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Wow! It’s April already, and here we are at in-cosmetics Global and CPhI North America, not to mention some other exciting partnered events where you can pick up your latest copy of Chemicals Knowledge.

In this issue we are focussing on digital innovation in the pharma industry, and on emerging trends in cosmetics. Our editorial team has provided us with some fantastic exclusive articles on these topics, and I hope you enjoy reading them.

Since our launch in December 2017, we have been overwhelmed by the amount of positive feedback and support we have received from the industry. I would like to take this opportunity to extend my heartfelt thanks to everyone who has sent us their news, taken part in interviews, contributed technical articles and, of course, supported us through advertising.

Our goal remains simple – to be a one-stop shop for informative and topical news and articles in the speciality chemicals industry. Thanks to everyone who has helped us to move towards this ambition so quickly.

Together, I truly believe we can make an impact, and help to move the industry forward in a positive, innovative way.

Ellie Bruni
Publishing Director
Chemicals Knowledge Hub (Global)
Forthcoming Events

in-cosmetics Global 1
17–19 April 2018
Amsterdam, The Netherlands
www.in-cosmetics.com/global

CPhI Japan  2
18–20 April 2018
Tokyo, Japan
www.cphi.com/japan

Adhesive & Sealant Council Annual Spring Convention & EXPO 3
23–25 April 2018
Miami, FL, USA
ascouncil.site-ym.com/events

CPhI North America  3
24–16 April 2018
Philadelphia, PA, USA
cphinorthamerica.com

Making Pharmaceuticals 4
24–25 April 2018
Coventry, UK
www.makingpharma.com

April 2018

MAY 2018

4th Future of Formulations in Cosmetics Summit
16–17 May 2018
Barcelona, Spain

GC3 2018 Startup Technology Showcase
18 May 2018
Kingsport, Tennessee, USA
greenchemistryandcommerce.org/startup-network/tech-showcase-2018

Highly Potent Active Pharmaceutical Ingredients (HPAPI)
21–22 May 2018
London, UK
www.smi-online.co.uk/pharmaceuticals/uk/Highly-Potent-Active-Pharmaceutical-Ingredients

Surfex 2018  4
22–23 May 2018
Coventry, UK
www.surfex.co.uk

18th International Conference and Exhibition on Materials Science and Engineering
28–30 May 2018
Osaka, Japan
materialsscience.conferenceseries.com/asia-pacific

JUNE 2018

FECC Annual Congress  5
4–6 June 2018
Nice, France
www.fecc.org

6th Anti-ageing Skin Care Conference
5–6 June 2018
London, UK
www.summit-events.com

in-cosmetics Korea
13–15 June 2018
Seoul, South Korea
korea.in-cosmetics.com

Cosmetics Europe Annual Conference (CEAC) 2018
13–14 June 2018
Brussels, Belgium
www.cosmeticseurope.eu/news-events

Biobased Coatings Europe 2018
20–21 June 2018
Antwerp, Belgium
www.wplgroup.com/aci/event/biobased-coatings-conference

DCAT Sharp Sourcing  6
26 June 2018
New Brunswick, NJ, USA
www.dcat.org/SharpSourcing.htm

APRIL 2018

in-cosmetics Global  1
17–19 April 2018
Amsterdam, The Netherlands
www.in-cosmetics.com/global

CPhI Japan  2
18–20 April 2018
Tokyo, Japan
www.cphi.com/japan

Adhesive & Sealant Council Annual Spring Convention & EXPO 3
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April 2018
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R&D in the spotlight at in-cosmetics Global

A host of new initiatives unveiled ahead of this year’s event in Amsterdam from 17th to 19th April.

in-cosmetics Global will land in Amsterdam this April for the first time in a decade, bringing with it hundreds of the most innovative personal care ingredients and an in-depth education programme featuring the world’s leading analysts, formulation experts and consultants.

Around 9,000 visitors are expected to travel to the Netherlands from more than 100 countries when the event opens on 17th April. Over three days, the exhibition will provide a one-stop-shop for manufacturers to enhance business relationships, learn about the latest trends and get a first look at novel ingredients created in all four corners of the globe.

What’s new for 2018

With global expenditure on research and development reaching almost US$1.7 trillion,1 the organizers of in-cosmetics Global have announced the launch of new R&D-focused tours that will run in Amsterdam.

Exclusively for R&D professionals and sponsored by Mibelle Biochemistry and Novacap, the ‘silent’ tours will zero in on two of the industry major trends – Biotechnology Actives and The Future of Anti-Ageing – and will be led by technical consultant and cosmetic chemist Rouah Al-Wakeel.

In another new initiative for 2018, in-cosmetics Global will hold a half-day Regulatory Conference in partnership with Conusbat and sponsored by Ithos Global on 16th April at 2pm. The conference will provide tailored content on cosmetics frameworks and regulatory and testing modules in the European Union, United States of America, China and the rest of the world. Delegates are also invited to network at a drinks reception and take part in one-to-one ‘speed meetings’ with the experts.

The Formulation Challenge, sponsored by Croda, will also hit in-cosmetics Global for the first time this April. Six cosmetics giants will be tasked with creating an innovative formulation from a box of mystery raw materials in just 90 minutes.

The secret to winning formulations

Since its launch, the in-cosmetics Formulation Lab has become renowned across the world as a unique opportunity to learn from top suppliers about how to maximize the potential of their ingredients.

Taking place in a purpose-built lab and sponsored by Brenntag, the in-cosmetics Global 2018 programme will feature practical presentations from The Institute of Personal Care Science, as well as the world’s most innovative suppliers including BASF, Kobo, Cosphatec and Ashland.

Innovation highlights

The in-cosmetics Innovation Zone will return to the 2018 event, providing a launchpad for more than 100 state-of-the-art concepts and enabling time-poor R&D scouts to find the latest ingredients all in one place. Mintel will also host a series of live demonstrations, presenting market-leading finished products and the trends that inspired them.

Product developers, formulation experts and marketing professionals will also be able to touch and experiment with latest innovations in pigments, textures and technology at the show’s Make-Up Bar and Sensory Bar.

To support personal care manufacturers in adopting more environmentally-friendly practices, the in-cosmetics Sustainability Corner will return to the Global event to showcase a selection of environmental and social initiatives.

Insights from industry leaders

As ever, in-cosmetics Global’s Marketing Trends programme will deliver hot-off-the-press consumer trends and research. Representatives from the top market analysts, including Euromonitor, PeclersParis, GlobalData and Mintel, will share the latest data and insights into the hottest industry trends from DIY beauty to athleisure.

In the Technical Seminars Theatre, sponsored by Givaudan, suppliers of the world’s most technologically advanced ingredients, including Evonik, AkzoNobel and Lipotrue, will share the science behind each innovation and how to make the most out of these concepts to create products consumers will love.

Meanwhile, the Workshop programme will enable participants to stay ahead of industry issues such as what’s new in the field of protecting the skin against the radiation of the electromagnetic spectrum and new avenues of research into the skin microbiome.

After Party and Awards

Industry professionals are also invited to the in-cosmetics Global After Party on 17th April, which is new for 2018. Attendees will enjoy an evening of music, food, drink and entertainment, as well as celebrating the achievements of the in-cosmetics Global Award winners.

Speaking ahead of the 2018 event, Roziani Zulkifli, Exhibition Manager, commented: “Amsterdam is a central hub of business in Europe, easily accessed by international suppliers and manufacturers – from the USA to the Middle East – which is why we’ve decided to return after ten years. We’re thrilled to be introducing our exciting new elements, which have all been imagined to further inform and inspire our visiting cosmetics manufacturers and we look forward to welcoming them all in April.”

in-cosmetics Global will take place at RAI Amsterdam from 17-19 April 2018. For more information and to register for the show, please visit http://www.in-cosmetics.com

Reference

1. UNESCO Institute of Statistics.
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CPhI North America returns to Philadelphia

Bigger, bolder, stronger: CPhI North America 2018 focuses on Fostering Innovation in Drug Development and Manufacturing. Here, we provide a preview of this year’s conference and exhibition.

Building on the success of last year’s inaugural event, CPhI North America returns to the Pennsylvania Convention Center on 24–26 April, bringing together the complete North American pharmaceutical and biopharmaceutical supply chain for two days of networking, expert industry insight, exhibitor showcases, and illuminating keynote sessions.

Vital, visionary keynotes

At the heart of this year’s event is the CPhI Conference, a mix of education, inspired thinking and motivation. The year’s featured keynotes include The Medical Futurist, Dr Bertalan Meskó, and Nik Leist, Senior Director of Ingestible Sensor Manufacturing and Site Leader at Proteus Digital Health. Keynote sessions are open to all Conference Pass, Exhibitors, Expo Only and VIP attendees.

Bertalan Meskó, a self-professed ‘geek physician’ with a PhD in genomics, envisions the impact of digital health technologies on the future of healthcare, helping patients, doctors, government regulators and companies work to make it a reality. At CPhI North America, his keynote address will focus on Science Fiction in Healthcare, and explore how science fiction becomes science fact, the role that patient-led design is having on technological developments, the new challenges presented by patients finding an unregulated, technological solution for health problems, how disruption is helping to tackle these new challenges, and how this is resulting in a cultural transformation as we move towards highly personalized, digital health solutions. Dr. Mesko’s keynote takes place on Tuesday 24th April from 1.30 pm to 2.15 pm.

Nik Leist is at the forefront of the digital health revolution, working to commercialize a new category of therapy: Digital Medicines. These offerings include widely-used drugs, formulated so they ‘communicate’ when they have been swallowed; a wearable patch that detects medicines and captures physiological responses; mobile applications to support patient self-care and physician decision-making; and data analytics to serve the needs of health system managers. In his keynote address, which takes place on Wednesday 25th April from 1:30 pm to 2:15 pm, Mr Leist will discuss how his teams develop integrated medication with sensors, wearable patches, and physiological algorithms that deliver the core functionality of Proteus’ FDA-approved Digital Medicines.

Relevant, comprehensive conference tracks

This year’s comprehensive conference agenda includes insightful discussions on pharmaceutical manufacturing, outsourcing, R&D, drug delivery and supply chain related topics for small and large molecule finished drugs, biopharmaceuticals, and biosimilars/biogenerics. With three designated tracks of programming – two tracks dedicated to development and manufacturing for small and large molecule finished drugs, and one track dedicated to advances in bio-manufacturing – the central theme for 2018’s conference is Fostering Innovation in Drug Development and Manufacturing. Highlights of each conference track include:

**Drug development track**
- Solubility enhancement and improving oral bioavailability
- Hot melt extrusion challenges and solutions
- Fixed dose combination (FDC) – a cost-effective approach for simplified dosing
- Precision medicine – changing the paradigm of drug development.

**Drug manufacturing track**
- Continuous processing technologies for API and intermediate manufacturing – innovation meeting market demand
- Fireside chat with Michael Levy, Head of Research & Innovation at USP: the role of quality standards in emerging technologies
- Regulatory considerations, strategy and best practices for choosing a quality contract manufacturing organization (CMO)
- Risk management in technology transfer.

**Bio-processing track**
- A molecule’s journey – breaking down roadblocks to commercial success
- USP standards to support qualification of raw materials and cell substrates for biomanufacturing
- Cell line development and new technologies
- Case study – implementing novel technologies to reduce timelines.

In addition to the keynote addresses and conference program, a series of Insight Briefings, in-depth seminars on technical and business topics, will be freely accessible to all exhibition visitors. Topics include accelerated drug approval programs, the digital transformation of the pharmaceutical industry, supply chain security advancements, amongst others. There will also be a number of free Exhibitor Showcases taking place, providing a platform for industry professionals to present forward-thinking perspectives on their key products, innovations and services. Finally, the pharmaceutical Serialization Series provide a forum for thought leaders to present and discuss the latest insights and developments within the serialization sector.

...CONTINUED ON PAGE 8
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More zones, more possibilities

This year’s event has been expanded to introduce two new featured zones – the Bioprocessing Zone, with a focus on innovations in biopharmaceuticals, and the P-MEC Zone, a machinery zone to promote the latest technology in manufacturing equipment. The full zoning at CPhI North America now consists of:

**Bioprocessing Zone:** Consider these statistics – biopharmaceuticals currently generate global revenues of $162 billion. The biopharmaceutical market is projected to grow at CAGR 9.4% in the period 2017-2021, reaching $278 billion by 2021. Biomanufacturers will be spending more on innovation, increasing their budgets an expected 6% for new technologies. Outsourcing of biopharmaceutical manufacturing will continue to increase as companies aim to increase testing services and production efficiencies. New for 2018, the Bioprocessing Zone provides a specialized platform that showcases innovations and developments in this vital space, facilitating a one-stop-pharma-shop for companies to source their requirements on manufacturing and processing.

**CPhI Zone:** With global pharmaceutical sales expected to grow at a CAGR of between 3% and 6%, fueled in part by a HPAPI and Generic APIs market estimated to reach $186 billion by 2020, and coupled with improved awareness for the environment, more sustainable ingredients, and better waste management, there are huge market opportunities in ingredients manufacturing. The CPhI Zone focuses in on these market trends and expansion opportunities to bring manufacturers, partners and customers together.

**PDF Zone:** Increased global demand for affordable prescription and OTC drugs are forcing the industry to manufacture high levels of safe, high quality, and cost-effective drugs efficiently. Focused on small and large molecules finished drug products, the PDF Zone highlights a wide variety of discussion areas relevant to the finished drug products market, including new business models, the ongoing convergence between drugs and devices, data intelligence, single-use systems, disposables, the increasing demand for generics, quality compliance, and regulatory scrutiny.

**ICSE Zone:** Home to 25% of the world’s pharmaceutical contract research and manufacturing, North America owns the largest market share of these vital services. The ICSE Drug Development Zone focused on pre-clinical and clinical research and drug development, providing the largest global stage for companies providing contract services across key areas such as clinical trials, contract research, contract manufacturing, biotech, IT, analytical services, packaging services, and logistics, amongst others.

**InformEx Zone:** Focused on fine and specialty chemicals, the InformEx Zone showcases the complete range of specialty chemicals and provides an opportunity for suppliers to connect with a broad spectrum of end use applications. It’s a marketplace designed to foster an environment for people of like interest to connect, learn, inspire, and become plugged into the centers of both the high-value chemical and pharma industries.

**InnoPack Zone:** Focused on the latest in packaging products and technology, the Innopack Zone provides a dedicated platform to showcase the latest and greatest innovations in this highly competitive space, highlighting both the opportunities and challenges associated creating sustainable, user-friendly packaging with innovative designs in a cost-effective way.

**PMEC Zone:** With the global pharmaceutical packaging machinery market expected to reach $8.25 billion by 2022, new industry regulations requiring reliable and high-end inspection technology equipment to be integrated into production lines, and manufacturers shifting to fully automated solutions to increase and improve efficiency and inspection accuracy, the P-MEC Machinery Zone brings together all the key role players involved with the science and technology used throughout the supply chain—from the production of API all the way to enclosing or protecting products for distribution, storage, sale, and use.

Last word…

“We’re excited to bring CPhI North America back to Philadelphia and continue to evolve our distinct Zones to meet industry demands to embrace the synergy that exists between them and the fact that all aspects of the pharma industry are represented in one place. As visitors from years’ past have told us, there are wonderful opportunities at CPhI to meet new people and create lasting business relationships,” commented Joseph Marks, Brand Director for CPhI North America.

He continued, “We’re thrilled to have such inspired keynotes joining us to provide visionary insight into the future of research, diagnostics, personalized healthcare, and technology, and how these elements continue to intersect at an increased rate. CPhI events around the world are renowned for bringing the brightest and best from the pharmaceutical, biopharma and life science industries to provide illumination and insight that highlights innovation, emerging trends and technologies and seeks to address some of the challenges ahead.”

Registration for CPhI North America is open at: [www.CPhINorthAmerica.com/register](http://www.CPhINorthAmerica.com/register)
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**Mergers & Acquisitions**

**Sanofi** has completed its previously announced $11.6-billion acquisition of **Bioverativ**, a Massachusetts-headquartered company created from the spin-off of **Biogen’s** haemophilia business.

**SGS Institut Fresenius** has acquired the testing institute **SIT Skin Investigation and Technology Hamburg**. As a result of the merger, the prestigious laboratory service provider is expanding its testing services for cosmetics, personal care and hygiene products.

**Azelis** has signed an agreement to acquire **Distralim**, a distributor of food ingredients in Morocco. With this deal, Azelis will become one of the leading food distributors in Morocco.

**2M Holdings** has acquired privately held, Germany-based **FrankenKosmetic-Chemiehandel (FrankenChemie)**, a distributor of specialty chemicals, primarily into the personal care, home care and food ingredients sectors, in Germany, Croatia, Macedonia, Slovenia and Benelux.

**BASF** is in exclusive talks to acquire **Bayer’s** entire vegetable seeds business, operating under the global trademark **Nunhems**. Bayer intends to divest this business in the context of its planned acquisition of **Monsanto**.

**Deere & Company** has signed a definitive agreement to acquire **King Agro**, a privately-held manufacturer of carbon fibre technology products with headquarters in Valencia, Spain and a production facility in Campana, Argentina.

**Nufarm Limited** has acquired the Century portfolio from **Adama Agricultural Solutions** of Israel and **Syngenta** of Switzerland.

**Italmatch Chemicals Group** has bought the Chinese **Jiayou Chemical**, active in the antisalant phosphonate component business, from **Ecolab**.

Private equity firm **Agilitas** has acquired **Hydro International Limited**, a provider of services and technology to treat wastewater and control stormwater for municipal, industrial and construction industries.

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**Novartis and Pear Therapeutics collaborate on digital therapeutics**

Novartis has partnered with Pear Therapeutics, a US-based digital therapeutics company, to develop prescription digital therapeutics using software applications designed to improve clinical outcomes for patients. The collaboration combines Novartis’ experience in biomedical research and clinical development with Pear’s experience in digital therapeutics design and implementation.

Novartis and Pear will work together on new treatments for patients with schizophrenia and multiple sclerosis. Pear’s prescription digital therapeutics are designed to deliver treatments, such as cognitive behavioural therapy, to patients through mobile and desktop applications. Once approved, they could be prescribed alongside drug therapies and have the potential to be developed to treat a range of conditions.

Novartis will work with Pear to advance clinical development of its digital therapeutic, Thrive, for patients with schizophrenia. The companies will also collaborate on a new application to address mental health burdens in patients with multiple sclerosis. The technologies may be used to monitor patient data in real-time, detect day-to-day behavioural and biological changes in condition, and improve patient adherence.

Novartis says this collaboration is part of its strategic effort to work with digital-health companies.

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**Takeda to invest €25 million in new cell-therapy facility in Ireland**

Takeda Pharmaceutical Company plans to invest €25 million to construct a new regenerative medicine facility at its site in Grange Castle, Dublin, Ireland. The investment will expand the Grange Castle site with the construction of a new stand-alone modular cell-therapy facility dedicated to manufacturing a stem-cell therapy.

The facility will begin commercial operation by 2021.

In 2002, Takeda chose Dublin as the location for its first active pharmaceutical ingredient facility outside of Japan. In 2017, Takeda announced a €40-million investment for the construction of a stand-alone production facility for manufacturing part of its oncology portfolio at Grange Castle.

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**Catalent completes $4.6-million expansion in Singapore**

Catalent Pharma Solutions, a leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, has announced the completion of a two-year, $4.6 million expansion at its Singapore clinical supply facility.

The facility is a key strategic hub in Catalent’s Asia-Pacific network and global clinical supply business, supporting multinational customers’ growing needs for full clinical supply services, while providing flexible solutions for local customers in the Asia-Pacific region. The new expansion provides additional GMP space for secondary packaging, has doubled ambient storage, and quadrupled cold storage capacity at the site.

“We are particularly pleased to have completed the expansion in a year that marks the 20th anniversary of what was Catalent’s first facility in the Asia-Pacific region,” commented Bernie Clark, VP Marketing, Catalent Clinical Supply Services. “Supported by many long-serving employees, the Singapore site has undergone tremendous growth over the past two decades and now routinely distributes to 18 countries in the region.”
Alcami supports centre for substance abusers

Alcami Corporation has donated $10,000 to Triangle Residential Options for Substance Abusers (TROSA), a Durham-based multi-year residential program that helps substance abusers by providing comprehensive treatment, work-based vocational training, education, and continuing care.

Alcami’s donation will properly outfit TROSA’s medical department with computers, monitors, and accessories for its exam rooms, which will enable its medical specialists to quickly assess and document treatment for residents. It will also equip their medical office bullpen, where residents receive vocational training. The upgrades will optimize TROSA’s overall operations, increase efficiency, and ultimately improve the physical and mental health outcomes of individuals enrolled in their long-term recovery program.

“Alcami is proud to support TROSA, an incredible, nationally-recognized care provider with a revered standing in the recovery and public health communities, and a true source of hope for people struggling with addiction,” said Alcami CEO, President and Chairman, Dr Stephan Kutzer. “We share TROSA’s compassion for the community and believe an investment in their organization is an investment in saving lives.”

Alcami’s Durham, North Carolina global headquarters and development services laboratories are situated in the heart of Research Triangle Park (RTP), a region known for its cutting-edge innovation, invention, and medical advances. The growing facility, currently undergoing a technology expansion into biotherapeutics, specializes in abuse deterrence studies to reduce or eliminate the abuse and misuse of opioids. Alcami also supports the industry and patients with the development and manufacture of opioid addiction therapeutic treatments.

Biogen buys Pfizer’s schizophrenia drug

Biogen is buying Pfizer’s experimental drug PF-04958242, which is being developed for cognitive impairment associated with schizophrenia, in a deal that could be worth $590 million.

PF-04958242 is an AMPA receptor potentiator designed to facilitate neurotransmission, a process often disrupted in a number of neurological and psychiatric diseases, such as schizophrenia. The drug has already shown an acceptable safety profile and treatment effect trends in various domains of cognition in early studies, and a Phase IIb trial is planned to start later this year.

Biogen will pay Pfizer $75 million upfront, as well as up to $515 million in additional development and commercialization milestone payments, plus tiered royalties.

More than 20 million people around the globe have schizophrenia, the majority of which are thought to be living with some degree of cognitive impairment attributable to the disease.

Xeris invests in production of ready-to-use glucagon

Xeris Pharmaceuticals, a specialty pharmaceutical company leveraging its novel technology platforms to develop and commercialize ready-to-use injectable and insufible drug formulations, is investing up to $55 million to accelerate commercial preparation of its lead product candidate, a ready-to-use glucagon rescue pen for the treatment of severe hypoglycaemia in diabetes patients.

The investment will help accelerate the development of additional product candidates applying Xeris’ ready-to-use glucagon to intermittent and chronic-use indications that require administration over a longer period. These additional conditions include: post-bariatric hypoglycaemia; congenital hyperinsulinism; hypoglycaemia-associated autonomic failure; exercised-induced hypoglycaemia; and as the glucagon component of a fully-integrated, bi-hormonal artificial pancreas via a closed-loop pump.

Paul R Edick, President & CEO of Xeris, said the funding would be used to “help prepare for submission of a New Drug Application [NDA] and accelerate commercial preparation for Xeris’ lead product candidate, an investigational ready-to-use glucagon rescue pen for treatment of severe hypoglycaemia in people with diabetes.”

Minakem to extend production capacity in France

Minakem, the contract manufacturing division of Minafin, specialized in custom development and manufacturing of building blocks, intermediates and APIs for the pharmaceutical industry, has initiated the extension of its manufacturing capacity at its Dunkirk site in France.

The €14.5M ($18M) investment from parent company Minafin is the first of this magnitude. It will enable the company to set up a new production line, increasing production capacity by 28m³. In parallel, existing production assets are being upgraded in order to increase flexibility. This will free up an additional 26m³ production volume. In total, the production volume at the Dunkirk site will increase by 54m³ to a total capacity of 148m³. This investment comes at a time when Minakem is seeing an increasing number of innovations and new molecules hit the market, which is driving the need for more production capacity among quality suppliers in Europe. More volume capacity means that Minakem can extend its product range and continue meeting client expectations in terms of international standards and flexibility. The increased volume will also enable Minakem to remain competitive as a supplier of active ingredients to the pharmaceutical industry.

The engineering phase has already started on the site; a former AstraZeneca facility that Minakem bought in 2009. It meets the highest standard requirements from all authorities worldwide. Commission tests are planned for early 2019, with an expected operational starting date in May 2019.

ProBioGen and Surface Oncology sign up for antibody manufacturing

ProBioGen, a premier German service and technology provider for complex therapeutic glycoproteins, has signed a second antibody development agreement with US-based Surface Oncology, an immuno-oncology company developing next-generation antibody therapies that target the tumor microenvironment. Under the terms of the agreement, ProBioGen will develop several stable cell lines in parallel, with the aim of identifying a single antibody product for process development and GMP manufacturing. This multi-candidate approach is intended to reduce development timelines. ProBioGen’s CBO, Dr Gabriele Schneider, commented “We have worked together with Surface Oncology very well for quite a while and this is now our second potential clinical antibody project together. We have established a seamless team working across our companies and we are very pleased to continue to expand this relationship with Surface Oncology”.
Ashland and Robertet collaborate on fragrances

Ashland and Robertet will offer new and existing customers access to Robertet fragrances with Ashland’s deposition and encapsulation expertise for fabric care, home cleaning and personal care applications. The planned collaboration aims to leverage the unique capabilities and experience of both companies to develop technology to enhance the delivery, longevity and release profile of fragrance with measurable performance rendering consumer perceivable benefits.

“At Robertet, we are excited at the prospect to extend our product offering as part of this collaboration to provide even greater value to our clients,” said Philippe Maubert, Chairman and CEO of Robertet. “Providing a more complete solution of both fragrances and functional ingredient technology is a key strategic goal and we look forward to exceeding our client’s expectations with the combination of Ashland’s exciting Captivates encapsulation technology and Robertet’s expertise in fragrance creation.”

“Enhancing the overall sensory experience is a growing consumer trend influencing laundry and household cleaning purchases,” said Vito Consiglio, group vice president, Consumer Specialties, Ashland. “By partnering with Robertet, our customers will have the added advantage of accessing new encapsulation technology without the use of formaldehyde and isocyanate in the process. The new Captivates encapsulation technology is designed to optimize the fragrance delivery, longevity and olfactory cues. This new technology expands Ashland’s encapsulation portfolio.”

Itaconix expands portfolio of naturally-derived polymers

Using a patented technology with highly efficient green processes, Itaconix offers novel and high performing functional ingredients to support natural claims in the cosmetics market. Following the successful commercialization of RevCare NE 100S, the first styling polymer to receive COSMOS approval from ECOCERT Greenlife, Itaconix has expanded the portfolio to include RevCare HP and RevCare MC-XD.

“We are delighted to be promoting at in-cosmetics Global yet another COSMOS approved functional ingredient,” said Louise Crascall, Chief Commercial Officer. “The hair styling market is dominated by synthetic polymers and our sustainable production process, breakthrough economics and excellent performance, finally gives formulators a real alternative choice”.

RevCare HP has been proven to protect the hair cuticle from damage during hot iron styling, and also reduces the relative drying time when using a hair dryer, compared to other heat protection polymers on the market.

RevCare MC-XD was designed to be easy to use in a variety of deodorant and personal care formulations. The product eliminates unpleasant malodours by bonding with volatile components. Because of the mode of action, RevCare MC-XD will not constrict pores or inhibit perspiration, and has no effect on the skin’s own natural microbiome.

Roquette enters cosmetics market

Roquette, a global leader in plant-based ingredients for the food, nutrition and health markets, has announced the launch of an innovative and dedicated offering of high-performing and natural-based specialties for the cosmetics market. The Group will unveil this new product range, branded Beauté by Roquette, at the in-Cosmetics tradeshow in Amsterdam this month.

Headquartered in France, Roquette has been working closely with the French cosmetics ecosystem to design and test its offering, which aims to address key consumer trends – notably the growing demand for plant-based products, and for high-performance and innovation. These trends are reinforced by increasing environmental concerns, the growth of the middle-class, urbanization and ageing populations, which will continue to contribute to dynamism of the global cosmetics market. The range will focus on anti-ageing and sun protection properties, as well as improved sensorial benefits.

Jean-Marc Gilson, CEO of Roquette, said: “The upcoming launch of our Beauté by Roquette range is an important development milestone for the Group. We believe that Beauty is all about skin health and nutrition, and we see our new activity in cosmetics as a complementary promising pillar to our existing offering.”

L’Oréal and SkinCeuticals unveil personalized skin care service

L’Oréal has revealed CUSTOM D.O.S.E, a personalized skin care service and the latest innovation from the company’s Technology Incubator to meet consumers’ growing demand for personalized beauty solutions. Developed in partnership with L’Oréal-owned skin care brand SkinCeuticals, the D.O.S.E process evaluates consumers’ specific skin needs to create a tailor-made serum.

Customers begin their experience with a one-on-one consultation with a skin care professional, to determine which ingredients are appropriate for their skin needs. The professional transfers the assessment data via a tablet to the D.O.S.E machine, which then mixes a personalized serum from its range of active ingredients that target different skin ageing issues, including wrinkles, fine lines and discolouration. The technology is said to be the first of its kind as it combines ingredients that were previously unmixable outside of a factory setting, creating a single serum that can address multiple skin concerns.

Guive Balooch, Global Vice President of L’Oréal’s Technology Incubator, said: “At L’Oréal, we are poised to leverage technology to respond to the rising wave of consumer demand for personalized products and services. D.O.S.E acts like a mini skin care laboratory, combining lab grade formulation and factory grade manufacturing into a machine that sits on the counter.”
People

Helsinn, a Swiss pharmaceutical group focused on cancer care products, has appointed Paul Rittman as its new CEO.

3M has appointed Michael Roman as CEO, effective 1st July 2018. He succeeds Inge Thulin, who is appointed Executive Chairman of the Board, also effective 1st July.

DowDuPont is making leadership changes as the merged company spins itself into three separate firms. Jim Fitterling will take on the role of CEO, and Howard Ungerleider will be President and CFO, of the newly-created Dow Material Science Division.

Johnson Matthey is pleased to announce the appointment of Jason Apter as Sector Chief Executive, Health.

Envigo, a leading provider of non-clinical contract research services and research models, has appointed Lynn Lewis to the position of Senior Vice President, Global Sales.

Inotex has announced that Michael J Fevola, PhD will join their senior ranks as Vice President, leading the company’s global R&D functions.

Marken, a North Carolina-based provider of logistics and supply-chain services for clinical trial materials, has appointed Navnit Patel, PhD, as Vice President, Global Quality Assurance.

Dr Jonathan Goff has been promoted to Vice President of Research & Development at Gelest, and Dr Youlin Pan has been named Senior Research Fellow, adding to his current title of Senior R&D Manager.

PCI Pharma Services has announced the appointment of Frank Andrew as Business Development Manager, with responsibility for supporting clients in the Asia-Pacific region to ensure continued growth and success in this expanding market. Paul Williams has been appointed Business Development Manager at Pertinax Pharma, where he will drive global expansion – primarily through the international woundcare sector.

Jaime Gómez-Arnau has been nominated the new Chairman of Sapec Agro Business’s Board of Directors.

Royal DSM has granted a Lifetime Achievement Award to Professor Doros Theodorou from the National Technical University of Athens to recognise and reward excellence in innovative research in Materials Sciences. With this Materials Sciences Award 2018, the jury recognised the major contributions that Professor Theodorou has made to the field of molecular and meso-scale modelling of polymers.

Andrew Witty, formerly CEO of GlaxoSmithKline, will become CEO of Optum, the health services company of the insurer United Health Group, on 1st July 2018.
P&G launches new bottle made from ocean plastic

The Procter & Gamble (P&G) Company has launched the bottle made completely from post-consumer recycled (PCR) plastic and ocean plastic. The project aims to raise awareness of the issue of ocean plastic, and what can be done to prevent plastic waste from reaching the ocean.

The Fairy Ocean Plastic Bottle was created in partnership with recycling expert TerraCycle, and will reach consumers in 2018. It is made from 10% ocean plastic, collected from the ocean and beaches around the world, and 90% post-consumer recycled plastic.

Virginie Helias, Vice President of Global Sustainability at P&G commented, “As the world’s No. 1 dishwashing liquid globally, we want to use Fairy to raise awareness about the plight of our ocean and raise awareness about the importance of recycling. Our consumers care deeply about this issue and by using ocean plastic we hope to show that the opportunities are endless when we rethink our approach to waste.”

CPL Aromas Dubai harnesses solar energy

CPL Aromas’ major manufacturing facility in Dubai is to create a private solar power plant that will offset 326,041kg of carbon dioxide annually.

The CPL Board of Directors recognises the need to minimize the environmental impact of its operations and products in order to protect the environment. The project will take 9 years before it begins to pay for itself but the overall aim is improved environmental sustainability and not money saving.

The plant is being installed by ALEC Energy which will be handling the installation at the facility in the Jebel Ali Free Zone in Dubai. The solar project forms part of CPL’s Environmental Management System in accordance with ISO14001:2015.

The System is based on four key objectives:
1. Reduction in CO2 emissions and energy consumption
2. Products of limited environmental impact
3. Reduction in waste
4. Pollution control.

Following the launch of the Dubai Clean Energy Strategy 2050, Dubai aims to produce 25% of its total energy using solar plants by 2030 and 75% by 2050. This contract is in line with the Shams Dubai programme and is regulated by DEWA (Dubai Electricity and Water Authority) who have prepared a specific solar code for Dubai which allows consumers to use solar on rooftops without compromising the quality and safety related with use of solar.

Whilst there are several larger, Government-backed solar panel developments taking place in Dubai, CPL Aromas believes it will be one of the first manufacturing companies to install Solar Power in JAFZA (the Freezone - from which CPL Dubai operates).

BASF in JV for battery materials

BASF, the world’s largest chemical supplier to the automotive industry, has closed its agreement to form BASF Toda America (BTA). As the next step in BASF’s business growth strategy for its battery materials business, the new entity will be majority owned and controlled by BASF and is the second successful collaboration of BASF and Toda. BTA will produce and market high energy nickel cobalt manganese and nickel cobalt aluminium oxide cathode active materials for e-mobility applications.

With facilities in Elyria, Ohio and Battle Creek, Michigan, BTA will deliver leading expertise in the manufacturing of cathode active materials. This expansion of its North American footprint allows BASF to offer a strategic supply position and produce innovative cathode materials to meet the needs of key global customers.

“With local production, BASF can better collaborate with and serve our automotive customers located in North America,” explained Jeffrey Lou, BASF’s Senior Vice President, Battery Materials. “In combination with BASF’s global R&D resources and a combined portfolio of technologies, BASF is able to support the requirements of our customers and take an active role in developing the rapidly growing e-mobility cathode active materials market in North America, and beyond.”

ECHA seeks comments on mancozeb

The European Chemicals Agency (ECHA) is looking for comments on the harmonized classification and labelling proposals for mancozeb. The deadline for comments is 27th April 2018.

Mancozeb is a fungicidal active substance used in plant protection products with an existing harmonized classification and labelling in Annex VI to CLP. Comments are invited issues such as skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity and hazards to the aquatic environment.
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11:15 am - Buffet Luncheon
12:20 pm - Please be at your Carts
12:30 pm - Shotgun Start/ Scramble Format
5:00 pm - Cocktail Networking Reception
6:00 pm - Buffet Dinner & Awards Ceremony

Our event, thanks to strong participation from the US, UK, Germany, Switzerland, China, India, Japan and Italy has become one of the largest of its kind in the chemical world.

This worthy cause has turned out to be the largest and most diverse golf outing in the global chemical marketplace... over $140,000 has been raised for university students majoring in chemistry, chemical engineering and related sciences since its inception. It's also a tremendous networking event, with participants representing 11 different countries in 2017.

Join companies such as Alcami, AMRI, Carleone Partners, Ampac Fine Chemicals, Amryn, Brenntag, Bristol-Myers Squibb, ChayseChem, Chemours, Dow Chemical, Exeris, FMC, Global Chemsources, i-Chess Chemicals, Johnson Matthey, Moulder Center for Drug Discovery Research at Temple University, Notch Communications, Optima Chemical, Piramal Pharma Solutions, Siegfried, VanDeMark Chemical, Vertellus, UBM, Trinseo, Quaker Chemical, TCI, PHT International, Iofina, Cambrex, AbbVie, C&EN/ACS Publications, Saltigo, Albemarle, ChemDesign, FAR Br2, Chiral Technologies, Chemical Week, Kingchem, Perry Videx, Robinson Brothers, Sabin Metal, Sandrine, Scientific Update, Uquifa, Sumitomo Chemicals Europe, SOCMA, Villanova University, Praxair, United Therapeutics, Nation Ford Chemicals, Arkema, Onconova Therapeutics, Genesis, CDI, Axis Global Logistics, Fres-co System USA, BASF, Morre-Tec, Univar/ChemPoint, to name a few.

Contact: Ben Jones - President, Century Global LLC (Chemspec Events Consultant & Scholarship Golf Outing Chairman), Tel: +1 610.517.0844 - bjones@centurygloballlc.com
Lubrizol plans $80 million global expansion for TPU

Lubrizol Corp will expand production capacity and technology for its engineered polymers thermoplastics polyurethane (TPU) business as demand grows for its materials. The multimillion dollar expansion will see new capacity added in key plants in North America, Europe and Asia. A combined investment of nearly $80 million has been earmarked for the development plan.

"Ongoing investments in engineered polymers are an integral part of Lubrizol’s global growth strategy and strengthen our position in every region of the world," said Arnau Pano, Vice President and General Manager for Lubrizol Engineered Materials.

Lubrizol is witnessing a robust market with a rebounding global economy and increasing demand for higher performing, more sustainable materials. In North America, the company is adding new production capabilities, expanded raw material storage, warehouse space and improved site logistics. With the latest investment, new capacity is expected to come on stream later this year.

Meanwhile, in Songjiang, China, the company held a ribbon cutting ceremony earlier in February to inaugurate a new compounding line and new extrusion lines. This marks the fourth major expansion in Songjiang since the early 2000s. Further investment is planned in Asia in 2019. In Europe, the company is extending production capabilities for elastomers, aliphatics and adhesives. These expansions build on the acquisition of Barcelona, Spain-based Merquinsa in 2011, and improvements to R&D laboratories in 2016. Lubrizol’s next major European expansion is planned for 2019.
Belchim launches natural alternative to glyphosate

Belchim Crop Protection has launched Katoun Gold, a natural herbicide that guarantees to be an effective alternative to glyphosate, for the management of vegetable coverage in urban areas and roads. Katoun Gold is a product based on pelargonic acid, a natural substance extracted from plants and common in nature. It has an innovative formulation and acts through contact, ensuring effectiveness over the most troublesome weeds. The product is already available in Portugal, where it is sold by Fitosistema.

According to Laurent Dartouh, European head of Belchim’s non-crop segment, “The management of weeds should always be done by taking into account the location and its biodiversity, and this should be done with the smallest impact on human and the natural environment. Katoun Gold is an innovative tool for the management of vegetable coverage in urban areas and roads, which will ensure effectiveness and will help control the weeds in locations where it is necessary.”

The product has no persistence in the soil, and degrades very quickly without toxicological classification. It is a reference product in France and other countries, where it is part of solutions used for biocontrol and organic farming.

Cospatec launches natural replacement for silicones

Cospatec has launched Cosphaderm Feel, an ingredient suitable for natural cosmetic producers that do not want to miss out on silicone-like features.

As a replacement for silicones (e.g. cyclomethicone D5) the product has a very high spreadability and excellent skin compatibility. Cosmetic formulators can apply Cosphaderm Feel as an emollient in W/O- as well as in O/W-emulsions and create products with a light, mildly lubricating and silky skin sensation. Cosphaderm Feel is an ideal solvent for UV-filters and pigments and therefore fits well with sun care products as well as colour cosmetics. Moreover, Cosphaderm Feel is an easy-to-apply liquid which can be used pH-independently in a concentration of 5%–10%.

On top of all these properties, Cosphaderm Feel is a 100% naturally derived triglyceride of heptanoic acid. Sourced from castor oil, the cosmetic raw material is palm oil-free and Cosmos certified.

Natural Sourcing makes addition to naturals range

Natural Sourcing has introduced Chokeberry Seed Oil into its catalogue of certified organic and conventional natural ingredients for personal care product development.

“Chokeberry Seed Oil absorbs rapidly and serves as a versatile, nutritive oil within a wide array of cosmetic, personal care and aromatherapy applications,” said Kibby Mitra, CEO of Natural Sourcing. “It is a primarily polyunsaturated oil that helps to soften, soothe and protect the skin, leaving it feeling nourished and hydrated. It is well suited for sensitive, parched, dry, itchy, mature and problem skin types. Within scalp and hair care applications, Chokeberry Seed Oil helps to condition and restore vitality to the scalp and normal, dry and damaged hair.”

Natural Sourcing’s Chokeberry Seed Oil is expeller pressed and filtered. The Aronia melanocarpa shrub produces small chokeberries that are encased in a skin that is dark purple to black in hue. When consumed raw, the berries are extremely tart, thus lending to its chokeberry nickname. These astringent, flavourful, polyphenol-rich berries are commonly used in jams, syrups, wines, juices, tisanes, flavourings and other culinary applications.

Symrise to launch organohalogen alternative

In its search for alternatives to organohalogen actives, Symrise developed SymGuard CD, a safe, skin and environmentally friendly ingredient. It is an effective alternative to antibacterial agents triclosan and triclocarban, which are increasingly being removed from many cosmetic applications due to consumer over exposure, environmental concerns and regulatory changes.

“We have dedicated ourselves to provide the cosmetics industry with effective alternatives to traditional antimicrobials. It’s also our aim to always offer our customers and thus consumers cutting-edge solutions,” says Dr Florian Genrich, Senior Global Product Manager at Symrise.

“Thanks to its versatile characteristics, SymGuard CD offers a great deal of potential for all manufacturers of cosmetic products.”

Symrise created SymGuard CD, a fast-acting modern hygiene ingredient, based on non-organohalogen technology. This multifunctional ingredient protects the skin and the cosmetic product. SymGuard CD is a colourless, low-odour, easy to process liquid and can be used in different kinds of personal hygiene products such as soaps, oral care products, refreshing gels and deodorants. The company will unveil the new product this month at the in-cosmetics Global exhibition in Amsterdam.
In the 21st Century, technology and instantaneous communications have made the world a much smaller place. Geography is no longer a limit to communications, and nowhere is this potentially more impactful and important than in healthcare. Artificial intelligence, machine learning, nanotechnology, cloud-based data, 3D printing, wearable personal devices, personalized genomics – these technologies are the tip of a rapidly developing iceberg that pharma is starting to embrace, while provider and patient engagement further drive innovation.

From genomic sequences, cell types and the workings of the brain to individuals, populations and our environments, we know more about the human condition than ever before. Our understanding of individual health needs, disease states and targeted therapeutic treatments, allied to innovations in both technology and thinking, are enabling us to live longer. We have more tools to meet our health needs. The depth of personal data available to providers and information around therapeutics available to patients means more informed consumers who have an active interest in both the prevention of, and best responses to, health issues.

CPhI events around the world have always been about bringing the biopharma and pharma supply chains together – to catch up, to share thoughts and ideas, to find out about the latest and great products, services and technologies, and to discover emerging trends that will drive the industry forwards. 2018 is no different, and we’re focused, through the theme of CPhI North America Fostering Innovation in Drug Development and Manufacturing with visionary keynote speakers including The Medical Futurist Dr Bertalan Meskó, and Dr Jeremy Frank, Vice President of Digital Medicine Platform Development at Proteus Digital Health, on showcasing the possibilities existing in future of healthcare and technology.

In line with our focus on innovation, we thought it would be interesting to look at some of the trends we might expect to see gaining significant traction in the Pharma market. With the digitization of health, the supply chain has become much more integrated. Consumers have access to more information and, as a result, are likely to become more engaged in their own health and lifestyle management. Opportunities exist for Pharma companies to engage in a more holistic approach, integrating and customizing services for individuals. Here we look at just three of the many trends that are leveraging human ingenuity to advance technology to make healthcare truly personal.

Forewarned is forearmed

As the old saying goes, ‘prevention is better than cure.’ Today, this adage rings truer than ever before. When the Human Genome Project was completed, the foundation of the development of personalized medical treatments was in place. In tandem with this, patient empowerment, made possible by the intersection of social media, wearable devices and ability to easily analyse big data, is evolving the narrative between health providers and patients.

Rather than going to see your doctor when you are sick, hopefully being prescribed an effective remedy, and taking it, we now have access to genomic data that is already helping to highlight individual susceptibilities with specific genetic markers that could adversely affect
future health if not addressed. Pre-emptive actions have potential to prevent certain diseases, if appropriate lifestyle adjustments are made. We see this prevention approach mirrored as pharma companies develop therapeutics that can help prevent certain conditions occurring or, at the very least, alleviate severe symptoms.

This time, it's (more) personal

Historically, drugs have been designed on a ‘one size fits all’ basis for consumption by, potentially, millions of patients with little consideration for their physiological and genetic variance. As medical data becomes more genetically granular, we could see the evolution of pharma to the point where drugs are produced on demand at the point of consultation or even at a pharmacy simply based on a patient’s data and the providers’ findings. For example, while a therapeutic treatment plan is being tailored to a patient, a 3D printer could be synthesizing powdered drugs, layer by layer, in the suggested composition and dose. In addition, comparing treatments that are effective based on disease type, physiological data and genomic profiles could make diagnosis and treatment efficacy potentially more potent and on a global scale.

Speaking of 3D printing, this technology lends itself particularly well to personalized medicine and customizable on-demand treatment plans. It’s possible that in the not-too-distant future, medicine could be printed on demand, providing greater flexibility for patients and providers. We’ve already seen the first ever FDA-approved 3D printed medicine Spritam, a porous pill designed to treat epilepsy formulated from levetiracetam produced by New Jersey’s Aprecia. It was approved by the FDA in August 2015.

3D printed medicines offer a number of potential benefits. People suffering with several chronic conditions, for example, might no longer have to take a cocktail of drugs. Instead, they can fold all of their daily medications into a single 3D printed pill tailored to their exact needs. Another advantage is that medicines can be printed in appropriate batch sizes, containing several active ingredients, with its dosage personalized to age, gender, race, weight, genetic makeup and physiological profile. This has great potential to reduce the risk of incorrect dosing and adverse reactions.

The rise of AI

Although Artificial Intelligence has been a technology buzz word for around two decades, it’s only in the past several years that it has really started to appear in everyday life, AI, along with cognitive computing, enables us to rapidly process vast amounts of data. Potentially this will expedite the drug development process, enabling ‘cognitive trials’ to be run instantaneously, rather than taking months or even years in trials, and potentially reducing the need for animal testing. The time savings and associated cost savings will be game changing, and patients will be able to receive treatment much quicker.

Another element of AI focuses on personal technology. Wearable technologies that monitor personal physiology such as heart rate are already widespread. Speaking of 3D printing, this technology lends itself particularly well to personalized medicine and customizable on-demand treatment plans. It’s possible that in the not-too-distant future, medicine could be printed on demand, providing greater flexibility for patients and providers. We’ve already seen the first ever FDA-approved 3D printed medicine Spritam, a porous pill designed to treat epilepsy formulated from levetiracetam produced by New Jersey’s Aprecia. It was approved by the FDA in August 2015.

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(anonymous) fitness data. Fitbit claims to have 105 billion hours of heart rate data, 6 billion nights of sleep and 200 billion minutes of exercise tracked.1

As AI continues to expand into the consumer space, in addition to highly functional wearable devices we could see further developments for health applications that promote informed decision-making. The use of body sensors, for example, body microchips, ‘digital tattoos’, nano-robots and other devices able to obtain patient data and share in real-time to healthcare professionals, potentially alerting them to problems, providing a heads up on appropriate treatments. We are seeing wearable technology evolve to the point where it can enable healthcare providers to better support patients beyond the confines of medical facilities, which can lead to better health outcomes and, ultimately, lower medical costs.

Join the conversation

Of course, we’re really only scratching the surface here when discussing the breadth and depth of innovative thinking that is advancing healthcare services, products, platforms and technologies that can be leveraged, ultimately, throughout the pharma and biopharma supply chains, from laboratory bench to production to consumers. Drug development, drug delivery and bioprocessing – the three key focus tracks within CPhI North America this year - all stand to benefit from optimized timelines, improved targeting and on-demand generation trends, reducing time to market, enabling leaner operations and sharing enhanced knowledge up and down the supply chain. One thing is certain: the pace of innovation is not slowing down.

Reference

CPhI North America takes place from 24th to 26th April 2018, at The Pennsylvania Convention Center, Philadelphia, PA, USA. For more information, and to join the conversation around innovation at CPhI North America, go to http://cphinorthamerica.com
The future of medicine: Science fiction or fact?

Dr Bertalan Meskó, Director of The Medical Futurist Institute, explores the evolving convergence of digital health communications, patient-led changes and highly personalized preventative care.

In recent years, medical care has been transforming into an equal partnership between patients and healthcare professionals. Augmented by a number of technological inventions, the concepts of personalized self-diagnosis and self-management offer tremendous opportunities. We spoke Dr Bertalan Meskó, Director of The Medical Futurist Institute and author of My Health: Upgraded and The Guide to the Future of Medicine, ahead of his keynote presentation at CPhI North America — if you are attending the event, you can hear him on 24th April at 1:30 pm.

People were talking about personalized medicine more than a decade ago, but it related primarily to ‘pharmacogenomics’. Was this the start of the revolution?

Dr Meskó: The completion of The Human Genome Project showed that it would be possible to get personalized treatments. But at that time, it seemed a bit far-fetched. With the swarm of wearable devices providing data for the patients that flooded the market in the 2010s, it got to the next level. Now we know it’s not just possible, but there is no other way of managing conditions properly knowing how much we are all different from each other genomically and metabolically.

Which technologies have had the greatest impact on healthcare?

Dr Meskó: Patient empowerment has had the greatest impact. This is not a technology in itself, but was brought upon because of new technologies such as social media, wearable sensors or big data analytics. This has been shaping the doctor-patient relationship and the whole status quo of healthcare. Nothing will have a bigger impact until real artificial intelligence comes into action.

Are advanced diagnostics promoting a focus on prevention rather than cures?

Dr Meskó: Digital health technologies promote prevention because it makes sense to shift the focus from treatment to prevention; and because companies found a simpler business need in people who wanted to live healthier, rather than choosing a population of patients dealing with a medical condition. The regulatory environment is also much more complicated for treatments than prevention.

As well as influencing the way pharmaceutical products are used, how are new technologies affecting the way in which they are manufactured?

Dr Meskó: The whole process of the supply chain is going to be affected by disruptive technologies that are more efficient, faster and cheaper than any technology before them. Exoskeletons could aide factory workers. Augmented reality glasses could let workers start their job without prior training. 3D printing will change how and where we manufacture drugs. Artificial intelligence will change drug design and development.

Blockchain technologies will help fight against counterfeit drugs. The list is very long.

You recently described blockchain as “More transformative than Trump on Twitter”. Can you summarize how blockchain will impact healthcare and pharma?

Dr Meskó: Blockchain has immense potential in healthcare. According to the IBM Institute for Business Value blockchain study, new adopters of the technology expect the greatest blockchain benefits across time, cost and risk in three areas: clinical trial records, regulatory compliance, and medical/health records. Due to its time-sensitive nature, blockchains shift the lens from disparate bits of information held by a single owner, to the lifetime history of an asset. Instead of big data, capturing long-term data becomes more easily possible. And that’s exactly why it is the perfect solution when we need to document a patient’s health record to set up reliable vaccine registries or to secure the movement of drugs through the supply chain.

By giving non-medically trained patients the ability to monitor and treat themselves, are we removing an important level of professional input?

Dr Meskó: This would mean that professionals know everything out there, therefore no informed decision could be made without them. That’s simply not true. When 27 million medical studies are available in the public database on Pubmed.com, physically no physician can be up-to-date. They need technologies to fill that gap. Also, the final decision should always be made by the patient (that’s a basic patient right). Digital health is about transforming the hierarchy of healthcare into an equal-level collaboration. It’s certainly not about pushing patients to diagnose themselves.

How can pharmaceutical R&D and manufacturing companies keep up with new technologies?

Dr Meskó: Companies can’t keep up with the changes, but people within the companies can. They can learn about new technologies, they can be open-minded about how those would affect their job and the company. They could be curious about their own health through technologies which is a great introductory step into digital health. Basically, they could find a way to force themselves to keep asking challenging questions. For me, this motivation comes from science fiction.

Reference
1. The Medical Futurist. medicalfuturist.com

Interview with:
Bertalan Meskó, Director of The Medical Futurist Institute, Budapest, Hungary. http://medicalfuturist.com
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A new level of security for pharma and cosmetics supply chains

Michael Hogan, PhD, Vice President, Life Sciences at Applied DNA Sciences, explains how DNA-marking technology provides a potential weapon against counterfeit pharmaceuticals and cosmetics.

All living things have DNA that identifies them uniquely – the DNA in any organism acts as a molecular barcode. With breakthroughs in nanotechnology, forensic science and material sciences, it has become possible to formulate DNA into materials that are non-biological: to generate DNA-containing plastics, fabrics, inks, pharmaceutical coatings, oils, emulsifiers and detergents. This offers a potential weapon against counterfeiting in two wide-reaching areas: pharmaceuticals and cosmetics.

Supply chains have been contaminated by counterfeiting and by diversion of legitimate products. The net result is a loss of brand credibility, a loss of faith in regulatory authorities’ processes, and an inability to protect patients and consumers. Most important is the substantial harm incurred by patients who buy “fake” or otherwise substandard medications. An estimated 1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified, according to the World Health Organization.1 The new fields of DNA barcoding and DNA-specific formulation chemistry could offer a solution.

How the technology works

DNA barcodes (also known in the pharmaceutical industry as a physical, chemical identifier or “PCID”) are composed of short, unmodified double-stranded DNA molecules generated biochemically. Although synthesized from standard DNA building blocks, the PCIDs have been designed to be a product identifier, without any biological function. By fabricating DNA as very small fragments, the PCID becomes highly stable with respect to extreme heat, UV light and dryness. DNA barcodes have the capacity to convey a large amount of information, permitting the tracking of a product through the supply chain, employing only femtogram amounts (10^-15 grams) of DNA per identifier.

Such industrial-scale DNA formulation is now possible based on the use of two complementary technologies. The first is computer-assisted DNA design and manufacture. It is now possible to assign a bar-code-like message to a small DNA molecule and then fabricate that molecule under computer control so that the resulting DNA barcode can be produced in any amount needed to support its industrial application. The second technology is DNA-specific formulation chemistry. From the perspective of the pharmaceutical and cosmetic supply chain, advanced DNA formulation flexibility means that most pharmaceutical and cosmetic products can now be DNA barcoded. For cosmetics, the DNA barcode can become part of almost any component, including the core formulation. For pharmaceutical tablets and hard-capsule shells, the DNA barcode can become part of the dosage form’s surface coating, API or food-grade ink labelling.

Use in pharmaceuticals and cosmetics

Applied DNA’s proprietary DNA-based PCID technologies are being combined with the product offerings of two industry partners in tablet excipients and hard-capsule shells. These collaborations will commercialize platforms for traceability directly on dose, and are intended to reduce the risks associated with counterfeit and falsified medications entering the drug supply chain. This creates a simple and seamless solution to address counterfeiting and product diversion issues for solid oral dosage forms.

The use of DNA-based PCIDs also presents an opportunity to help pharmaceutical companies enhance patient safety by using intelligent data and analytics gathered from authentication of the dosage forms themselves. By better understanding trade flows and vulnerabilities in a complex global supply chain, pharmaceutical leaders can make better decisions on managing distribution patterns, frequent monitoring and deploying preventive measures for their products. When coupled with emerging IT technologies such as blockchain, the power of DNA barcodes only increases.

Similar considerations hold for the ability of DNA barcode technology to address concerns in the cosmetics and personal care sector, where consumers increasingly demand transparent labelling and ethical trade practices. DNA barcodes can authenticate ingredients such as shea butter and Aloe vera, as well as identify the sources of these ingredients.

Applied DNA’s in-house analysis of several commercially available Aloe vera products was unable to detect a conventional molecular marker – known as the “Bar Code of Life” (BCOL) – which may have conclusively revealed the presence of Aloe vera.2 The BCOL may have been damaged during processing of the Aloe vera product. However, further testing showed that when these Aloe vera products were tagged with DNA barcodes, the tags were 100% detectable at extremely minute quantities.2 A wide range of cosmetic products can be tracked and traced with DNA-based PCIDs.

The potential rewards of DNA barcode technology are clear: a world in which we no longer need to worry about the provenance and quality of the pharmaceuticals we depend on to save our lives or the cosmetics and personal care products we use on our bodies.

References


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April 2018
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In the garden of microflora

Dr Stefan Hettwer, Senior R&D Manager - Cosmetics Actives at RAHN AG, explains the latest developments in skin microbiome research.

The skin is home to a complex microbiome comprised of trillions of bacteria and lymphocytes that form part of the human immune system. As with any eco-system, the microbiome is a delicate balance of nature. Upsetting that balance can lead to problems such as inflammation, blocked pores and acne.

A recent interest in exploring the microbiome for personal care has opened up a brave new world for research and development, with the goal of re-balancing the skin’s microflora to avoid a cascade of responses culminating in blocked pores or acne formation. Chemicals Knowledge spoke to Dr Hettwer about this field of research, in advance of his technical presentation at in-cosmetics Global – if you are attending in-cosmetics Global in Amsterdam, you can hear his presentation on 18th April in Technical Seminars Theatre 3 at 3:40 pm.

Approximately how many types of bacteria are living on our skin, and what do they do there?

Dr Hettwer: The advances in recent microbiome analysis techniques revealed a much higher bacterial diversity on the skin as can be detected by traditional culture-based methods. In our own studies on acne prone skin, we detected bacteria from six phyla, more than 80 families and not less than 500 different species. You can imagine that this is only a fraction of what can be found in normal skin. Furthermore, skin of different ethnicity and on different places on our planet might harbour even more different species.

All in all, the amount of microorganisms living on our skin pretty much resembles the total cell number of our skin cells. The function of the bacteria is to block niches where pathogenic bacteria might be able to settle. To achieve this, our body creates the best conditions to feed the “good” microorganisms to enable a protective shield against unwanted intruders.

This emergence of research in the skin microbiome might be seen as following the recent success of the food industry in promoting the benefits of ‘good bacteria’ – are the two areas of research connected?

Dr Hettwer: We have to distinguish where the microorganisms are used. Food industry targets the inside of our body, mainly the gut. On the one hand, you can re-balance a disturbed microflora by adding beneficial bacteria (pro-biotic). On the other hand, you can try to change the nutritional environment of the habitat of the microorganisms to promote the growth of the wanted species (pre-biotic). By doing so, food industry tries to change the ecosystem of the gut to stimulate a proper digestive function and also boost the immune system, as it is known that the gut is a very important organ for maintaining its strength.

Skin biology is not as well investigated in respect to the microflora. However, in today’s tidy world, microflora are on bad terms as we regularly use cleansing products which will reduce the number of bacteria on our skin every day. Other external factors also stress the skin microflora. As such, it can be an important approach to take care of the skin’s microbiota.

For many years, problems like acne were managed with antibiotics. In light of new views on ‘good bacteria’, is this approach now considered detrimental?

Dr Hettwer: Severe acne cannot be treated with cosmetic solutions but is a pathological skin condition which needs to be diagnosed by a dermatologist. Retinoid treatment and antibiotics, the most powerful anti-acne therapeutics, have the advantage that they can be used topically and systemically to cure especially severe cases. Today’s antibiotics are in most cases selective to the target phylum of the bacteria and do not create a “tabula rasa” condition on the corresponding area of use. Cosmetic solutions for acne prone skin can mimic the dermatological armoury to prevent an aggravation of a mild condition. As a healthy microbiota is important to prevent the growth of deleterious species, it is crucial to choose intelligent molecules which target a specific sub-population of bacteria, in case of oily skin predominantly Propionibacterium acnes.

What sort of physiological factors can be managed to encourage a healthy balance in the skin microbiome?

Dr Hettwer: It is much debated whether diet habits can influence the skin or the skin microbiota. It’s clear that an excess of testosterone, in combination with an elevated inflammatory condition of the skin, leads to an increased sebum production which creates a greater likelihood that P. acnes can settle in pores. This will lead to an aggravated inflammation with the development of spots and pimples. To keep the balance, we need to suppress the subliminal inflammatory condition of the skin by physical exercise, a plant-rich diet, the use of non-comedogenic cosmetics and mild cleansing products. Additionally, we can influence the microbiota by optimizing the underlying skin condition through controlling the sebum amount, preventing it from being a feeding ground for bacteria and reducing the inflammatory state of the skin with a suitable personal care product.
What research has RAHN been doing in this field, in terms of developing personal care applications?

Dr Hettwer: We investigated the microbiome of oily skin to understand the distribution of bacteria in this condition. We were surprised to find that up to 98% of the bacteria in the malar region on acne prone skin were represented by *P. acnes*. This makes it clear that microbial diversity is heavily affected by certain skin conditions. The aim should be to achieve a re-balancing of this condition by selective reduction of *P. acnes*.

How does SEBOCLEAR-MP work?

Dr Hettwer: RAHN developed SEBOCLEAR-MP, a new cosmetic active ingredient designed to adjust the basic principles that lead to oily and acne prone skin. With bioflavonoids from *Maclura cochinchinensis*, we can reduce the sebum production by the direct inhibition of the steroid 5-alpha reductase and providing retinoid-like activity on the corresponding nuclear receptors. SEBOCLEAR-MP shuts down inflammation by the direct inhibition of the COX and LOX enzymes producing prostaglandins and leukotrienes from arachidonic acid. As such, the subliminal inflammatory state of the skin is re-balanced. Furthermore, the bioflavonoids are capable of selectively inhibiting the growth of *P. acnes* responsible for a pronounced inflammatory response leading to acne.

What are the next challenges in skin microbiome research?

Dr Hettwer: Obviously, with today’s analytic capabilities, it is easy to create a huge amount of data and a very detailed view on the presence of microbiota on the skin’s surface. The challenge will be to develop suitable evaluation tools to separate valuable from unessential data. As the diversity of bacteria on the skin is extreme, we are standing just at the beginning of understanding the contribution of each species. The vast majority of these species is not described in detail and it is completely unknown under which conditions a normally beneficial microorganism can cause irregular skin conditions. The big danger is that by trying to understand every single detail of the skin’s microbiota we will lose track of the whole picture, which must be to provide a suitable environment for all the beneficial species which like to share their lives with our skin.
24 hour perfection – lashes, locks, lips and face

Richard Giles, EMEIA Manager, Technical Service & Development Manager Personal Care at AkzoNobel Surface Chemistry, explains how to create products with long-lasting, consumer-driven effects.

Long lasting perfection is the demand of the modern consumer, who believe moisturizers should last all day, colour cosmetics should never smudge and hair should look perfect from dusk till dawn.

Is it feasible to rise to these expectations?

Chemicals Knowledge found the answer when we spoke to Mr Giles in advance of his technical presentation at in-cosmetics Global – if you are attending in-cosmetics Global in Amsterdam, you can hear his presentation on 17th April in Technical Seminars Theatre 1 at 1:40 pm.

How has this expectation for ‘24-hour perfection’ evolved – it wasn’t there in my mother’s day!

Mr Giles: The consumer wants to feel confident that they look perfect at any moment throughout the day, this is especially true for the younger generation as their social day is longer and involves more communication through social media. We feel that the underlying issues are frustrations with smudging, smearing and wear of eye and lip make-up and by frizzing-out or loss of volume and style for hair.

How does a formulator create a moisturizer that lasts all day?

Mr Giles: We tend to focus on a good long-lasting humectant such as Hydrovance (INCI hydroxyethyl urea) which provides 24-hour corneometry performance and skin firming, but without the tackiness of glycerine when dosed at higher levels (4% and above); this should be used in combination with a good emollient such as dicaprylyl carbonate.

How can colour cosmetics be prevented from smudging?

Mr Giles: For eye make-up and mascara a good quality water resistant film forming polymer such as Dermacryl C (INCI Acrylates Copolymer) allows the formulator to create a clump-free colour film that, when applied smoothly and strongly, resists smudging due to touch or tears.

How can lip applications be formulated to withstand consumers’ eating and drinking?

Mr Giles: Lipcare Dermacryl 79 (INCI Acrylates/Octylacrylamide Copolymer), allows the formulator to create a flexible, very water and touch resistant colour film that is particularly resilient to smudging due to eating or drinking.

How do you prevent powdered cosmetics from ‘brushing off’?

Mr Giles: In the market, we see a trend towards make-up fixing sprays often using Dermacryl 79 (INCI Acrylates/Octylacrylamide Copolymer) or Dermacryl AOF (INCI Acrylates Copolymer) that prolongs the look of powder make-up and protects it from brushing off.

How can hair products be formulated to provide a longer-lasting hold?

Mr Giles: Humidity in the air is the most significant cause of a style failing or frizzing-out throughout the day. So, to prevent this we recommend using styling polymers with very good, high humidity curl retention performance (a standard industry test that assesses how well a product can maintain a style under humidity stress). The best performing products we have seen for this benefit are the Amphomer polymers (INCI Octylacrylamide/Acrylates/Butylaminoethyl Methacrylate Copolymer).

Are these longer-lasting formulations good for the skin and hair, or do they come with added issues of their own?

Mr Giles: In terms of skin care the film forming polymers typically improve TEWL and so improve the moisturization levels of the skin. Although the products give a water and/or touch resistant film they are balanced to be readily removable with mild soap and water cleansing.
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Korean trends continue to influence cosmetic formulations

Martin Gunson, Business Unit Manager – Personal Care at OQEMA, looks at the impact of ‘K-beauty’ on the global beauty industry, with a particular focus on the novel rheology that many of these products exhibit.

The fact that South Korea is among the top 10 global beauty markets, with a market value estimated at just over $13 billion in 2017, it is understandable that western brands are exploring the Korean market’s success. Facial skincare accounts for more than half of the total market share, with $6.5 billion in retail sales and a projected 5.8% CAGR over the next five years to reach $7.2 billion by 2020. It’s no surprise that growth is influencing product development in brands closer to home.

A 2017 Mintel market report indicated that Korean beauty (‘K-beauty’) trends were having a major impact on the global beauty industry by challenging traditional western formulations, and that this trend was set to continue its drift westwards. This is resulting in a demand for novel ingredients that enhance texture, and enable new higher levels of active ingredients to be incorporated into formulations, creating products that challenge our perceptions and ultimately provide an enhanced product experience for the consumer.

Innovation in rheology

Product innovations that drive the Korean and Japanese markets quickly become adopted into European brands. For example, we are now seeing a steady increase in the numbers of finished products and formulations that challenge the limitations of the traditional “go to” rheological additives. The multifunctional, yet targeted, approach of these new Korean-inspired concepts often calls for higher electrolyte activities than can be obtained with the use of the standard carbomers. The crystal-clear nature of many of the formulations also limits the extent to which gellant gums, such as xanthan and guar can be used.

Our more traditional approach of western formulation is also being challenged by the novel rheology many of these products exhibit. Key brand leaders such as Shiseido, Amore Pacific, Kosé and Pola all play with the rheological characteristics of their newest formulas to create memory gels that flow seamlessly back to their original form in an “as if by magic” way, or create products that look like a gel yet behave like a liquid that can be sprayed to leave a light enhanced skin feel. These effects puzzle and perplex consumers, who are intrigued by them, play with them, and ultimately purchase them. These innovations challenge formulators to be ever more creative in developing new textures and concepts that constantly push the limits of what is possible, all of which create a demand for new raw materials that can deliver these dreams.

The personal care division of OQEMA, Europe’s newest speciality chemicals distribution company, has been monitoring these trends and, by reviewing the ingredient listings of many of the cutting edge Korean skincare products, OQEMA has identified that many of the formulations contain a novel ingredient manufactured by the Japanese chemicals company ADEKA Corporation: PEG-240/HDI Copolymer Bis-Decyltetradeceth-20-Ether.

What is PEG-240/HDI Copolymer Bis-Decyltetradeceth-20-Ether?

In summary, this is a non-ionic urethane polymer, that forms a water gel and can maintain the viscosity of the product, even in the presence of organic and inorganic salts, to enable thickening and thixotropic effects to the associated formulation.

As can be seen from the comparative images in Figure 1, PEG-240/HDI Copolymer Bis-Decyltetradeceth-20-Ether can be used to create a clear non sticky highly elastic gel, where 1% traditional carbomers create gels that are sticky and don’t easily flow back to their original form and
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which entrain significant air in production. In comparison, Xanthan Gum at 2% produces a flowable sticky product that will flow, but the resultant gel is not clear.

PEG-240/HDI Copolymer Bis-Decyltetradeceth-20-Ether, manufactured by ADEKA Chemicals Japan under the tradename of ADEKA NOL GT-730, contains two hydrophobic sections that are bonded by urethane groups to a hydrophilic PEG backbone. This structure enables the polymer to create a gel structure with water which, once the polymer concentration reaches a point at which micelles start to form. See a diagrammatical representation of the structure in Figure 2.

**How does it work?**
The hydrophobic tails of the polymer form micelles in the aqueous system, whilst the hydrophilic centre creates a network or matrix plugging across the aqueous phase linking into other micelles, thus gelling the water to create a stable framework (Figure 3). The resultant gel remains solid, but breaks easily, dependant on the level of polymer present, to flow and reform quickly. This characteristic enables formulators to develop interesting and novel characteristics in the rheology of the end product.

It also reduces the likelihood of air entrainment, a problem often associated with gel manufacture, as any bubbles formed during the manufacturing process are able to easily flow upwards and burst at the surface, which then reforms to create a smooth layer. PEG-240/HDI Copolymer Bis-Decyltetradeceth-20-Ether can produce gel viscosities of over 100,000mPa with additions of between 1.5-2% solid without adversely affecting this characteristic (Figure 4).

The non-ionic nature of urethane polymer enables higher addition levels of organic and inorganic salts than would be possible with a more traditional carbomer based system. This enables higher inclusion rates of active ingredients to be considered and achieved.

The matrix structure created by ADEKA NOL GT-730 can also be employed to create simple emulsions by gelling oils to form silky creams without any need to add a surfactant. Up to 10% of oil can be incorporated into an aqueous gel using just 1.5% of solids. Additionally, the stability of the gel in both high and low pH ranges makes it ideal for use in many skin-care, Make-up and Hair styling application where both acidic and alkaline properties may be required.

OQEMA found that PEG-240/HDI Copolymer Bis-Decyltetradeceth-20-Ether is most tolerant of surfactants or amphipathic substances having hydrophobic and hydrophilic groups which are delocalized and do not contain a hydrocarbon chain, examples would be Poloxamer, Polyquaternium-6 and PVP. Surfactants containing delocalized groups and hydrocarbon chains can be used up to 5% without significantly disrupting the gel.

**Formulating the customer experience**
A number of formulations with novel rheology are already available from OQEMA Ltd. The Personal Care team of OQEMA Europe are on a journey to further evolve and develop the customer experience. We will drive synergies and expertise in our key locations, becoming evermore the key European partner for product innovation and value.

**Figure 2.** PEG-240/HDI Copolymer Bis-Decyltetradeceth-20-Ether contains two hydrophobic sections that are bonded by urethane groups to a hydrophilic PEG backbone.

**Figure 3.** The hydrophobic tails form micelles in the aqueous system, and the hydrophilic centre creates a network, thus gelling the water to create a stable framework.

**Figure 4.** Viscosities and shear rates for various concentrations.

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Ethical sourcing is an issue that exercises responsible manufacturers across the world. Nowhere is the need for responsible sourcing of materials more keenly felt than at CPL Aromas, the world’s largest ‘fragrance-only’ fragrance house. The company, which is based in the UK, has just announced that it has added another ethically-sourced and sustainably-produced essential oil to its fragrance materials palette: the much-prized Sandalwood.

Sandalwood, sought after and widely used in perfumery as an oriental woody note, is now cropped in many places in the world, such as New Caledonia, Australia, Indonesia.

Sandalwood is thought of by the lay-man as a single material but in fact there are different species, each of which plays a slightly different role in a finished fragrance. These varietals include album, apicatum, and austro-caledonicum, and all have their uses in perfumery.

However, perfumers the world over agree that Indian Sandalwood album is the most precious. Costing several hundreds of pounds per ounce, it is a valuable — as well as a valued — addition to fragrances.

According to Francis Pickthall, one of the Directors of CPL Aromas, “This material is celebrated for its exceptionally soft, milky tones and subtly enduring quality. Other varieties have different odour profiles”.

The name ‘Album’ refers to the white colouration of the highly-frangrant heartwood of the tree. Over the years, irresponsible practices due to the high prices of this variety have left the Sandalwood album vulnerable to over-exploitation and even extinction.

Francis Pickthall explains, “Until now, no sustainability programme for Sandalwood album existed in India. To meet this demand, the Sandaforest Sustainable Plantation was founded in Sri Lanka by BioPower in 2007, allowing fragrance houses — including CPL Aromas — to continue to use the best quality Sandalwood, sourced by sustainably-managed practices, far into the future”. Sandalwood is chiefly used for Fine Fragrance creation, due to its value.

Unlike coffee or tea plantations, Sandalwood trees need to grow in a wild environment and they flourish best, of course, in their natural habitat. A 100-hectare forest was found in which initially 3,000 Sandalwood trees were naturally propagated and grown, and the natural propagation methodology was successfully adapted to increase the number of trees in the forest.

“Sandalwood has been subject to theft and piracy, so for us having this agreement ensures us future supply of high quality, reliable Sandalwood,” said CPL Aromas’ Global Purchasing Director, Nick Moore.

The growers created a Sandalwood album nursery and they have installed water reserves and an irrigation system along with 10km of fencing to secure the property from wild animals and thieves. A natural, organic fertilizer for the forest is being produced at this site.

Over 30,000 trees have been planted over the years, with a survival rate of over 85% due to the favourable growing conditions. It is planned that 5,000 trees will be planted in the next three years and approximately 10,000 trees are expected to grow as a result of natural propagation. The plantation ensures that, for every tree used, another six are planted.

Essential oil production is currently 1.2 to 1.5 tons, with a future output of 2 tons being forecast.

The programme currently employs 40 people, including agronomists and specialists in sustainable growing (including organic fertilization). In an area largely comprised of wild land, there are few job opportunities for the local population. The plantation is providing thirty families with long-term work and much-needed job security. The workers’ income is 20% above that of the average for the area, and health care and insurance is provided — a rare benefit for many people in Sri Lanka.

As the property was formally a tea plantation, the scheme maintains many of the tea bushes, to give workers an additional source of income. Specific training also aids workers in future employment opportunities.

Nick Moore adds, “The programme is certified by the Forest Stewardship council, which gives internationally accredited proof of our sustainable forest management. It shows the concern for the long-term future of Santalum album in Sri Lanka. ControlUnion has also given the programme an organic certification, a world-wide accredited certification to prove that the care is taking of the soil, water and the fragile eco-system - as well as providing employment for the local people”. 

CPL Aromas is the world’s leading international, fragrance-only fragrance house, with 17 sites throughout the world. Employing 550 people globally the company produces fragrance concentrates suitable for fine fragrances, personal care products and household applications. CPL Aromas has sites in: UK, US, France, Dubai, Germany, Turkey, Hong Kong, Colombia, China, India, Indonesia, Malaysia, Philippines, Thailand, South Korea, Vietnam, Taiwan and Australia.

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In our daily lives, we are confronted with energy loss, sleep deprivation, ageing, allergens, pollution, UV damage . . . to name just a few. Novel technology now provides a way to boost the textiles we may wear or sleep on, so they can help to reduce negative impacts from outside, and enhance our well-being.

In order to boost textiles with well-being active ingredients, Devan makes use of microcapsules that can act as reservoirs of active ingredients that are stored and protected in the core from the surrounding environments like textile treatment processes, temperature, light or oxidation. In addition, the microcapsules allow an efficient fixation and consequent increase of the durability of the boosted textile.

For this, it is crucial to understand both textile surface chemistries and the functional groups displayed at the microcapsule walls. That requires, on one hand, straightforward functionalization of microcapsules shells with reactive groups compatible with textile fibres (e.g. hydroxyl groups) and, on the other hand, a bi-functional coupler that can react selectively and stepwise with microcapsules and textile substrates. As a result, the microcapsules are more durably bound to the textile surface, enhancing the added benefits of the treated textiles (Figure 1).

Under particular stimuli (a ‘trigger’), the encapsulated active ingredients may be released, giving the textile substrate a new and desired functionality. For Devan’s R-Vital capsules, the trigger is usually the friction resulting from the normal use of a textile.

With R-Vital products, the aim is to protect our skin against free radicals by enhancing the body’s natural defences, which decline with age. To accomplish this ambition, a range of ingredients are carefully selected – they include as anti-oxidants, which offer extra protection against free radicals, ageing, pollution or UV when absorbed by our skin.

As an example of such an ingredient is the coenzyme Q10 (CoQ10), which is a vitamin-like nutrient (a quinone) associated with the mitochondria — the ‘energy factories’ — of our cells. This nutrient promotes the production of energy by the ATP molecule at a cellular level through perpetual energy cycles. Moreover, this coenzyme is a powerful anti-oxidant that ‘wipes up’ potentially harmful free radicals in our cells and can even regenerate other anti-oxidants such as vitamins E and C.

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In partnership with the Japanese pharmaceutical company Kaneka, Devan has selected the Kaneka Q10 as the active core inside of its microcapsules. This product is manufactured by a yeast fermentation method, meaning it contains less impurities; and, very important, the main component is Ubiquinol, which is the reduced and more stable form of CoQ10. The other form, Ubiquinone, is oxidized and less stable. This may appear to be a small detail, but it is an important factor as 96% of the CoQ10 within our bodies is actually in the form of Ubiquinol.

In order to demonstrate the high concentration of Ubiquinol in the microcapsules, in a laboratory experiment the microcapsules were ground with a mortar and pestle and the content was extracted with an ethanol/ n-hexane solvent mixture. By analysing the extract by HPLC, a Ubiquinol ratio up to 95.5% was quantified – very similar to the ratio of our bodies.

Finally, the skin absorption of CoQ10 has been analysed, using in vitro permeation tests over 6 hours using vertical Franz diffusion cells with pig-skin membrane as a model for human skin. The Franz cell technique is widely used in the cosmetics and pharmaceutical industries and, in simple terms, comprises two chambers separated by the pig-skin. In Devan’s experiment, the CoQ10 product was placed in the upper chamber and the product was allowed to permeate the pig-skin to be collected in the lower chamber; this method can be correlated to human skin absorption from the stratum corneum (SC) into the blood stream. The quantification of the product was made by HPLC and the results presented in Figure 2. Within 4 hours CoQ10 (labelled UB), was completely absorbed and permeated through the whole thickness of the SC at both concentrations.

Devan’s R-vital textile treatments are intended to help strengthen the body’s natural defence against free radicals. These capsules may contain single or multiple active substances, including light fragrances, to tailor the treatment to specific needs.

The patented encapsulation technology is environmentally safe and skin friendly, and enables Devan to create the right blend for the required purpose.

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**Figure 1.** Scanning electron micrograph of microcapsules with reactive groups grafted on polyester textile fabric.

**Figure 2.** Cumulative amount of Ubiquinol and Ubiquinone permeated through 0.79cm2 pig skin over 6 hours.
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#WhatBrandsWant reveals brands’ perspectives on biomaterials

Noémie Léonard, Junior Consultant at Sustainability Consult, presents results from #WhatBrandsWant, the company’s survey focused on brand perceptions of bio-based materials.

We often hear the questions: how can we encourage brands to invest in renewable materials? How can biomaterials manufacturers make it easier for brands to engage?

To answer these questions, we launched #WhatBrandsWhat — Sustainability Consult’s first ever stakeholder survey. The goal was to assess attitudes towards the bioeconomy, and highlight opportunities to help mainstream solutions. Over a six-month period, we gathered responses from over 40 brands across different sectors ranging from apparel, footwear & textiles, to food & beverages and personal care.

Consumers will boost sustainability

One clear trend stood out: consumers are the engine for change. Consumers’ interest in sustainability is influencing brands, who in turn pay attention to the bioeconomy.

Most brands surveyed believe we will witness a moderate to strong growth in the sector by 2025. Besides consumer demand for environmentally-friendly products and packaging, this expected growth is mostly due to brands wanting to improve their public image. When brands use biomaterials, they are proud of it — 71% said they communicate externally about using them.

Bioeconomy challenges remain

A range of barriers to biomaterials continue to affect the sector. A majority of respondents (87%) agreed that cost is the main barrier for adoption, followed by performance and availability. Some brands were also worried about recyclability of bio-based materials.

For our wider network of bioeconomy and sustainability experts, the lack of awareness about bio-based solutions is seen as the second most important barrier after cost. Biomaterials producers understand brands do not have all the information they need on certain aspects of bio-based alternatives, therefore more awareness-raising is needed.

Nevertheless, forward-thinking brands are investing strategically to bring sustainable, innovative products to market. If biomaterials producers engage with the entire supply chain to identify performance benefits, this could offset concerns around higher costs.

Communicating with brands and consumers

Brands in our survey felt knowledgeable and informed about bio-based materials. However, when evaluating whether to adopt bio-based materials 63% said they needed more information about pricing, 61% mentioned needing to know more about availability, and 57% wanted to find out more about performance.

It is important for manufacturers to provide tangible evidence on product advantages. This means it is essential for producers to communicate credibly about renewable products. It will be necessary for brands to also communicate openly on the type of biomass they use, and on their products’ end-uses for both food and industrial applications. Where possible, Life Cycle Assessment (LCA) and third-party certifications should be undertaken to promote responsible sourcing.

However, for general public communications, tools like LCAs are too complex. Product information should be simplified and communication focused on consumer benefits. To help brands communicate credibly and increase awareness of bio-based products, Sustainability Consult’s CEO Kathryn Sheridan developed her “five commandments for the bio revolution” which still influence our work today.

What will boost bio-based uptake?

Overall, #WhatBrandsWant reflects positively on the sector and growth is expected. Consumers are on board and stakeholders are pressuring brands for bringing more renewable options to market. However, some barriers remain and, if the benefits offered by biomaterials are not made clear, perception of high cost could continue to impact uptake.

If cost and lack of awareness are seen as crucial barriers, action needs to be taken. The market is ready, and brands need to be provided with the information they need to choose sustainable options. From the work we are doing with our bioeconomy clients, we can see that this is already happening. We believe that the future is bright for biomaterials.

Reference

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The enemy of my enemy is my friend

(Ancient proverb)

Manufacturers, growers and consumers can all appreciate the benefits of adopting and using biological controls, and this recognition has fuelled the industry’s growth over the past couple of decades. In fact, the global biological control market, which began from rather modest size in the 1990s, is now a multibillion dollar business that is growing at a much faster rate than the conventional crop protection industry. Companies involved in the R&D and/or manufacture of biological products include some of the biggest names in the business, including BASF, Bayer, DuPont, FMC, Koppert, Monsanto and Syngenta.

However, the balance of nature dictates that, although biological agents may control pest populations to a degree, they are unlikely to ever completely eradicate target pests, or offer the efficacy of a synthetic pesticide. And faced with a growing world population and its perpetual demands on the food chain, we must be pragmatic. In order to maintain the yields required by the world’s population, it needs to be acknowledged that synthetic chemistry will continue to be a backbone of the crop protection industry for the foreseeable future.

Nevertheless, advocates of natural solutions need not despair. The new kid on the block is the hybrid.

Increasingly, there is a move toward finding the right biological products and technologies that complement synthetic products, and which enable growers to minimize the overall chemical load (and residues), and improve safety. This approach has evolved in recent years to form the basis of many ‘integrated pest management’ (IPM) solutions, as industry groups and governments have advocated the use of traditional, biological and synthetic approaches to pest control in carefully devised integrated programmes. However, these programmes can be complex to plan and implement. A novel answer to this complexity is the emergence of pre-mixed hybrid products that combine both synthetic and biological active ingredients.

Stockton (STK), a company that develops and produces botanical-based solutions for food protection, launched its first hybrid in 2017. The hybrid product, Regev, combines a botanical extract from the Melaleuca alternifolia (tea tree) bush and difenoconazole, a broad-spectrum fungicide that is widely used as a spray or seed treatment. The result is a non-toxic solution, with a lower synthetic chemical load, and multiple mechanisms of action that can help minimize the emergence of resistance.

Similarly, chemical giant BASF’s research on biological solutions has always been viewed as complementary to the company’s chemical crop protection. In 2016, BASF opened a new R&D centre for biological crop protection in Limburgerhof, Germany. “With BASF’s unique skills in research and state-of-the art formulations, we are one of a few companies that can provide a seed treatment with a mixture of both biological and chemical compounds,” said Philipp Rosendorfer, Vice President R&D Functional Crop Care for BASF’s Crop Protection division, at the time.

The advantages of these products, which combine synthetic and biological active ingredients, offer a route to more sustainable agriculture, without the efficacy limitations usually associated with ‘pure’ biological pest control, and avoiding the complexity of bespoke IPM programmes.

In the words of Guy Elitzir, CEO of STK, speaking at last year’s Chemical Industry Regulations Conference Biopesticides Session, “We think hybrids will accelerate the integration of biological solutions into conventional programmes.”

This development should mark a positive move for the agricultural industry, and for the speciality chemicals companies that service it, as it enables us to move further toward a more sustainable future and a cleaner, safer world.
China started production of vitamins in the 1950s, and grew steadily to become the largest producer and exporter of vitamins worldwide by the early 21st century. With some Chinese companies owning global vitamin market shares of 50% or more, the development of China’s industry plays a key role in the worldwide market.

China mainly exports low-priced vitamins such as vitamin active pharmaceutical ingredients (API). Most of the products are exported to the USA, Malaysia, Germany, Japan, the Netherlands and Vietnam for further processing. With the export volume of vitamins continuously increasing, the overseas markets are ever more important for manufacturers in China. Demand changes from overseas markets can have a significant impact on vitamin prices in China, adding further to the sharp fluctuations seen in recent years due to supply shortages and environmental protection pressures.

China’s monthly export volumes of vitamins, Jan–Dec 2017, tonne

<table>
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<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
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</table>

Data source: CCM & China Customs

Looking at the Chinese vitamin industry itself, fierce competition and progress of production technology have been pushing the industry to be more centralized. Some big enterprises such as Northeast Pharmaceutical Group, North China Pharmaceutical, Zhejiang Medicine, Zhejiang NHU and Zhejiang Hangzhou Xinfu Pharmaceutical are dominant and can easily influence the price trend of vitamins in China.

China’s top vitamin enterprises

Market intelligence firm CCM revealed a list of China’s top 500 enterprises in December 2017. In this list were 33 pharmaceutical enterprises, with two vitamin manufacturers among them. The two most successful vitamin enterprises are CSPC Pharmaceutical and Zhejiang NHU.

CSPC Pharmaceutical

Headquartered in China’s Hebei Province, close to the Chinese capital Beijing, CSPC Pharmaceutical Group Limited is the world’s largest vitamin C producer. Besides vitamin C, the company produces caffeine, ampicillin, penicillin and amoxicillin. The enterprise has been one of China’s 500 Most Valuable Chinese Brands and Top 500 Chinese Enterprises for many years. CSPC, which states a vitamin C API production of 30,000t/a to 40,000t/a, benefited from a large vitamin C price rise in 2017, caused largely by decreased output of China’s vitamins in 2017, resulting from the stringent environmental policies and limitations for production processes. CSPC also suffered production cuts in 2017, which pushed up the price of vitamin C. CCM is of the opinion that the situation is unlikely to change in the near future, further decreasing supply and pushing up prices.

Zhejiang NHU

Zhejiang NHU is China’s leading vitamin A producer. The company also produces a significant share of vitamin E for the world market. As one of the leading producers of vitamin A, the company is enjoying high market prices at the moment. In October 2017, the price reached an historical peak, resulting from tight supply. CCM predicts that the vitamin A price will continue rising in the near future. Zhejiang NHU is also a leading producer of biotin. This raw material for feed additives and pharmaceuticals witnessed price hikes in 2017 as well. In the first half of 2017, the company revealed a financial report which showed a revenue of more than US$388 million, which represented a growth of 13.26% and a net profit of US$87, up by 13.62%. The improvement was attributed by company officials to higher prices and increased sales of some leading products.

Environmental pollution pressure

China’s government has taken actions to counter air pollution caused by winter heating. This especially affects the vitamins industry in Northern China, which is one of the highest polluting regions in the country. Reduced supply and higher prices are the results of such measures. Enterprises that are buying pharmaceutical products from China should inform themselves if their suppliers are affected. Supplies from China might be limited and prices could climb to a higher level when inventories run low.

Cancelled the inspection and quarantine of vitamins

What’s more, the General Administration of Quality Supervision, Inspection and Quarantine announced in late January 2018 that it would cancel the inspection and quarantine of vitamins food grade and feed grade for export, starting 1st February 2018. China is currently the world’s largest vitamin producer and exporter, but high export costs and complicated customs procedures have dampened the enthusiasm of producers and traders. According to the China Customs, China exported a total of 251,759 tonnes of vitamins in 2017, up 13.47% year on year. The cancellation of export commodity inspections will reduce the costs of exporting producers, and the simplified procedure will also benefit traders. CCM holds that this will stimulate the export of vitamins in China in 2018.

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How will carbon-ion cells shape our future?

Stephen Voller, Founder and CEO of Zap&Go, explains how carbon-ion cells are shaping the future of energy storage for consumer electronics and automobiles.

Lithium-ion batteries are widely used in consumer electronics and automotive because they have a high energy density. However, they contain highly flammable electrolytes that can become unsafe if overcharged. While work is ongoing to address this, another solution presents itself in the form of supercapacitors, which store and deliver electrical energy at ‘super’ speeds.

Currently, commercially-available supercapacitors are made using activated carbon with an organic electrolyte – due to the electrolytes, they remain flammable. About 6 years ago, however, researchers at Oxford University developed a cell that uses nanocarbons and ionic electrolytes. The cell works safely at higher voltages, which offers increased energy density.

Stephen Voller is a recognised authority on energy storage devices, having co-founded the hydrogen storage company Cella Energy, launched the first ever CE-marked hydrogen fuel cell product, and most recently (in 2013) founded ZapGo to produce carbon-ion cell technology, based on that developed by Oxford University a few years back. We spoke to Mr Voller about the technology underlying ‘C-Ion cells’, and the potential for these cells to shape the future of consumer electronics and in the automotive industry. (C-Ion is a registered trademark of Zap&Go.)

As an overall introduction, can you summarize the advantages of C-Ion cells versus lithium-ion batteries?

Although it is currently the industry standard for rechargeable batteries, Li-ion works by an electrochemical reaction, raising the risk of fires in consumer products. Also, Li-ion batteries can take hours to recharge fully, and they are limited to about 1,000 charge-recharge cycles before they begin to wear out. These drawbacks formed the impetus for a new rechargeable technology that does not involve a chemical reaction or the risk of fire, can be recharged up to 100,000 times without wearing out, and can be recharged in a matter of minutes rather than hours.

As such, ZapGo has developed carbon-ion (C-Ion) technology, a faster-charging, environmentally friendly, safer alternative to rechargeable batteries. C-Ion is being used today in a range of products, including cordless power tools and autonomous electric vehicles, combining the capacity and slow discharge performance of Li-ion batteries with the time to charge, safety and environmentally friendly features of supercapacitors.

How do cells like these deliver energy at ‘super’ speed?

ZapGo’s C-Ion cell incorporates patented advanced nano-structured carbons, a proprietary ionic electrolyte and improved fabrication techniques for enhanced energy density. C-Ion cells work in a manner similar to supercapacitors, i.e. maintaining their ability to provide rapid charging and long cycle life. However, C-Ion employs different carbon and electrolyte materials than current supercapacitors, which enables them to operate at higher voltages, thereby delivering energy densities that are more in line with current Li-ion batteries but without any of the fire risk or safety concerns.

ZapGo believes that it has developed the next-generation battery with four technological advantages: (1) sub five-minute charging with slow discharge; (2) increased safety; (3) significantly greater charge/discharge cycles; and (4) they are easier to recycle.

Currently-available supercapacitors have low energy densities so it has not been possible to use them to store energy over a long period of time – how has this been addressed with the new C-Ion?

By using synthetic carbons and nano-carbons it is possible to fabricate electrodes with controlled porosity. The amount of electrical energy that can be stored in a C-Ion cell is dependent on the surface area and electrical conductivity of the electrode, as well as the operating voltage of the electrolyte. In recent years, advances in nano-structured carbons as electrodes and non-flammable ionic liquids as electrolytes have significantly enhanced the performance.

Carbon materials have a high surface area and can be used as electrodes in electrochemical capacitors. The physical and chemical properties of synthetic and nano-structured carbon materials such as graphene, carbon nanotubes and carbon onions are of interest as these materials have large surface area, unique nano-structures and the pore size in some of these materials is below one nanometer. Nanoporous carbon has been reported with specific capacitance value as high as 284F/g (Farads per gram) and 131Wh/kg. Graphene based
nanocomposites have been explored as an electrode material, and they have shown significantly increased capacitances – functionalized graphene sheets have achieved the specific capacitance value of 230F/g.

Ionic liquids are a new class of electrolyte that are stable at higher operating voltages beyond 3.0V. Ionic liquids, having a wider electrochemical window, sufficient conductivity and lower viscosity, can be used as electrolytes in C-lon cells. Selected ionic liquid electrolytes show electrochemical stabilities up to 6V, and it is possible to tune the stability window by changing the cation-anion combinations.

Why are C-lon cells less likely to overheat?

There are no electrochemical reactions inside a C-lon cell that cause heat. Instead it is an ionic reaction, similar to static electricity or on the surfaces of a supercapacitor. This is also the secret of a very long life, as there is no chemistry to be used up.

How do they recharge so quickly?

Because it is an ionic reaction, there is nothing to slow it down. We recently demonstrated a cordless power tool that could be charged in 15 seconds. To do this we had to boost up the plug in the wall, because the maximum that the wall plug can deliver is about 3kW. To charge at these rates requires a higher rate of charge, so we ‘buffer’ the grid by storing energy in our cells and then when the drill needs charging, energy is transferred at very high rates.

I understand you have been testing prototypes of your C-lon batteries in some interesting applications – can you tell us about those?

We are targeting a range of verticals, from toys and transportation to power tools and cleaning devices. We have already incorporated our C-lon batteries into a variety of prototype products that will eventually be targeted for the consumer market. These include a functioning electric scooter; a powered bicycle energy pack; a Bluetooth five-minute charging speaker; an 18-volt power drill; and a cordless cleaner. In each of these cases, the recharge time was reduced from hours to less than five minutes. Additionally, we are aiming to incorporate our C-lon batteries into driverless “PODs” that transport travellers at London’s Heathrow Airport, supplementing their existing lead-acid batteries, which would assist in reducing their recharge time from four hours down to 35 seconds.

When will the technology be commercially available?

ZapGo is currently focused on three key factors as it analyses potential market opportunities: revenue potential, competitive landscape, and time to market.

While ZapGo believes that there are many potential applications for its technology, current targeted products have been chosen for optimal commercial deployment in the near term. Specifically, ZapGo’s business model for the commercialization of its C-lon technology is to partner with prominent brands in the following industries: cordless power tools and floor care products, lightweight electric vehicles, and vehicle emergency start packs. Chosen partners in these sectors will incorporate ZapGo’s technology directly into their products and commercialize and sell the products under their own brand names but with ZapGo’s technology as a key differentiator, akin to the Intel Inside initiative. ZapGo believes that this strategy not only shortens time to market for this new technology but also allows it to utilize the resources of its partners to accelerate market penetration.

Following the debut of its technology at the Consumer Electronics Show (CES) in January 2017, ZapGo expects the first ZapGo-enabled products to be available for consumer purchase by Q3 2018.

What impact do you think this will have on our future?

The UK Government recently announced a total ban on the sale of new gasoline and diesel vehicles from 2040. Similar announcements have also been made in China, France, Holland, Norway and Sweden, but in some countries, the ban occurs as early as 2025. As part of this mandate, the UK Government, along with other countries, is also likely to announce incentives to encourage the uptake of EVs in the near term, mainly to improve air quality in inner cities.

Most analysts predict that there will be an inflexion point in 2025, when a new generation of battery electric vehicles will become available, that will offer similar cost and driving experience as existing gasoline and diesel vehicles. These vehicles will use new battery technology that can be charged much more quickly and provide additional driving range.

In order to gain widespread acceptance of battery electric vehicles, the automotive industry believes that drivers will demand a five-minute charge for 100-mile range and a 15-minute charge for a 300-mile range. This is possible only with ultra-fast charging 350kW (kilowatt) chargers and would mean that 30kWh (kilowatt-hours) is transferred to the vehicle in five minutes and 90kWh in 15 minutes. (Currently, it takes 10 hours to provide a 100-mile charge at home; the fastest chargers available today are the Tesla Super Chargers that can do it in about 20 minutes.)

To minimize capital investment, and to keep the price of electricity low for drivers of electric vehicles, ZapGo proposes to install large containers on filling station sites that initially contain 1MWh (megawatt-hour) of stored energy in its C-lon cells. On sites with high vehicle throughput, there may be multiple containers installed. The containers will be charged up at night at off-peak rates using existing electrical connections to the site. Ultra-fast-charging 350kW chargers will be installed on site connected to the container storage, not directly to the site grid connection. Vehicles will be charged from the stored energy at the 350kW rate.

This ultra-high transfer rate is possible for two reasons:
- C-lon can charge and discharge very quickly
- C-lon does not catch fire, so it is safe to have a large energy store next to existing tanks of gasoline and diesel.

In summary, the new technology would provide competitively priced electricity compared to sites that have had to invest in new, expensive electrical infrastructure, and state-of-the-art ultra-fast charging capability at automotive industry rates of 350kW.

1 MWh is 1,000kWh or the equivalent of about 33 vehicles charged with 30kWh of energy.

Interview with:
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Consistency in meeting high product performance standards is a hallmark of quality control, but we work in a marketplace where the regulatory landscape varies by jurisdiction, and consumer preferences evolve along cultural and regional lines. The globalization of the personal care market, the speed at which consumer trends come and go, the plethora of government regulations and the growing demand for ‘cosmeceutical’ products collectively create an environment which increases responsibility on the ingredient supplier to understand regulatory trends and requirements.

Moving targets

Much of the cosmetics industry lacks an overarching global standard. In the USA, the industry is largely self-regulated but is overseen by the Food & Drug Administration (FDA). The Cosmetic Ingredient Review (CIR) Expert Panel assesses the safety of cosmetics ingredients, and works with the FDA, the cosmetics industry and consumers in an effort to keep cosmetics safe. However, the list of substances prohibited or restricted by regulation in the US identifies 11 items. In comparison, in the European Union and Brazil, prohibited or restricted cosmetic ingredients number in the hundreds.

In addition to jurisdictional variation, the growing popularity of multi-functional cosmetics adds another layer of complexity. Scientific advances and growing consumer demands have given rise to product categories that straddle the traditional boundary between cosmetics and pharmaceuticals. Products that make therapeutic claims or offer functional properties beyond cleansing or changing the appearance of the body often fall under a regulatory “grey area.” These products, like sunscreens or anti-acne treatments, are regulated as cosmetics in some jurisdictions and as over-the-counter (OTC) pharmaceuticals elsewhere.

Whether defined by jurisdiction or function, it’s critical to stay current on the regulatory status of ingredients. The vast majority of jurisdictional regulations and best practices are under nearly continuous scrutiny and revision.

Singular solution

Throughout the supply chain, there is a desire to operate under a single solution that meets global compliance, but this is a challenging task. Higher qualification expectations often call for increased traceability, process control and change management on the supplier side. These and other factors associated with stricter regulations generally result in higher ingredient costs. A quality system for active pharmaceutical ingredients (API) and excipients requires considerable investment, and greater time and resources to design and implement, than for cosmetic ingredients.

Another factor that impacts cost is the decreasing level of flexibility as product categories move from industrial grade to topical pharmaceuticals. At one end of the spectrum, ISO 9001 is a standard that gives suppliers and producers the flexibility to adapt their quality system requirements to meet varying industry needs. It does not define the end use of an ingredient nor does it prescribe specific requirements. At the other end of the spectrum, the GMP guide for API is specific to pharmaceutical applications and prescriptive in its requirements.

Walking the quality–cost tightrope

Figure 1 presents some of the complexity of quality control and regulatory compliance for the manufacture of cosmetic and pharmaceutical ingredients. As the end use application or ingredient category moves from industrial to pharmaceutical, there are increased requirements for validation, documentation and testing, making the holistic view of one category to another vastly different.

Clearly, a static standard of quality control might meet objectives in one product category, but fall short in another. The biggest challenge is establishing a flexible quality system that can balance customer expectations and emerging trends—while remaining compliant with current regulations.

![Figure 1. Quality system requirements and standards aligned with various uses of a given ingredient.](image-url)
End use familiarity
Many chemical companies find themselves operating across the regulatory landscape and a broad spectrum of finished product categories. For instance, silicones are widely used in the cosmetic, OTC and topical pharmaceutical product segments for superior aesthetics and multi-functionality. They are also used as release agents in food applications and API in anti-flatulent drug products.

To help navigate these regulatory waters, the supplier’s quality management system must balance a full range of factors. This includes regulatory and industry standards, adaptation to emerging trends and adherence to product performance. The quality framework would be built on quality risk management principles that identify three key steps in the process: risk analysis, mitigation and review (Figure 2).

Successful implementation of the three-step risk management process demands transparency between ingredient supplier and finished goods producers to determine the “where” and “why” of end-use applications. An ingredient manufacturer must work closely with its customers to understand use, evaluate governing standards and regulations, and apply these factors to the manufacturing process.

Working together
The growth of multi-functional cosmetics and regional variations in product categories, standards and regulations presents challenges and opportunities in today’s global marketplace. Through partnership, transparency and a flexible framework, suppliers can establish a quality system with manufacturing processes and controls that can satisfy the desired balance of customer expectations, industry standards and emerging trends.

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What is ‘Associate Membership’ of ECHA?

The British Prime Minister has announced that the UK wishes to seek “associate membership” of the European Chemicals Agency (ECHA) as part of the country’s withdrawal from Europe.

Background

When the people of Britain voted for a British exit – now commonly dubbed Brexit – from the EU in an historic referendum on 23rd June 2016, few could have understood its full implications. With impacts on customs control, immigration, academic research, international agreements and the economy, to name just a few, governing bodies in the UK – and anyone wishing to deal with the country after 29th March 2019 – certainly have their work cut out for them.

One of the primary concerns of the UK’s Chemicals Industries Association (CIA), which was early to offer its own ‘Brexit Manifesto’ as soon as July 2016, was an impact on regulatory matters. For example, would existing REACH approvals remain valid? Would mutual recognition between the UK and EU be feasible? Was this an opportunity to reduce red tape, or was Brexit going to add yet another layer of complexity?

The UK is a leading global chemical producer, with the chemical industry adding £14 billion of value to the UK economy every year, from a total annual turnover of around £40 billion. This is a vital part of the Brexit negotiations that the UK government cannot afford to get wrong.

One wishes to explore...

On 2nd March 2018, the British Prime Minister, Theresa May, told an audience in London that the UK wishes to “explore with the EU the terms on which the UK could remain part of EU agencies, such as those that are critical for the chemicals, medicines and aerospace industries – the European Medicines Agency, the European Chemicals Agency, and the European Aviation Safety Agency”.

In return, the UK would be willing to abide by the rules of those agencies and make appropriate financial contributions. Many in the industry heaved a sigh of relief at this suggestion. After all, such an ‘associate membership’ would provide assurance that products would only need to undergo one series of approvals, and this would benefit companies in the UK, as well as those in the EU that trade with the UK.

In a press release issued on 2nd March 2018, the CIA urged industry, trade unions, NGOs and all political parties to work to achieve the Government’s aim of associate membership of the European Chemicals Agency as part of a post-Brexit future.

Steve Elliott, Chief Executive of the CIA said, “Today’s statement by the Prime Minister is an encouraging step forward, which acknowledges our industry’s long-standing call for regulatory consistency in leaving the European Union…. we would urge the UK and EU negotiating partners and all of the European chemical industry to respond positively to this initiative, keeping in mind the desired aim of minimal disruption to EU chemicals trade and investment as an outcome from Brexit”.

Obstacle race

However, the enthusiasm of industry bodies and affected companies must be tempered by caution – a number of unanswered questions remain.

For example, in the case of REACH registrations, it is unclear whether this single approval is to be granted by the European Medicines Agency (EMA), or by a new UK agency that would then be mutually recognised by Europe. In fact, it seems highly unlikely that the EU would mutually recognise registrations within a new UK system that did not comply with all existing EU regulations. Most likely, any possible ‘associate membership’ of ECHA would encompass a commitment to follow EU laws.

History supports this assumption – Brexit may be unique, but that does not mean there are no precedents for reference. In 2008, Switzerland – which exported about 60% of its chemicals to the EU at the time – was denied membership of REACH. In order to avoid a similar fate, the UK would need to commit to following all EU decisions on chemicals, and any notions of independent UK legislation would need to be abandoned. This would extend to include all EU decisions on chemicals manufacturing, inspections, data collection and evaluation, worker health and safety, and industrial emissions.

It is unclear how this would work in practice. Certainly, the UK has the expertise and experience to deal with such a situation, but the organization and infrastructure for dealing with a new system that works alongside ECHA needs to be devised and implemented.

Other commentators have also picked up on Mrs May’s references to “substantially similar” regulatory standards between the UK and EU, and the fact that she appeared to retain an option for breaking away from EU “standards and outcomes”. These issues may raise serious concerns within the EU who are most likely to demand full and total compliance with EU regulations.

And all the while, the clock is ticking.

With only 12 months to achieve agreements on these and a range of other topics, a number of obstacles still need to be overcome if the UK’s chemical industry is to remain open for business as usual after March 2019.
We Know You Don’t “NEED” Us

We’ve never really embraced or understood the notion of an “unmet need.” In fact, in this noisy, highly fragmented fine chemical industry, we have yet to encounter a need among our small molecule pharmaceutical chemical clients that goes unmet for very long. However, we have figured out ways to help our clients do what they do better. Whether it’s de-risking your supply chain, outsourcing a chemical intermediate, lowering your weighted average COGS, you will find Exeris works hard to find out how you do those things, and then helps you do it better.
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- DCAT Week, March 19–22, Lotte NY Palace, New York
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