

A Changing World for CMOs

Consolidation in Pharma a Win for Custom Manufacturing

Advantages – With more and more players in big pharma looking to outsource in order to focus on core competencies, custom manufacturers stand to benefit from this shift.

The most exciting trend in pharma custom manufacturing is ...

M. Griffiths (Carbogen Amcis): ... changes in big pharma. Costs of bringing a new drug to the market rose above \$1 billion according to the PhRMA due to longer clinical trials and tougher regulations for drug approvals. The numbers of NCEs approved by the FDA declined and the patent cliff has increased competition from generics drugs. Job cuts, mega merges and co-development programs are some of the strategies implemented to reduce costs, improve profit margins and mitigate the risk of drug development. Big pharma is gradually transitioning away from the historical heartland of primary care therapeutics and the blockbuster model towards hard to treat conditions with requiring high value drugs targeting complex niche diseases such as oncology. Access to leading edge technology and specialized skills is paramount for the development and manufacture of high value small molecules, biologics and conjugates. Consequently, the trend among many CMOs is to invest in highly specialized technologies necessary to handle complex drugs.



Mark Griffiths
CEO, Carbogen Amcis

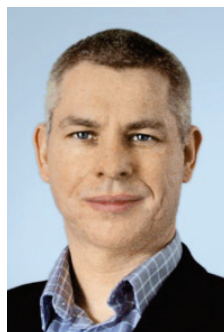
W. Schmitz (Saltigo): ... the full integration of the custom manufacturer in the business process of the customer. Whereas in the past only the product has been bought by the customer nowadays the custom manufacturer has to provide a wide variety of services. These product related services, like quality risk assessments, definition of design of experiments and design spaces, etc., and the integration of chemistry and technology at the custom manufacturer site allow the customer to focus on its core competencies and hence reduces the time to market. The integration of the CMO in the business process leads to an alignment of the two parties and ideally to a long lasting partnership.



Wolfgang Schmitz
CEO, Saltigo

N. Johnson (SAFC): ... pharma companies outsourcing, continuing the shift away from manufacturing in their own assets and opening up major opportunities for the contract manufacturing sector. While a large proportion of pharmaceutical manufacture remains within pharma companies' assets, eventually, an even greater proportion will reach the merchant market.

Pharma companies are also continuing to develop innovative, highly novel therapeutics, which again creates new demands and requirements for CMOs. To capitalize on these new opportunities, CMOs need to take a technology leadership position and also to invest in the necessary capabilities and infrastructure.



Nick Johnson
Strategic Marketing Manager, SAFC

J. Bléhaut (Novasep): ... the increasing complexity of the new APIs reaching the market. Over the years, the new synthetic molecules developed in the pharmaceutical industry have become larger and more challenging to synthesize. This trend is driven by two major factors: the development of more and more targeted therapies, leading to specifically designed, highly functionalized molecules; and the intellectual property mine field, forcing innovators to look for unpatented molecular structures to protect their future markets. This has impacted on our customer's expectations, they need chiral separation, purification of molecules that are insoluble in organic solvents, thermally labile,



Jean Bléhaut
Director, Marketing & Business Development, Novasep

contain sensitive functionalities, cannot crystallize, etc.

The biggest challenge we face in custom manufacturing today is ...

M. Griffiths (Carbogen Amcis): ... the fact that world we inhabit as CMOs has changed markedly in the last four years. Continuing retrenchment and consolidation of our large pharma customers' activities and cash available for small biotech to pursue innovative NCEs will be key in the next five years. With large pharma divesting much of their historical API manufacturing operations and with the biotech sector continuing to struggle for funding, a new model is starting to become reality.



Custom Manufacturing

Big pharma are increasingly filling their pipelines through in-licensing innovative therapeutics from biotech, which in turn provides additional funding for the biotech sector to re-invest. For CMOs this means that strong relationships across both biotech and pharma sectors is increasingly a requirement. CMO organizations like the Dishman group having significant exposure in both areas clearly have an advantage here. Business mix is likewise key for CMOs, those who are over exposed to and over reliant on early development revenues are disadvantaged as the pharma industry realigns itself to a greater emphasis on specialist drug platforms, biologics and generic products.

W. Schmitz (Saltigo): ... the huge overcapacity and the overdue market consolidation in combination with the trend towards shorter timelines, less new molecular entities, continuous price pressure due to health care reforms and blockbusters going off patent.

Continues Page 17 ▶

Fine Chemicals Developing Well In 2011

Agro Segment Showing Particularly Strong Growth

Showing Muscle – Fine chemicals have had a strong showing in 2011, thanks in particular to a strong agro segment. Also, the industry is seeing more requests for challenging chemical syntheses from blue-chip life science and chemical companies.

We see Asia as ...

Dr. M. Wienkenhöver (CABB): ... an attractive market for our products, especially in the acetyls business. CABB is meeting the opportunity head on, having established a foothold in Asia in 2008 by taking over Karnataka Kasayan, India's market leader operating the country's biggest MCA (monochloroacetic acid) plant. This was only the first step. We are looking for further regionalization of our business into Asia, especially China, the biggest market for MCA globally. Asia as a whole – and particularly China – is increasing the quality requirements for this important chemical building block, particularly as it intends to participate in the export area for the downstream products.

Dr. P. Seuffer-Wasserthal (Codexis): ... as a great and proven partner for using our enzymes to produce pharma intermediates and APIs, and a growing market for our intermediates and APIs. We have been selling our products in India for many years to a growing number of customers. In January, we were very pleased to announce a collaboration with Danippon Sumitomo Pharma, one of Japan's 10 largest pharmaceutical manufacturers.

Dr. J. Winterfeld (Wacker): ... an important focus region for the Wacker Group. The company has already in-



Dr. Martin Wienkenhöver
CEO, CABB

vested heavily in production plants – for instance for silicones – and set up a comprehensive sales organization in countries like China, Japan, Korea and India. Concerning the fine chemicals segment, we will continue to focus on our core markets in Europe and the U.S. Asian countries like China and India also offer large business opportunities and growth prospects for fine chemicals. But on the other hand, it is a very competitive region with benefits for domestic producers.

Dr. M. Wienkenhöver (CABB): ... developing well, driven by extraordinary growth in the agro chemicals. But also custom manufacturing for pharma intermediates and for the personal care segment was strong.

Dr. P. Seuffer-Wasserthal (Codexis): ... is growing because of the re-structur-



Dr. Peter Seuffer-Wasserthal
SVP Pharmaceuticals, Codexis

ing at our customers. We find our pharmaceutical customers turning to qualified suppliers such as Codexis for process development of intermediate and API manufacturing.

Dr. J. Winterfeld (Wacker): ... improving further, following the economic crisis in 2009. Sales and profitability recovered in 2010 and in the first half of 2011 and were driven by a strong market demand, especially from industrial applications like automotive and construction. Wacker, too, benefits from this positive business environment by selling organic fine chemicals like acetyl acetone, chlorinated carbonyl compounds and special silanes.

The most promising trend in fine chemicals is ...

Dr. M. Wienkenhöver (CABB): ... an increasing demand for custom manufacturing services coming from the



Dr. Jörn Winterfeld
Director Business Line Pharma/Agro at Wacker Bioreolutions, Wacker

blue chip life science and chemical majors. Our clients have now asked us for more innovative and complex products that until recently they were manufacturing in-house. Overall, we see a strong growth in the outsourcing of fine chemicals – especially of more challenging chemical syntheses. CABB can apply its core competencies to the customers' – and our own – benefit. We are prepared to grow with the customers by investing in these partially complex synthesis routes and by continuing to provide on-time, best-in-class service and reliability.

Dr. P. Seuffer-Wasserthal (Codexis): ... openness for the use of new technologies in the manufacture of the products rather than only moving to lower cost areas to improve economics.

Dr. J. Winterfeld (Wacker): ... beside a growing market place, especially for agro chemicals and some industrial applications, the improvement

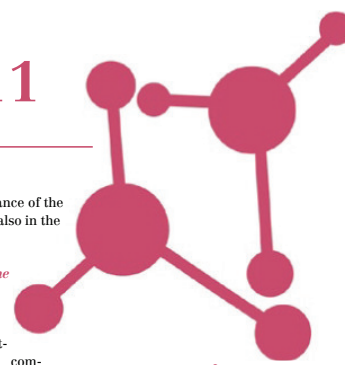
of ecological compliance of the chemical industry – also in the emerging countries.

The future of fine chemicals is ...

Dr. M. Wienkenhöver (CABB): ... looking attractive for those companies who can add real value to the business of their customers. CABB thrives to be the partner of choice by applying intelligent solutions and innovative technical and chemical concepts, supported by sizable investments both into assets and know-how; as well as a well-perceived service offering enabling the customers to concentrate on their core business considerations and rely on a strong outsourcing partner.

Dr. P. Seuffer-Wasserthal (Codexis): ... in more advanced and more complicated products using new technologies. We find customers are rapidly adopting biocatalysis into their operations as this technology has moved broadly into the mainstream.

Dr. J. Winterfeld (Wacker): ... positive, with a growing global market demand. However, business will remain competitive, with competition coming especially from Asia. Wacker considers its backward-integration to basic chemicals, the long-standing know-how and experience regarding certain technologies like chlorinations, silane and ketene chemistry, as well as production at a fully integrated site as particular strengths for the fine chemicals business. Constant process improvements and upgrade in technology are also key success factors in the fine chemicals field.



Fine Chemicals

Consolidation in the fine chemicals industry will ...

Dr. M. Wienkenhöver (CABB): ... further continue. CABB just acquired KemFine in August with the support of our new owner, Bridgepoint. For CABB KemFine is absolutely the right partner to help grow and develop our business further – especially in the area of custom manufacturing.

Dr. P. Seuffer-Wasserthal (Codexis): ... happen! It also means that synergies will be used in existing Western plants and that these companies will have to deal with technologies they have not been familiar with. This allows for new technologies to be used as well.

Dr. J. Winterfeld (Wacker): ... continue, since it is a very fragmented industry. Many small players may vanish or merge to attain the so-called critical mass. This trend includes producers in China.



Custom Manufacturing

Continued Page 16

N. Johnson (SAFC): ... the fact that market for general small molecule contract manufacturing remains highly competitive, with a significant supply/demand imbalance. Coupled with this is the general reduction in R&D funding, with 2009 being the first year that the total spend actually decreased. Collectively these points mean challenged profitability in certain segments and at some point there will need to be some significant asset closures to allow these over-capacity segments to return to profitability.

J. Bléhaut (Novasep): ... the perception of our value by the customer. Lately, fine chemical outsourcing decisions have often been essentially driven by price considerations. However, fundamental factors have sometimes been overlooked by pharmaceutical companies. For instance the lack of professional project management on the supplier's side may have dramatic impact on the timing of delivery of an intermediate for clinical trials, thereby delaying critical development milestones. This is par-

ticularly relevant as more and more lead compounds are developed by emerging pharmaceutical companies, dealing with limited resources and very tight timelines to carry on with the development process. For these companies, the delay of a clinical milestone can threaten their existence. They really need partners they can trust.

For custom manufacturing, Asia is ...

M. Griffiths (Carbogen Amcis): ... a factor. In 2010, Western companies were still the preferred outsourcing partners for premium services and products e.g. complex new chemical entities, technical flexibility, speed and commercialization expertise. The Dishman group has a significant presence in Asia which allows the group as a whole, including Carbogen Amcis traditional customer base the advantage of leveraging the right skills and assets at the right time throughout the drug development process and during product lifecycle management.

W. Schmitz (Saltigo): ... a challenge and, at the same time, a chance.

Saltigo benefits indirectly through its customers from the trend to expand business in Asian regions. The Asian competition has been rapidly growing in recent years and our customers from different industries have been exploring this supply base using multiple strategies.

Saltigo benefits in Asia directly from the network that its mother company Lanxess has built in Asia by building various production sites. Saltigo can offer unique services especially with regard to procurement by utilizing this network and the direct access it provides.

N. Johnson (SAFC): ... an established base for generic APIs and early-

stage intermediates. However, in custom manufacturing, customers need open communication, reliability, excellence in quality and compliance and manufacturing efficiencies. Taken collectively, these are characteristics not found to be localized regionally, but are rather characteristics of individual companies and their capabilities and culture.

J. Bléhaut (Novasep): ... an opportunity, but also a market where savings might come at a cost.

For us, the Eastern market place represents an opportunity to source early intermediates in a cost effective manner, and we ensure that we make the best of it. However, we remain extremely cautious in the establishment and control of our supply chain to avoid any delays which would impact the time to market for our customers.

Now, from a competition point of view, Asian companies undoubtedly present financial advantages but many other elements are to be accounted for. The custom manufacturing market is a complex equation in which the human factor has become the precious resource nowadays. Geographical and cultural proximities are advantages Western Europe companies will always retain for their European and U.S. customers. Simple aspects like shorter travel times and less jet lag for example – which both impact on productivity – can make the difference. Combined with strong relationships and mutual trust we develop with our clients, this makes European CMO companies attractive for the western industries.

In 10 years, custom manufacturing will be ...

M. Griffiths (Carbogen Amcis): In the future, CMOs will increasingly be

required to offer a more integrated approach for development and manufacture of drug products, where complimentary services will be offered under one umbrella (such as MedChem, early phase development, formulation services, commercialization and integrated commercial supply of drug substance and drug product). The ultimate goal is to reduce time to market through streamlined project management, or at least to "fail fast." We expect to see a more intimately integrated approach among drug substance and drug product manufacture at least in the development stages of NCEs.

W. Schmitz (Saltigo): ... influenced by growing population, resource scarcity, increasing urbanization and mobility. In the long run, we see a positive market environment for agrochemicals and pharmaceuticals. This comes from the increasing demand and interest in biofuels and changing eating habits, particularly in Asia. And we see also growth potential in the pharmaceutical sector, because big pharma companies are outsourcing more and more to concentrate on their core strengths and emerging pharma companies continue to drive new drug developments through innovation.

N. Johnson (SAFC): As pharma companies continue to simplify their supply base, we are likely to see further consolidation amongst custom manufacturers and fine chemical companies, with the possible exit of some lower performing players. We expect that strategic relationships will transition to symbiotic inter-dependency, with more integrated and productive working practices. Additionally the trend towards more niche therapies and personalization of medicines will

require custom manufacturers to reconsider their asset base and manufacturing technologies according to the product needs of these developing areas.

J. Bléhaut (Novasep): ... certainly more concentrated. At the moment this market is constituted by a multitude of relatively small companies. In the coming years a more limited number of larger companies will emerge from these. In addition, specialist CMOs like us, able to solve certain types of manufacturing challenges (coupling multi-step synthesis with advanced purification technologies to make complex APIs or global manufacturing of antibody-drug conjugates are good examples) are aiming at becoming real references on the market place.

Our most crucial differentiating competence is ...

M. Griffiths (Carbogen Amcis): ... the quality of our people throughout the entire group, who offer both broad and deep expertise in many areas, from chiral organic chemistry, peptide chemistry to complex separation sciences and their absolute passion for problem solving and customer service. The majority of the projects we handle are highly technically demanding and require an open approach and effective communication to quickly define the project's specifications and deliverables, the must-have versus nice-to-have, and the project's timeline.

W. Schmitz (Saltigo): ...our expertise in the chemical development in combination with technology, up-scaling and refinement of chemical processes for efficient, cost-effective and safe production of complex molecules, state of the art waste disposal and HSE compliance. Using this core competence to meet customer

demands is the cornerstone to generate profitability.

Our strategy as a service-provider combines professional outsourcing, first-rate method development and ongoing improvement with the aim of achieving a high degree of flexibility and reliability, while keeping the overall cost of the products that we supply to customers, as low as possible.

N. Johnson (SAFC): ... not easy to define as a single characteristic. For sustainable performance a custom manufacturer needs to build close relationships with their customer, with flexibility and commitment to quality and service. It is also paramount to develop deep and broad technology and capabilities to address the wider needs of the customer. In isolation, none of these elements is sufficient to be successful.

J. Bléhaut (Novasep): ... our ability to offer choice to our customers. We have a unique position on the market place as a technology expert and a process developer. We can supply our client with purification equipment that we develop within our company and/or provide them with the custom synthesis and purification of their products. This places us as the ideal partner for development through large scale manufacturing.

In addition, our presence in many markets (including pharmaceutical, biopharmaceutical, food and functional ingredients, bio industries, agrochemicals ...) enables cross-fertilization of our know-how, resulting in the design of smarter and more cost effective processes.

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

Functional Ingredients

Excipients Not Just Additives Anymore



Excipients

Multifunctional – The expectations on excipients have grown over the last years. No longer seen as mere fillers and binders, pharma is now looking toward excipients that add value to their end product and are multifunctional.

The most exciting trend in excipients is ...

Hans Ole Klingenberg (global marketing director at Novozymes): ... the pharmaceutical industry's shift towards recognizing excipients as functional ingredients rather than non-functional additives. As a result, manufacturers are increasingly looking for novel, value-added multifunctional excipients, that offer real advantages to both the manufacturer and patients. In addition, advances in technology offer new opportunities to explore simpler product formulations with reduced numbers of excipients.

For the excipient business, Asia is ...

H. O. Klingenberg (Novozymes): ... one of the fastest growing countries in terms of innovation. For example, in China, recent years have seen double-digit growth in the country's biotechnology industry, transforming it into one of the fastest growing in terms of biotech innovation. Novozymes was one of the first western biotech companies to enter China and has more than 20 years' experience running and operating facilities in the country. With this experience in hand, Novozymes is now looking to push the boundaries further with the opening of a new dedicated Q7 cGMP facility for the production of state of the art cGMP grade hyaluronic acid (HA) making it suitable for biomedical and pharmaceutical applications.

cGMP certification for excipients manufacturers is ...

H. O. Klingenberg (Novozymes): ... vital to ensure that drug development processes are as efficient and effective as possible. Working with raw materials that are already Q7 compliant can help medical device and pharmaceutical manufacturers to reduce testing time, minimize documentation requirements, save on manufacturing costs and take products to market faster.

Our most crucial differentiating competence is ...

H. O. Klingenberg (Novozymes): ... Novozymes' commitment to providing solutions that help its customers solve their most demanding challenges. The company does this by providing access to high-quality in-

gredients, proprietary technologies and unique know-how, contributing toward the development of improved drug products that provide real and sustainable benefits to patients. As a company, we are constantly reviewing industry trends and looking for new opportunities to improve our customers' processes by developing better and safer alternatives to the products that they are currently marketing. However, we are more than a mere supplier of enabling technologies or products; we see our relationship with each customer as a partnership. By combining our scientists' unique knowledge of Novozymes' biological solutions with the customers' specific application knowledge, we work with our customers to find the right answer to their development challenges.

In excipients, innovation is driven by ...

H. O. Klingenberg (Novozymes): ... the demand for safe and consistent biologically-derived solutions that can ultimately improve treatments for patients. Novozymes develops and manufactures high-quality, animal-free, recombinant ingredients and technologies. We provide pharmaceutical manufacturers with proven options based on our established technology platform that has been developed over the last 50 years, and which will enable them to develop safer and more consistent products. Currently, 14% of Novozymes' total revenue is spent on R&D projects.

www.chemanager-online.com/en/tags/excipients

Siegfried | expect more



Siegfried combines compliance with flexibility

As an integrated supplier with a broad range of technological competence along the value chain, full compliance for all products and work processes to ensure safety is a high priority. As the ideal outsourcing partner Siegfried combines this track record with the greatest possible degree of flexibility targeting to reduce a project's complexity.

Expect more with Siegfried as your preferred partner

www.siegfried.ch

Visit us at booth 50F59, hall 5

'As Reliable as a Swiss Watch'

Innovation Expected from API Manufacturers

Up To Task – Facing a huge patent cliff and a less-than-robust pipeline, pharma companies must look to customized and personalized medicines. This is where API manufacturers are expected to step up to the plate.

For our API business, Asia is ...

M. Blocher (Dottikon): ... still a minor market today. Margins are rapidly decreasing with increasing number of players attracted by high growth rates of non-branded and branded generics in pharmerging markets such as Eastern Europe and Latin America besides Asia. In addition, intensified price pressure by regulation is taking place as governments seek to keep healthcare spending under control, similar to industrialized countries. China plans to motivate scientists from the U.S. with hundreds of billions to start up biotech within China, and Indian generics manufacturers are increasing their efforts to develop their own branded drugs. Despite these facts, the custom manufacturing for Asian biotech and drug innovators is still in the introduction and years from entering the growth phase. Therefore, for the time being, Asia remains a source for low-cost starting material and generic APIs, and a direct and indirect market to sell high-valued intermediates finally ending up in generics.

Dr. A. Dietrich (Vice President Launch and Strategic Products at Boehringer Ingelheim): ... remains important. Macroeconomic indicators point to continued growth of the pharmaceutical market. Of course, each region of the world influences growth in different ways. Changes in demographics in Europe, rising disposable income in Asia, wider availability of health insurance schemes around the world are just a few changes to mention here. The Asia-Pacific pharmaceutical market has been emerging as a fast growing region over the past decade. The reason for these changes can in particular be attributed to a favorable manufacturing cost environment and the need to access better healthcare. Consequently, Asia has seen important developments in contract manufacturing, especially for APIs and generics, and has to no surprise positioned itself as a front-runner of global API production. We believe this positive development will continue to strengthen Asia as a global API production hub, a trend which is predominantly driven by continued pressure around the world on drug product cost, as well as by technology and partnership advancements.

H. Sieger (CEO, CU Chemie Uetikon): ... an interesting market, offering opportunities of economic growth. With



Markus Blocher
CEO, Dottikon



Dr. Andreas Dietrich
Vice President Launch and Strategic Products at
Boehringer Ingelheim



Heinz Sieger
CEO, CU Chemie Uetikon

the two largest populations residing in India and China the drug market in Asia and in the other E7 countries is expected still to grow much faster than in the developed markets and will reach a market share of about 20% in 2020 that means will at least double within the next nine years.

Especially because of our GMP compliance, our high and reliable quality in general and the trend setting GMP design of our production facility, we see good chances to grow our business in these countries.

The most promising trend in APIs is ...

M. Blocher (Dottikon): ... that the number of new drug approvals by the FDA in the first half of 2011 has already exceeded the total of 2010 approvals, despite high attrition rates and therefore low number of NDAs for approval. The majority of approvals involve significant improvements over existing treatment options and may mark the beginning of a new era of customized and personalized medicines. Indications and treatments of the newly approved drugs typically address small and highly targeted patient groups. The novel chemical core structures of these APIs often require state-of-the-art technology in the synthesis. However, their significantly lower annual volume needs economically disfavor commoditized monoplant manufacturing. The demand for rapid process development, reliable scale-up and safe manufacturing of commercial API quantities is increasing. This is a clear effect from the deferral of chemical process development to later clinical phases with the aim to avoid R&D spend on unsuccessful projects; and the need to substitute each lost blockbuster by a multiple of smaller new drugs. In essence, the future successful contract manufacturing consists of exclusive synthesis by partnering with an experienced, reliable, highly flexible supplier having the right versatile technology portfolio to tackle today's chemical manufacturing control challenges.

Dr. A. Dietrich (Boehringer Ingelheim): ... will be influenced by several factors. Finding new and innovative synthetic routes, and continued manufacturing efficiency gains to lower overall API cost will remain important. Emerging markets are benefiting from expansion of medical infrastructures and an increase in per-capita income. A successful growing penetration of health insurance, a growing aging population and information campaigns of pharmaceutical companies prepare the way for API market growth. Also biopharmaceutical APIs, which currently make up the smaller part of the global API market compared with chemically produced counterparts, are of interest. The growth prospects for these kinds of actives represent attractive opportunities for growth for innovator companies, as well as for biosimilar API manufacturers.

H. Sieger (CU Chemie Uetikon): ... stricter regulatory legislation and better international coordination and co-operation. The New Falsified Medicines Directive, which we very hard worked for in the last 10 years with APIC and EFCC and which has been in place since July 1 will change the API supply chain and is a good step forward towards safe and trustworthy medication especially in Europe. The regulation will also help to level the playing field for fine chemical companies in Europe.

The most drastic change that has happened in the last 10 years is ...

M. Blocher (Dottikon): ... the loss of the U.S.' hegemonial power, symbolically initiated by the collapse of the World Trade Center at the beginning of this century. Lacking of financial resources and political will, unilateral global stability will no longer be provided by the U.S. A reverse of globalization to regional fragmentation is the result and will affect global supply chains, also of pharmaceutical industries. The cascade of financial

market and government debt crises drastically increased pressure to reduce healthcare spend in all industrialized countries. Generation promises inherent in the social security systems in combination with over-aging populations exacerbate this situation. This is changing the pharmaceutical industry structure fundamentally. For instance, pharma manufacturing capacity is dispatched, consolidated and reduced employing the aid of short-term cash flow maximizing financial investors as undertakers. In the long run, this improves the bargaining power of financially sound, experienced, technology-leading and reliable manufacturers.

Dr. A. Dietrich (Boehringer Ingelheim): ... cost pressure on API synthesis in manufacturing pharma companies and their inability to maintain margins once products are off patent. In response to this problem, many companies turned to Asian manufacturers that were trying to gain market access by offering products at a lower-priced starting point. While corresponding quality and regulatory understanding was still in need of development, today's Asian manufacturers have become better at responding to needs which go beyond price. In response to this development, many Western API manufacturing pharma companies have expanded their API outsourcing activities beyond the traditional high quality European or North American partners to also include upcoming Asian manufacturers. For the pharma companies, it is not only an opportunity to focus more on their core competencies developing innovative medicines, but it is also a way to offload their balance sheets with manufacturing assets. The manufacturing and growing supply of APIs out of Asia has enjoyed the trend of diversification and globalization of the supplier base. In the long-run, these advances will increase the cost for CMO services out of Asia and will shift towards meeting a growing local demand. Consequently, one

could expect that during this decade the manufacturing cost advantage between East and West will shrink and eventually vanish. In parallel, the need of Western pharmaceutical manufacturers to select strategic suppliers within reach will continue to be important. Not only do they want to maintain a supplier base close to their wholesaler markets, but they also require expertise and understanding of the local regulatory environment and launch expertise. One can already see today operational excellence advances and cost focus, which have transformed some Western API manufacturers into global cost competitive players – without jeopardizing the expected high standards of launch services or product quality.

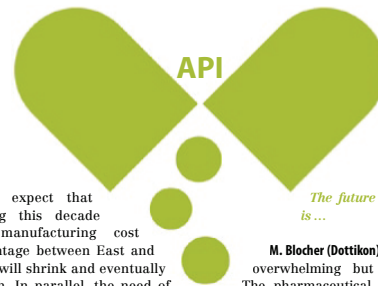
H. Sieger (CU Chemie Uetikon): ... the global, worldwide interconnection and expansion of information exchange and technology. This has improved the availability of health care data, our knowledge management and the speed and scale of economy, creating thereby major opportunities and challenges for an increasing global business. Pharmaceutical Industry, being a highly research and knowledge driven global industry, is in the process of profiting from and adapting to these changes. This long lasting socio-medical-economic change will undoubtedly lead to a strong but different pharma industry in the future.

Generic APIs will ...

M. Blocher (Dottikon): ... have a considerable share of the pharma market as the population gets older, as healthcare cost pressure continues and as emerging economies progress.

Dr. A. Dietrich (Boehringer Ingelheim): ... will benefit from the fact that the global pharmaceutical market is expected to continue growing overall and from the fact that over \$100 billion in revenues in 2013 will be at stake due to patent expiry of blockbuster products. Here it is noteworthy, that the API world is divided into two types of producers. On the one side are the captive API producing pharma groups which exclusively manufacture APIs for their finished, branded products and on the other side are the so called third party manufacturers which serve the merchant market as supplier of APIs. The growth of the merchant API market for generic products has substantially outpaced the growth of the API for innovator products. As we know, many of these third-party manufacturing companies are located in Asia. China, in particular, is expected to increase its participation in this growth significantly. Even though the amount spent by emerging generic markets for medication is still small compared with those of Europe, North America and Japan, it nevertheless announces that generic drugs will most likely be responsible for the future growth of the pharmaceutical industry. China, India, South America and Russia consequently represent attractive growth opportunities for generic APIs.

H. Sieger (CU Chemie Uetikon): ... be an important pillar of our future health care system and of Chemie Uetikon's pharmaceutical custom manufacturing activities. It is likely, that branded Generics will be a success by reducing health care costs while providing high quality medication. This will hold true as long as manufacturing sites and processes do comply with highest, European standards and are not sacrificed for economical reasons by manufacturing in uncontrolled and unregulated markets.



The future of APIs is ...

M. Blocher (Dottikon): ... not overwhelming but sound. The pharmaceutical companies are concentrating on their core competencies of clinical research and development, patenting and distribution, and will increasingly seek out strategic cooperation with experienced, innovative and reliable partners in process development and manufacturing. Such chemical exclusive synthesis partners need to possess a versatile technology portfolio like a Swiss army knife and be as precise and reliable as a Swiss watch.

Dr. A. Dietrich (Boehringer Ingelheim): ... is certainly driven by a number of exciting trends. We know that the global market for biopharmaceutical APIs is expected to grow continuously at approximately 4% per year. Average growth for large molecule-based APIs is outperforming the projected corresponding rate for chemically derived small molecule APIs. The majority of the worldwide market for biopharmaceutical APIs is located in Europe; North America and Japan show satisfactory growth rates. Only Asia promises an even better outlook for growth since the biosimilars market will grow more than the innovator's biopharmaceutical APIs. When looking at the market for biosimilars, the potential is somewhat less defined when compared to chemically designed generic APIs, since it is still a more complex issue to establish a bioequivalence for a biopharmaceutical versus a chemically synthesized API. Consequently, this matter creates an uncertain regulatory framework for approving biosimilars in some parts of the world which needs to be addressed and solved. In addition, the costs of developing a biosimilar are more expensive due to the required time and resources needed for the protein analytics and clinical trials requirements. We believe that despite all these challenges there will be attractive market growth for these types of APIs down the road. Novel, chemically derived APIs will continue playing an important part in helping to bring new and innovative medicines to the market. Of course, managing cost early on will play an ever increasing role, independent of the life cycle stage the product is associated with. Lowering cost for already well established products has to be examined carefully and weighed against benefits. Reducing cost will more and more be designed early on into the discovery routes. In order to support such efforts, the various internal stakeholders from R&D, procurement up to operations have to work hand in hand to manage the total cost design of the final drug. There are many opportunities and challenges for novel and generic APIs in the future. Pharma companies have to be smart about the ways they can increase the economic value product by product.

H. Sieger (CU Chemie Uetikon): ... most likely a future of more diversification. The age of block-busters is over. We will probably see an increasing number of highly specific drugs to treat rare diseases for rare or yet not treated diseases and for prevention rather than treatment. Preventative healthcare provides significant opportunities for Pharma industry and healthcare systems alike.

SEE YOU IN FRANKFURT

This year's CPhI Worldwide is taking place in the heart of Germany. From Oct. 25–27, Frankfurt is the place to be if you do business in the pharma industry. We're looking forward to seeing you there!

Do you have a story to tell? Or just want to find out more about what CHEManager Europe and CHEManager have to offer? Then just drop us a line – we'd love to hear from you.

Editor-in-Chief
Brandt Schuster
Tel.: +49 6201 606 755
brandt.schuster@wiley.com

Editor
Dr. Birgit Megges
Tel.: +49 9617 448250
birgit.megges@wiley.com

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

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

GIT VERLAG

www.chemanager-online.com/en



General

Challenges – The challenges facing the pharma industry today – impending patent cliff, pressure coming from pharmerging markets, etc. – make the playing field rife with opportunities for pharma service providers.

Innovation in the pharmaceutical ingredients industry is being driven by ...

R. Hardy (Aesica): ... the versatility of contract manufacturing organizations, which are now in a much stronger position because of their ability to offer a greater portfolio of services. The trend to outsource has been significantly shaped by the rising cost pressure on the pharmaceutical companies. Demand for pharmaceuticals has increased worldwide and this, coupled with improving standards of manufacturing facilities and rising cost pressure on companies, are the prominent factors contributing to the huge growth in the contract manufacturing sector. The pharmaceutical industry is facing several challenges, which lead to increased demand for contract manufacturing services. These include the rising cost of new product development, increasing competition in generic

markets, declining R&D productivity, decrease in average patent life and government pressure to reduce drugs prices. In these circumstances contract manufacturing as a strategic option offers several advantages. Using an outsourced company provides flexibility, a quicker time to market and lower scale up costs. This means that emerging pharma and biotechnology companies can meet the growing demand for new drugs and focus on their core competencies. Furthermore, outsourcing enables companies to reduce excess capacity in their manufacturing networks and restructure supply chains.

Dr. R. Fink (BASF): ... new APIs for the typical therapeutical areas. However, we think that lower solubility and bioavailability will become a significant challenge of our industry and requires intensified innovation efforts in the area of excipients. BASF is part of this innovation process by own R&D activities as well as together with its customers and partners.

B. Freiberg (Merck Millipore): ... customer needs. In this industry, services and solutions are constantly evolving to improve customer productivity, minimize complexity and lower costs while reducing risk.

In 10 years, our industry will be ...

R. Hardy (Aesica): ... much stronger, competitive and diverse with the most significant contribution to the pharmaceutical market coming from emerging economies such as Brazil, Russia, China and India. In fact, the 2010 IMS Health forecast predicts that pharmaceutical markets in

Center Stage: Emerging Countries

All-round Pharma Service Providers See Potential in Asia, Elsewhere



Robert Hardy
CEO, Aesica

emerging economies will grow at 14–17% year on year between now and 2014. These regions are expected to grow three times faster than mature markets due to a combination of evolving demographics including a rise in incomes, upgrading of health systems and an increased investment in the treatment of chronic diseases. Factors such as low-production cost and minimum taxes on production will ensure China is an attractive region for drug manufacturing and the export of pharmaceutical products from China has increased considerably during the last few years alone.

Dr. R. Fink (BASF): ... different. Cost pressure, strong growth in emerging countries, ongoing market consolidation as well as the emergence of new regional or even global players and a significant higher demand for performance excipients are scenarios we want to be prepared for.



Dr. Ralf Fink
Vice President and Head of
Pharma Ingredients at BASF

B. Freiberg (Merck Millipore): Redefined by forward thinking companies, like Merck Millipore, who are willing to push the envelope in the interest of innovating the pharmaceutical ingredients industry.

The most drastic change that has happened in the last 10 years is ...

R. Hardy (Aesica): ... the trend for large pharma companies to outsource various stages of the manufacturing process to minimize overheads and reduce capital investment. As they concentrate on R&D and focus on uncovering new compounds while investing in marketing and brand building, they are choosing to outsource all aspects of the manufacturing process to specialist providers. In particular, over course of the last five years there has been an increased demand for formulated products and packaging services.



Burghard Freiberg
Senior Vice President Pharm Chemicals
Solutions, Merck Millipore

However, working with a partner that can provide a full service offering from formulation development through to commercial supply, packaging, as well as regulatory support is a unique proposition in the industry.

Dr. R. Fink (BASF): ... the importance of the emerging economies and their increasing role along the whole value chain, including R&D.

B. Freiberg (Merck Millipore): ... increased global regulation. Now more than ever, pharmaceutical companies are faced with regulatory pressures that need to be addressed. That is why partnering with an organization that deeply understands your challenges and can help assure the quality and safety of products you bring to market, is paramount.

For our business, Asia is ...

R. Hardy (Aesica): ... a critical market for Aesica and an area we're actively looking at expanding into. Aesica is already a global business with six manufacturing facilities in our growing portfolio. However, further expansion is planned and we are looking at opportunities for strategic acquisitions and the potential of forming long-term partnerships in the U.S. and Asia, especially India, as we look to grow the business further globally.

Dr. R. Fink (BASF): ... very important, fascinating and challenging. We are keen to play an even more active role in that part of our world.

B. Freiberg (Merck Millipore): Essential. We are striving and continuing to build relationships in Asia that will allow us to expand our reach and provide customers – in this rapidly developing market – with innovative products and solutions to meet their goals. We are deeply committed and invested (more than 30 years) to increasing innovation and the quality of the drugs that are made in the region.

Governmental healthcare reforms and cost-reduction plans will ...

Dr. R. Fink (BASF): ... continue.

B. Freiberg (Merck Millipore): Drive innovation in the market and ensure that manufacturers will continue to streamline processes (while advancing technology) to deliver the best possible product to the market.

chemanager-online.com/en/tags/pharma



EVENTS

The ChemShow, Nov. 1–3, New York City Showcasing the latest process equipment, products and technology, the Chem Show brings together manufacturers and innovative new suppliers with executives, process engineers, production teams and plant personnel.

► www.chemshow.com

Expoquimia 2011, Nov. 14–18, Barcelona This year's show will be putting an emphasis on the scientific side of chemicals, with a program of conferences, seminars and other activities. Expoquimia aims to provide solutions for emerging markets, such as alternative energies, biotechnology, industrial pharmaceuticals, fine chemicals and food-related sectors.

► www.firabn.es

10th Annual World Drug Manufacturing Summit, Nov. 29–Dec. 1, Berlin Now in its 10th year, World Drug Manufacturing is firmly established as the must attend event for small molecule and biologic manufacturers. Over the course of the three days, the industry will gather to discuss many hot topics. The 2011 WDM program will address the major issues affecting the pharmaceutical and biotech industries at the current time, such as change management; cost reduction; changing product portfolios; and much more.

► www.wdmsummit.com

Industrial Green Chemistry World-Symposium & Expo (IGCW 2011), Dec. 4–6, Mumbai Industrial Green Chemistry World is India's first flagship platform that brings together mainstream issues concerning Green Chemistry and Green Engineering (GC&E) to all Chemical Industry stakeholders. At the IGCW 2011, you can be assured of in-depth exposure to diverse and successful endeavors in the industry and bring on par your technological and business practices with world leading practices and global trends in GC&E.

► www.industrialgreenchem.com

European Chemical Region Network 2011 Congress in Germany

The chemical industry has played a vital role in the industrial sector in Saxony-Anhalt, Germany, for many years now. Generating 14% of overall turnover and employing 9% of the total workforce, it has a leading position among the various industries in the federal state of central Germany. In terms of exports, it is top of the pile. The chemical industry makes up one fifth of all industry export turnover in Saxony-Anhalt.

So, it's all the more pleasing that the local chemical industry has had such a strong start to 2011. At the home of the central German chemical industry, turnover from January to March rose to €1.9 billion. Seasonally adjusted in comparison with the previous quarter, turnover has risen by more than 21%. Compared to the same quarter the previous year, business volume has risen by a third. The main impetus behind this rapid development has been the classic chemical industry. The pharmaceutical industry has contributed nearly €300 million to this sector's turnover in the federal state.

"Investing in innovations is an absolute necessity if we want to continue to drive growth forward and ensure competitiveness, because knowledge is increasingly becoming a decisive production factor," said Prof. Dr. Birgitta Wolff, Minister for Science and Economy in Saxony-Anhalt and president of the European Chemical Regions Network (ECRN).

ECRN currently brings together 21 chemical regions from across Europe. This year's 9th Congress of the European Chemical Regions Network, will be held at Oct. 27 in

Halle/Saale Germany. This year the congress host is the federal state of Saxony-Anhalt in central Germany and the organizers expect a range of high-ranking representatives from politics, business, academia and public authorities to put a spot on the European regional policy.

Particularly the potential and challenges of sustainable use of structural funds in the European chemical regions in terms of the Europe 2020 Strategy will be one of the main topics.

The congress aims to support the exchange of views and experiences from different stakeholders in the chemical sector at a European level and fruitful discussions with representatives from the European Commission, the European chemical industry associations, unions and the member regions.

Additionally visitors are free to attend the workshops "Demographic Change", "New ways in the politics of innovation" and "The contribution of chemical logistics to the maintenance of the competitiveness of the chemical industry in Europe." The report of Prof. Dr. Birgitta Wolff on the active role of the German federal government in developing European transport corridors to create the base for chemical logistics completes the congress program.

► www.ecrn.net
► www.investieren-in-sachsen-anhalt.de



PEOPLE



Thomas Büttner

Büttner New AllessaChemie President and CEO Dr. Thomas Büttner became AllessaChemie's president and CEO on Oct. 1. Büttner, who has been directing the company's group functions since May 1, takes over from Almut Pötz. He began his career in chemicals in 1984 with Rütgerswerken in Frankfurt, where he worked in various subsidiaries in several different positions until 2003. Before joining AllessaChemie in May, he was managing director at WeylChem and Sensient.



Michael Träger

Träger Relected as Euro Chlor Chair Michael Träger, managing director and COO of Vestolit, has been reelected as chairman of Euro Chlor for another one-year term. This re-election is the logical consequence of a change in the Euro Chlor statutes to extend the term of the management committee chairman to two years. Träger has been involved with Euro Chlor activities for over 11 years. During his chairmanship, he said intends to help further develop the new and improved sustainability program for the coming decade in order to foster and strengthen the achievements of the chlor-alkali industry's reputation and its sustainable contribution to a safe and healthy community.



Kenneth Frazier

Merck & Co. Announces New Chairman Merck & Co. announced the retirement of its chairman Richard Clark, effective Dec. 1. Kenneth Frazier, president of chief executive officer will succeed as chairman. Clark has been with the company since 1972 and served as chairman since 2007. He was president and chief executive officer from 2005 through 2010. From the role of quality control inspector, he progressed through increasingly responsible roles. He left the company to join Merck-Medco Managed Care subsidiary as executive vice president and chief operating officer. He later became the chairman, president and chief executive officer of Medco Health Solutions. In 2003 Clark rejoined Merck as president of manufacturing division.