 5 Make sure the industry gets involved. In tobacco, the industry is perceived as part of the problem, but manufacturers have the best visibility of the legitimate supply chain and therefore the best intelligence as to what is going on. They have to be part of the solution.
- 6 Realize that denial is not an option. Tobacco companies denied that there was a problem for years and as a result had the World Health Organization's Framework Convention on Tobacco Control (FCTC) forced on them. Denial effectively lost them a place at the table.
- 7 Standardize, standardize, standardize. When you have to deal with multiple countries, multiple sectors and multiple companies, it becomes vital to standardize interfaces, systems, coding technologies, and so on in order to manage complexity and cost. Consider a factory that sources product for 10 different countries. If each country legislates differently, that factory has 10 times the complexity of manufacture, unless standards for printing, line systems and so on are put in place.
- 8 Create a portfolio of solutions. Each country has a different mix of issues and therefore some solutions are more suited for some countries than others. For example, increased enforcement and border control might work best in Africa, whereas in Western Europe high-tech track and trace systems can be preferable. Companies need to create not just one set of solutions but a portfolio from which they can select the most appropriate combination for each situation.
- 9 Know what success looks like. Particularly in negotiations with governments, it is vital to be able to demonstrate return on investment. For anti-illicit trade measures, however, it is typically extremely difficult to prove that a given change has had the intended effect. There is no agreed metric or methodology for counting counterfeits.
- 10 Collaborate with the public sector. The public sector can supply regulation and enforcement muscle provided the right commitment is there (which it should be, given the harm illicit trade does to the global economy and population). The private sector will bear the brunt of any implementation, however, and so it must involve itself actively in the debate about what should be implemented.

Cross-industry Influences Are Already Affecting the Pharmaceutical Sector

Activities in the tobacco world are starting to spill over into other sectors. For example:

- Turkey has a system for tracking and tracing cigarettes, spirits and beer; it has now launched a similar system for pharmaceutical products.
- Albania launched a tender for a track and trace system, not only for cigarettes and spirits but also for pharmaceutical products.
- Morocco has implemented a security marking system for all beer, soft drinks, mineral water, alcohol and tobacco products.
- A couple of years after implementing security product marking for tobacco, Brazil introduced a requirement for medical products, too, to be marked with a unique serial number to allow track and trace.

These Cross-industry Currents May Strengthen

Given the FDA's ownership of both tobacco and pharmaceutical regulation, we can expect to see accelerating crossover between the two industries driven from the U.S. In the EU, there is a clearer separation between, for example, the tobacco and pharma regulation. Even so, health officials are part of the European negotiating team for the FCTC, and it is inevitable that the thinking and rationale from one sector will slip into another in Europe.

The pharma industry could in future face some onerous conditions copied from tobacco regulation, such as global track and trace, which could require manufacturers to uniquely identify packs of drugs and mandate scanning at each point of transfer in the supply chain. Other possibilities include licensing of manufacturing equipment, prohibition of internet sales of products and equipment, and "know your customer" provisions. Governments may pass the cost of implementing measures like these on to the industry.

The tobacco industry experience repays study, then, and not only to help formulate anti-counterfeiting strategy: given the cross-over trends, pharma companies may soon find themselves subject to some of the same anti-counterfeiting policies as tobacco companies.

If pharma adopts a "wait-and-see" approach, as the tobacco industry did, governments are likely to impose technology solutions that companies do not want, and will find punitively expensive. The pharma industry, and individual pharma companies, need to formulate a coherent global strategy, and then seize the initiative.

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Capacity Expansion

Evonik's Dr. Klaus Stingl on the Growth of Highly Potent APIs

Pacesetter – Evonik recently made news when it opened its laboratory for highly potent APIs (HPAPIs) in Hanau, Germany while expanding its cGMP capacities for these ingredients to kilogram-scale production at its Tippecanoe site in Indiana. The new lab enables the company to develop and optimize syntheses for HPAPIs in Germany. Also, the capacity expansion gives Evonik access to a total reactor volume for HPAPIs of 170 m^3. This breaks down to about 135 m^3 for production of HPAPIs in ton-scale and about 35 m^3 for production of small quantities. "This allows us to cover the entire spectrum of HPAPI production, from clinical phases through commercialization," said Dr. Klaus Stingl, manager of Exclusive Synthesis within Evonik's new Health Care business line. CHEManager Europe spoke to him about the growing trend of HPAPIs.

Why did Evonik establish an HPAPI lab in Hanau and decide to expand the capacity in Lafayette?

Dr. K. Stingl: The acquisition of the Tippecanoe Laboratories site in Lafayette, Indiana, USA, in 2010 gave Evonik a leading position in the cGMP manufacturing of HPAPIs. As demand for this capability is increasing, Evonik recognized the need for further investment in this area in order to serve customers at all stages of the HPAPI life cycle, from development to commercial production. Our investment in HPAPI pilot plant capacity at our Tippecanoe site complements our commercial scale manufacturing and allows us to provide customers with initial small volume quantities for clinical trial application. Our new HPAPI Process Research and Development center in Hanau, Germany, is a resource dedicated to the development and optimization of HPAPI chemical processes.

What are the main reasons for the growing demand for HPAPIs?

Dr. K. Stingl: The pharmaceutical industry is continuing to develop more specialized and targeted compounds with strong therapeutic effects, e.g. in the oncology space. These compounds are becoming increasingly potent, or have other effects at very low concentrations, which necessitate a specialized manufacturing capability. The successful handling of HPAPI compounds requires a proven expertise across all key production functions to protect employees, the environment, and product quality.

Dr. Klaus Stingl
Manager Exclusive Synthesis Health Care business line, Evonik

What growth for HPAPIs do you expect for the coming years? Do you see differences between NAFTA, EU and Asia?

Dr. K. Stingl: As the understanding of the underlying causes of diseases improves, specially designed pharmaceuticals will be increasingly able to treat diseases at lower doses. This will result in a growing global market for HPAPIs. In NAFTA and EU we forecast HPAPI growth for innovative originator products, while in Asia we predict significant growth for generic HPAPIs.

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EU Agency Issues Guideline on Biosimilar MS Drugs

European regulators took another step towards opening the market for copies of biotech drugs on by releasing a draft guideline on how companies should test biosimilar medicines containing interferon beta, used to treat multiple sclerosis. The guideline is open for consultation until the end of May 2012 and is part of a package of new regulations being prepared by the London-based agency.

Guido Rasi, the organization's new executive director, told Reuters on Jan. 6 the watchdog would issue its final guideline on biosimilar monoclonal antibodies — the biggest category of biotech medicines — in March or April.

Leading multiple sclerosis (MS) drugs containing interferon beta include Merck KGaA's Rebif and Biogen Idec's Avonex.

Under the guideline, companies wishing to copy such drugs would have to carry out a one-year clinical study and use magnetic resonance imaging (MRI) look at lesions in patients.

Up to now, complex biotechnology medicines, which are given by injection, have been largely immune from generic competition, unlike conventional chemical pills and capsules. But the regulatory landscape is starting to change, posing a threat to leading biotech groups like Roche and Amgen, as well as makers of MS drugs and suppliers of insulin, such as Novo Nordisk. ■

Illinois Tool Works Acquires AppliChem

Illinois Tool Works (ITW) has acquired AppliChem, a German based chemical company with particular focus on fine chemicals and biochemical products for laboratory, pharmaceutical, cosmetic and food industries. Founded in 1992 and lead by Dr. Frasch and Dr. Oeler, AppliChem has its production facility in Darmstadt, Germany, with some 130 employees. The company exports 50% of its products to 70 countries all over the world.

"AppliChem is going to play key role in the development of value-added chemicals, reagents and life science products. This process began in 2010 with the acquisition of Panreac Quimica SLU and Nova Chimica Srl" said Joan Roget, Panreac's general manager.

AppliChem will become part of ITW Performance Polymers & Fluids and will be integrated strategically into the business platform led by Panreac Quimica SLU. The former owners and CEOs Dr. Frasch and Dr. Oeler will continue their management activities. ■

Interoperability in the Pharma Supply Chain

Should Regulations Dictate Technology?

Framework – When asked, most people say that they believe regulations should avoid dictating specific technologies but instead should dictate desired outcomes and let industry figure out the best technologies to achieve them. The concern is usually that technologies mandated in regulations will inevitably grow old and the regulated industry would then be blocked from taking advantage of newer, more innovative technologies. This is often true, but whenever interoperability is necessary to achieve the desired outcomes, a supply chain may benefit by having certain technologies dictated by the regulation.

Movement by the industry in unison is the real benefit of carefully mandating a single technology for identifying drugs in the supply chain.

What is 'Interoperability'?

Interoperability is a system characteristic that means the system is able to work effortlessly with other systems. In a supply chain context, it means that systems owned by each trading partner are able to communicate with and understand each other and can then work together to do something useful. Interoperability is a highly desirable characteristic but it requires all trading partners to agree on a single approach to communications protocols, data format and content. Typically, interoperability is achieved through the enforced use of standards. The question is who enforces the use of the standards that result in interoperability?

In the automotive and aircraft manufacturing supply chains these standards are dictated by the small number of large manufacturers – the "800 pound gorillas." Suppliers who wish to participate in those supply chains must voluntarily conform in order to have access to those markets.

Traceability Regulations in the Pharma Supply Chain

Drug traceability regulations of one form or another are under consideration by governments around the world to fight supply chain crimes such as counterfeiting, diversion, tampering, theft and reimbursement fraud. Countries like Turkey, Korea, India, Italy and Brazil are among a growing list of countries that have enacted such regulations.

At a high level, all drug traceability regulations share at least one characteristic: They require two or more members of the drug supply chain to contribute data that describes their connection with each drug. That can include information about its manufacture, distribution and dispensing. This information must be understandable to parties inside and outside the supply chain, and the data contributed by each party must be interoperable with the data contributed by the others. To be interoperable, every party must follow the same standards for formatting, storing and sharing this data. But in the pharma supply chain, who enforces the use of those standards?

The U.S. FDA Bar Code Regulation

Back in 2004, the FDA published their final bar code rule that required all prescription drugs distributed in the U.S. to have a linear barcode at the unit level to carry the National Drug Code (NDC). The final rule took effect in 2006. That rule did not specify a particular linear symbology, only that the barcode had to be linear.

The members of the U.S. pharma supply chain benefitted from the fact that the regulation dictated linear bar code technology. That prevented manufacturers from each selecting a different technology to carry the NDC, thus allowing downstream supply chain members to invest in a single reader technology and establish a single operating process to read the NDC. That is, by enforcing this one technology standard the FDA ensured efficient interoperability.

Other Examples

Electronic Data Interchange (EDI) is an example of a supply chain technology that requires interoperability as a characteristic. But here the interoperability is only necessary between two direct trading partners, since EDI documents do not get passed beyond the initial recipient. The files they exchange can be said to be interoperable as long as those two parties agree on the data elements to be included and their formatting. Because these are point-to-point data exchanges between no more than two parties, no regulatory mandate is necessary or desirable.

Electronic pedigrees and generalized supply chain track and trace systems like those under consideration in the U.S. and E.U. pharma supply chains are a lot like the example of the NDC data carrier discussed in our first example above. They only work if they are fully interoperable throughout the entire supply chain. In this case the use of standards is imperative and if they enact any laws at all, here is where the regulations should mandate the specific technical standards and ePedigree or track and trace model that must be used within a given jurisdiction.

Without such a mandate in the pharma supply chain – which does not have any "800 pound gorillas" who can force alignment – the members are unlikely to voluntarily agree on a single approach and interoperability will not occur naturally. But with a regulatory mandate of the technology and the specific model the supply chain would benefit from the efficiencies that result from assured interoperability, just like the FDA's 2004 linear barcode mandate.

Time for a New Carrier Technology Mandate?

Today the U.S. FDA is considering revising their original bar code rule to allow other technologies to carry the NDC and perhaps the Standardized Numeric Identifier (SNI) that they defined, but did not mandate, in 2010. The SNI Guidance defined how to combine a 10-digit NDC with a serial number. The FDA's guidance noted that the SNI can be rendered within a GS1 Serialized Global Trade Item Number (GTIN), or SGTIN. Technically, an SGTIN can be carried within a linear bar code but because an SNI can reach to as many as 40 characters, a 2D bar code or an RFID tag are better suited.

So, just as it did with the NDC in a linear barcode in 2004, to ensure continued efficient interoperability the FDA should now select a logical new carrier technology and mandate it for the SNI, giving manufacturers at least two years to deploy the necessary system changes. But once the new carrier technology mandate goes into effect, every manufacturer must be required to use the same, single carrier technology on all saleable units. That way the downstream supply chain organizations can once again invest in a single technology to read the SNI and perhaps the lot and expiration date (if so mandated now or in the future).

Moving In Unison

As these examples show, it is the movement by the industry in unison that is the real benefit of carefully mandating a single technology for identifying drugs in the supply chain. The mandate is the key to maintaining and even improving supply chain efficiencies. The mandate provides the assurance of interoperability to all members of the supply chain.

Does it stifle innovation? Yes, but it does it in a way that allows the most efficient changeover by members of the supply chain to each new innovation, which actually leads to more benefits than allowing any company to make use of any innovative supply chain technology at any time. This works as long as the regulatory body is willing to periodically work with the industry to determine if it is time to switch to a better technology, as the U.S. FDA is doing right now in the bar code example.

No one likes to be regulated, but whenever supply chain-wide interoperability is necessary to achieve something desirable, a well-designed technology mandate can help everyone.

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Pharma Asks the Money Question Earlier for New Drugs

GlaxoSmithKline executive German Pasteris is in charge of an Alzheimer's treatment that is years from reaching the market, if it ever does. But he already wants to make sure the global healthcare system will pay for it.

Pasteris is one of 25 executives appointed last year to shepherd the British drugmaker's experimental medicines. He consults insurance companies and former officials from national health agencies about the Alzheimer's drug on the best way to show its value to patients.

In the past, that meant proving that a drug worked, and did so safely, so that health regulators would approve it. But as governments in the United States and Europe look to slash spending and avert a debt crisis, Glaxo and its rivals want to make sure their medicines are a must-have for patients.

To do it, they are seeking input from the people who hold the purse strings earlier than ever in the clinical research process, in some cases five years or more before regulators would even look at a product, executives told Reuters.

"The ultimate goal was not optimal reimbursement and access," Pasteris said. "Today it is."

These views are shaping more clinical trials, such as which products to test against and study goals to pursue. And that's having major ramifications for the business of Big Pharma.

"If you're going to go out there with a drug that you don't know whether it's better than what's out there, what are you trying to do? Who are we all trying to kid?" said Angus Russell, CEO of British drugmaker Shire. His company has more than doubled its "pharmaco-economic" staff focusing on the value of medicine in the past few years.

Pharmaceutical investors are also a huge source of pressure, with little forgiveness on Wall Street when it comes to medicines that cost hundreds of millions of dollars to develop, but do not get widely used once they reach the market.

Even smaller players are changing their ways.

Ron Cohen, CEO of Acorda Therapeutics, regrets not consulting insurers early about its Ampyra, the first drug to help multiple sclerosis patients walk better.

Now, Acorda plans to hold discussions with health insurers once products reach mid-stage development and is getting informal input earlier – including for a potential multiple sclerosis treatment yet to enter human testing.

"I have no question that the entire industry is moving toward this sort of model," Cohen said.

As drug manufacturers invite marketing input earlier than before, some fear they risk the very innovation that leads to landmark new medicines.

Industry experts point to advances that took time to prove their worth or worry that drugmakers may abandon categories where "good enough" medicines already exist, like depression, partly because it's not worth the economic risk.

Glaxo, which brought antidepressants Paxil and Wellbutrin to market, is one company to pull away from the field. Atul Pande, who leads Glaxo's neuroscience research, says the science has not advanced enough to identify new ways to significantly improve treatment, but he acknowledged the reimbursement fears.

Closer Ties

The drug industry has been sharply criticized for launching expensive new medicines that proved only slightly better than their predecessors. Health insurers and government agencies pushed back, and now drug companies are forging closer ties with those "payors."

This year alone, Pfizer allied with insurer Humana to research elderly health; AstraZeneca and HealthCore, a unit of insurer WellPoint, agreed to study how to economically treat disease; and Sanofi signed on pharmacy benefit manager Medco Health Solutions Inc.

Sanofi may soon overtake Pfizer as the world's top drugmaker. CEO Chris Viehbacher says the industry's new crop of drugs must demonstrate "why is this better than what we've already got."

"In defining value – in whose eyes? So you need a payor perspective," he said.

A closer relationship to payors allows access to vast databases of medical claims to see how drugs are used once they are approved. Drugmakers can learn which medicines they should be comparing their own products to and what goals they should seek in clinical trials. ■

Takeda to Cut 10% Of Workforce By March 2016

Takeda Pharmaceutical said that it would cut about 10% of its workforce through job reductions outside Japan as it seeks to streamline its global operations after its acquisition of Swiss drugmaker Nycomed last year.

Japan's largest drugmaker plans to cut 2,100 jobs mainly in Europe and 700 in the U.S. by March 2016. As a result, Takeda expects to save about 200 billion yen ($2.6 billion) during the same timeframe, it said in a statement. But Takeda, which employs about 30,000 people globally, said the move initially would lower its profit by 35 billion yen in the fiscal year ending in March. It will announce revised forecasts for the current fiscal year on Feb. 1.

Takeda, which competes against Astellas Pharma, Otsuka Holdings and Daiichi Sankyo on its home turf, is struggling to boost profits due to a strong yen and costs related to the Nycomed buyout. Takeda in November cut its full-year operating profit forecast by 31%.

Takeda in May agreed to buy Nycomed for €9.6 billion, to boost its presence in emerging markets and add a new lineup of drugs. ■

Novartis Cuts 2,000 US Jobs After Drug Setback

Novartis plans to axe nearly 2,000 of its U.S. workforce ahead of the patent loss of top-selling blood pressure drug Diovan there and will take a $900 million charge after another of its key drugs failed to live up to expectations. Novartis is the latest in a long line of global drugmakers to cut its sales force as the industry faces its biggest wave of patent expiries ever.

Novartis plans to shed 1,630 jobs in its U.S. field force and another 330 positions are expected to go as it reorganizes the headquarters of its U.S. general medicines business. The changes are expected to take place in the second quarter of this year. Novartis' latest round of redundancies comes only a few months after it said it was cutting 2,000 jobs in Switzerland and the United States to keep costs under control in the face of growing price pressures.

The company has already cut thousands of jobs and shut several sites, notably in Britain. In 2010, it said it was cutting 1,400 jobs in the United States as it focuses increasingly on specialty medicines to boost profitability. ■

Sanofi Chemist Admits Trade Secret Theft

A research chemist for Sanofi pleaded guilty to stealing trade secrets and making them available for sale through a Chinese company. Yuan Li appeared before federal court and pleaded guilty to one count of theft of trade secrets. A Chinese national, Li worked as a research scientist at Sanofi's U.S. headquarters in Bridgewater, NJ, from August 2006 to June 2011, where she directly helped develop a number of compounds the company viewed as potential "building blocks" for future drugs.

While at Sanofi, Li also was a 50% partner in Abby Pharmatech, a U.S. subsidiary of a Chinese chemical company engaged in the sale and distribution of pharmaceuticals. Li admitted that between October 2008 and June 2011, she accessed an internal Sanofi database and downloaded information about a number of compounds, including their chemical structures, to her company laptop. She transferred the information to her personal home computer made the stolen compounds available for sale on Abby's website. In a statement, Sanofi spokesman Jack Cox said Li was terminated from the company for policy violations.

Li's attorney Paul Brickfield said his client accepted responsibility for her actions and agreed to pay $131,000 in restitution. To make Abby look credible, she listed a number of compounds that were being developed by her employer, Brickfield said. Li faces up to 10 years in prison and a $250,000 fine when she is sentenced on April 23. ■

Atlanta – The Center for Global Health

Bioscience Is Thriving in This Southeast U.S. City

Down South – Atlanta has a healthy biosciences community with a rich mix of pharmaceutical, medical devices, diagnostic and medical supply companies; contract laboratory, preclinical and clinical research organizations; and world-class public and private institutions and universities.

Atlanta's Bioscience Cluster

More than 300 bioscience companies have operations in metro Atlanta. This number includes domestic headquarters and operations for major companies such as Kimberly-Clark, CR Bard, Stryker, Sanofi-Aventis and Pfizer. Major international employers include Ciba Vision Corporation, Siemens, Columbian Chemicals Company, Akzo Nobel Coatings, Merial Limited, Lafarge Materials and UCB Pharma.

Large-scale health organizations bolster Atlanta's reputation as a center for global health. The city is home to the headquarters of the Centers for Disease Control and Prevention (CDC), American Cancer Society and the Arthritis Foundation. The Carter Center, Task Force for Global Health, CARE and Habitat for Humanity also have headquarters in Atlanta.

Georgia has embraced the life sciences industry because of its ongoing and positive economic impact, and developed multiple programs that encourage growth. Metro Atlanta and the state share a business friendly reputation. Life sciences companies have access to tax credits, sales tax exemptions, job training, cash grants and property tax relief.

The 2011 Shaping Infinity Study shows that the life sciences industry and university research, plus the U.S. CDC, employ more than 105,000 people in the state of Georgia. The bioscience industry alone employs more than 75,000 people.

Education

As a top higher education center with more than 57 colleges and universities enrolling more than 250,000 students annually, metro Atlanta maintains a strong pipeline of talent entering the workforce. Metro Atlanta's population is younger (median age of 34.4 years) and better educated (34.1% hold a Bachelor's degree or higher) than the national average.

Metro Atlanta's eight technical colleges enroll more than 48,000 students a year and offer studies in more than 50 disciplines. They are a vital workforce training and retooling resource for the local business communities.

Research facilities at Emory University, Georgia State University, Georgia Institute of Technology, Morehouse School of Medicine, University of Georgia and Georgia Health Sciences University are abundant and continue to grow. Many of these schools benefit from the Georgia Research Alliance (GRA), an independent non-profit entity that facilitates research among industry and academic entities. Since 1990, a multitude of renowned scientists have been recruited to metro Atlanta through GRA's Eminent Scholars program.

The Georgia Institute of Technology and Emory University provide a joint biomedical engineering degree program that is ranked second in the nation, and has become a model for successful and innovative research collaboration. Both schools anchor several centers of excellence including the Biomedical Technology Research Center and the Center for Behavioral Neuroscience. Along with Children's Healthcare of Atlanta, those same schools recently launched a first-of-its kind research center that links healthcare to engineering and is devoted to pediatric nanomedicine.


© SeanPavonePhoto - Fotolia.com

Atlanta, Capital of the U.S. Southeast

The Atlanta Metropolitan Statistical Area (MSA) is the business capital of the southeastern U.S. and a global business hub. The Southeast's population exceeds 77 million and employment is greater than 37 million. GDP in the Southeast measured $2.9 trillion in 2008, 22% of the U.S.

If the Southeast were a country, it would have the seventh highest GDP in the world, larger than the GDP of all but six countries: China, France, Germany, Japan, the U.S. and the United Kingdom. Metro Atlanta is the second fastest growing metro in the U.S. and has the 10th largest GDP in the U.S.

Atlanta is the capital city of the state of Georgia. The City of Atlanta is governed by a mayor and a 15-member city council that is managed by the council president. The 28 counties that make up metro Atlanta are individually governed by boards of commissioners, city councils and mayors.

Gateway to the U.S. and the World

The metro Atlanta area offers market access to destinations around the U.S. and the world. Metro Atlanta is a global logistics gateway, one of the nation's top distribution hubs, and is often described as one of the largest inland ports in the world. More than 80% of U.S. consumers can be reached from metro Atlanta in two hours by air or two days by truckload delivery.

In 2010, nearly 90 million passengers passed through the world's most-traveled airport, Hartsfield-Jackson Atlanta International Airport, of which nine million were international passengers. International non-stop service is available to more than 80 international cities in 50 countries.

Metro Atlanta is located just a few hours away from the Port of Savannah, the fourth busiest container port in the U.S. The Port is connected with Atlanta via a system of railroad lines and highways, making the transport of goods to Atlanta a quick and easy process. Containers entering through Savannah can be unloaded and transferred to a train and arrive in Atlanta by the next morning. Products can then continue on to their destination via rail or truck.

Ethnic And Cultural Diversity

Metro Atlanta is currently home to more than 5.2 million people, of which more than 700,000 were born in foreign countries. Atlanta's population is made up of newcomers from throughout the United States, Latin America, Europe, Africa and all parts of Asia. In fact, between 2008 to 2009, more than 20,000 people moved to metro Atlanta internationally – greater than the amount of people who moved to metro Atlanta domestically.

The metro area is home to more than 2,800 foreign-owned business locations. Currently, 65 countries have representation in Atlanta in the form of a consulate or trade office. In addition, the Atlanta area hosts many bi-national chambers of commerce, and organizations designed to strengthen metro Atlanta's ties around the world.

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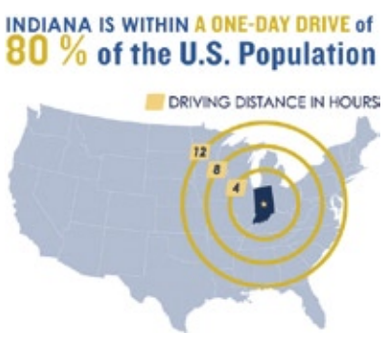
Innovation In The Midwest

Indiana's Government Caters to Businesses

Bio-Logical – Indiana is developing a breakthrough that will change the future of life sciences. It's a new way of encapsulating the infrastructure, tax incentives, research partnerships and distribution networks that biotech industries need to compete in the 21st century, and delivering them in a single, concentrated dosage. With world-class universities, the nation's top destination for logistics, a AAA credit rating and pro-business environment, Indiana is the bio-logical choice for life sciences.

Case in point: Indiana is the orthopedics capital of the world, which in itself is a bold statement, but also a testament the state's potential to not only have some of the largest medical device manufacturers like Zimmer, DePuy and Biomet on Indiana soil, but also to maintain an attractive environment to retain operations in the state with some of these companies for more than 100 years. Obviously top-notch products and a vision to continually innovate and develop the devices that medical professionals and their patients have come to rely on are the keys to that success story. But businesses across all sectors enjoy the competitive advantages afforded to them through Indiana's sound fiscal policies, low tax structure and cooperation between the public and private sector.



Helping Businesses

From the top down, Indiana's entire government administration has been structured to help businesses bring home more money to their organizations, their investors and their employees by keeping business costs and regulation at the lowest levels possible. Those are the basics for any industry to have a competitive edge. For life sciences companies in particular, those advantages stem from access to some of the top research universities in the world, which produce one of the most highly skilled and effective workforces anywhere. As home to the nation's second largest medical school at Indiana University and the world class biomedical engineering program at Purdue University, the Hoosier State alone has delivered more than 2,600 advanced science degreed graduates in the last five years.

Infrastructure And Location

With any company, distribution cost and efficiency are always major variables affecting profitability, and Indiana has the infrastructure, location and cost structure to deliver the goods. With the world's second-largest Fed-Ex hub, three international ports, more than 4,100 miles of active railway and more intersecting interstate highways than any other state in the nation, Indiana has a strategic advantage for delivering products to the rest of the country and the world. According to a 2011 industry report from BioCrossroads, Indiana's life sciences exports totaled $7.4 billion in 2009, the third highest in the U.S. Inside the country, Indiana's central location allows access to 80 percent of the U.S.'s population in a single day's highway transport.

Indiana has one of the top three most specialized and concentrated life science workforces in the United States. – Battelle, 2010

Notable Hoosiers

Eli Lilly is another notable example of a global life sciences company that has Hoosier roots dating back to 1876 and is now the 10th largest pharmaceutical company in the world. Across the globe, Lilly has developed productive alliances and partnerships that advance its capacity to develop innovative medicines at lower costs. Lilly is consistently ranked as one of the best companies in the world to work for, and generations of Lilly employees have sustained a culture that values excellence, integrity, and respect for people. Lilly has proven – and their strategy continues to prove – that by working together, they can help people live longer, healthier, and more active lives.

According to their president and chief executive officer, John C. Lechleiter, PhD, "Our number-one priority is increasing the flow of innovative new medicines that make a real difference for patients. To realize this goal, we recognize that Lilly. Successful, productive partnerships are essential for Lilly's ongoing pursuit of innovation and excellence."

Dow AgroSciences, a high-tech agricultural company based in Indiana, recently chose the Hoosier State over every location in the world, to expand its research and development capacity and continue its legacy as one of the top international companies in the world. The company is currently making a $340 million expansion, one of the largest investments in the company's history, and adding more than 500 high-wage positions at its Indianapolis headquarters. A global technology leader in agriculture with a proven track record of innovation and sustained success, Dow Agro Sciences has a broad geographic reach with sales in more than 130 countries and an expanding global research and manufacturing presence worldwide. In fact, it leads the industry in proportion of R&D spending with outside collaborators to cultivate innovative ideas and discoveries.

Advantage Indiana

These are only a few examples of Indiana's commitment to encapsulating a comprehensive formula of business-friendly and entrepreneur-friendly remedies in a single and highly palatable delivery system that gives Indiana companies a competitive edge. From land cost and availability to streamlined permitting and shovel-ready building sites, to its AAA credit rating, low taxes and affordable utilities, Indiana's basic formulation for business success is second-to-none. Mix in research partnerships, world-class universities, plus a concerted public and private effort to make the state a global hub for advancing life-improving scientific discoveries, and it's easy to see that Indiana has developed a break-through remedy for life science companies to compete for and win, not only America's bio business, but the world's.

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EVENTS

Informex Global, Feb. 14–17, New Orleans The Informex USA promises to offer attendees a direct view of what is happening in the varied chemical marketplaces. With this focus, there is exceptional vertical insight many markets, including: textiles, electronics, food and beverage, fuel and lubricants, soaps and detergents, water treatment, flavors and fragrances, adhesives and resins, paint and coatings, cosmetics and personal care, biopharmaceuticals, plastics and polymers, organic chemicals, agrochemicals, pharmaceuticals and more.

▶ www.informex.com

DCAT Week 2012, March 12–15, New York DCAT Week is one of the largest gatherings for the pharmaceutical and related industries in the world. Its unique model brings industry CEOs, presidents, global sales managers and directors of supply chain management from around the globe for high-level meetings, strategy sessions, education programs and networking events. DCAT Week is organized by the Drug,Chemical & Associated Technologies Association (DCAT). Member companies represent the entire spectrum of the pharmaceutical industry, including pharmaceutical innovation and production, chemical manufacturing, supply chain and logistics management and packaging.

▶ www.dcat.org

Reach Asia 2012, March 20, Frankfurt In the wake of the Reach implementation in the European Union, several Asian countries such as China, Japan and Korea have recently updated their chemical management regulations to close the regulatory gap they see between Reach and their own regulatory systems. The workshop is targeted at decision makers and regulatory affairs managers in the chemical industry who wish to enhance their knowledge and facilitate their participation in the Asian market. The workshop will give participants the opportunity to check, evaluate and optimize their current business strategy for Asia.

▶ www.knoellconsult.com

LogiChem 2012, April 17–19, Antwerp The 11th edition of LogiChem's program covering the most pressing issues affecting senior supply chain professionals within the chemical industry in a format that fosters high levels of interactive networking, learning and benchmarking. The market is now very concerned about the volatility of the economic environment, particularly since lower production levels (particularly in August) and amid fears about a double dip recession that will ultimately impact even the fairly robust chemical industry.

▶ www.wbresearch.com/logichemeurope/home.aspx

Combatting Counterfeiting in the 21st Century

The scourge of counterfeit drugs poses an ever-increasing threat to the global healthcare system. The problem is not limited to internet pharmacies or developing countries but has the potential to affect all of us. Fighting back against fake and diverted medicines requires a mix of laws, processes and technologies, underpinned by a sound understanding of the strategic principles. There are already a number of major initiatives to increase the traceability of drugs and improve supply chain security, such as serialization, e-pedigree, SMS verification etc. Some of these will become mandatory requirements (for example in Europe and California) within a few years. Individual companies also put security features on their packaging to aid in the authentication of their products when suspected fake drugs are identified. The number of technology options and legal obligations can be confusing and clear guidance has been hard to come by.

With "Pharmaceutical Anti-Counterfeiting," Pharmaceutical consultant Mark Davison, CEO of Blue Sphere Health has written a comprehensive guide for drug company executives, technology vendors, healthcare professionals and policy-makers. The book covers the key concepts and explains the available options in pharmaceutical anti-counterfeiting including a mix of policy, strategy, tactics and practical implementation tips.

See page 11 to see how you can win a free copy of this book!

▶ Davison, Mark
Pharmaceutical Anti-Counterfeiting
John Wiley & Sons
€77.90
2011, 426 pages, hardcover
ISBN: 978-0-470-61617-8

Researchers Discover Particle Which Could 'Cool The Planet'

Researchers from The University of Manchester, The University of Bristol and Sandia National Laboratories report the potentially revolutionary effects of Criegee biradicals. These invisible chemical intermediates are powerful oxidizers of pollutants such as nitrogen dioxide and sulfur dioxide, produced by combustion, and can naturally clean up the atmosphere.

Although these chemical intermediates were hypothesized in the 1950s, it is only now that they have been detected. Scientists now believe that, with further research, these species could play a major role in offsetting climate change. The detection of the Criegee biradical and measurement of how fast it reacts was made possible by a unique apparatus, designed by Sandia researchers, that uses light from a third-generation synchrotron facility, at the Lawrence Berkeley National Laboratory's Advanced Light Source.

The researchers found that the Criegee biradicals react more rapidly than first thought and will accelerate the formation of sulfate and nitrate in the atmosphere. These compounds will lead to aerosol formation and ultimately to cloud formation with the potential to cool the planet. In the last 100 years, Earth's average surface temperature increased by about 0.8°C with about two thirds of the increase occurring over just the last three decades.

Most countries have agreed that drastic cuts in greenhouse gas emissions are required, and that future global warming should be limited to below 2°C. ■

PEOPLE

Personnel Changes at BASF


Wayne Smith


Stefan Marcinowski


Andreas Kreimeyer

Wayne T. Smith has been appointed to BASF's board of executive directors effective at the end of the Annual Meeting on April 27. He will be replacing Dr. Stefan Marcinowski, who will retire with the expiration of his contract in April. Smith is currently head of BASF's Polyurethanes division headquartered in Brussels, Belgium. Raimar Jahn, currently head of BASF's Coatings division, will become president of BASF's Polyurethanes division, headquartered in Brussels, Belgium effective March 1.

At the same time, the supervisory board has extended the appointment of Research Executive Director Dr. Andreas Kreimeyer until the end of the annual meeting in May 2015. He has been a member of the board of executive directors since 2003.

John R. Donovan Appointed as Univar's Chief Growth Officer

Univar has announced that John R. Donovan joined the company as executive vice president and chief growth officer. Donovan reports to John Zillmer, Univar president and chief executive officer, and is responsible for strategic growth and development of the company's global business relationships.

Donovan has spent much of his career in executive leadership roles heading sales, marketing and general management teams. Most recently, he served as president of Omakase, a growth-strategy consulting firm that he founded. Univar has worked closely with Omakase since 2010 to further enhance its sales force effectiveness and training programs.
Prior to the founding of Omakase, Donovan held various executive roles in business development and general management at Aramark and contributed to the company's unprecedented growth. Before Aramark, he worked for both Morrison's and Servomation.

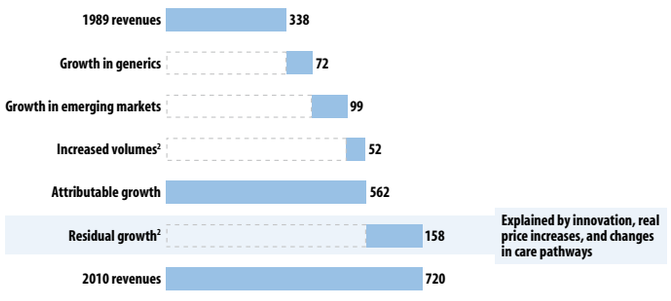
Joseph M. Mahady Joins Albemarle Board of Directors

Albemarle's board of directors has elected Joseph M. Mahady to the company's board, effective Feb. 1. In 2009, Mahady retired from Wyeth Corporation, a global manufacturer of pharmaceutical products, following its acquisition by Pfizer and after 30 years with the company. At the time of his retirement, Mahady served as president of Wyeth Pharmaceuticals.

Wake Up, Big Pharma

Historically, the biggest contributors to industry revenue and growth have been innovation, real price increases and changes in care pathways.

Contributions to revenue growth for pharma, biotech and generics players, 1989-2010, $ billion[1]



[1]In real 2009 dollars; figures do not sum totals because of rounding
[2]For originator products in developed markets

Source: S&P Capital IQ Unit; McKinsey analysis

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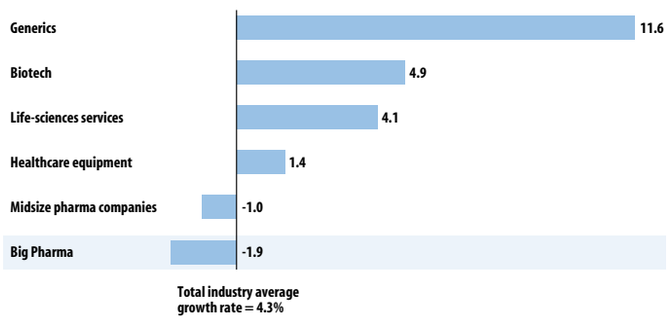
The pharma industry's composition has evolved considerably.

Growth rate relative to industry[1], 1989-2010, in %



[1] Includes only companies with > $500 million in revenues in real 2009 dollars. Midsize pharma companies defined as those with $500 million to $5 billion in revenues; Big Pharma s those with > $5 billion.

Source: McKinsey

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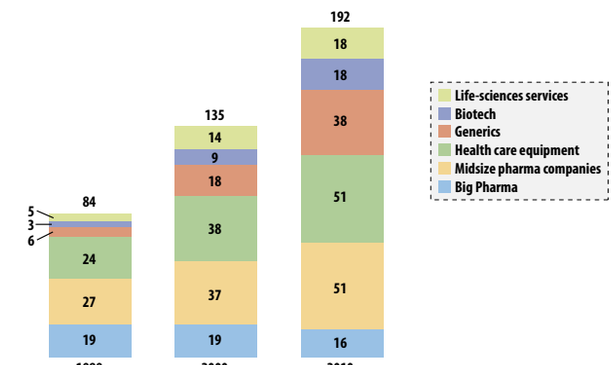
The number of companies competing for the profit pool has more than doubled.

# of companies in the pharma industry,[1] 1989-2010



[1] Includes only companies with > $500 million in revenues in real 2009 dollars. Midsize pharma companies defined as those with $500 million to $5 billion in revenues; Big Pharma s those with > $5 billion.

Source: McKinsey

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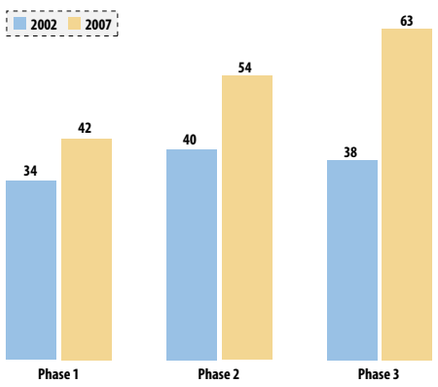
% of pipeline compounds originated externally



Source: McKinsey

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With governments worldwide working to put a lid on drug spending – and with emerging markets following this lead – Big Pharma is up against some weighty challenges in the year to come. Regulatory requirements – particularly the linkage among the benefits, risks, and cost of products – will increase, while the industry pipeline shows little sign of delivering sufficient innovation to compensate for such pressures. According to a recent study by McKinsey, a bold and radical approach to Big Pharma's operating model is in order.

The case for difficult times ahead is straightforward. McKinsey analysis shows that over the years, real price increases, rewarding past innovation and changes in pathways for treating patients, have been the most significant driver of the pharma industry's growth. Less attention has been paid to managing the cost base. The industry may have recently begun to focus on that, but its heart doesn't seem to be in the effort, and it has little to show for these efforts.

The era now drawing to a close may have brought outstanding innovations to patients and profitability to Big Pharma, but the industry's composition evolved considerably during this period, and not necessarily in favor of large companies. Conventional wisdom, perhaps fed by high-profile mergers, holds that the industry has consolidated. But on the contrary, McKinsey analysis shows that it has become more fragmented: the number of companies competing for the profit pool has more than doubled. As a result of that fragmentation, Big Pharma must compete for parts of the value chain with focused players – for example, generics companies that excel at manufacturing; life-science service providers that offer flexible, specialized services (such as managing clinical trials) at scale; and biotechnology companies that generate innovative ideas and products.

But speaking of biopharma, it's no secret that the industry has been grappling with diminishing R&D productivity. R&D investment more than doubled over the last decade, while new molecular-entity approvals plummeted. The return on investment for a typical biopharmaceutical portfolio today often will not even cover its cost of capital. In response, industry players have embarked on a range of initiatives – in particular, externalizing more R&D to increase the number of drug projects and thus the chances of getting a major new product to market. In fact, over half of late-stage pipeline compounds are now externally sourced.

McKinsey summarizes that Big Pharma companies will require new and improved capabilities in financial planning, capital allocation, communication, the management of external resources, and market access, to name but a few things. Executives must tighten their companies' financial discipline, ruthlessly reallocating capital across businesses and, in particular, away from underperforming R&D assets and mature markets that can no longer sustain big sales forces. Informing a more competitive R&D strategy with commercial understanding, rather than simply targeting regulatory approval, could help companies emerge as winners in the industry.

Source: McKinsey

Sustainable Sticking The Karlsruhe Institute of Technology in Germany is working on an adhesive based on local renewable resources. The research project, which is being conducted in conjunction with the Agency for Renewable Resources, got underway at the beginning of the year and is expected to run through the end of 2013. The project will examine the possibility of creating an attractive alternative to the petroleum-based products that are currently dominating the market. The goal is to evaluate to which extent adhesives can be made from renewable resources. Corresponding polymers will be synthesized and their processing and adhesive capabilities characterized. Different monomers will be used for the syntheses; the adhesive properties will be improved through the variation of the degrees of polymerization and cross-linking, as well as the addition of co-monomers. With an eye on resource-saving and ecological processing, the adhesives will be made using miniemulsion polymerization as an aqueous dispersion. www.kit.edu/english FNR/T.Fehrmann

Coming up in our March issue

- **Dr. John Williams of the UK's National Centre for Biorenewable Energy, Fuels and Materials looks at bioplastics and their possible impact on agriculture.**
- **Materia Nova's Vincent Berthe offers an overview of new biobased polymer building.**
- **Bing Yu of GLS Syntech explores issues and opportunities in developing strategic sourcing relationships in China.**
- **Our China expert Kai Pflug kicks off his 2012 article series with a report on the development of mid-markets in China.**
- **And much more!**

Don't miss out!
The advertising deadline for the March issue is Feb. 27. The paper will be published on March 8!

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