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IUPAC Top Ten Emerging Technologies

The International Union of Pure and Applied Chemistry (IUPAC) has released the 2022 Top Ten Emerging Technologies in Chemistry. The goal of this initiative is to showcase the transformative value of chemistry and to inform the general public about the potential of chemical sciences to foster the well-being of Society and the sustainability of our planet. The Jury – an international panel of prestigious scientists with a varied and broad range of expertise– reviewed and discussed the diverse pool of nominations of emerging technologies submitted by researchers from around the globe and selected the final top ten. These technologies are defined as transformative innovations in between a discovery and a fully-commercialized technology, having outstanding potential to open new opportunities in chemistry, sustainability, and beyond.

The 2022 finalists are (in alphabetical order):

- Aerogels
- Fibre batteries
- Liquid solar fuel synthesis
- Nanoparticle mega libraries
- Nanozymes
- Rational vaccines with SNA
- Sodium-ion batteries
- Textile displays
- VR-enable interactive modeling

IUPAC President, Professor Javier García Martínez, said that "the role of chemistry is central to finding and implementing innovative solutions that enable a more sustainable future. With this initiative, IUPAC informs policy and industry leaders, granting agencies, and the general public about technologies that are already creating new opportunities and opening new avenues for research and industry."

The 2022 Top Ten Emerging Technologies in Chemistry are further detailed in a feature article published in the October issue of Chemistry International (CI). Fernando Gomollón-Bel, the author has said, "This project, recognized by experts worldwide, highlights the value of the chemical sciences in the transition to a green economy and a more sustainable world, in line with the United Nations' Sustainable Development Goals (SDGs). This year IUPAC joins the celebration of the International Year of Basic Sciences for Sustainable Development (IYBSSD), a UN resolution to reaffirm and emphasize the importance of basic sciences, chemistry among them, to attain the ambitious SDGs by 2030. Each of the technologies gives us a glimpse of what chemistry can achieve and how creativity and commitment for a more sustainable future can yield the solutions we so urgently need."

More information: *iupac.org*

Strategic Research and Innovation Plan (SRIP) for Chemicals and Materials

The European Commission published a Strategic Research and Innovation Plan (SRIP) to accelerate the shift to safe and sustainable chemicals and materials. In order to boost the protection of people and the planet against hazardous substances, the SRIP highlights crucial research and innovation needs for this transition and guides funders in their investments.

In addition to listing the research and innovation needs for the whole life cycle of such chemicals and materials, SRIP also provides guidance on how to make the most of such R&I activities. The aim is to encourage and guide funders in EU, national and private financial programmes. It reflects the priorities of authorities, scientists and companies alike.

Mariya Gabriel Commissioner for Innovation, Research, Culture, Education and Youth, said: "Protecting people and the planet calls for a strategic approach. We can harness a big economic opportunity by focusing on safe and sustainable chemicals and materials. European industry can gain a competitive advantage and win consumers' confidence by investing in such innovative solutions."

The Commission will refer to the SRIP in the upcoming Horizon Europe work programme 2023–2024 expected to be adopted before the end of the year, as an overarching strategy. In order to maximize SRIP's impact the Commission sets out a monitoring scheme for its implementation. The zero-pollution ambition for a toxic-free environment is one of the four interlinked policy goals of the European Green Deal. Underlining the role of research and innovation the Commission recently published a report on how Horizon 2020 project results help us to preserve biodiversity, while keeping land, water and air clean.

Background

The SRIP, first announced in the 2020 Chemicals Strategy for Sustainability and part of the Green Deal zero pollution ambition , identifies research and innovation (R&I) areas crucial for boosting the transition to chemicals and materials that are safe and sustainable. It provides a comprehensive outlook of R&I needs from production to (re)use, disposal and the decontamination of our environment. The Chemicals Strategy aims to tackle the dual challenge of answering to Europe's need for essential substances and protecting human health and the environment. The EU must have access to these chemicals and materials and achieve its Green Deal goals in a time when manufacturing and supply chains are increasingly complex. In this context, developing a strategic approach to research and innovation for safe and sustainable chemicals and materials is also an economic opportunity.

More Information: *research-and-innovation.ec.europa.eu*

EFMC-Prizes 2023 – Call for Nominations

To acknowledge and recognise outstanding young medicinal chemists and chemical biologists (≤12 years after PhD) working in European industry and academia, EFMC established the "EFMC Prize for a Young Medicinal Chemist or Chemical Biologist in Industry" and the "EFMC Prize for a Young Medicinal Chemist or Chemical Biologist in Academia".

The two prizes are given annualy and consist of:

- a diploma
- a €1.000 money prize
- an invitation for a short presentation at an EFMC symposium

For the 2023 edition, the prize-winners will be invited to give an oral communications at the IX EFMC International Symposium on Advances in Synthetic and Medicinal Chemistry (EFMC-ASMC 2023), scheduled to take place in Zagreb, Croatia on September 3–7, 2023. Two additional nominees will also be identified and acknowladged as most meritorious runners-up.

The eligibility criteria are as follow:

- Not exceed 12 years after PhD on the year during which the prize will be conferred
- Working in European industry and academia
- Be a registered member of one of the EFMC National Adhering Organisation

More information: *efmc.info*

IUPAC Awards in Analytical Chemistry – Call for Nominations

The Analytical Chemistry Division of IUPAC has established two awards, including:

– The Emerging Innovator Award in Analytical Chemistry – an award to recognize outstanding work undertaken by an emerging analytical scientist that corresponds to the aims of the Analytical Chemistry Division.

– The IUPAC Analytical Chemistry Medal – an award to recognize significant lifetime contribution to the aims of the Analytical Chemistry Division.

The awards are open worldwide to researchers working in the field of analytical chemistry. The Emerging Innovator Award is for researchers who are at an early stage of their independent career, as measured by the completion of a PhD within the last ten years. Appropriate consideration will be given to those who have taken a career break or followed a different study path. Nominations must be based on published works in the field of analytical chemistry. The Analytical Chemistry Medal is for researchers who have a substantial record of achievements demonstrated by the number and quality of their publications, by being actively involved in international partnerships as well as by their commitment in the training of the next generation of analytical chemists.

The Award will be presented every two years during the IUPAC General Assembly/World Chemistry Congress. The awardees will be invited to the meeting of the Analytical Chemistry Division to receive their award and to present a lecture.

Complete applications must be received via the submission form no later than 31 January 2023

More information: *iupac.org*

Swiss Physical Society (SPS) Prizes 2023 – Call for Nominations

With the SPS awards, the SPS aims to recognize young physicists for outstanding scientific work in the early stages of their careers, in any case before they reach a permanent academic position or before they have been working in a start-up company or in industry for more than three years.

The papers submitted must have been carried out either in Switzerland or by Swiss nationals abroad. The work is judged on the basis of its significance, quality and originality.

Deadline for nominations is March 1st, 2023.

More Information: *sps.ch*

A Warm Welcome to Our New Members!

Period: 27.09.–31.10.2022

Gaël Jarjoura - Fribourg, Peter Stacko – Zurich, Sara Fornera – Zurich, Daniel Civettini – Zurich Maximilian Moser – Zurich, Alicia Werlen – Frankfurt, Jean de Montmollin – Lausanne Wei Wang – Zürich, Etienne Cotter – Zürich, Christoph Kaul – Zurich, Julian Bechtel – Schlieren, Simona Baghai Sain – Zurich, Subhradip Kundu – Geneva Shahar Dery – Zurich.

HONORS, AWARDS, APPOINTMENTS

Prix Schläfli Award Symposium at ETH Zurich

The Swiss Academy of Sciences awards the Prix Schläfli Prizes every year for the best dissertation in chemistry, biology, physics and geosciences. Due to the Corona pandemic, no award ceremony has yet taken place for the 2020 and 2021 prize winners. The winners of the Prix Schläfli in Chemistry for 2020, 2021 and 2022 were honored for their dissertations at a mini-symposium and ceremony at ETH Zurich on October 3, 2022. Since both the prize winner for 2020 and the prize winner for 2021 had written their dissertations in a working group at ETH Zurich, the awards ceremony took place at ETH Zurich.

Prix Schläfli Award Winners 2020-2022

Prof. Dr. Robert Pollice, Laureate 2020
«London Dispersion in Molecular Systems»
Dr. Claudia Aloisi, Laureate 2021
«Site-specific detection of mutagenic DNA damage with an artificial nucleotide»
Prof. Philippe Schwaller, Laureate 2022
«Accelerating Organic Synthesis using Chemical Language Models»

Source: *ethz.ch*

JOURNAL NEWS

Helvetica, Volume 105, Issue 10, October 2022

Reviews

The Phenazine Scaffold Used as Cytotoxic Pharmacophore Applied in Bactericidal, Antiparasitic and Antitumor Agents
Beata Miksa

Research Articles

Cyclohexane and Beyond: Tangled Hexagons and Octahedra
Michael O'Keeffe, Michael M. J. Treacy

Grafting of Group-10 Organometallic Complexes on Silicas: Differences and Similarities, Surprises and Rationale
Domenico Gioffrè, Lukas Rochlitz, Pierre-Adrien Payard, Alexander Yakimov, Christophe Copéret

Website: *onlinelibrary.wiley.com/journal/15222675*

INDUSTRIAL NEWS

Source: *www.chemanager-online.com*

Lonza Completes HPAPI Expansion at Visp

September 29, 2022: Lonza has completed of the expansion of its Highly Potent API (HPAPI) multipurpose suite at the Basel-based CDMO's alpine production site in Visp, Switzerland, adding development and manufacturing capacity for ADC payloads.

The move supports the entire development and manufacturing pipeline from feasibility studies to commercial supply and underlining the strategic position of ADCs in the company's portfolio. It now has enhanced in-house capability to develop and produce all components, including cytotoxic payloads, antibodies and the required linkers. Extending the capacity of the kilogram-scale HPAPI suite leaves Lonza well positioned to benefit from the growing demand for the payloads in novel cancer therapeutics with higher targeting abilities, the Swiss player said. Utilizing the new capability, the CDMO will be able to handle to compounds with occupational exposure levels down to 1 ng/m3, with a variety of containment solutions and a flexible setup. Equipment on-site includes reactor sizes from 1 liter to 50 liters with a temperature range of –80°C to +150°C, isolation and drying equipment, lyophilization and chromatography equipment for the manufacture of payload-linkers. Lonza's latest expansion represents a key new asset for payload-linker manufacturing, enabling the production of these highly potent compounds at scale with high flexibility for the execution of different types of operations, said Giovanna Libralon, senior director for commercial development in oncology. "With this new fully integrated offer in Visp, we simplify the supply chain under one roof, from the production of an antibody to the chemical synthesis of complex payload-linkers and bioconjugation," added Iwan Bertholjotti, senior director for commercial development and strategic marketing. Lonza said the expansion in Visp is supported by a dedicated team of experts who have produced more than 300 cGMP batches and developed 15 payload-linkers and 50 HPAPI programs in the past decade.

GSK Names Julie Brown as first female CFO

September 30, 2022: From next year, GSK's top management will be led by a double female team, a pioneering move for the global pharmaceutical industry. The UK drugs giant this week announced the appointment of Julie Brown, the first woman to be its chief financial officer. Brown, who will serve beside Emma Walmsley, the first woman to hold the job of chief executive at GSK and the first to run a major drugmaker, will succeed Iain Mackay, who will leave the company on May 1, 2023. "Julie is a highly respected CFO with a tremendous understanding of the biopharma sector," Walmsley said. "We also share a strong passion for people development, diversity, inclusion and sustainability," she said. The drugmaker's future finance chief is currently chief operating and financial officer at the Burberry Group, the British fashion brand. Prior to that, she did a three-year stint as CFO of British medical technology Smith+Nephew after working 25 years at AstraZeneca. Brown currently serves as a non-executive director of Swiss pharma Roche, where she will step down upon joining GSK. Mackay is credited with successfully overseeing the spinoff of the GSK's spinoff of its consumer health business, Haleon, completed in July this year. The manager also won praise for overseeing several key acquisitions aimed at boosting the drugmaker's pipeline and keeping activist shareholders at bay. Prior to Mackay's departure, Brown will join GSK in April 2023 and work with him to transition responsibilities, taking responsibility as CFO and as an executive director, the company said. GSK said the new CFO – both Brown and Mackay are 60 years old – will receive a shareholder-approved annual base salary of £915,335, in line with that of her predecessor, and will have the potential to earn an annual bonus of the same amount as well as a long-term incentive award of £1.83 million. Pharma industry journals note that drugmakers with women in the top two slots are still rare, but they are increasingly making inroads into boardrooms. Following its 2021 buyout of rare disease specialist Alexion, AstraZeneca named that company's chief financial officer, Aradhana Sarin, to the corresponding position on its own team. Eli Lilly has a woman, Anat Ashkenazi, as CFO. The CEO of Germany's Merck, Belén Garijo, is also female.

Green Hydrogen Is the Way out of the Energy Crisis

The recently merged Port of Antwerp-Bruges positions itself as an import hub for Europe

October 1, 2022: Green hydrogen is experiencing an enormous upswing in the current energy crisis. The increased demand will be difficult to meet on a local level. So, right on time, the Port of Antwerp-Bruges is preparing to bring large quantities of the climate-friendly energy carrier from non-European countries to Western Europe. Experts estimate that the demand for green hydrogen in Germany alone could be as high as 180 terawatt hours in the future. That is three times as much as the current hydrogen consumption in total. Imports will thus undoubtedly become the only alternative to make the climate-friendly and meanwhile comparatively cheap energy carrier sufficiently available in Europe. Coastal locations and domestic regions are gearing up to support this development within the framework of national hydrogen strategies in many countries The Belgian Port of Antwerp-Bruges also will play an important role in the hydrogen economy - not only for Belgium, but also as an import hub for Germany and other Western European countries. While Antwerp with its existing terminals can immediately receive and store hydrogen carriers such as ammonia or methanol, Zeebrugge has the advantage of direct access to the sea. Here, large quantities of both gaseous and liquefied hydrogen can be unloaded with just a few adjustments to the infrastructure. Via pipelines, for or example, the hydrogen then reaches the end users.

2030: Green Hydrogen directly to Germany

The port expects the first large ships with hydrogen carriers such as ammonia or methanol to arrive within the next two years. In a first stage, these capacities will be used by the companies in Antwerp's chemical and petrochemical cluster. A hydrogen pipeline for the port area is planned to be built by 2025. By 2030 at the latest, Germany will also be supplied with green hydrogen from Antwerp. The decision on where the port will source the green hydrogen will be based on a whole range of parameters, from the distance to Zeebrugge and Antwerp to the stability of the local political regime and, of course, the availability of solar and wind resources. Possible countries are Oman, Chile, and Namibia, but also Canada or Australia. The potential for wind and solar energy is large in these countries and the production of green hydrogen is correspondingly cheap there, so that the costs for transport are balanced out.

Production of Green Hydrogen Directly in the Harbour

In addition, a 100-megawatt plant to produce green hydrogen is being built in Antwerp's NextGen District. The company Plug Power signed a 30-year concession agreement and leased a 28-hectare plot of land. The Americans want to produce up to 12,500 tonnes of liquid and gaseous green hydrogen annually here for the European market. The first pilot production of green hydrogen is planned for 2024, the commissioning of the factory for 2025. In addition, the port continues to focus on reducing its carbon footprint together with its industrial and maritime customers and is exploring the application of Carbon Capture, Utilisation & Storage (CCUS). In this way, the Port of Antwerp-Bruges is helping companies in the chemical industry in Europe to meet the energy challenges of this time in two ways.

Bachem Buys DSM's Sisslerfeld Site

October 10, 2022: Swiss peptide and oligonucleotide specialist Bachem has agreed to buy an undeveloped site in Sisslerfeld from DSM. It has completed the purchase of a first plot, with others to follow in the coming years. In a first step, Bachem plans investments totaling 750 Swiss francs, creating more than 500 new jobs by 2030, when a first production building for peptides and oligonucleotides will be operational. Peptides and oligonucleotides are increasingly being used as active medical ingredients for treating a wide range of diseases such as diabetes and cancer. The Sisslerfeld site, which will be Bachem's third in Switzerland and add to existing locations in Bubendorf and Vionnaz, offers space for further expansion, eventually allowing for the creation of up to 3,000 new jobs. Bachem said the decision to select Sisslerfeld in northwestern Switzerland was based on the region's "strong locational conditions" that include a skilled workforce, a network of suppliers, and a high concentration of pharmaceutical and chemical companies. The selection of Sisslerfeld as a future new site followed a multi-stage selection process. The decision in favor of a site within northwestern Switzerland was made early on for Bachem due to the region's strong locational conditions (including a skilled workforce, a network of suppliers, and a high concentration of pharmaceutical and chemical companies) "The new site will once more significantly increase our production capacity. In addition to the ongoing investments in Bubendorf, it underlines our strong presence in northwestern Switzerland," said CEO Thomas Meier, "In the region alone, our workforce has almost doubled in the past five years with 1,200 colleagues who work in our team here today." Bachem's expansion at Bubendorf, costing about 550 million Swiss francs, is expected to go online in 2024. The company plans to add about 800 new jobs there in the next three years, taking the site's total workforce to more than 2,000 employees.

Bachem Innovates its Manufacturing Capabilities

October 14, 2022: Interest in oligonucleotide therapeutics has grown, as has the market demand, since their emergence as a new drug modality two decades ago. Initially focusing on rare diseases, oligonucleotide therapeutics are moving into more common chronic indications like asthma, diabetes, chronic renal failure, as well as cardiovascular and liver diseases. The need for large-scale manufacturing to support market requirements for oligonucleotides has never been so high and is coupled by the emergence of new challenges related to scalability, sustainability and cost. Bachem is the leading CDMO for oligonucleotide and peptide manufacturing and has been rising to these challenges in a number of ways to support the best their customers in drug development and commercialization. Bachem's new oligonucleotide manufacturing facility provides innovative solutions for large-scale oligonucleotide API (active pharmaceutical ingredient) production. Customizations, such as in-line mixing of dichloroacetic acid (DCA) solution – enabling the right amount of DCA to be transferred and avoids side reactions, ensure a more efficient process and results in a high-quality crude API. The production line is also equipped with the first MCSGP (Multicolumn countercurrent solvent gradient purification) equipment for large-scale continuous chromatography. This set-up brings significant benefits such as time optimization, cost-efficiency, and lower solvent consumption during the purification step. A focus on Industry 4.0, the automation and digitalization of traditional industrial processes through smart technology and integration, is a key industry trend. Bachem sees digitalization as an enabler to meet uncertain demands, compliance and ambitious timelines to deliver high-quality APIs. Within this concept, a "smart factory" is characterized by machines which are interconnected, and interoperable, and can process data autonomously. Such "smart factories" require only limited human decision-making or intervention and are therefore sometimes referred to as "intelligent automation". Entering Industry 4.0 and developing the Bachem "smart factory" represents a big step forward in providing their customers with more flexibility, consistency and speed in manufacturing. Bachem has primarily been focused on automating and digitalizing solid phase peptide synthesis (SPPS). This improves the reliability of the process, reproducibility of results and safety, while significantly increasing the cost-effectiveness of operations. Major innovations, such as a robot-operator, called BALU (Bachem Amino acid Loading Unit), and Process Analytical Technology (PAT) have recently been rolled out. BALU was designed and programmed to support commercial scale of SPPS. The robot handles the containers with the amino acid powders and can perform the powder transfer into the activator vessels for Bachem's 150L SPPS reactors without the involvement of an operator. BALU can perform other critical tasks, such as cleaning the amino acid transfer port to prevent cross-contamination. A barcode scanner that reads the labels placed on the amino acid containers ensures correct handling. PAT performs inline analytics after key steps. PAT removes the need for manual In-Process Controls (IPC) and provides a better control of Critical Process Parameters (CPP). Additionally, this automated process enables data recording and analytics as well as paper-free cGMP documentation. Implementing PAT to their process control decreases human contributions and cost of goods. Manual tasks are no longer required, freeing resources for other tasks and projects. Furthermore, PAT leads to a higher reproducibility with minimized chemical side reactions. Continuous innovation is key to transform oligonucleotide and peptide manufacturing and ensure a high-quality, sustainable, and cost-effective process. Investments in new production facilities and into automation of traditional processes enables companies to utilize assets more efficiently and streamline production scheduling for a higher capacity and flexibility. Bachem will

continue to drive innovation, set high industry standards and expand their capabilities to help their customers in transforming patient's lives.

Investing in Growth Through Innovation

Arxada Addresses Customer Needs with Innovative and More Sustainable Solutions

October 17, 2022: Interview with Marc Doyle, CEO of Arxada, which was created following the carve-out and sale of Lonza Specialty Ingredients to private equity firms Bain Capital and Cinven.

Swiss specialty chemicals company Arxada was created following the carve-out and sale of Lonza Specialty Ingredients to private equity firms Bain Capital and Cinven. © Arxada

Arxada was created in 2021 following the completion of the carve-out and sale of Lonza Specialty Ingredients to private equity firms Bain Capital and Cinven. The Swiss specialty chemicals company is active in three businesses: Consumer Microbial Control (CMC), Industrial Microbial Control (IMC) and Specialty Products Solutions (SPS). Following the carve-out, Arxada announced the acquisitions of Troy Corporation, a global leader in industrial preservation, and Enviro Tech Chemical Services, a category-leading manufacturer of proprietary and high-efficacy antimicrobial and biocidal products. CHEManager asked Marc Doyle, CEO of Arxada, about the start of the new company, its plans and vision for the future, and current CDMO market trends.

CHEManager: It has been a busy first year for Arxada. Will you maintain this pace for further acquisitions?

Marc Doyle: M&A is a critical growth lever for us. Given the highly fragmented market for the preservation of infrastructure, the environment and human health from microbiological threats, we see a number of potential opportunities to acquire new technologies or new products that tick these boxes.

What do the company's new owners, Bain Capital and Cinven, expect from you in terms of further development?

M. Doyle: Bain Capital and Cinven's strategy is to carve out good companies and make them great through strategic acquisitions and by investing in growth through innovation. They also have a strong focus on sustainability – part of the financing for the carve-out of Arxada included a sustainability-linked bond, which was the first of its kind for a private equity transaction. As a company, we are investing heavily in our sustainability strategy to help our customers adapt to long-term environmental and social change, and develop cleaner, greener solutions.

Arxada's roots go back more than 120 years. Does this longstanding heritage of innovation and technology still live on today?

M. Doyle: Arxada has an extremely strong track record in innovation, which spans beyond our history as part of Lonza. You can also trace Arxada's roots back to one of the biggest breakthroughs in the history of biocides: part of our history stems from Arch Chemicals through Avecia and Zeneca to ICI, who developed benzisothiazolinone – BIT –, which is still one of the most important antimicrobial chemicals in our industry today. We acquired Troy Corporation in 2021, who again have a long history of innovation, the most notable being the invention of 3-iodo propynyl butyl carbamat – IPBC –, which is another major preservative chemistry still in use today.

As well as developing these major classes of chemistry that we are still the leader in today, we continue to innovate and bring new products and chemicals to the market. For example, we created Tanasote, a more sustainable alternative to Creosote, which we are trying to make the industry standard in Europe. This forms part of our strategy of using our strength and heritage in innovation to develop more sustainable products.

Going forward with the Enviro Tech business we have been innovating around new uses of peracetic acid – PAA– to bring it to new applications to replace the use of chlorine and chlorinated chemicals. With all this history, Arxada today is the global leader in preservation, providing products and solutions that enable our customers to protect their products from microbial spoilage, improve health and safety and reduce their environmental footprints. We continue to harness our world-class regulatory, engineering and R&D capabilities to develop and launch new products to support our customers in addressing the challenges they face.

What do the two companies – Troy and Enviro Tech – add to Arxada's offering?

M. Doyle: Both Troy and Enviro Tech brought us innovative technologies that enable us to keep abreast of regulatory trends. Troy is a leader in IPBC – a more sustainable fungicide – and we see a lot of ways in which we can harness our technologies to further evolve its use, for example by expanding our offering of controlled release formulations which reduce exposure to the active. With Enviro Tech, we saw a great opportunity for PAA to displace chlorinated chemicals given that it has a lower environmental impact and is easy to work with – and we see further ways to use Enviro Tech's innovation capabilities to widen its use.

Are there any interesting trends or drivers you are seeing in the CDMO market? And what is your strategy as a CDMO to benefit from these trends?

M. Doyle: For the CDMO market as a whole, we are seeing three trends: more consolidation of a highly fragmented market, continued outsourcing and additional reshoring. These trends have been primarily driven by the agro and pharma end markets, which are the heaviest users of CDMO. Our CDMO strategy has been to move into additional end markets which are increasingly using CDMO capabilities – such as nutritional ingredients, food and flavors and industrial biotech – where we see further opportunity to grow. At Arxada, we have CDMO capabilities both in traditional chemistry at our heritage site in Visp, Switzerland, and within the industrial biotechnology space at our Kouřim site in the Czech Republic, which puts us in a unique position within the market.

Which market sectors do you primarily address, and how is Arxada positioned in these markets in terms of portfolio range and core competences?

M. Doyle: The four core markets for Arxada are paints and coatings; home and personal care; professional hygiene and wood protection; in addition to industrials including energy, nutrition and mobility. One way of thinking about this is that we have a focused theme of addressing the need for more sustainable preservation across both human health and infrastructure related end markets through the breadth of our product offering, our technologies and our regulatory capabilities. The Consumer Microbial Control side of our business primarily focuses on human health and protecting us from the threat of microorganisms. There is now a much greater awareness of the threats from bacteria, viruses, fungus and algae, in part because the increasing human population is bringing us more into contact with microorganisms, and also because global warming is leading to a proliferation of these microorganisms. We are working to help fight the threat posed by microorganisms in a sustainable, natural way, consistent with regulatory trends, by bringing our scientific capabilities to bear – both in chemistry and industrial biotechnology. Within our Industrial Microbial Control business, we leverage the same products, regulatory capabilities and technologies into the protection of infrastructure from mi-

croorganisms.Whether we're looking at the marine anti-fouling industry, where coatings enable ocean transportation to be more fuel efficient, or the plastics industries, which require solutions to microbial contamination and surface disinfection, we provide customers with the assurance that we can solve their most difficult challenges in the preservation space and together improve the sustainability of our infrastructure and the environment. Our businesses within microbial control are complemented by our work to protect human health through our Specialty Products Solutions business. We are a key supplier of vitamins and nutritional ingredients globally. We also have deep technical and manufacturing process development capabilities in SPS that fuel our advanced developments to support the microbial control markets and our deep capabilities within industrial biotech within SPS offer a roadmap for greener and more natural solutions for a range of industries.

Do you plan to add certain capabilities or capacities in order to support demand growth?
M. Doyle: We've already significantly expanded our capacity over the past year: investing CHF 20 million in our industrial biotechnological plant in Kouřim, Czech Republic, which serves our CDMO business, and last month announcing a CHF 20 million expansion of our vitamin capacity to support our partner DSM. Other recent projects include NOx abatement at Visp, Switzerland, quat expansion in Mapleton, IL, USA, increasing capacity for methoxyethyl cyanoacetate and butyl cyanoacetate in Conley, GA, USA, and Tanasote capacity expansion in Huddersfield, UK. We're expecting to make further investments in our operations over the next 12 to 18 months, not only to continue to support the growth of our business but also to make our business more sustainable.

In terms of customer needs, where do you see market trends that you want to support and benefit from?
M. Doyle: Increased regulatory pressures are driving transitions to new chemistries which better protect human health and the environment. We're helping to drive the preservation industry's transition to more sustainable and cleaner solutions through our investments in boosters, potentiators and controlled release technologies. There is a shift in the home and personal care market from hard preservatives, such as quats, to what are called soft preservatives such as our Geoguard technology. We strongly support this transition and work closely with customers to enable them to adapt their formulations to the new solutions available in this space. Another trend we are able to support within our SPS business is the move towards 5G electronics applications. We recently entered a partnership with Novoset where we will develop, manufacture and commercialize a next generation hydrocarbon-based dielectric resin developed by Novoset which will find application within rigid circuit boards used for telecommunications and advanced semiconductor packaging markets. We're also working to leverage our manufacturing process technology expertise to deliver more efficient manufacturing processes for some of our key chemistries that have lower CO2 and greenhouse gas emissions.

What do you see for the company's future?
M. Doyle: When Arxada was carved out from Lonza it was a transformational opportunity for the business, allowing us to accelerate our growth strategy within the consumer and industrial microbial control area and in specialty chemicals markets with the strong, long-term support of our new owners.
Independence is allowing Arxada to be a more responsive and agile business, developing unique, innovative solutions to help our customers protect their products from microbial spoilage, improve health and safety and reduce their environmental footprints. We look forward to supporting customers to better address their most difficult preservation challenges in a more sustainable manner.

DKSH to Acquire US Distributor Terra Firma
October 17, 2022: Swiss distributor DKSH is poised to acquire North American specialty chemicals distributor Terra Firma, expanding the platform of its Performance Materials business unit to the US and Canada. Under the deal it called an important step in in its strategy to build a global distribution platform, the Swiss distributor said it will acquire at least 80% of Terra Firma' shares, with the remainder continuing to be held by the company's existing management team. The transaction that values the Baltimore, Maryland-based US company at $360 million will be financed via debt and cash and is expected to be EPS-accretive. Closing is slated for late 2022. Across the continent, Terra Firma's clients are active in the core product segments of Coatings, Adhesives, Sealants and Elastomers and the markets for plastics and construction, agrochemicals, health and nutrition, in addition to personal care. DKSH said the addition of a strong player in the North American industrial specialty chemicals distribution sector will bolster its international presence in particular as Terra Firma's product slate is complementary to its own specialty industrial business. It will also provide a strong base to expand further into food, pharma, and personal care in the region. With offices in Los Angeles, Dallas, Baltimore, and Toronto, Terra Firma currently employs around 100 people. The company expects net sales of around $240 million in 2022.

AI Maturity Model for GxP Application
A Foundation for AI Validation in the Pharmaceutical Industry, Part 1

October 18, 2022: Artificial intelligence (AI) has become one of the supporting pillars for digitalization in many areas of the business world. The pharmaceutical industry and its GxP-regulated areas also want to use AI in a beneficial way, but only a small fraction of companies follows a systematic approach for the digitalization of their operations and validation. However, the assurance of integrity and quality of outputs via computerized system validation is essential for applications in GxP environments. There is no specific regulatory guidance for the validation of AI applications that defines how to handle the specific characteristics of AI. The first milestone was the description of the importance and implications of data and data integrity on the software development life cycle and the process outcomes. No life-science-specific classification is available for AI. There are currently only local, preliminary, general AI classifications that were recently published.
This lack of a validation concept can be seen as the greatest hurdle for successfully continuing digital products after the pilot phase. Nevertheless, AI validation concepts are being discussed by regulatory bodies, and first attempts at defining regulatory guidance have been undertaken. For example, in 2019 the US Food and Drug Administration published a draft guidance paper on the use of AI as part of software as a medical device, which demonstrates that the regulatory bodies have a positive attitude toward the application of AI in the regulated industries.

Introducing a Maturity Model
As part of our general effort to develop industry-specific guidance for the validation of applications that consider the characteristics of AI, the ISPE D/A/CH (Germany, Austria, and Switzerland) Affiliate Working Group on AI Validation recently defined an industry-specific AI maturity model (see figure). In general, we see the maturity model as the first step and the basis for developing further risk assessment and quality assur-

ance activities. By AI system maturity, we mean the extent to which an AI system can take control and evolve based on its own mechanisms, subject to the constraints imposed on the system in the form of user or regulatory requirements Our maturity model is based on the control design, which is the capability of the system to take over controls that safeguard product quality and patient safety. It is also based on the autonomy of the system, which describes the feasibility of automatically performing updates and thereby facilitating improvements We think that the control design and the autonomy of an AI application cover critical dimensions in judging the application's ability to run in a GxP environment. We thus define maturity here in a two-dimensional matrix spanned by control design and autonomy and propose that the defined AI maturity can be used to identify the extent of validation activities.

Control Design

Control design is a five-stage process. In stage 1, the applications run in parallel to GxP processes and have no direct influence on decisions that can impact data integrity, product quality, or patient safety. This includes applications that run in the product-critical environment with actual data. The application may display recommendations to the operators. GxP-relevant information can be collected, and pilots for proof of concept are developed in this stage. In stage 2, an application runs the process automatically but must be actively approved by the operator. If the application calculates more than one result, the operator should be able to select one of them. In terms of a 4-eye principle (*i.e.*, independent suggestion for action on the one hand and check on the other hand), the system takes over one pair of eyes. It creates GxP-critical outputs that have to be accepted by a human operator. An example for a stage 2 application would be a natural language generation application creating a report that has to be approved by an operator. In stage 3, the system runs the process automatically but can be interrupted and revised by the operator. In this stage, the operator should be able to influence the system output during operation, such as deciding to override an output provided by the AI application. A practical example would be to manually interrupt a process that was started automatically by an AI application. In stage 4, the system runs automatically and controls itself. Technically, this can be realized by a confidence area, where a system can automatically control whether the input and output parameters are within the historical data range. If the input data are clearly outside a defined range, the system stops operation and requests input from the human operator. If the output data are of low confidence, retraining with new data should be requested. In stage 5, the system runs automatically and corrects itself, so it not only controls the outputs but also initiates changes in the weighting of variables or by acquiring new data to generate outputs with a defined value of certainty To our knowledge, there are currently no systems in pharmaceutical production at level 4 or 5. Nevertheless, with more industry experience, we expect applications to evolve for applications at levels 4 and 5.

Autonomy

Autonomy is represented in six stages. In stage 0, there are AI applications with complex algorithms that are not based on machine learning (ML). These applications have fixed algorithms and do not rely on training data. In terms of validation, these applications can be handled similar to conventional applications. In stage 1, the ML system is used in a so-called locked state. Updates are performed by manual retraining with new training data sets. As the system does not process any metadata of the produced results by which it could learn, the same data input always leads to the generation of the same output. This is currently by far the most common stage. The retraining of the model follows subjective assessment or is performed at a regular interval. In stage 2, the system is still operating in a locked state, but updates are performed after indication by the system with a manual retraining. In this stage, the system is collecting metadata of the generated outputs or inputs and indicates to the system owner that a retraining is required or should be considered, e.g., in response to a certain shift in the distribution of input data. In stage 3, the update cycles are partially or fully automated, leading to a semi-autonomous system. This can include the selection and weighting of training data. The only human input is the manual verification of the individual training data points or the approval of the training data sets. In stage 4 and stage 5, the system is completely autonomous with reinforced ML independently based on the input data.

In stage 4, the system is fully automated and learns independently with a quantifiable optimization goal and clearly measurable metric. The goal can be defined by optimizing one variable or a set of variables. In production, the variables could be the optimization of the yield and selectivity of certain reactions. In stage 5, the system learns independently without a clear metric, exclusively based on the input data, and can self-assess its task competency and strategy and express both in a human-understandable form. Examples could be a translation application that learns based on the feedback and correction of its user. If the user suddenly starts to correct the inputs in another language, in the long term, the system will provide translations to the new language.