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Regions & Locations
US Chemical Industry, Foreign Investment in China, Chemical Logistics in France, Italian Biotech Sector

Pharma & Biotech
Covid-19 Impact on Pharma CROs/CDMOs, Virtual Formulation Prediction, Industry Challenges & Trends

Innovation
Digital Transformation, Sustainability, Physical Property Prediction, Data-driven Solutions, Binding Technologies

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Regions & Locations

Pharma & Biotech

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Successful worldwide trading of commodities and specialties

Trade, Innovation and Investment

The US Chemical Industry is Poised to Remain a Global Hub for Production

A world leader with $565 billion in shipments, the United States accounts for 14% of global chemical shipments and is the second largest chemical producing nation after China. The chemical industry is also a large exporting sector in the US, accounting for around ten cents out of every dollar of US exports. In addition to the industry's contributions to the global economy, innovations in chemistry have created countless economic and societal benefits: longer and healthier lives through medical advancements; improved standards of living from fertilizers and water treatment; and instant access to information from anywhere, thanks to smartphones and other smart devices, to name a few. Thanks to chemistry, groundbreaking products are improving the world all around us by making it healthier, safer, more sustainable and more productive.

At present, the world continues to cope with a global pandemic that has disrupted supply chains and affected the lives and livelihoods of billions of consumers while claiming a large and growing human toll. While there is increased demand for chemical products that serve as essential inputs to many products used in response to Covid-19 (hand sanitizers, disinfectants, face masks and other personal protective equipment and more), many other key end-use markets and export customers have experienced a sharp decline in demand over the past year.

Amidst near-term uncertainty, the products of the US chemical industry remain in demand around the world. The competitive advantage enabled by domestic shale gas development has resulted in more than $200 billion in announced investment in US chemical manufacturing capacity over the past decade. Along with ongoing investment in innovation, the US chemical industry is poised to remain a global hub for production in the years ahead.

Heather R. Rose-Glowacki, American Chemistry Council

US Trade

US chemistry remains in demand around the world despite ongoing trade tensions and Covid-19. In 2019, the US chemical industry was one of the world's largest exporters, at $136 billion. The industry has a large and growing trade surplus, reaching more than $35 billion in 2019. Trade is essential to the success of the US chemical industry, and it benefits the broader economy as well. Today, the chemical manufacturing sector is one of America's top exporting industries, accounting for around 10% of all US exports.

US trade in chemicals (both imports and exports) has grown steadily over the years but, on balance, the US chemical industry has maintained a net exporter position. Due to access to abundant and affordable shale gas, US chemical manufacturers benefit from comparatively lower production costs. Some of the segments that benefit the most from the shale gas revolution, such as petrochemi-

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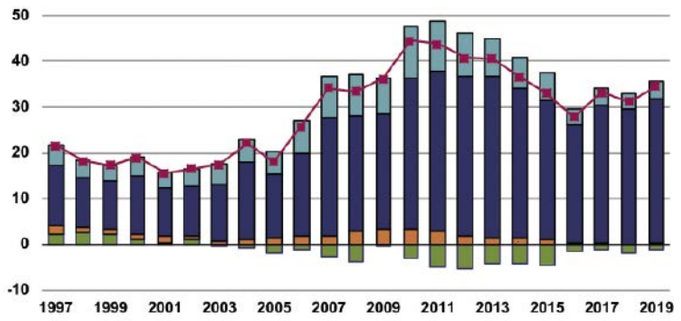

Fig. 1: US Chemicals Trade Balance by Segment ($ billions).

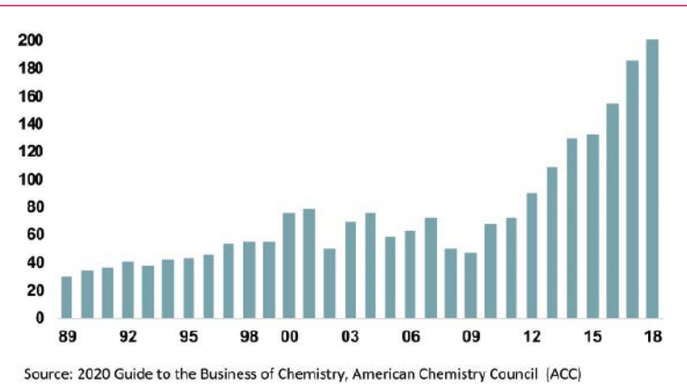

Fig. 2: Foreign Direct Investment in US Chemistry ($ billions).

cals, intermediates and plastic resins, account for the majority of chemicals trade and the increased competitiveness of the industry could lead to a growing trade surplus, particularly in these segments.

A significant portion of US trade is within North America: Canada, the largest single national market for US chemical exports, and Mexico, the second-largest, together consistently account for around one-third of US chemical exports (nearly $43 billion in 2019). In addition to regional proximity, more than 70% of US materials imports, and almost half of US chemical exports, are intra-company, meaning one company exchanges materials with its overseas affiliate.

Nearly one-fourth of US chemical production is exported. Outside North America, the largest markets for US chemistry exports are China, Brazil, Japan, and South Korea. While imports account for a slightly lower percentage of domestic consumption, more than half of US chemical imports are essential inputs used for domestic chemical production. Canada is the largest source of chemical imports to the US, most of which are plastic resins and commodity chemicals. After Canada, the top countries for US chemical imports are China, Germany, Japan and Ireland.

US chemicals trade has been greatly impacted by Covid-19, as well as by steep tariffs on US-Chinese chemicals trade and increased trade policy uncertainty. Both imports and exports of chemicals have declined in 2020, although the US has maintained its net exporter position.

Guide to the Business of Chemistry

The "Guide to the Business of Chemistry", published regularly by the American Chemistry Council (ACC), is an important source of data on the US chemical industry. The publication characterizes the chemical business in ways that are familiar to the industry, as well as its observers. Since 2018, ACC has been publishing most of its data on a chemicals (excluding pharmaceuticals) basis. It made this change in order to align its statistics with those of its global partners and the business community who view chemicals and pharmaceuticals as separate industries. The pharmaceutical industry remains a key end-use market for chemical ingredients.

Innovation & Investment

A key driver of competitiveness and economic growth, innovation is at the core of value-added products and services, more efficient production processes, and improved business models. Innovation is found in all aspects of the chemical industry, from research and development (R&D) to business processes to customer relationships and knowledge. The US chemical industry is consistently one of the largest private-sector industry investors in R&D. Even times of lower profit margins and economic uncertainty, chemical companies generally maintain their R&D activity: the US chemical industry has invested more than $10 billion, on an annual basis, in R&D spending for over a decade.

Successful innovation in the business of chemistry requires intensive effort and major expenditures and it can take years from the time a project is conceived to the time a chemical product is brought to the marketplace. A 2013 McKinsey & Company study ("Chemical innovation: An investment for the ages") found that it takes from two to 19 years for a chemical product to reach the market.

Capital investment (the investment in structures and equipment) is also essential to the continued competitiveness of the US chemical industry. Over the past decade, annual capital investment in US chemicals has more than doubled, reaching $35 billion in 2019. A key factor for the increased investment has been the competitive advantage enabled by shale gas development. With more than $200 billion in announced investment since 2010, investors from around the world recognize the advantage of building chemical capacity in the US. Indeed, 69% of these investments are foreign-direct investment or include a foreign partner.

Innovation is a long-term driver of future financial performance and value creation. It provides business opportunities, as well as the sustainable foundation for continued growth.

"US chemistry remains in demand around the world despite ongoing trade tensions and Covid-19."

Innovation can lead to shifts in relative cost relationships, and provide sustained competitive advantages. Indeed, it is at the heart of the business of chemistry, and is crucial to economic growth and improvement in the quality of life.

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Thist text is based on — and includes excerpts from — the American Chemistry Council's publication "**2020 Guide to the Business of Chemistry**". The report is available via bit.ly/2020-ACC.

Foreign Investment in China's Chemical Industry

Which Chemical Products and Segments are Affected by the Government Strategy of Shaping the Industry?

On July 31, 2020, the National Development and Reform Commission and the Ministry of Commerce of China published a draft of the "Catalogue of Industries Encouraging Foreign Investment (2020 Edition)" and asked for comments until Aug 30, 2020. The catalogue includes 34 categories related to the chemical industry. What are these categories, why are they included, and what does it mean for potential foreign investors?

Kai Pflug, Management Consulting — Chemicals

Four Industry Segments

The draft groups the 34 categories into 4 segments:

- Petroleum processing, coking and nuclear fuel processing (1 category)
- Chemical raw materials and products (23 categories)
- Chemical fibers (5 categories)
- Rubber and plastics (5 categories)

First Segment

"Petroleum processing" etc., covers some methods of oil processing and is of less interest to the downstream chemical industry.

Second Segment

"Chemical raw materials and products" is by far the biggest segment, accounting for two thirds of all chemical categories. A strong focus within this segment is on innovative materials with properties superior to the existing ones. Examples include the categories

- High-performance fluorine resins
- High-performance coatings
- New fertilizers
- New forestry chemicals
- New pesticides
- New catalysts and other fine chemicals
- Organic polymer materials (e.g., aircraft skin coatings, lithium ion battery separator, nanocoating materials, self-repairing surface treatment etc.)

This partly overlaps with materials with superior environmental properties and materials improving the environmental impact of chemical processes, as indicated by categories such as

- Biological pesticides
- Membranes for environmental protection
- Low-volatility inks
- High-solid coatings
- Propylene oxide by hydrogen peroxide oxidation
- Utilization and treatment of waste gas and liquid
- Hydrogen fuel production

The catalogue also promotes the development of a stronger fine and specialty chemicals segment in China.

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Categories include
- Production of natural and synthetic fragrances
- Fine chemicals including paper chemicals, adhesives, sealants, oilfield additives
- New catalysts

Another important thrust is to reduce China`s dependency on imports of chemical materials, most of which are at the higher end of the value scale. Categories for which this applies include
- Production of engineering plastics (e.g., PBT, PA, LC)
- Production of high-purity electronic grade hydrofluoric acid and hydrogen fluoride
- Production of high-end polyolefins (while China has increasing capacity for standard polyolefins, the country still imports many of the more sophisticated grades)
- Specialty rubbers
- Production of high-purity industrial gases including electronic gases
- Production of fiber raw materials such as nylon 66 salt and 1,3-propanediol

Third Segment

"Chemical Fibers" primarily contains categories that similarly focus on innovation, sustainability and high-performance materials. Examples include the production of high-performance fibers (e.g., carbon fiber, aramid, UHMWPE, PPS), the use of renewable resources to produce biomass fibers (e.g., Lyocell, PLA, PHA) and the production of new polyamides such as the different nylon varieties nylon 11, nylon 12, nylon 1414, high-temperature nylon. Innovative polyesters and their applications play a prominent role in this segment, e.g., production of new polyesters such as PTT and PEN, production of functional polyesters (e.g., biodegradable, low-melting, non-crystalline, flame retardant, antibacterial).

Fourth Segment

"Rubber and Plastics" is strongly focused on environmental aspects of these products. Relevant categories include the development of biodegradable plastics, the recycling of waste plastics, and environmentally friendly agricultural films. The innovation aspect is covered in a category promoting new technologies for flexible packaging.

What Is New?

How does the 2020 draft catalogue compare with the 2019 version? In fact, the differences are relatively small. Most categories have remained unchanged, none have been removed, and two have been added. These are "Production of Polyethylene Polyamine Products" in the chemical raw materials section and "Development, Production and Application of Silicone Products" in the rubber section.

Polyethylene polyamines are primarily used as hardeners in epoxy resins but also in the production of ion exchange resins, as crude oil demulsifier, additive for drilling fluids, and as a raw material for corrosion inhibitors, amino resins, varnishes, disinfectants and detergents. Presumably this broad application spectrum merits their inclusion in the 2020 version of the catalogue. Similarly, silicone rubber is used in a large variety of applications such as automotive, cooking products, apparel, sportswear, electronics and life science applications (including respiratory masks, which presumably due to Covid-19 feature much more prominently in people`s thinking).

"Investment in the areas listed in the catalogue is supported by a variety of incentives."

The limited number of changes in the catalogue is consistent with its representation of a long-term government strategy of shaping the chemical industry. Setting up capacities in each of the categories is a process that will take several years or even decades—any massive shifts from year to year would therefore be counterproductive. This also means that investors can expect the currently promoted industries to stay in favor at least in the medium term, if not longer.

Government Encouragement

In summary, China`s catalogue of promoted areas for foreign chemical investment is in line with China`s broader industrial policy of phasing out backwards, heavily polluting industries, and promoting investment in high-tech areas that move China up in the global value chain. In addition, self-sufficiency is regarded as a goal on its own. In the chemical area, this results in four basic subjects for investment promotion:
- Chemicals and production processes with improved environmental balance
- Chemicals and materials with improved functional properties
- Chemicals for which China currently strongly depends on imports
- Chemicals which are associated with higher value creation (this of course partly overlaps with some of the other areas, but may also be a goal on its own, e.g., in fragrances)

Implications for Investors

What does the catalogue mean for foreign chemical investors in China? Investment in the areas listed in the catalogue is supported by a variety of incentives. These incentives include customs duty exemptions for imported self-use equipment and preferential land transfer fees (no lower than 70% of the corresponding lowest national standard price for industrial-used land). Local governments may also offer tax incentives and streamlined approval procedures. In addition, inclusion in the list of promoted categories may be vital to secure space in a high-quality chemical park. For example, Shanghai`s chemical park (SCIP) has become extremely selective in choosing new tenants but allowed Invista to build an adiponitrile plant in the park, likely because adiponitrile is among the chemicals listed in the catalogue (with a minimum production capacity of 50 kt, which is easily surpassed by Invista`s capacity of 400 kt).

Foreign investors may therefore want to familiarize themselves with the catalogue and try to match it with their company strategy. Any China investment aligned with the policy outlined in the catalogue will certainly find a warm response by Chinese authorities. And while the catalogue is focused on greenfield investments in China, it may also have an impact on M&A activity. Foreign companies acquiring domestic players in the areas listed in the catalogue with the promise of upgrading the technology and portfolio of their targets will have a powerful argument in their favor.

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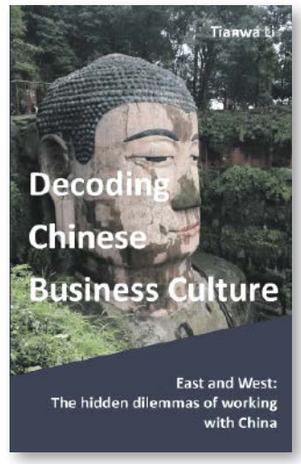
Decoding Chinese Business Culture



This book by Chinese intercultural expert Tianwa (Tina) Li helps decode the dynamic Chinese business culture from the inside and from a Western perspective. The author, who comes from Jilin, China, and works as a university lecturer in Germany, puts her adopted country forward as an example of a nation that has managed to find its own way of working pragmatically with the Chinese—not kowtowing to them, but finding ways to collaborate that are realistic. Tina Li, due to her personal background, is specialized in the communication between West and East and offers cutting-edge insight and practical strategies for those who have business contacts with Chinese professionals. The book is rich with real-life examples, and insights into language, including many Chinese proverbs; differences between Chinese and Western philosophies; a brilliant summary of Chinese history, and an exploration of issues of truth, trust, leadership and how to persuade and sell to the Chinese.

Tina Li has also published articles in business media, for instance in last year's December issue of CHEManager International, where she describes how to navigate the complexities of cultural differences between East and West when doing business in China. She says: "There is no list of Dos and Don'ts regarding doing business in a foreign culture. Intercultural competence is a dynamic give-and-take. Read the article here: bit.ly/TinaLi-DoingBusinessInChina

Decoding Chinese Business Culture
East and West: The hidden dilemmas of working with China
Tianwa (Tina) Li · 2020, Spitzenberg World Press · Pages: 202, Price: 14.99 EUR · ISBN-13: 978-3982226088 (Paperback)

On the Edge of a Disruptive Digital Revolution

DigiChem SurvEY Shows: Digitalization Is Gaining Momentum in the Chemical Industry

After other sectors including retail and the music and media industry were already severely shaken by digitalization a few years ago, the chemical industry has so far been largely spared from its fundamental upheavals. The digital transformation got off to a comparatively leisurely start in the chemical industry — without any major shocks to existing business models. But that could change now.

Sven Mandewirth

Frank Jenner

A total of 66% of 369 top decision-makers worldwide participating in the DigiChem SurvEY 2020 expect revolutionary or even disruptive changes as a result of digitalization in the next three years. The noticeable transformation phase is thus imminent.

For the moment, the situation can be described as the calm before the storm. Looking back over the past three years, only 31% of respondents perceived revolutionary or disruptive changes brought about by digitalization. On a scale of 0%–100%, the participants rate the progress of implementation on an average of 63%. However, it should be noted that this value primarily indicates the perceived transformation and not the extent to which companies have achieved their defined goals.

Deeper Transformation Shifts Focus on Central Issues

Medium-sized and larger chemical companies are currently experiencing a profound transformation. It is no longer a question of implementing digital technologies. The goal is now to completely transform existing processes and structures. And this also involves more complex challenges that are being tackled in the longer term. As business models change or new ones emerge and different players in the ecosystem cooperate more closely, new digitalization issues are arising. The degree to which objectives have been achieved should therefore be seen as a snapshot, since on the one hand existing projects are being successfully processed, while at the same time new projects are being initiated.

As the changes have become more fundamental, the focus has also shifted in terms of content. For example, the study participants see a growing influence of digitalization on their companies' strategic and operational positioning. The strongest influence of digitalization is expected in the areas of innovation and development (56%) and customer interface (56%). The influence on processes and efficiency along the value chain (55%) is also estimated to be very high. Regarding operational competitiveness, the area of logistics and distribution (62%) ranks first, followed by sales and order management (59%) and customer service (58%). Thus, the influence of digitalization is expected to be most noticeable in areas that are directly perceived by the customer. Primarily internal processes such as supply chain planning, production and quality management, and purchasing are farther down the list.

> *"The effects of digitalization are shifting more strongly in the direction of customers, service and logistics."*

When it comes to the improvements already achieved through digitalization, cost reductions are clearly ahead with a share of 51%. The more tense economic environment and increasing investment in digitalization have certainly also contributed to this. This is followed by faster throughput times (47%) and a stronger customer-centricity (43%). Lastly, improved market and customer access is mentioned, which shows that in this case the digital transformation is still ahead for many companies.

Pandemic as a Practical Test

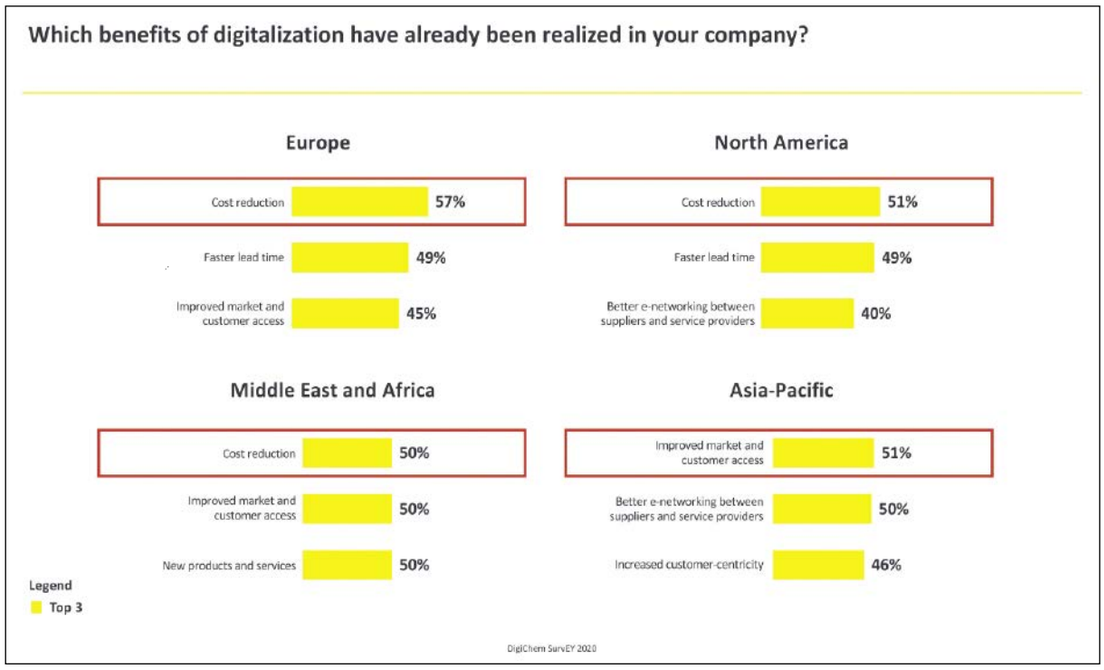
This year, the Covid-19 pandemic was a test for the progress of digitalization in companies. Within a very short time, they had to switch to remote work, remote customer service and digitize processes that had been analog. For most of them, this was apparently not a problem: overall, 57% of the participants rated their company at the beginning of the crisis as very well or well prepared. Depending on the individual company functions, this varies between 61% who regard administration and back-office management and 52% who regard production and technology as important issues. To be even better prepared for comparable crises in the future, companies want above all to create more transparency about changes (73%), formulate clear rules (70%) and facilitate digital access to information and documents (69%).

International Comparison: Asia-Pacific is Leading

From an international comparison, how advanced are European coun-

tries in the digital transformation? In contrast, how far have companies in the North America and Asia-Pacific regions progressed? The survey provides answers to these questions for the first time. According to the results, the participants in the Asia-Pacific region see their companies making progress in implementation by an average of 77%. In contrast, North America (59%) is nearly on a par with the European countries (60%) on a much lower level. It should be noted that among Asia-Pacific participants, the proportion of large companies and the basic petrochemical business segment is significantly higher than in other regions. Parallels between Europe and North America can also be seen in the business areas that are positively affected by digitalization. The participants in these regions see a strong or very strong influence on the operational success of the company—above all on processes and efficiency, customer service, and innovation and development. In contrast, Asia-Pacific participants rate the influence on operational and strategic topics equally high. The impact of digitalization on corporate strategy, portfolio, business models and the depth of value creation is rated much higher in Asia-Pacific than in other regions. Ultimately, this is also reflected in the assessment of the benefits already realized from digitalization.

"As chemical companies in Europe and North America are focusing on efficiency, they may miss the market opportunities of digitalization."



Fine-Tuning Focus to Take Advantage of Opportunities

While other regions put cost reduction first, improved access to markets and customers is a top priority in the Asia-Pacific region. From our analysis, this is a result of the growth ambitions in the Asia-Pacific region and the associated market, and customer orientation. In addition, the high degree of maturity of the chemical regions in Europe and North America, where process efficiency and cost reduction have played an important role in recent years, is also evident. For companies in Europe and North America, however, this also entails a risk: missing out on the new market opportunities offered by digitalization and the digital transformation of their own business model. This closes the circle in terms of process efficiency and cost reduction. After all, significant improvements can often only be realized in a market-oriented and modern business model.

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Italian Biotech: A Vital and Dynamic Industry

The biotech industry in Italy is vital and is showing a constant growth. About 700 biotech firms are currently based and doing research and business in Italy. The biotech turnover exceeds €12 billion, with an average annual increase of 5% between 2014 and 2018.

80% of the Italian biotech industry is made up of small and micro companies, which have been a driving force in the growing dynamics for the entire field. More than 50 new innovative start-ups, active in the biotech field, have been registered between 2017 and 2019. In total, innovative biotech start-ups represent about 20% of the total sector.

These figures are taken from the report on the Italian biotech industry, prepared in cooperation by Assobiotec (Italian Association for the Development of Biotechnology, part of Federchimica) and ENEA (National Agency for New Technologies, Energy and Sustainable Economic Development) and published in May 2020. The analysis offers an update on the current Italian biotech industry in 2019.

On the basis of this data, the Italian biotech industry proves to be a growing field with a number of companies which has consolidated in time, but should strengthen in terms of size, also in order to improve its competitiveness on an international level. The R&D activities are a true strong point, with real excellence in all biotech fields of application.

The biotech research intensity is above average when compared to the overall Italian industry. Although the biotech industry makes up only 0.02% of the total national companies, its biotech R&D investments represent 3.4% of the total Italian business enterprise R&D investments.

49% of the biotech companies in Italy are mainly involved in human healthcare, 30% are active in the production and/or development of products and services for industrial or environmental applications, 8.6% in agricultural and veterinary applications, and 12% of the companies are working in the genomics, proteomics and enabling technologies (GPET) application field. The same exact field distribution can be found among the innovative start-ups, which represent 20% of the national biotech companies.

The biotechnologies underpin the innovation capacity of the bioeconomy, intended as a system that utilizes terrestrial and marine biological resources, in addition to waste, to produce fuel and energy products as well as to provide inputs for industrial production processes. Bioeconomy's importance over the total economic activities in Italy has grown from 8.8% over the national total in 2008 to 10.1% in 2017.

Two thirds of the Italian biotech turnover are being generated by foreign capital companies, which are mainly active in the human health industry. The Italian capital companies instead, generate more than half of the biotech turnover in the industrial and environmental field of application, reinvigorating the traditional chemical specialization of the national productive fabric. (mr) ■

Don't Waste, Innovate

A Sustainable Industrial Symbiosis in Flanders

Within the last 24 months, a whole range of companies announced a series of massive investments in their sites in Flanders, the Northern region of Belgium. Borealis is building a brand-new billion-euro propylene plant, Covestro is investing €300 million in an aniline production facility, BASF is pumping €500 million in a new production complex for ethylene oxide and derivatives, while Ineos is spending a whopping €3 billion on a new propane dehydrogenization plant and ethane cracker. This investment by Ineos represents the single largest investment in the European chemical industry in two decades.

On top of that, other chemical companies like Evonik, Nippon Shokubai, Standic and Air Liquide also signaled multi-million euro investments in their Flemish sites. These combined investments will create hundreds of jobs across Flanders and reinforce the Port of Antwerp's role as Europe's leading chemical cluster.

And there is more. With the ports of Ghent, Zeebrugge and Ostend, Flanders boasts three more international seaports. Known for its quality infrastructure, the Port of Ghent—which has joined forces with Zeeland Seaports in the Netherlands to form North Sea Port—is determined to invest in future services. With the Rodenhuizedok bio-refinery, it is already hosting Europe's largest integrated bio-energy production complex, producing bioethanol, biodiesel and bio-electricity under one roof. In addition, a new circular economy will be created in North Sea Port: waste from one enterprise will be used as a raw material by another one.

The North-C-Methanol Project

Launched in October by ten private- and public-sector partners, North-C-Methanol is the first large-scale demo plant which is part of the North-CCU-Hub program, representing an initial investment of €140 million. Together they will reduce the CO_2 emissions each year by 140,000 tons. The ten partners comprising the project are multinationals and smaller players from various sectors: ArcelorMittal, Alco Biofuel, Engie, Fluxys, Mitsubishi Power, Oiltanking, PMV, Proman, the development agency East-Flanders (POM) and North Sea Port. They will also generate 44,000 t of "green" methanol locally, which can be used as feedstock for the chemicals and renewables industries, as well as fuel for ships and trains.

Jessica Manthey, Flanders Investment & Trade

Stef Denayer, North-CCU-Hub

This CO_2 reduction is equivalent to the carbon absorption of around 6 million trees per year. This is a world-class project and is expected to have the largest renewable hydrogen-to-methanol complex in the world.

Important Raw Material

The Carbon Capture & Utilization technology (CCU) technology

to transform CO_2 into green methanol is one of the most mature CCU technologies. Different demonstration plants are available. However, North-C-Methanol will be a "first of its size" project. Methanol is an important raw material, also for the industry in North Sea Port. Its production is however still based on fossil sources (oil and gas). Different sectors have a need for methanol, which will need to be green methanol in the future. It is an essential building block in the production of methylamines, biodiesel, formaldehyde and acetic acid, and it has very interesting properties to be used as an alternative fuel: high flame speed, high vaporization heat, low combustion temperatures and others. Used as a blend component or in its pure form, it can be applied in internal combustion engines or in methanol fuel cells, and is easily handled, transported and stored.

Sustainable Industrial Symbiosis

The North-C-Methanol project is a landmark example of sustainable industrial symbiosis: raw materials are extracted locally, and finished products and secondary flows are used locally. All by-products of the methanol production process, such as oxygen, heat, and water, will also be recycled locally. This will ensure a unique and far-reaching industrial and circular integration. Of course, this will fully go hand in hand with the building of much supporting infrastructure, such as new pipelines and storage tanks, in order to transport raw materials, by- and finished products to the correct location. Fluxys and Oiltanking are to be responsible for this, with Mitsubishi Power overseeing the integration and coordination of the entire construction process. Nancy De Groof, VP Business Development of Oiltanking EMEA, says: "Our world, our planet, our home, our responsibility. Circularity is no longer an option but a must. Flanders has all the assets a circular economy could wish for: land, ports, energy, chemical industry and recyclable waste. The will of authorities and industry to work together is strongly present."

Local, Green Economy

The Ghent part of North Sea Port is the ideal location. There is a large quantity of industrial CO_2 emissions to be captured, a high-voltage offshore renewable energy link, plus many potential buyers of green methanol. "This collaboration means we are consolidating our position in the sphere of the circular economy which already exists in the port", explains Daan Schalck, CEO of North Sea Port. "The port also has at its disposal extensive logistics activities, a massive storage capacity and links via the sea, inland shipping, rail, and road." Additionally, there exists within the North-CCU-Hub significant expertise in the field of chemical and biotechnology. The City of Ghent and the Province of East Flanders are assisting in the facilitation of the project. Investment Partner PMV also supports the financial section.

Supporting Innovation and FDI

In addition to the advanced integration of the different processes and various industrial partners, the North-C-Methanol project is also unique in terms of its scope and its medium and long-term innovation program. This is no coincidence, as private, public and academic players in Flanders go to great lengths to join forces and innovate together. The innovation trajectory is coordinated by the local knowledge institutes Ghent University, Capture and Bio Base Europe Pilot Plant and supported by the spearhead clusters Catalisti and Flux50. On top of that, the government of Flanders strongly supports business innovation through R&D subsidies and tax incentives. Looking at the North-C-Methanol project as a landmark example of sustainable industrial symbiosis and collaboration, it doesn't come as a surprise that it is also through FDI that research is turbocharged. According to EY's latest Attractiveness survey, foreign-owned firms account for a quarter of business R&D in Germany and France, between 30% and 50% in Sweden and the UK, and more than 50% in Belgium. Give it a sustainable thought.

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NextGen District — a Hotspot for the Circular Economy

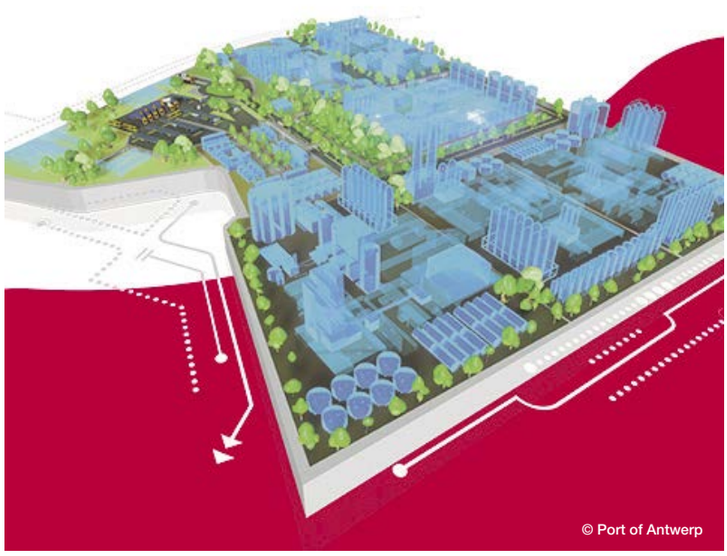
Port of Antwerp continues to play a pioneering role in the switch to a climate-neutral port and has launched a market consultation to find investors for the new "NextGen District". The project includes "NextGen Demo", a testing ground for start-ups, the "NextGen Park", a chemical park aimed at industrial players, and "NextGen Lots", a few stand-alone lots.

The former 88 ha General Motors site will thus be given a new sustainable purpose. "The goal is for NextGen District to become a hub for innovation and cross-fertilization in the circular economy, giving a boost to the new generation," explained Jacques Vandermeiren, CEO of Port of Antwerp.

The market consultation was launched on Oct. 5, 2020. Port of Antwerp is specifically targeting applicants focusing on the circular economy to realize NextGen District's sustainable ambitions.

The NextGen District is one of the last remaining available large sites in the port which, thanks to its location close to Europe's largest chemical cluster, offers various opportunities. Port of Antwerp said that it consciously opted to set aside this large area for the circular economy, thereby taking a further step in the transition to a sustainable and climate neutral society. It will also provide opportunities to mayor players and start-ups.

Port of Antwerp intends the NextGen District to be an industrial site where end-of-life products will be given a second or third life, circular carbon solutions will be researched, and experiments will be conducted with renewable energy.



The district incorporates a testing ground where start-ups are given the space to grow further, as well as free-standing plots of various sizes aimed at chemical and industrial players. In order to develop the site as sustainably and optimally as possible, Port of Antwerp currently examines which services and facilities can be organized collectively.

For the development of the site, NextGen District is looking for companies who want to give a boost to the circular economy, specifically candidates with core activities within the circular processing industry (primarily chemical processes) and the manufacturing industry, with an interest in the energy transition.

Together with industry, Port of Antwerp's goal is to reduce CO_2 emissions and the transition to alternative energy sources through ambitious transition projects, such as generating renewable energy, using residual heat, and importing, storing and converting hydrogen into sustainable building blocks for the chemical sector. (rk)

Vive La Chimie

French Challenge in Chemical Logistics

France has a long, grand history in chemistry. More than two-thirds of its broadly diversified production portfolio is destined for the export market, which poses a challenge to European logistics networks and their solutions for chemical logistics.

Marie Curie, Henri Moissan, Emmanuelle Charpentier, and more—France's ten Nobel Prizes in Chemistry to date are testament to the global significance of the country's chemical industry. Generating some €74 billion in revenue (2019), France's chemical industry is second only to Germany's in Europe and is the fourth largest industrial sector by domestic R&D expenditure. Over the past decade, its annual growth averaged 2.1%.

Chemical products are everywhere in everyday life, especially in the form of soaps and laundry detergents, cosmetics, paints, inks, glues, and adhesives. There are also fine and special chemicals as well as sustainable solutions for the next generations of solar panels, wind turbines, and electric vehicle batteries. A full 70% of French chemical production is earmarked for the export market, so all signs point to growth and a promising future.

Logistics Requirements

As it grows, France's chemical industry is seeing a particular benefit from the increasing connectivity of Europe's groupage transports. Integrated European logistics networks, which can combine standard services with dangerous goods expertise and a strong understanding of the chemical industry's logistics requirements, play a special role.

Two of our locations in France have already been certified by the strict Safety and Quality Assessment for Sustainability (SQAS), and we can also confirm the trend toward exports. This explains how over the past 10 years, Dachser Chem Logistics was able to increase its revenue in France from €10 million to more than €73 million as of 2019.

One factor amplifying this growth is the increasingly closer cooperation between Germany and France—the number one destination for German chemical exports. The German chemical industry exports goods worth €13.9 billion (2018) to France, accounting for around 7% of German chemical exports. Conversely, Germany imports 7.4% of its chemical products from France, corresponding to a goods value of €10.8 billion.

While important hubs of the chemical industry have historically been located along natural traffic arteries—e.g. along the Rhine (Basel, Ludwigshafen, Leverkusen)—a top 100 logistics study by the Fraunhofer Center for Applied Research on Supply Chain Services SCS shows that decisions about future locations will be made differently. More and more, companies are looking for production locations situated away from the traditional centers and closer to the customer. For their part, customers want increasingly tailored products and increasingly shorter delivery times.

Diversified Chemical Industry

Logistics has to be able to provide answers to these challenges, for instance by offering more widely distributed transport flows via their networks. This also benefits all the smaller producers that have no significant logistical resources of their own. A whopping 94% of French chemical companies employ fewer than 250 employees, and primarily these smaller businesses want to achieve synergy effects through clustering in priority regions.

Important sites in the specialty chemicals sector for cosmetics and perfume production are located in Grasse, France. The Auvergne-Rhône-Alpes region is home to industrial and research clusters, and the greater Le Havre area is now the largest site for fertilizer production in Europe and for petrochemicals in France. Other clusters, focused on research and specialty chemicals, are located in the north of the country, in the greater Lille area, and around the capital city.

In other words, France's chemical industry is broadly diversified and closely linked to the growth markets in Europe via logistics. This is also how the industry will master the new challenges of the coronavirus pandemic. If circumstances call for a reconfiguration of supply chains, then efficient and flexible logistics networks will be in high demand—and that is precisely what Dachser Chem-Logistics offers in France, today and in the future.

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Michael Kriegel, Dachser

Michael Kriegel, Department Head Chem-Logistics, Logistikzentrum Rhein-Neckar, Dachser Group SE, Mannheim, Germany

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The Impact of the Coronavirus Crisis

Experts of CMOs, CDMOs and CROs Share Their Opinions

The pharmaceutical industry and its value-chain partners have been responding well to the impacts of the coronavirus pandemic. In light of recent successes in developing vaccines and medicines to get a grip on the disease, the sector lives up to its responsibility and the hopes of billions of people. But the current global economic crisis caused by Covid-19 has uncovered problems that have been smoldering beneath the surface of the pharmaceutical industry — including CMOs/CDMOs and CROs — and need to be addressed.

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During the first half year of 2020, when the virus spread across the globe and nations forced many of their businesses to close, it has become obvious that supply chains are vulnerable to disruption when major development, production and transportation hubs are on halt. Although the pharmaceutical industry on a global scale is rated system-relevant for winning the fight against SARS-CoV-2 and ensuring health care of the general public, and thus by and large exempt from shut-downs, the ongoing pandemic is putting R&D strategies to the test and also challenging manufacturing planning and supply chain management. Particularly in this industry segment, the supply chain is global, complex and interconnected. Each link must be strong enough to ensure that the road from lab to final drug product is as smooth as possible, even under the most difficult circumstances.

In addition to the pandemic, the growing threat of a no-deal-Brexit amid old and new trade conflicts and increasing protectionism is putting even more stress on companies operating in the pharma sector.

In cooperation with cross-border investment bank Wombat Capital, CHEManager asked experts of CMOs, CDMOs and CROs operating in the pharmaceutical sector to share their opinions on current challenges for their industry and how these challenges may trigger changes in the market. Find excerpts from their insightful answers on the following pages and read the complete interviews here: *bit.ly/CHEManager-Wombat-Survey*

Search for Agile, Reliable and Competent Partners

Michael Quirmbach, CEO & President, CordenPharma

What in your opinion are the main impacts of the coronavirus pandemic on the drug supply chains?

Michael Quirmbach: The Covid-19 pandemic showed the fragility of global pharma supply chains, resulting in companies and governments having to now carefully reconsider and rethink their current strategy. Thus, while the past focus was mainly on cost reduction, the future focus will be a much stronger shift towards security of supply and the resiliency of the supply chain. Although the term resilience of the supply chain is becoming a new buzzphrase which is rather vague and open to interpretation, it generally means that suppliers will face more scrutiny and the need for a deeper understanding about the sourcing behind their partners and suppliers.

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What do you think the impact of the repatriation of the drug supply chain on the M&A activity in the CMO/CDMO industry will be?

M. Quirmbach: As the consolidation of the highly fragmented CDMO industry continues through M&A activities, the repatriation of the supply chain will, for sure, additionally contribute to it with an even stronger emphasis on companies with assets & technology based in the US and EU. Companies with the right geographical and technological footprint will therefore have higher valuations compared to those prior to the Covid-19 pandemic.

What is your opinion on whether and to what degree the CDMO industry will enjoy long-term benefits from its role in tackling the current crisis?

M. Quirmbach: The CDMO industry will continue to benefit from the crisis — short and long-term — as pharma & biotech companies engage in the ongoing search for agile, reliable and competent partners to meet the increasing demand for drug substance, drug product and ideally, integrated supply services. Also, as the NCEs are showing ever-increasing complexity, this will require various technologies, leading to greater and greater requirements to outsource service providers for the most optimal use of pharma's know-how, resources and infrastructure.

Stepping Up to the Challenges

Mark Quick, Executive Vice President Corporate Development, Recipharm

The CMO/CDMO industry has managed to support efforts to develop vaccines and therapeutics for Covid-19 despite already being at a high level of utilization. What made that possible?

Mark Quick: The CMO/CDMO service sector is uniquely positioned to address many of the challenges that drug developers are facing amid the Covid-19 pandemic. We understand the additional pressures being placed on customers to maintain the supply of medicines and the processes which are necessary to accelerate the development of safe, effective drugs and vaccines at this time. We are well versed in offering customers capacity according to their changing needs, and this pandemic has been no different. Our global manufacturing footprint, access to a broad range of expertise, regulatory experience and technologies have all made it possible for us to provide support at short notice and manage this complexity. I believe the key to being in this position is to have the flexibility and alacrity to be able to respond. The pharma industry has demonstrated this and is challenging many of the paradigms on the time lines required to develop drugs. CDMOs must be efficient and flexible, so this has come naturally.

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The pandemic crisis has created opportunities, too. What is your opinion on whether and to what degree the CDMO industry will enjoy long-term benefits from its role in tackling the current crisis?

M. Quick: The CDMO industry will continue to be a crucial support for pharmaceutical companies and that has been demonstrated over the past few months. Operations have continued in some exceedingly difficult areas of the world and supply chains by and large maintained. When the time comes, CDMOs have demonstrated they are able to step up to the challenges presented and be ready to help. Furthermore, the need for fast turnaround of products may lead pharmaceutical companies to outsource more elements of their development and manufacturing to CDMOs who have the necessary capacity and expertise already in place. This could have a long-term effect and may change how many pharmaceutical companies choose to work with their CDMOs in the future.

Investments Need to Make Sense

Jean-Luc Herbeaux, Chief Operating Officer, Hovione


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Pharma companies are leveraging their internal manufacturing networks but also partnering with CMOs/CDMOs. What supply and manufacturing strategies/alliances are in play?
Jean-Luc Herbeaux: The Covid-19 pandemic has engendered an all-out search for treatment options. Many hundreds of compounds for prophylactic and therapeutic use have been tested in the race against this deadly disease. Pharma companies have sought the help of their partners to ramp up raw material supply and custom manufacturing services to help them deal with this colossal challenge. In times of pressing requirements, strong partnerships are key and unsurprisingly pharma companies have tended to reach out to their existing partners — especially those who demonstrated the ability to meet complicated supply challenges involving new asset deployment and commissioning.

Many Western CDMOs have shifted operations back to the USA and Europe as intensive business activity in China has driven up labor costs. In addition, national policies, trade-related developments and the impacts of pandemics are accelerating this trend. Could CMOs/CDMOs be beneficiaries of restructured supply chains?
J.-L. Herbeaux: CMOs/CDMOs have a chance to benefit from the repatriation trend. The first wave of relocation, which started some 4 or 5 years ago, stemmed from quality and regulatory considerations. This repatriation was very beneficial to CDMOs with assets and quality systems in good standing as they were able to gain access to business which had escaped them up to that point.
The new wave seems to be driven by countries and their citizens coming to terms with the fact that most of their medical supplies are from foreign countries and entities. We ought to recognize that the Covid-19 pandemic is extreme in terms of impact and medical supply needs. It has overwhelmed the global supply chains in unprecedented ways and no economically sound supply strategy could have prepared us for an event of such global proportion. In these special times, there is a risk of overheating and of wrong capital investment decisions. Investments need to make sense not only for the short term but also for the long haul. In this overheated environment, experienced western CDMO´s with flexible assets and operating models and with meaningful engineering capabilities are probably the best bet for this industry.

Most Bottlenecks Will Remain

GianMarco Negrisoli, President Flamma USA, Flamma Group


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How do you rate the impacts of the coronavirus pandemic on the drug supply chains?
GianMarco Negrisoli: We have seen a wide variety of scenarios playing out in the last couple of months, mostly related to the supply of raw materials. We have seen small delays of a few days to major delays lasting weeks. Fortunately, the long delays have been rare. The pharma industry by nature tends to invest a lot of time and money developing risk assessments and profiles. I believe we — as an industry — were somewhat more prepared compared to other industries.
Rather than plunging us into an unknown scenario, I think the pandemic showed the limits of existing supply chains and where we need to mitigate the risk for the future. For instance, increasing the number of approved suppliers even deeper in the supply chain. In general, I do not foresee a radical shift in how we supply drugs at the moment, at least for drug substance manufacturing.

Could CMOs/CDMOs be beneficiaries of restructured supply chains?
G. Negrisoli: Repatriation of a portion of the supply chain was already an ongoing process and the current geopolitical scenario has certainly accelerated it, however there are numerous, deeper barriers in un-doing 30 years of globalization and re-integrating the drug manufacturing process. European and US CDMOs could certainly benefit from the shift but only up to a certain point in the supply chain, most of the bottlenecks of today will be still there. Regardless, the pharma supply chain is global and has been for a long time.

What is your opinion on whether and to what degree the CDMO industry will enjoy long-term benefits from its role in tackling the current crisis?
G. Negrisoli: This current geopolitical situation has brought a strong interest in the general healthcare sector and, in particular, the drug manufacturing side. There are certainly some short-term benefits, but I believe that the looming recession which is endangering some countries' entire welfare system will bring a potential long-term disruption.

mRNA Technology Will Blossom

Andrew S. Thompson, President and CEO, J-Star


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For some industries the Covid-19 pandemic has created opportunities. What is your opinion on whether and to what degree the CDMO industry will enjoy long-term benefits from its role in tackling the current crisis?
Amdrew Thompson: We learned about the vulnerability of the supply chain. When you have so much stuff being made outside the country, people didn't know how vulnerable we were, and they start to realize it now. An effort to bring more API and manufacturing back to the US just to mitigate supply chain interruption in a crisis like this is a good thing for us.
Once there will be a vaccine, the dire need for products and medicine for Covid-19 will go away and a lot of projects will disappear, and work will be done on other diseases. However, the Covid-19 pandemic has revealed new processes, technologies, which will benefit the industry in the long run. For example, I believe that mRNA technology will blossom, as people see what it does and how fast we can develop vaccines. There should be more emphasis in developing that technology for all kinds of viral infections, etc.

Could CMOs/CDMOs be beneficiaries of restructured supply chains?
A. Thompson: As of now, I haven't seen any change in the amount of outsourcing. From my perspective the amount of work that is being sent to China is the same amount. But if there was a change and supply would shift dramatically back to the US, then US players would benefit greatly from it, but I have not seen it happening yet.

What do you think the impact of the repatriation of the drug supply chain on the M&A activity in the CMO/CDMO industry will be? Do you think that this would create an impact on valuations?
A. Thompson: Yes, if the work is shifted back to the US or Europe, the valuation of that local asset would go up. This phenomenon should increase cross-border M&A for foreign entities looking to buy locally to produce locally for their clients.

Ensure the Long-term Supply

Andrew Henderson, Chief Commercial Officer, Sterling Pharma Solutions


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Small (bio)pharmaceutical companies are important customers for CMOs/CDMOs but are mostly dependent on the availability of financing, which could become more restricted due to the economic downturn. How is this going to affect your business?
Andrew Henderson: We have placed significant strategic focus on ensuring we have a diverse customer base and project portfolio. We work globally with big pharma customers through to small virtual companies and are working on projects from pre-clinical through all phases of clinical development in addition to supplying an extensive launched product portfolio. This diversity is important in providing a robust platform for any shift in future market dynamics and demonstrates to our customers we have a stable business to ensure the long-term supply of their key products.

For the biopharma CMO/CDMO industry, the pandemic crisis has created opportunities. What is your opinion on whether and to what degree the CDMO industry will enjoy long-term benefits from that?
A. Henderson: The flexibility of CDMOs and their ability to innovate and mobilize resource and capacity quickly has been critical in the response to the Covid crisis. These key attributes are not only important in the response to the Covid situation but also to support the growing complexity of pharmaceutical products and their associated development and supply chains. The CDMO's that are able to demonstrate these key attributes and deliver exceptional service will be well placed to benefit from the current crisis and ongoing evolution of pharmaceutical product development, manufacture and supply.

Could CMOs/CDMOs be beneficiaries of restructured supply chains?
A. Henderson: I think governments and industry globally will be looking at restructuring supply chains for at least their critical products to ensure they have some domestic supply. This shift was to some degree already in motion pre-Covid but has now been accelerated. CDMOs will play a critical part in this evolution.

Need for De-risked Supply Chains

Matthew Moorcroft, Global Head Central Marketing, Lonza

What from your perspective are the main impacts of the coronavirus pandemic on the drug supply chains?
Matthew Moorcroft: I think in contrast to other industries, the pharmaceutical and CDMO industry has fared well overall during the turbulence of the coronavirus pandemic. The notion of healthcare and medicine has been once again thrust in the spotlight. The industry has responded with herculean efforts to keep employees safe and keep manufacturing plants open and concerns over drug manufacturing and supply have fortunately not materialized to the extent people were forecasting. Pharmaceutical companies have likewise turned to their CDMO partners to help balance the load and support the explosion of Covid-19 vaccines and treatments in their pipelines and, in turn, CDMOs have done their part to respond.


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Could CMOs/CDMOs be beneficiaries of restructured supply chains?
M. Moorcroft: Reshoring and repatriation of outsourcing activity to the US and Europe is not a new concept and over the last decade CDMOs with western assets have long been net beneficiaries to capture the changing buying behavior of pharmaceutical customers. CDMOs with a proven track record of quality systems and manufacturing excellence have been in the best position to capture the bulk of these trends. The recent pandemic illustrates the need for de-risked supply chains that include assets across different geographies working to the highest global standards.

How long will that take?
M. Moorcroft: It is fair to say that supply chains won't be transformed overnight and relocating projects can take many months, even years, so there will be a slow and gradual cadence to any change. As more drug substance and drug product business repatriates to the West, there will naturally be more opportunities for US and European CDMOs to fill existing and new capacity. Small molecule CDMOs with idle capacity will be able to take an opportunity to fill empty slots and update their order books, and biologics manufacturers will be in a strong position to prioritize projects to maximize their product mix.

Valuations Are at Record Highs

Peter Pekos, CEO, Dalton Pharma Services

Could CMOs/CDMOs be beneficiaries of restructured supply chains due to the impacts of the pandemic or other reasons?
Peter Pekos: 'Made in the West' is not that much more expensive than Asian suppliers are, and travel limitations challenge relationship building. A Western supplier is now preferred for the North American new drug development industry.

What do you think the impact of the repatriation of the drug supply chain will have on the M&A activity in the CMO/CDMO industry?
P. Pekos: Valuations are at record highs and as the impacts of repatriation play out in marketed products it could lead to new company creations to provide specialized manufacturing capability for complex pharmaceutical product manufacturing. This in turn will lead to more takeover targets with specialized manufacturing expertise.

Small (bio)pharmaceutical companies are mostly dependent on the availability of financing — which could become more restricted in the wake of Covid-19. How is this going to affect your business?
P. Pekos: The identification of pandemics as an existential threat to humans and a reversion to protectionism in the supply of critical medicines has led to massive amounts of capital being funneled into the biopharmaceutical space by governments. This new source of funding is being leveraged with venture and other sources of risk capital to fund these new companies. So, we now have more capital in the space looking for new medicines, therefore CDMO's have benefited.

Dual Sourcing is a Valid Option

Alan E. Walker, Vice President Marketing & Development, Kaneka

What from your perspective are the main impacts of Covid-19 on drug supply chains?
Alan Walker: The pandemic has forced buyers to initiate plans to mitigate risk of buying from overseas suppliers. Dual sourcing with a focus on local suppliers is a valid option.


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Could CMOs/CDMOs be beneficiaries of restructured supply chains?
A. Walker: Of course, as long as they are located in countries where Western CDMO's operate.

What impact will the repatriation of the drug supply chain have on the M&A activity in the CMO/CDMO industry?
A. Walker: It brings credibility back to Western-based CDMO business models and I think could lead to more acquisitions even from buyers in China, Korea, India etc. but at higher prices.

Despite operating at a high level of utilization the CMO/CDMO industry supports the efforts to develop vaccines and medicines for Covid-19.
A. Walker: Yes, the ability to work with flexible schedules and the priority placed on this by governments, regulators and customers made that possible.

What is your opinion on whether and to what degree the CDMO industry will enjoy long-term benefits from its role in tackling the current crisis?
A. Walker: It will work out project by project. As things settle down the successful projects will move forward. The pandemic has given the chance to CDMOs to build some new relationships. The success of the projects will determine how these play out.

Valuations for High quality CROs/CDMOs Will Increase

David Zimmermann, Chief Executive Officer, Kalexsyn, and North America Sales Director, Dipharma

What in your opinion are the main impacts of the coronavirus pandemic on the drug supply chains?
David Zimmermann: The last few months have shown that pharma and biotech companies are becoming more risk conscious. They are moving to European and US suppliers that they feel provide a more stable work product from both a low turn-over labor base and high quality of material.


© Kalexsyn

Could CMOs/CDMOs be beneficiaries of restructured supply chains?
D. Zimmermann: I think we are already seeing that in the industry. Certainly, the growth in our European and US business are a result of that emphasis.

What do you think the impact of the repatriation of the drug supply chain will have on the M&A activity in the CMO/CDMO industry? Do you think that this would create an impact on valuations?
D. Zimmermann: I would expect that repatriation will continue to fuel the M&A activity. Just as we see in the pharma models, large is typically followed by larger, large CDMOs will seek to gain business share through acquisition. Valuations for high quality CROs and CDMOs will definitely increase. However, finding those high-quality prospects will become more and more challenging.

The Perspective Has to Be Global

Peter Halkjaer-Knudsen, Executive Vice President, Raybow Pharmaceuticals

Many Western CDMOs have already shifted operations back to the USA and Europe due to increasing labor costs in China. In addition, national policies, trade-related developments and impacts of pandemics are accelerating repatriation of at least part of the supply chain. Could CMOs/CDMOs be beneficiaries of this trend?
Peter Halkjaer-Knudsen: The labor cost, while important, is only a fraction of the cost of a finished drug, so an increase in the actual labor is not the big driver of change. Regarding the Covid-19 pandemic, there have been effects in supply of raw materials if sites were located in the zones that were under repeated lock-down or prolonged lock-down, but with others stepping up production, the supply situation has experienced some tight spots but in general it has worked out. The shortage of some materials has not been due to Covid-19 but mostly to the continuous tightening of environmental standards and the tightening of safety regulations.

It seems like the outcome of the whole situation is still uncertain — reshoring the manufacture of API is an important topic, but from a Western perspective no firm commitment has been made by any government on how to allocate the significant costs involved in funding the shift of the manufacturing infrastructure out of Asia. These costs are huge, and China already has a very modern infrastructure today. It does make a lot of sense to further strengthen the process of improving supply chain management to ensure that sourcing, manufacturing and logistics are safe and sustainable on a global perspective — but then the perspective has to be global, not national.

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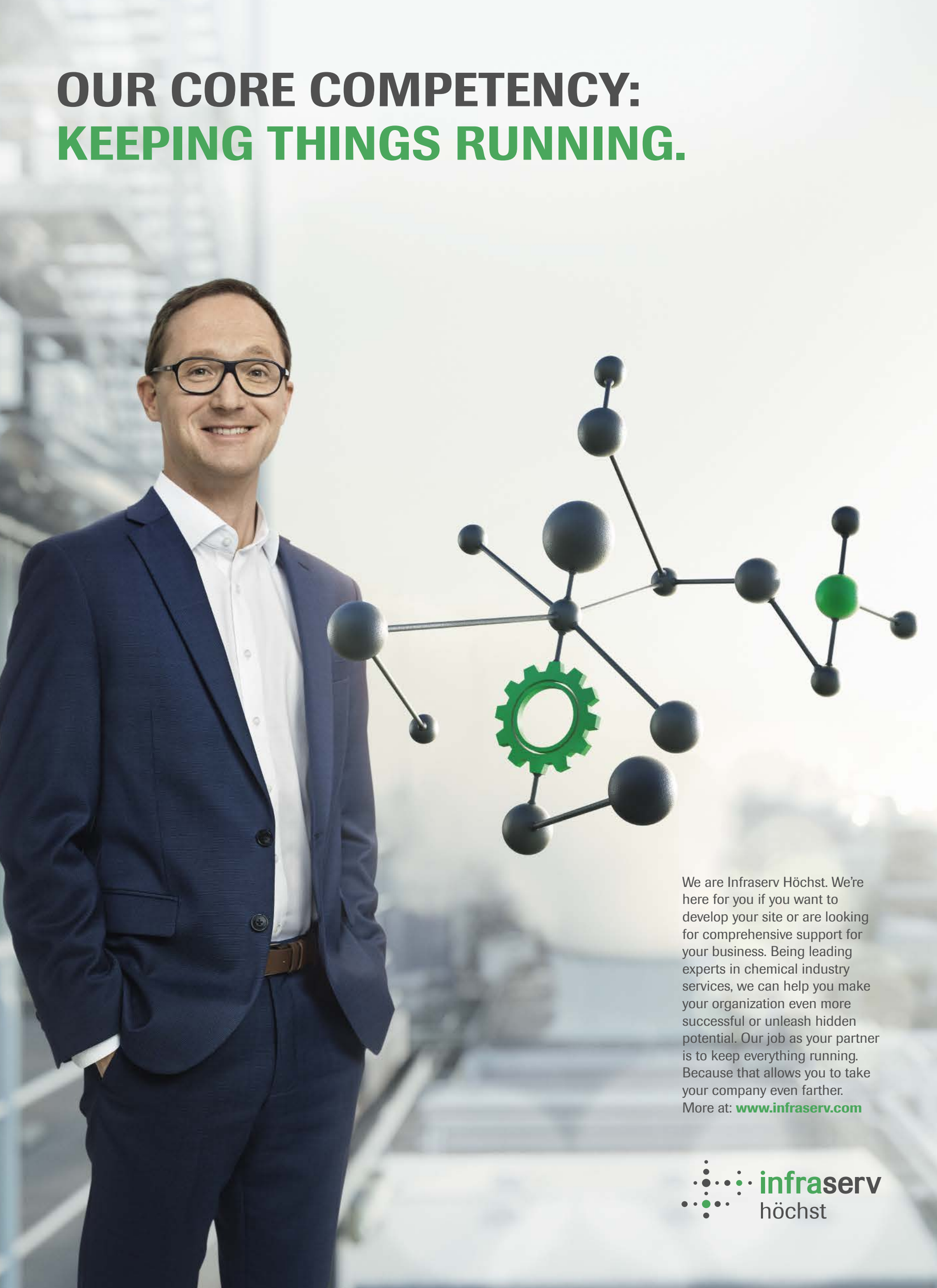

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Challenges Facing Pharmaceutical Manufacturing

New DCAT President Sean Diver Discusses Industry Issues and Trends

On November 1, 2020, Sean Diver took the reins as president of DCAT. He has been in the pharmaceutical industry for over 30 years, having served technical and commercial leadership roles for both innovator companies and CDMOs. Currently, he is director of Commercial Development in the Pharma Biotech & Nutrition segment at Lonza focused on late-stage, small-molecule drug substances. Sean Diver has been an active member of DCAT for many years by participating on various committees, including serving as chair of the DCAT Technology Committee, as a member of the Advisory Council, and as a member of the Board of Directors. CHEManager asked him to discuss the pharmaceutical industry's role during the Covid-19 pandemic, trends in drug manufacturing, and key issues for the EU pharmaceutical industry.

Sean Diver, President, DCAT

CHEManager: Mr. Diver, almost one year since the coronavirus SARS-CoV2 began to spread across the globe, how has the pharmaceutical industry met the challenges posed by the Covid-19 pandemic?

Sean Diver: Covid-19 has certainly presented significant challenges to pharmaceutical companies and their suppliers. Patients need medicines for treatment of serious, life-threatening symptoms, and the general population needs prevention options. The industry has demonstrated the ability to provide solutions for both, not just in the creation of the medicine, but also working with suppliers to manufacture these products to support patients. It is not sufficient to just understand the science well enough to innovate new medicines; these medicines also need to be produced at a scale large enough to support the patient population.

What would you identify as the industry's key contributions to the battle against the pandemic?

S. Diver: The key contribution to the fight against Covid-19 from the pharmaceutical industry is that together, innovators and their suppliers, rapidly bring safe and effective medicine to those that need it.

Due to the global health risks and time pressure related to the pandemic, the industry's development timelines for Covid-19 treatments have been greatly accelerated. What new understandings and insights will be useful for the industry not only as it relates to Covid-19, but also for future development and commercialization approaches overall?

S. Diver: The world has observed that when needed, new medicines can be developed quickly and effectively. The experience of innovators, manufacturers and regulators working so closely together is likely going to shape the future expectations for speed to market of safe and effective medicines. Certainly, the focused effort by innovators and suppliers with respect to Covid-19 is extreme, but with aligned goals, we have seen that timelines to get safe and effective medicines to the market can, and likely will be, accelerated substantially.

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Aside from the coronavirus pandemic, what do you see as the major issues and trends impacting the pharmaceutical industry today?

S. Diver: I see a few issues and trends for the industry today. One observation that comes to mind is that the cost of development and the affordability of medicines are still major obstacles in getting medicines to patients globally. Another one is that technical innovation has been outstanding and will continue to be critical in the future for treatment—and cures!—of rare diseases. Also, capacity to manufacture everything coming out of the clinic across all of the technology platforms will continue to be a challenge.

The evolving pharma product mix—both from the industry's pipeline and recently commercialized products—is always a point of interest. Which technology platforms do you

identify as having particular impact in the near future?

S. Diver: If I look at what I see in the industry pipelines and absorb what I am reading in *DCAT Value Chain Insights*, among other sources, I see that innovative technology platforms in the fields of small molecules, biologics, and newer modalities, such as cell therapies and gene therapies, are yielding very exciting drug candidates and new potential therapies. More and more highly potent small molecules are emerging from the market, commercial biologic products are commonplace today, and not just for oncology and immunology, but across many therapeutic areas, and cell and gene therapies are bringing cures to our doorstep.

> *"The world has observed that when needed, new medicines can be developed quickly and effectively."*

And what is the associated impact on manufacturing and supply decisions?

S. Diver: The impact of all of this is that these products are driving technical innovation and need to be produced someplace. The worldwide capacity for the manufacturing of these products will need to expand to meet technical demands, so that these products can be delivered! In addition, facility design will need to continue to improve to deliver high-quality, safe and effective drugs in a cost-effective manner.

Over the next five years, what challenges and opportunities do you see in the pharmaceutical manufacturing sector overall, as well as for small-molecule APIs, biologics, and drug products?

S. Diver: For small molecules, I see a very robust pipeline of products, but they are very complex, and often quite potent. The ability to produce these products safely will require a wide variety of specialty equipment, at a variety of scales, to meet clinical and commercial demand.

For drug products, I believe that more complex formulations will be required since APIs are increasing in complexity. Bioavailability issues will continue to push innovation on the drug-product side for products that are inhaled or that have novel delivery systems.

In biologics, there are so many new products gaining approval, I believe that getting everything produced in the next five years will be the biggest challenge to overcome.

Overall, I see that manufacturing over the next five years will be a challenge and that the right capacity for the particular technology will need to expand.

As a business development association, what is the DCAT organization doing to deliver value to its member companies during the pandemic?

S. Diver: We proactively cancelled our DCAT Week 2020 event to ensure that the health and safety of our members were considered first and foremost. Our membership clearly expressed that travel in 2021 will be limited until vaccines are available. Therefore, we have moved DCAT Week 2021 to July 12–15, 2021, so that we have a better opportunity to meet in person and do what we offer best—business development networking!

> *"Highly potent small molecules, commercial biologic products, and cell and gene therapies are yielding very exciting drug candidates."*

DCAT continues to host year-round education and networking opportunities via virtual webinar tools. Two recent offerings looked at the market impact of the Covid-19 pandemic on companies' pipelines, product launches, and performance and another featured theater-based presentation techniques for effective, impactful presentations.

Our committees are engaged, and meeting through virtual systems. The Research & Benchmarking Committee is currently working with our member companies on a benchmarking study pertaining to maintaining operations during the Covid-19 crisis and business continuity planning processes.

We are looking forward to seeing everyone in person in 2021 in NYC, but in the meantime, we are so pleased to remain engaged with our entire membership throughout the year!

The European pharmaceutical industry and fine-chemicals industry is bracing for change as the UK and the EU continue to negotiate to define the UK's future relationship with the EU in the wake of Brexit. What issues are of particular importance for the industry in this process?

S. Diver: By far the greatest issue facing the industry will be maintaining a continuity of supply of products to patients. All eyes will be focused on ensuring that disruptions are minimal.

What would you identify as other key issues and trends arising in the European pharmaceutical industry? For pharma companies? For suppliers?

S. Diver: The key issues for the European pharmaceutical industry are: security of supply of products; capacity of suppliers to support the strong clinical and commercial demand for medicines; and delivering treatment and prevention medicines to Europe to combat Covid-19. ■

DCAT

The Drug, Chemical & Associated Technologies Association (DCAT), based in Robbinsville, NJ, USA, is a not-for-profit, global business development association whose unique membership model integrates both innovator and generic drug manufacturers and suppliers of ingredients, development and manufacturing services, and related technologies. DCAT is well-known for the organization of DCAT Week, an annual gathering of executives and high-level experts and business managers of companies collaborating in the biopharmaceutical/pharmaceutical manufacturing value chain. The next DCAT Week 2021 will take place July 12 – July 15, 2021. **www.dcat.org**

Sanofi is Overall Winner of ISPE's 2020 Facility of the Year Awards

The International Society for Pharmaceutical Engineering (ISPE) has announced Sanofi as the 2020 Facility of the Year Awards (FOYA) Overall Winner.

The FOYA program each year recognizes state-of-the-art projects utilizing new, innovative technologies to improve the quality of products, reduce the cost of producing high-quality medicines, and demonstrate advances in project delivery.

Sanofi was awarded the Facility of the Future Category Award in April 2020 for its Sanofi Digitally Enabled Integrated Continuous Biomanufacturing Facility in Framingham, Massachusetts, USA. This fully integrated bioprocessing facility takes the application of disposable process technology and flexible facility design to a new level. Using the best of already proven technology and design, they have expanded the use to allow design and construction of a facility that enables continuous upstream and downstream processing, said ISPE.

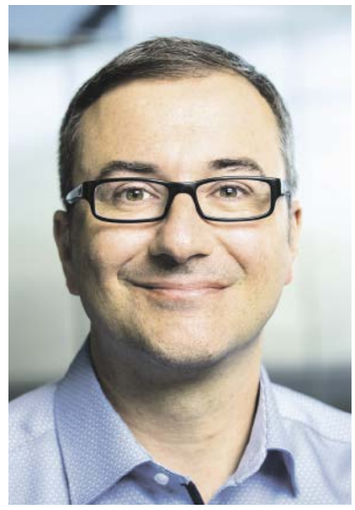
Sanofi has achieved a facility with higher capacity in a smaller footprint than traditionally achievable. This has provided the basis for: 80 times more production capacity than traditionally achieved, leading to potentially reaching more patients; more than 90% reduction in chemical usage per year; more than 90% reduction in water usage per year; 80% reduction in energy consumption and CO_2 emissions per year; and more than 320 t/y of waste saved from landfills.

From the early design phases Sanofi was dedicated to incorporating a full set of lean operations principles into the design. According to ISPE, they have broken new ground in digital integration. The entire facility is run using a comprehensive suite of digital solutions. (rk) ■

A Virtual Formulation Assistant

Leveraging Digitalization to Speed up Drug Product Development

The drug product development process can be time-intensive, costly, and has a high risk of failure. To help address the challenges of this laborious process, BASF has developed ZoomLab, a virtual formulation prediction and optimization tool. Currently, formulation is largely based on empirical methods with outcomes often depending on the expertise and intuition of individual formulators. With the aid of digitalization, formulators can have a significantly improved starting point and address certain challenges upfront rather than later, saving untold resources and mitigating risk of performance or stability failure. Ralf Kempf asked BASF's Ferdinand Brandl, Development Pharma Solutions, and Philipp Hebestreit, Technical Services Pharma Solutions Europe, about the technology and idea behind ZoomLab and how the virtual formulation assistant can speed up drug product development.



Ferdinand Brandl, Development Pharma Solutions, BASF

Philipp Hebestreit, Technical Services Pharma Solutions Europe, BASF

CHEManager: Where did the development of ZoomLab start? How did the idea for this virtual formulation assistant come up?

Ferdinand Brandl: The idea for ZoomLab comes from a workshop back in 2017. A few BASF colleagues met outside of their common office environment and brainstormed about different ways to make our customers' lives easier. Ultimately, we had the idea of developing a science-based formulation prediction system that provides our formulation experience in a progressive way and enables formulators to develop more robust drug formulations. In about a year and a half, we were able to bring this idea to life with ZoomLab.

When did you launch the first version of the platform?

F. Brandl: We launched the first version of ZoomLab in November 2019. The first version featured the Formulation Wizard, which is an easy-to-use tool that guides you through the process of identifying the best excipient combinations for a given drug substance. With the Formulation Wizard, our users create their own projects and receive a complete starting formulation based on the selected dosage form, the properties of the drug substance, and the desired target profile.

This version already included a tool that performs a risk analysis and recommends the best processing route for a given drug substance and another module that predicts the properties of a drug excipient combination.

How does ZoomLab work? How can it support formulators who use this tool?

Philipp Hebestreit: ZoomLab is built on a proprietary algorithm that simulates different ingredient combinations based on key parameters of a drug substance and the desired target dosage. The algorithm can predict the optimal formulation and provides step-by-step instructions on how to process it.

The main benefit for formulators is that the assistant, which we offer for free, is available 24/7. While other simulation tools take a significant amount of time to run predictions, ZoomLab provides immediate results. This helps reduce the number of time-consuming lab experiments by guiding the user to a scientifically optimized starting formulation.

Do users have to provide proprietary information about their product to get a useful result?

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P. Hebestreit: No. This is particularly important for our customers in the pharmaceutical industry. Formulators can fully utilize ZoomLab without providing proprietary information. The assistant does not require the formulator to disclose the name of the drug molecule or the chemical structure of the drug. Users just enter a few non-confidential physical properties of the drug substance and the target product dosages to let the tool provide predictions.

Additionally, the virtual assistant offers prepopulated drug substances from its database, but there is no obligation or need to enter the name of the drug substances at any time.

Does the assistant recommend exclusively BASF products?

F. Brandl: No, ZoomLab's algorithms are based on scientific publications; the formulation outcome is dictated by science. You will find a variety of substances in the assistant that are needed to create a starting formulation. The complete starting formulation is predicted using the most suitable excipients tailored to a drug formulation's specific needs, which includes chemistries beyond BASF's product portfolio.

Has the platform developed further since its launch?

F. Brandl: Yes, a lot. We have launched several updates of ZoomLab since version 1.0 was first released. To highlight a few features, we have introduced a content uniformity check, updated our excipient and formulation database, added an incompatibility check and integrated a tool which predicts the dissolution profile of the drug substance. Most recently, we launched ZoomLab 2.0 and added new modules that allow users to develop standard, protective, taste-masking, and enteric-release film coatings.

I recommend formulators sign up for our virtual formulation assistant and try out the different features. There's a lot more to explore.

How important is the feedback from users of this virtual assistant for the overall development of the platform?

P. Hebestreit: ZoomLab has been developed with the user experience in mind, and we continue to solicit and incorporate user feedback. This is particularly important because the assistant is continuously evolving. We normally launch an update every 1–2 months. User feedback helps us prioritize and develop the solutions we provide to our customers in each update.

What are your next plans for your tool? Which additional functions or components do you intend to add?

F. Brandl: ZoomLab is currently focused on oral solid dosage forms, but future releases are planned with additional dosage forms, manufacturing technologies, and more. For example, we will introduce additional features for topical dosage forms such as cream and ointments, and we are also working on features for sustained-release formulations.

https://info-mypharma.basf.com

Advertorial

High Quality and Flexibility for Pharmaceutical Customers

Custom Manufacturing by WeylChem

WeylChem's Custom Manufacturing division has a strong record of accomplishments operating in markets such as Pharma, Agro and Pigments. WeylChem covers the full spectrum in chemical synthesis from laboratory scale to pilot through to mid- or full-size commercial quantities. WeylChem's project management assures a smooth handover from lab to commercial scale guaranteeing the necessary safety and controls so important in the pharmaceutical sector.

Production facility at Allessa, Frankfurt-Fechenheim

In the pharmaceutical industry, more than any other, products interact with people. As a result, pharmaceutical customers need a fully dedicated custom manufacturing partner able to meet high compliance standards and, at the same time, flexibly realize their specific needs through modern technologies and highly experienced personnel.

The WeylChem Group has a long history in pharmaceuticals. Production sites in the heart of Europe in both Frankfurt am Main and Trosly-Breuil near Paris offer reliable, flexible and modern plant equipment for custom manufacturing requests from our pharmaceutical customers.

Many years of experience, certifications and plant equipment at Allessa in Frankfurt-Fechenheim

Located in the industrial park Frankfurt-Fechenheim, WeylChem Group member Allessa, with its experienced operating team, allows the parallel production of various pharmaceutical intermediates under highly regulated conditions. One example is Allessa's production of the active pharmaceutical ingredient Molsidomine, for which it also holds the CEP. Allessa holds a broad technical permit, which in combination with quickly adaptable multi-purpose equipment, enables excellent support of our pharmaceutical customers for their specific production needs.

Modern technical equipment also at our Lamotte plant

In Trosly-Breuil, the Lamotte team supplies the pharmaceutical industry with various high-quality intermediates (non-GMP).

The site has the ideal technical equipment to accompany pharmaceutical customers in all their development cycles—from piloting small quantities as little as a kilogram to industrial quantities of several hundred tons. Cross-site project management ensures fast processing of customer requests and allows the implementation and upscaling of new products within as little as three months.

Are you looking for a new and competent CDMO partner? Contact us via: **custom.manufacturing@weylchem.com or visit www.weylchem.com.**

Stress Test for The Supply Chain

Proactive Risk Management in Material Procurement in Times of a Pandemic

The pandemic triggered by Covid-19 has a major impact worldwide. As a result, all branches of industry are faced with various challenges. As a leading contract manufacturer (CDMO) for numerous pharmaceutical companies, the Aenova Group is an important part of the value chain in the pharmaceutical industry and is primarily confronted with the issue of always ensuring the supply of patients with partly vital drugs.

During the first phase of the Covid-19 pandemic in spring 2020, it became clear to many industries that the challenges of globalization and the relocation of raw material production to Asia had been accepted, if not ignored, for many years.

The special problem within the pharmaceutical industry is that, on the one hand, the active ingredients are either only available in Asia or—if they are produced in Europe—the intermediates are often of Asian origin.

An additional challenge is that in the highly regulated pharmaceutical market, many dossiers only allow for one source of raw materials, which further exacerbates the situation.

In order to master this stress test for the supply chain and to ensure that supplies run as smoothly as possible, proactive risk management and permanent communication with all stakeholders, both internal and external, is essential.

Creating Transparency

Creating a transparent end-to-end view of a complex multi-stage supply chain starts with the first step of identifying critical materials and the main reasons for their criticality. A distinction should be made between direct and indirect materials.

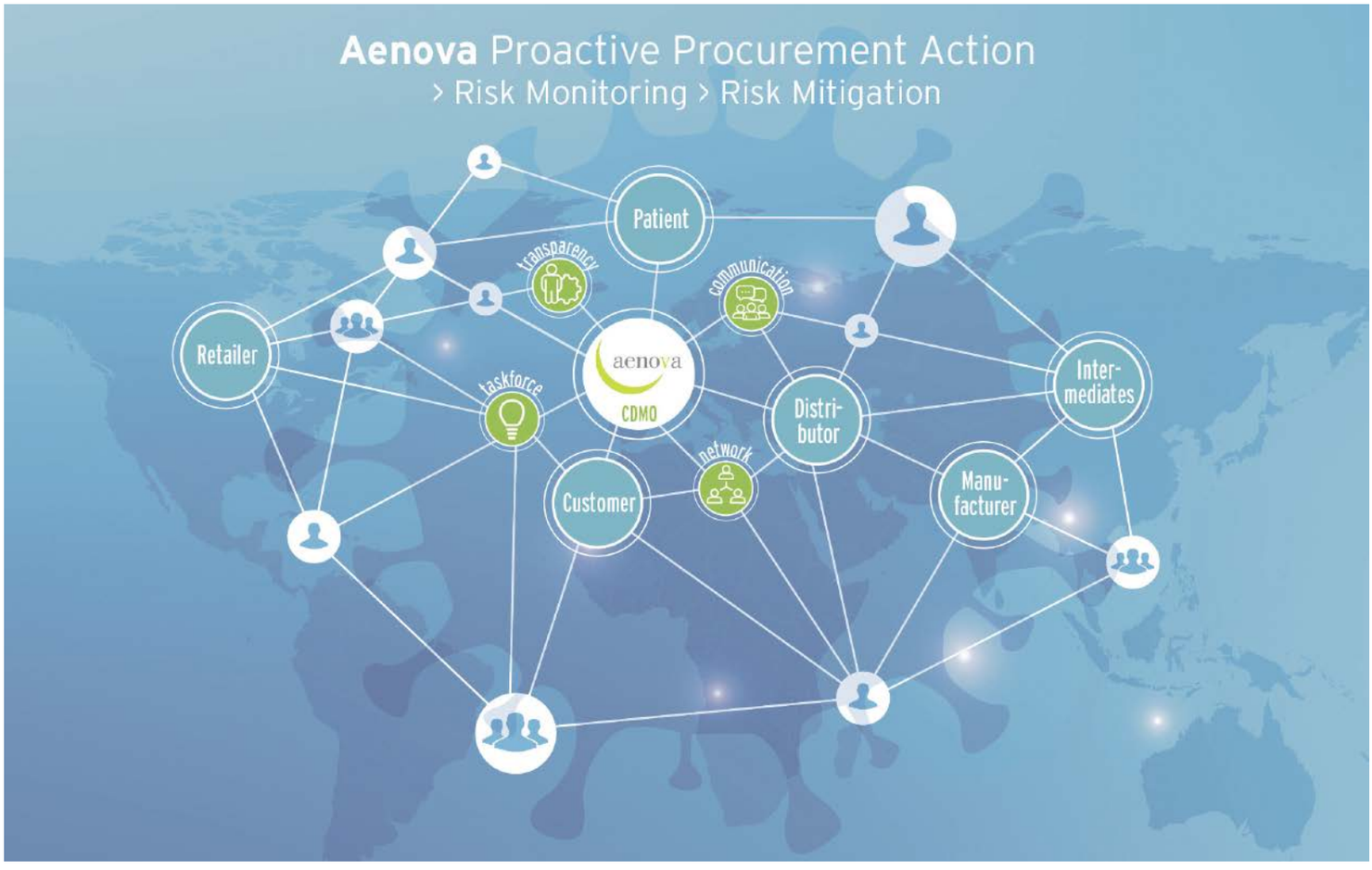
Affected indirect materials are mainly PPA articles (personal protection accessories), such as masks, gloves, etc. Here, during the first wave of the pandemic, availability was the main driver due to exploding demand and cost.

Direct materials are all raw materials like active ingredients, auxiliary materials, etc. and packaging materials.

The drivers for the procurement risk with the direct materials are the place of production for both the raw material and the preliminary products (so called intermediates), how high the local infection occurrence is (in the actual pandemic, the current status of the Covid-19 risk area), the number of alternative procurement sources and their location, the status of the stocks in the creation of value chain and the demand situation of the customers. In this context Aenova developed a risk index analysis on material level.

Philipp Ponton, Aenova Group

Furthermore, the relevant suppliers and subcontractors must be illuminated: Drivers for supplier risk are the current situation and the prob-



ability of a factory closure, capacity availability, supplier risk management, credit status, etc. This resulted in a risk index analysis at supplier level.

In addition, the risk factors that specifically occur in a pandemic are added: These are mainly factors that are difficult to influence and constantly changing, such as export regulations for certain raw materials, travel restrictions, border closures, availability of means of transport, etc. This resulted in a risk index analysis based on pandemic considerations.

As a result, these three risk indices were combined, a specific risk profile was derived from them and presented in a risk-based overview.

Derive and Track Measures and Established Supplier Networks

Based on the risk indices we at Aenova have developed a risk tracking tool. In this tool the risks are continuously evaluated, risk effects are estimated, measures for remedy are defined and the control of the individual risk is evaluated and monitored.

This approach allows to visualize and communicate the problems and solutions in a transparent and timely manner during the pandemic and to make quick decisions.

For the visualization of the process a traffic light logic was established, which divides the risks into three levels—red, yellow and green.

Aenova Group

Aenova is a reliable partner and a worldwide leader in drug product manufacturing and formulation development services. As one of the world's largest CDMOs, Aenova offers a full range of dosage forms and integrated packaging services as well as pharmaceutical services including clinical trial supply, analytical and formulation development services. The company, headquartered near Munich, operates 15 production sites and several sales offices in ten countries around the world. More than 4,300 employees contribute to the group's success.

- **Green**: Risk identified and measures initiated to avert risk.
- **Yellow**: Risk is already advanced, but effects can still be minimized or managed by replanning so that there is no "business impact".
- **Red**: The risk has occurred and efforts must be made to reduce the damage.

An important component for the implementation, communication and accuracy of information is digital support by systems and the associated creation of a "source of truth".

In the resulting risk tracking tool, the raw materials and packaging materials concerned are listed. For each risk material, the information described above, such as specification, single source status, possible alternative sources, expected delivery time, affected customers, etc. will be included. Furthermore, the exact facts of the risk are described and evaluated and measures are derived and implemented.

Due to the high volatility during the pandemic, risks and measures are tracked daily to enable an immediate response to constantly changing situations.

Lessons Learned

CDMOs depend on a large and complex global supply chain. The pandemic has highlighted were supply chains are at greater risk of being disrupted. Our "lessons learned" can be divided into external, industry-specific and internal learning effects.

In terms of external learning effects, the focus is on the obvious dependence on raw material sources, especially in Asia. Here, the political and strategic decision must be made to ensure that the production of vital raw materials is once again carried out in Europe. Another important point is the high proportion of single-source suppliers in a highly regulated environment. Here the identification and approval of alternative resources is fundamental.

Internally, the lessons learned and ad hoc actions are now being transformed into sustainable processes and integrated into the company's internal business continuity program.

A further step towards faster solution finding was to leave routines behind and to work together effectively in an agile and holistic way, even across company boundaries.

Innovation and digitization—including the use of artificial intelligence—, knowledge management and the integrated planning and networking of the entire value chain play a decisive role for the future and continuous improvement.

The result is an early warning system with more and more real-time data that can be incorporated into processes to react as quickly as possible to volatility in the state of a pandemic before the situation becomes problematic.

As a final overarching point, the importance of well-established supplier partnerships and networks has become clear. It is crucial to continue to invest in trustworthy supplier relationships in the future and to identify, build and develop strategic suppliers. Aenova has succeeded in doing this.

In conclusion, it remains to be said that the Corona crisis has highlighted many grievances that now need to be remedied in a holistic, systematic and sustainable manner in order to be even better prepared for future stress cases in the supply chain. After all, the focus remains on ensuring that patients are supplied with medicines, some of which are vital.

Philipp Ponton, Vice President Global Procurement, Aenova Group, Starnberg, Germany

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Rentschler Biopharma to Support BioNTech-Pfizer Vaccine

Leading CDMO Rentschler Biopharma has agreed with Pfizer and BioNTech to handle the downstream purification process for the partnership's mRNA-based Covid-19 vaccine.

No price tag was disclosed for the deal that also calls for the CDMO to handle small-batch manufacturing for a range of BioNTech's other mRNA clinical-stage projects.

Leveraging biologics capacities that were expanded at its Laupheim, Germany, site in 2015 and 2016, Rentschler Biopharma will be responsible for key aspects of cGMP-drug substance manufacturing of BNT162b2, the mRNA-based vaccine against Covid-19 being developed by Pfizer and BioNTech and currently in a global Phase 3 clinical trial.

A significant part of Rentschler Biopharma's task will be to remove impurities from the vaccine candidate's manufactured mRNA in order to ensure the highest amount of viable mRNA is harvested and the safety of the finished vaccine.

BioNTech and Rentschler Biopharma will use a business model that Federico Pollano, SVP global business development at Rentschler Biopharma, said is well suited for novel, urgently needed, technologies and allows maximum flexibility to address BioNTech's development and manufacturing requirements.

The companies, Pollano said, determined that the best way to address the vaccine developers' drug substance manufacturing needs was to establish a dedicated mRNA production suite

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at Rentschler Biopharma's Laupheim site. This approach, he said, ensures that capacity, staff and equipment are ready when needed, without interruption of other ongoing projects at the site. Moreover, "it is as quickly and easily scalable to meet future demands."

The Pfizer and BioNTech mRNA-based vaccine candidate from BioNTech's BNT162 program considered most promising has emerged as one of the frontrunners in the race to find a method of achieving immunity to the novel coronavirus.

On Nov. 18, the American-German partnership announced that, after conducting the final efficacy analysis in their ongoing Phase 3 study, BNT162b2 met all of the study's primary efficacy endpoints. Analysis of the data indicated a vaccine efficacy rate of 95% in participants without evidence of prior SARS-CoV-2 infection.

A rolling application has already been submitted to the European Medicines Agency, and Pfizer and BioNTech filed an Emergency Use Authorization (EUA) request with the US Food and Drug Administration (FDA) only a few days after the announcement of the study results. (dw, rk) ■

Expanding Into Oligonucleotides

Bachem's Large-Scale Facility to Come Online in 2021

The global market for oligonucleotide therapeutics is expanding rapidly. Bachem, an innovation-driven company based in Bubendorf, Switzerland, has entered this competitive environment in 2019. Specializing in the development and manufacturing of peptides and oligonucleotides, the group sees itself as a partner of choice for the biotech and pharma industry worldwide, and the decision to enter the field of oligonucleotide manufacturing was well-prepared and ultimately taken in line with the company's long-term growth plan. Torsten Woehr, head of Oligonucleotides at Bachem, explains the company's strategy in the field of oligonucleotide manufacturing.

CHEManager: Mr. Woehr, what is Bachem's strategy in entering the market for oligonucleotide therapeutics?

Torsten Woehr: We are operative since 2019 and are gradually expanding our expert resource pool, capabilities and capacity for oligonucleotides.

Despite having set ambitious goals we go step by step. Having said that, we are more and more shifting our focus from closing the oligo-specific technology gap to building a solid foundation for future growth.

Our large-scale facility, in fact, will come online in 2021. We took the time to thoughtfully design an equipment train featuring some innovative engineering solutions for increased utilization flexibility and improved process control.

Then, later on our way to become a first-choice manufacturer for oligonucleotides, we hope to make our own contributions to advancing the drug class by making oligonucleotide API production more scalable and cost-effective.

The CMO environment, in particular for oligonucleotides, is developing quickly. How do you see your chances and what are major hurdles?

T. Woehr: The progress in oligonucleotide-based drug development directly translates into a growing number of granted marketing authorizations. We actually might be seeing additional approvals before the end of the year. In addition, there is strong interest in the therapeutic application of antisense technology and non-coding RNA biology, which is reflected in an ever growing number of clinical programs in operation and in a global project portfolio that is spreading across a broader range of indications.

We therefore anticipate the demand for oligonucleotide custom manufacturing services to remain strong in the foreseeable future.

As for challenges: mastering oligonucleotide chemistry is not trivial, and building a track record of successfully completed scale-up projects is another major hurdle for every CMO entering the market.

In addition, building large-scale manufacturing facilities for oligonucleotides, meaning facilities with an output of 1-Mol per batch or even more, is very expensive. At Bachem a sizeable CAPEX budget has been granted to purchase special equipment and to build the necessary infrastructure.

Finally, almost the entire equipment train is custom-built. It is important to get the design details right, ideally on the first pass.

© Bachem

Torsten Woehr, Head Oligonucleotides, Bachem

What are the major technical challenges for the production of oligonucleotide therapeutics? Where can Bachem benefit from their expertise in peptide synthesis?

T. Woehr: Similar to peptides, the manufacture of oligonucleotides requires expert knowledge in solid-phase synthesis and protecting group chemistry. Downstream processing typically includes purification by chromatography and isolation by ultra/diafiltration techniques, precipitation and finally lyophilization. The manufacture of peptide APIs follows the same basic principle. And it is the core technology Bachem has developed over decades.

Still, there are important differences between peptides and oligonucleotides. The synthesis in flow-through columns consumes large volumes of solvents and reagents for which our facility infrastructure will be appropriately expanded.

Furthermore, oligonucleotides are negatively charged and highly water soluble, requiring the handling of aqueous solutions throughout the entire downstream process.

And let's not forget that oligonucleotide APIs, especially double-stranded entities, are considerably larger than peptides and pose challenges also from an analytical point of view.

Overall, it is fair to say that our peptide manufacturing background and our analytical capabilities are certainly very helpful in our quest to build a successful oligonucleotide business.

© Bachem

Covid-19 exposes the weak links in the pharma supply chain. How has the Coronavirus affected Bachem and your oligonucleotide development plans?

T. Woehr: Indeed, these are challenging times. Covid-19 affects all of us on a personal level, in our daily work life and social interactions.

Early on in the pandemic Bachem has received essential business status from the Swiss authorities, and our commitment is to our partners and patients, who depend on Bachem's products and an uninterrupted drug supply.

Bachem's corona task force monitors the Covid-19 pandemic closely and implements appropriate measures in a pro-active way. In addition, employees are repeatedly trained in preventing infections and reminded not to become complacent in the process.

So far the virus has not impacted Bachem's ability to produce, and so is our oligonucleotide program still on track. Fingers crossed we continue navigating this situation successfully and can make a contribution in battling Covid-19.

www.bachem.com

CHEManager INTERNATIONAL

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A New Standard for Process Simulation — and Beyond

Combining All Data and Models to Deliver Reliable Physical Properties

Hafnium Labs is tackling one of the toughest challenges in chemical R&D: Obtaining reliable physical property data — fast. The pioneering algorithms of the Copenhagen, Denmark-based start-up company combine cutting-edge modeling with all available data, setting a new standard for how physical properties of molecules and mixtures are predicted. Current customers of the company's Q-props software are process engineers, who need reliable physical properties to improve plant performance, but the aim is to make Q-props the standard for obtaining physical properties across industries and stages of R&D. CHEManager asked the founders of Hafnium Labs, Jon Christensen and Bjørn Maribo-Mogensen, about their journey and goals.

Bjørn Maribo-Mogensen, Hafnium Labs

Jon Christensen, Hafnium Labs

Personal Profile

Bjørn Maribo-Mogensen, co-founder of Hafnium Labs, has been developing chemical R&D software for over 10 years, previously at Haldor Topsoe, the Technical University of Denmark (DTU), and Linde Engineering. He received his PhD from DTU, for which he won the EFCE Excellence Award in Thermodynamics.

Personal Profile

Jon Christensen, co-founder of Hafnium Labs, worked 6 years for The Boston Consulting Group, most recently as a manager in BCG's artificial intelligence division.
He received his MSc in Chemical Engineering from the Technical University of Denmark (DTU).

CHEManager: How far back does the story of Hafnium Labs go?

Jon Christensen: Actually, it goes back to 2006. As first-year chemical engineering students, Bjørn and I used a process simulator to model the events that led up to the Texas City Refinery explosion. But the simulator did not predict the liquid overflow that had caused the explosion. One late night, we found that the assumption of constant density in the accident report might be wrong. And indeed: making the density temperature dependent, we could predict the overflow. Our results were published and the year after, a US government investigation came to the same conclusion. We have been passionate about physical properties for process modeling ever since.

Why are physical properties for process simulation important?

Bjørn Maribo-Mogensen: Over the last decades, process simulation software has helped chemicals and energy companies improve process performance and respond to fast-changing market conditions. But process simulators are only as accurate as the physical properties you put into them. It really is "garbage in, garbage out".

How does a process engineer get reliable physical properties for a simulation?

B. Maribo-Mogensen: Well, this is actually very difficult. With infinitely many combinations of molecules, mixtures, temperatures and pressures, experimental physical property data is very scarce. Experts estimate that we have experimental data for less than 0.2% of relevant chemical systems — and most of this data is for petrochemicals. There is almost no data for biochemicals or other molecules that we need for the green transition and our societal challenges around food and affordable medicines.

So, we always rely on predictions, typically using statistical models fitted to scarce experimental data. But choosing the right model for your process chemistry, fitting it correctly to the experimental data and ensuring that the data is actually sufficient and reliable is difficult, even for a physical property expert.

This is what your Q-props software helps with?

J. Christensen: Exactly! Q-props automatically evaluates all available data and models and creates the best possible physical property package. But it also turbocharges that work.

Based on millions of hours of stored computations, on-the-fly quantum chemistry calculations, and data for other molecules, Q-props finds the best possible data to fit the model to, even if there is no experimental data available.

And crucially, Q-props provides uncertainties on every data point, so the user can see how reliable the final model is and get guidance on experiments that will increase reliability most.

Who is your target audience?

B. Maribo-Mogensen: The underlying technology is very complex, but we have designed Q-props to be used by all researchers and engineers — not just computational chemistry experts. Q-props interfaces with leading process simulation tools, automatically performs heavy calculations in the cloud and handles all expert choices.

You can explore data and models, drill down to molecular detail and make manual changes. But you can also simply click a button to export the best possible property package for your process chemistry as well as edge-case packages to assess how uncertainties impact simulation results.

What are the next steps?

J. Christensen: We are fortunate to work with several industrial customers and universities that look for solutions to support their work with process simulation and digital twins. But we are always looking for more innovation-minded researchers and engineers to work with and are actively accepting beta-customers.

Why did you name the company Hafnium Labs?

B. Maribo-Mogensen: The chemical element hafnium is named after Hafnia, the Latin name for Copenhagen. Most of our 10-person team works from our offices here, so we thought Hafnium Labs was a nice way of showing love for our city while keeping it chemistry-related. We do not have any labs though — or any hafnium. ■

BUSINESS IDEA

A Standard for Physical Properties

Digital tools are playing an increasingly important role in chemical R&D. But to be valuable, they need reliable physical property data for the molecules and mixtures being investigated. Experimental data is scarce, so reliable predictions of physical properties are critical to good simulation results.

A pioneering software—Q-props—sets a new standard for obtaining reliable physical properties. Instead of building yet another model, Hafnium Labs have developed Q-props to intelligently and transparently use all available data and models for every prediction. Recognizing that "all models are wrong", Q-props is built on the idea that an accurate prediction is good but knowing how reliable it is and what experiments can improve reliability is better.

Q-props leverages cutting-edge models from quantum chemistry, molecular simulation and AI, that run automatically in the cloud without requiring expert user input. Hafnium Labs has built the world's largest combined database of experimental data and millions of hours of simulation data, which Q-props draws on for every prediction. And customers can add their own data and models—in full confidentiality—to greatly improve prediction accuracy and get more value from their in-house knowledge.

Q-props features:

- **Reliable**: Best possible prediction given available data and models—and its uncertainty
- **Fast**: Modeling typically 100–1,000 times faster than experimentation
- **Continuously improving**: Leverage all new data, models and hardware
- **Easy to use**: Does not require computational chemistry expertise and integrates with leading simulation tools
- **Transparent**: Explore how uncertainties impact results and get guidance on what experimental data to add to reduce uncertainty most

Q-props is currently targeted at customers working with process simulation and digital twins, providing a second opinion with uncertainties for existing simulations and auto-generation of best possible property packages for new simulations. The strategic goal is to establish Q-props as a standard for obtaining physical properties across industries and stages of R&D, including formulation, synthesis and discovery.

- Hafnium Labs, Copenhagen, Denmark
  www.hafniumlabs.com

ELEVATOR PITCH

Towards a Digital Future in R&D

Hafnium Labs was founded in 2016 to support the transition to a digital future in chemistry. Advances in chemistry change the world, but innovation is limited by slow and expensive experimentation. Digital tools offer a path to make R&D faster and smarter, but to be valuable they must simulate real-world chemistry, which is extremely difficult.

Hafnium Labs is solving part of the challenge with their pioneering software, Q-props, that provides reliable physical properties fast. The goal is to establish Q-props as a standard for obtaining physical properties across industries and stages of chemical R&D. To date, almost 3 million EUR has been invested in developing Q-props and it is currently being deployed with industrial customers and universities working with process simulation and digital twins.

Milestones

2016
- Hafnium Labs founded
- Q-props proof-of-concept

2017
- Q-props pilot tool
- First customer sales

2018
- Q-props v0.1 running on Hafnium Labs' cloud
- Chosen among 10,000 start-ups to pitch at the Web Summit main stage (capacity 30,000)
- Winner at TechBBQ

2019
- Q-props cloud tool used for contracted projects
- Raised over €2 million
- Chosen for the Merck Accelerator start-up program
- Winner at 'Redefining Chemistry', 'Get In The Ring' global finals and 'Pitch Marathon'

2020
- Q-props can be run on customer side
- Recognized by EU's Climate-KIC as one of Europe's leading climate impact start-ups
- Team size: 10 (7 PhDs)

Roadmap

2021
- Scale Q-props to more customers working with process R&D
- Launch Q-props.com

2022
- Expand to more R&D stages
- Raise next funding round

2023 onwards
- Establish Q-props as a standard for obtaining physical properties across industries and R&D stages

Hafnium Labs helps digitalize chemical R&D by providing a pioneering software, Q-props, that delivers reliable physical properties fast. The team is based out of Copenhagen and has received numerous awards as well as millions of euros in funding.

Excited About Coatings

Developing Innovative Insect-repellent and Disease-preventing Surface Treatments

Affix Labs over the past 5 years has specialized in binding technologies and commercialized first products in 2019. The proprietary technology focuses on binding safe chemicals in a way that boosts their effectiveness and longevity and led to products such as insect-repellent textile coating focusing on fighting insect-borne diseases such as Malaria, Dengue and Zika viruses. Established as a company in spring of 2020 and headquartered in Helsinki, Finland, the start-up company has harnessed its experience in disease prevention to create a long-lasting surface treatment proven to kill bacteria, fungi, and viruses including Covid-19. CHEManager asked CEO Tom Sam about the beginning and the future plans of the company.

CHEManager: Mr. Sam, Affix Labs was officially founded this year but has been operational for 5 years. How did it all start?

Tom Sam: The concept behind Affix Labs started when I was living in China for 7 years and worked in both textiles and a Chinese tech start-up. In 2015, when the first large outbreaks of Zika started appearing in Brazil and spreading beyond the borders we started looking into potential solutions to protect pregnant women from the virus. That research showed that whilst some of the most common pesticide solutions using Permethrin had some effectiveness, it was far from ideal considering its environmental and human health impact, which is when we started the development of Repeltec. This initially started us down the route of creating Repeltec-treated textiles using a safer chemical.

Next, we took it a step further along the line of disease prevention and started to integrate anti-microbial active ingredients into a coating, creating our product Si-Quat. Initially we were looking at ways to stop the spread of microbes that cause diarrhea.

Then the Covid-19 pandemic happened. Because of our relationships, we were able to get Si-Quat tested in a level 3 lab in Portugal proving that our coating was effective against the virus. This led us to make a temporary shift in our focus, but it is important to not forget that all the other issues have not gone away, and Malaria, Dengue and other diseases are still affecting millions worldwide.

What eventually led to the establishment of the company?

T. Sam: The company, Repeltec, started as a concept and was then officially established in the UAE first, where I am based. As we have grown and expanded our focus, we have rebranded ourselves to Affix Labs. Our company is a truly international organization; we employ the best people around the globe and are therefore not limited to talent in just one country. As we are growing fast we decided that Finland represents the right climate and culture for us to base the company out of, and relationships in the university of Helsinki also meant that we could easily test things like the durability of our coatings under various conditions.

What does 'Affix Labs' mean?

T. Sam: Affix stands for stick, attach, or fasten to something, and this is what our focus is on and is the foundation of our approach to tackling big, real-world problems. We create solutions focused on coatings and active ingredients. The word Affix just seemed to be the perfect description of the core of what we are doing.

Which obstacles did you have to master so far?

T. Sam: We knew when starting the company that the world is fast changing and that if we were to stand a chance against all of the chemical giants we would need to not only have the best working methods, but also think outside of the box and reframe the approach to issues that are being tackled. This has meant finding the right people and partners and being determinedly forward-thinking and innovative in how we work.

Also, our people are spread across the globe in multiple time-zones, as are the companies that we partner with, and these partners are based in many different countries, each having their own ways of doing things. This makes coordination and choosing the right partners and people a real challenge. Sometimes this is a fantastic experience and sometimes things don't go as smoothly.

Often the challenges are easily solved, but on occasion we must make difficult decisions not to move forward with potential partners. These decisions are not made lightly but in a remote working company, we do feel that it is more important to not only support but also be sure that we can trust the people we work with to reflect our ideals.

What kind of support, advice or funding did you receive?

T. Sam: Affix Labs has received a grant from EIT RawMaterials—initiated and funded by the European Institute of Innovation and Technology—in support of the developments around Si-Quat as an effective antiviral solution ideally suited to combating Covid-19. Besides this funding we have grown the organization without outside investments. We are, however, raising funds now to make the next steps.

What have been the most exciting projects so far?

T. Sam: We are growing fast and have new distributors coming on board weekly, especially now with our products that are effective against SARS-CoV-2. We also have great new developments going on with our new Clean 'n' Coat product line that cleans and leaves an anti-microbial coating at the same time, and we are ramping up to go into consumer products.

The things I get excited about are not always the most glamorous achievements, but our new partnership with the National Institute for Communicable Diseases in South Africa or our projects in Kenya get me excited.

We have just worked with two amazing companies, Logonet and Waste2Wear, on creating the perfect uniforms for the Jane Goodall Institute in Tanzania. The uniforms are made from recycled plastic bottles and use our Repeltec insect-repellent textile treatment. I have been a fan of Jane Goodall ever since I had heard about her work many years ago, so being able to create their uniforms is something amazing.

Tom Sam, founder and CEO, Affix Labs

What will be the next steps to develop the company from where you are now?

T. Sam: Our next challenge is now to keep up and carefully scale with the growth of the business. Getting the right people on board with the skill-sets and the right mindset is now key for us. The future of our company, and I believe every company, is to keep innovation going that is focused on creating products that take both people and the environment into account.

Business Idea

Creating Innovative Coatings

Affix Labs is a company that is breaking through the traditional industry of chemical coatings with a new approach that has the potential to protect millions of people from diseases. Originating as an offshoot of a textiles company researching ways to protect pregnant women from Zika virus, the company has evolved over the last 5 years to specialize in coatings that work on a multitude of surfaces and have a variety of effects.

Using carefully selected active ingredients that show the desired results in environmentally conscious and/or human safe ways, they have specialized in binding these ingredients in a solid state to surfaces, creating a layer that maintains its effectiveness but is durable and long lasting. With funding from the EU's EIT RawMaterials fund, they have ramped up testing and development of these solutions ready for global launch. The two main segments of products are insect-repellent and anti-microbial solutions.

Insect repellents: The first solutions developed by Affix came before the actual founding of the company with the textile treatment Repeltec. This, bound to clothing, created garments that protect wearers from insect bites, specifically disease-bearing varieties such as mosquitos. Under Affix this has now expanded into coatings that can be applied to almost any surface such as walls, textiles, furniture, pet accessories, outdoor gear, and beds. Treated surfaces are given skin-safe, long-lasting insect repellent properties that work even beyond the edges of treated areas but without killing insects or adversely affecting the local environment.

Anti-Microbials: The anti-microbial solution is based on Si-Quat, a highly effective anti-microbial that works on 99.9% of viruses, bacteria and fungi, and has been proven to work against Covid-19. As a highly durable semi-permanent coating it kills viruses and bacteria whilst being safe to humans and animals, and lasting potentially years if untouched. A second solution based on the same active ingredient is a combined cleaner and coat named Clean 'n' Coat, that replaces normal surface cleaners and leaves a thin anti-microbial layer that can last up to a week.

■ Affix Labs Oy, Helsinki, Finland
www.affixlabs.com

Elevator Pitch

Non-Invasive Protection

Affix Labs is focused on providing invisible protection to the people that need it the most. The long-term aim is to solve real world problems with simple solutions. The long-term focus of the Helsinki, Finland-based start-up company is to apply the technology as a cost-effective solution to protecting people from potentially deadly diseases like malaria, dengue or the microbes that cause diarrhea. In the immediate term there is significant growth in solutions focused on hygiene and specifically the Covid-19 pandemic are amongst the developments in the last years. These two goals have now combined and are happening at a much faster rate than initially expected.

Whilst research and development continues, routes to market are already being built for large scale commercial or government use through distribution partners around the world, and consumer solutions with products coming to the market in Q1 of 2021 allowing wide spread use on multiple levels.

Although headquartered in Finland, the team is all over the world from Somalia to Thailand, from the Netherlands to the United Arab Emirates. The dynamic team makes it possible to relate to communities that are otherwise far away from the people developing the products.

Partnerships with universities and testing facilities that represent a wide range of labs in the EU, South Africa, Uganda, India and the UAE, are used to provide a solid foundation for the claimed effectiveness of the company's solutions.

Milestones

2018
- Repeltec textile treatments come to market

2019
- Repeltec Active Coatings finish testing

2020
- Si-Quat tested and proven on Covid-19 and support received from the EU EIT RawMaterials fund to further research and release
- Si-Quat launched

Roadmap

2021
- Q1: Launch of first Repeltec and Si-Quat consumer products
- Q2/3: Launch in American markets and in all major global regions

Si-Quat, invented by Affix Labs' Repeltec development team, is based on the safe disinfectant quaternary ammonium, which is chemically bound to align silane quaternary ammonium molecules (silane quats). Testing has shown Si-Quat to adhere to almost any surface, performing as a durable surface treatment.

Connected Work

A new Definition of Industrial Work Environment

We are in an increasingly volatile global climate, from health and economic crises, to trade wars on multiple fronts, to political unease, to name just a few. During periods like these, it makes sense that corporations generally shift toward a more conservative stance, taking a "wait-and-see" approach to business decisions. However, instability can provide exceptional opportunities for companies to innovate and accelerate ahead of more conservative competitors. In manufacturing, the Fourth Industrial Revolution is fully upon us. Yet, only about half of manufacturing companies are in the early stages of smart factory transformation, and 20% "have a desire to adopt" digital, but are experiencing blockers. The number of companies just watching rather than acting needs to decrease and those that are already in the midst of digital transformation should consider leveraging this moment to accelerate their journeys. Ralf Kempf asked Lawrence Whittle, CEO of software company Parsable and member of the World Economic Forum, about current challenges of the process industry and why manufacturing leaders must get started on implementing their digital strategies now.

CHEManager: Mr. Whittle, the chemical industry is an essential materials provider for many industries. How is the industry doing in and dealing with the Covid-19 pandemic?

Lawrence Whittle: Chemical companies and the process industry at large are starting to determine how to best adapt to these new realities. Unlike many other industries, however, there is a universal reliance on them to produce so many of the day-to-day items we all need, like health and medical supplies, cleaning products and other consumer packaged goods. Any company making these products is seeing strong demand, and will continue to see that through the pandemic. The biggest challenge for them is related to how their workforce operations respond efficiently and safely to these changing demand patterns.

Lawrence Whittle, CEO, Parsable

What, in your opinion, are the greatest challenges for the process industry in the coming months or in the coming year?

L. Whittle: The pandemic will still dominate business decisions for several months ahead, and one of the biggest challenges remains worker safety on the processing plant floor. It's critical that organizations put increased emphasis on safety measures to not only better support their frontline workers, but also to strengthen their business. Secondly, these companies have to arm their workers with a more agile approach to work execution.

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> *"Connected worker technology is an essential solution to overcoming the safety and operational challenges."*

How will the process industry master these challenges? Or will they not be able to do so at all?

L. Whittle: Connected worker technology is an essential solution to overcoming the safety and operational challenges, ensuring that workers are adhering to safety policies and executing work in the correct sequence so that productivity and quality levels

remain as high as possible. Leveraging new mobile technology helps people better execute work through a digital approach—it digitizes work instructions and makes them accessible through mobile devices.

Plant managers can make changes to digital standard operating procedures (SOPs) at any time and make them accessible through mobile devices so that the most up-to-date safety policies and steps are integrated into the work itself. For example, SOPs can include safety guidelines, sending push alerts to workers to remind them to wash their hands before handling equipment, wear masks, and more.

Connected worker technology can also help with social distancing and remote collaboration. It can capture worker data and progress in its system so it knows exactly where certain processes were left with one person and where the next person needs to pick it up. This means a lesser need for close human interaction.

Which developments and trends, apart from the challenges mentioned, are currently influencing the process industry? Does the corona crisis accelerate these trends?

L. Whittle: Totally independent of the Covid-19 pandemic, there is huge concern—and opportunity—around two large factors. Firstly, sustainable operations, and secondly managing the changing workforce due to a large amount of late career workers retiring from the process industry.

There is more attention now than ever on the excess waste from the beginning to the end of the manufacturing process, as well as the environmental concerns and preservation of resources in manufacturing. The public is demanding more transparency, as are employees and workers themselves. The production efficiencies enabled through technology, and its ability to document gains made or waste averted, will be key to that transparency.

> *"Modern digital tools will be a recruiting competitive weapon in the near term and a 'must have' in the medium term."*

Additionally, the retiring workforce was an issue before the pandemic but now ever-increasing numbers are leaving the workforce with tacit knowledge. Hiring early career people with 10-centimeter binders for onboarding just will not work.

A major problem for the industry could arise from the shortage of skilled workers and young talents. How could this influence the long-term development of the industry?

L. Whittle: To expand on this subject, process companies need to rapidly rethink how they hire, retain and train at a far greater velocity than ever before. Modern digital tools will be a recruiting competitive weapon in the near term and a 'must have' in the medium term. Just as baby boomers drove change in the workplace as they began to fill management and executive roles, so, too, will millennials and young talent have an impact on the technology systems and solutions deployed in factories and on shop floors everywhere.

What role does the World Economic Forum play in tackling the challenges for the process industry mentioned above?

L. Whittle: I'm a member of the World Economic Forum's Platform for Advanced Manufacturing and Production, and we are absolutely addressing these challenges on multiple fronts. We have an active community of over 130 organizations from more than 22 industry sectors to accelerate technology while stimulating innovation, sustainability and employment. A new WEF group that my company, Parsable, is leading, called New Generation Manufacturing Leaders, is putting forth initiatives both internally at their organizations and externally to make manufacturing more sustainable, resilient and inclusive.

> *"Process companies need to rapidly rethink how they hire, retain and train."*

How can a platform for connected work support companies in the process industry? What insights can be gained from such a platform—and where are the limits?

L. Whittle: Simply put, connected worker platforms help employees on the shop floor get their job done right the first time and every time. In doing this, they help to uncover data on the human work in your operations, so you can drive continuous improvement. Companies can start to capture the data that's not currently captured by any systems, in real time. As you capture that data, it can be used for things like autonomous maintenance—making sure that machines don't break down. The systems can inform you when you need to make a change, or you can start to see benchmarking on how long it's taking to do a particular task or how many errors you're getting around a deviation. The fact that the data is now available in real time means that you can update dynamically that working structure, and then the next time someone executes that work, you've got a brand-new updated version.

The lack of modern digital tools for frontline workers has been a key topic for industrial companies. It's now clear that anyone still contemplating operating with paper-based work processes is running both a big risk and missing a big opportunity.

www.parsable.com

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Safety Is a Mindset, not a Department

Creating a True Safety Culture that Avoids Injuries and Accidents

The Dutch holding Stahl, headquartered in Waalwijk, produces specialty chemicals for coatings, processing, and treatments in industries like mobility, fashion & footwear, architecture & construction, interior spaces and paint, ink & packaging. CHEManager asked Alexis Pey, Global SHE & Process Safety Manager at Stahl, on the company's mindset on safety, health and environment (SHE), the impact of the coronavirus pandemic and how the chemical engineering community can benefit from Stahl's expertise on SHE. Ralf Kempf asked the questions.

CHEManager: Mr. Pey, what is Stahl's mindset regarding process safety? Does the holding have specific activities or policies in place to ensure the health and safety of its employees and to prevent environmental damage?

Alexis Pey: Knowledge is the cornerstone of Stahl's mindset for process safety. A strong process safety culture derives from having a complete understanding of the properties and characteristics of the substances, facilities and processes present at our sites, which define the potential hazards we are managing.

For these reasons, we have policies in place that describe hazards and define the methodologies, criteria and tools to be applied globally so that we take a consistent approach to key process safety points.

As well, in order to foster this knowledge to deeper levels, we rely on training and sharing experiences both internally and externally. For instance, we are active in several technical groups at international level and we are open to sharing this experience with other companies.

How did the coronavirus pandemic impact the SHE measures at Stahl?

A. Pey: Covid-19 represents a global health crisis, so Stahl has been impacted in the same way as many other industries in the chemical and other industrial sectors.

Our first reaction was to adopt measures to prevent people who could be carrying this disease from entering our sites. We did this by establishing criteria and denying access for people who had been in a so-called hot area in the previous 14 days. However, when this criterion was no longer feasible due to the spread of the virus at community level, we adopted measures to reduce the number of people at our sites to just those who are exclusively linked with essential production processes. Finally, as the pandemic and the characteristics of this disease evolved, we defined further measures. These measures recognize that it is not feasible to reliably exclude people from our sites who have been inadvertently infected with the coronavirus. The aim, therefore, is to prevent the spread of the disease within our facilities.

In addition, besides our criteria, we always follow the recommendations of the health authorities and the legal or other requirements to cope with the Covid-19 in the countries in which we have facilities.

Another thing I want to make clear is that managing Covid-19 requires a coordinated effort with all other departments in the company. Viewing it just as a health crisis, and therefore exclusively linked to SHE, is too simple an approach.

> *"Knowledge is the cornerstone of Stahl's mindset for process safety."*

Finally, from a process safety point of view, the situation caused by Covid-19 has not led to any lowering of the safety standards at Stahl. By adopting the necessary safety measure to avoid Covid-19 related hazards, we are ensuring that the right number of personnel oversee active processes. We also conduct all the mandatory inspections and maintenance work that are necessary to keep our operations in full compliance with legal requirements.

Stahl created the role of a Global SHE and Process Safety Manager in 2017 and you have held the position since then. What were the most important projects you realized during this time?

A. Pey: Stahl grew significantly between 2014 and 2017 by acquiring businesses from various companies. This made it necessary to establish a common approach on fundamental SHE & Process Safety aspects. In this regard, I would like to mention two significant projects.

Alexis Pey, Global SHE & Process Safety Manager, Stahl

The first involved defining and implementing a new hazard identification and risk assessment methodology which is now used globally. This helps to share and compare facilities between different sites and, as said before, adds a solid process safety concept to our operations.

Second, we defined a program focusing on safety perception and awareness. The aim is to influence behavior and establish root safety as an essential defining value for our colleagues. A true safety culture is only achieved when safety is a value in life and not just at work. This program is being implemented globally, though the travel disruption caused by Covid-19 has forced us to review the timetable.

In addition, we have reviewed our SHE Manual and transformed it into a set of global directives and rules dealing with most relevant safety topics. And this year, we have started to implement a project to standardize the clothing and PPE used at all Stahl sites.

How can the chemical engineering community benefit from your company's know-how and experience?

A. Pey: When it comes to safety and avoiding accidents and losses, we don't think in terms of 'competitors'.

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As a result, we are open to sharing our experience if it may be useful to other companies. This approach is, of course, not exclusive to Stahl; many companies view safety in this way, which enables us to also learn from them and share their knowledge and practices.

How has the role of SHE topics changed from—let's say—the 1980s and 1990s to today?

A. Pey: Answering this question in a general way may be unfair to those companies that began using now common concepts a few decades ago. So, I would say that thanks to those who had a different view and took the lead, other companies were able to evolve more easily, even if that evolution happened later.

In my view, the evolution of SHE and other disciplines was linked to the development of new management principles that shifted from a silo conception of companies to a shared responsibility in many fields. In a silo approach, departments are highly independent units with a few clearly defined interfaces with other departments. Under this concept, people did not feel involved in safety issues because safety was an exclusive responsibility of the safety department.

In contrast, the shared responsibility concept encourages everyone in an organization to be aware of their impact in terms of not only safety, but also quality, cost control, company culture, et cetera. Departments are still responsible for defining the principles and processes in their management field. However, once the principles and processes are defined, the responsibility to implement and keep them in place is shared throughout the organization.

How has it impacted corporate cultures and functions?

A. Pey: In terms of impact on corporate culture and functions, I would say that the perception of SHE has evolved in line with society's demands regarding healthy working conditions, environmentally respectful processes, accident prevention, et cetera. What was acceptable to society and legally in the '80s and '90s is no longer acceptable today, just as what was acceptable in the '50s and '60s was no longer acceptable in the '80s and '90s.

As society evolves, so do companies, too, and this evolution is in great part linked to the knowledge available. What we know today in many scientific and technical fields was unknown a few decades ago.

It is a self-evident truth, but every age in history has been the most advanced in history, at that time. However, this truism brings me to the concept that interests me the most and that is, how will we answer the same question in the 2050s and 2060s when we look back to how we do things today? I dare to say that there will be many evident changes and that it will be as hard to understand our current practices as it is for us to understand the practices of the past.

With this concept in mind, one of Stahl's aims is to contribute to this evolution by taking nothing for granted, analyzing objectively and, with constructive criticism, reviewing principles of SHE and taking initiatives to reach new paradigms.

www.stahl.com

Specialty & Custom Chemicals Show

On April 14–16, 2021, the Specialty & Custom Chemicals Show, to be hosted in Fort Worth, TX, USA, focuses on products and technologies across the full specialty and custom chemical supply chain. Participants cover a wide range of chemical end-uses like adhesives & sealants, agriculture & crop protection, coatings & paints, cosmetics & personal care, flavors & fragrances, pharmaceuticals, plastics & composites, and water treatment. The event, owned by SOCMA, is organized in collaboration with Chemicals America. **https://texas.chemicalsamerica.com**

Chemspec Europe

Chemspec Europe will take place May 19–20, 2020, in Frankfurt, Germany. The event is the key platform for manufacturers, suppliers and distributors of fine and specialty chemicals to showcase their products and services to a dedicated audience of professionals in the industry sector. The exhibition covers a maximum range of fine and specialty chemicals for various industries and offers networking opportunities and top conferences presenting the latest results of ongoing R&D projects. **www.chemspeceurope.com**

CPhI Worldwide

CPhI Worldwide, taking place August 31–September 2, 2021, in Milan, Italy, hosts more than 45,000 visiting pharma professionals over 3 days. 2,500+ exhibitors from more than 150 countries gather at the event to network and take advantage of free industry seminars. Every sector of the pharmaceutical market is represented under one roof. The event offers a place where professionals can meet to exchange knowledge and do business without obstacles, helping to propel the pharmaceutical and healthcare industries forward. **www.cphi.com**

Interphex

The International Pharmaceutical Expo (Interphex), scheduled to take place October 19–21, 2021, in New York, NY, USA, is the premier pharmaceutical, biotechnology, and device development and manufacturing event. The annual event brings over 10,000 global industry professionals and 625+ leading suppliers together, featuring a combination of no cost technical conference, exhibits, demonstrations, and networking events to leverage quality, efficiency and cost effectiveness. **www.interphex.com**

Due to the coronavirus pandemic, events may be postponed or cancelled. We therefore cannot guarantee the validity of the dates mentioned here.

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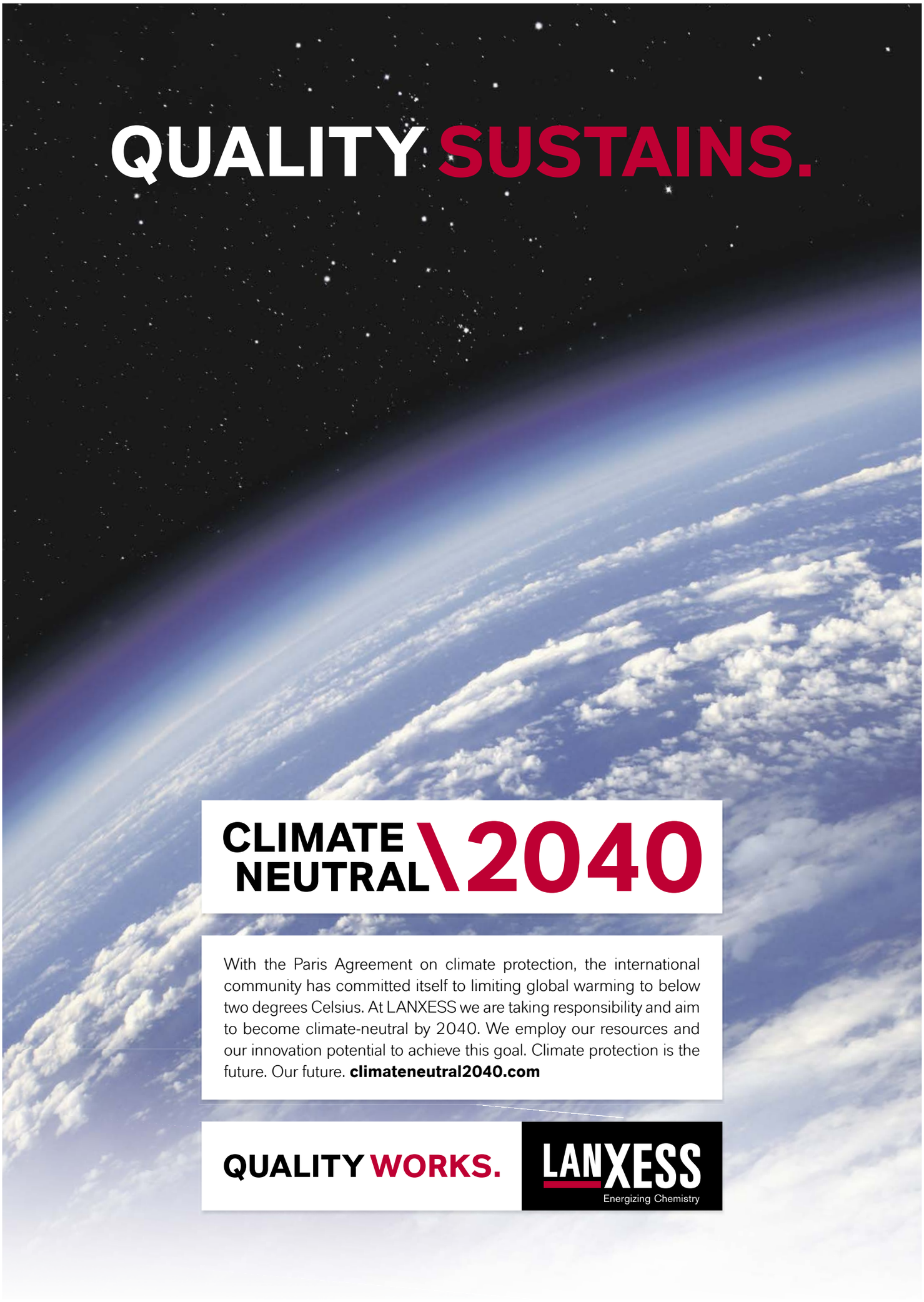
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