*Summer 2025*
**#102**

# the Medicine Maker™

## the Medicine Maker POWER *List*

Innovation in pharma isn't just about molecules and machinery; it's powered by people. Welcome to our annual celebration of the industry's leading lights.

**8 – 17**

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# A European Invitation

*European countries call for researchers to move their work away from the US*

In the last issue, I wrote briefly about the impact of the Trump administration on American science. Wherever you stand in your political allegiance, it's hard to see the changes at the FDA or elsewhere at the Department of Health and Human Science as beneficial for science and medicine. Companies are uncertain. Researchers are spooked.

And Europe is looking to take advantage.

CEO of The Danish Chamber of Commerce, Brian Mikkelsen, recently penned a rare LinkedIn post in English: "To all the brilliant researchers in the US feeling uncertain right now: Denmark is open – and we need you! If you are a researcher looking for stability, respect for your work, and the chance to make a real impact in a place where facts still matter. We would love to hear from you here in Denmark."

Elsewhere, Copenhagen Capacity has launched a campaign to attract US and other international researchers through funding from the Novo Nordisk Foundation, the Lundbeck Foundation, and the Villum Foundation.

A larger, more coordinated effort is also underway. European Commission President Ursula von der Leyen announced the launch of a €500 million initiative to attract scientific talent from the US with "super grants." Speaking at the Choose Europe for Science event in Paris, Von der Leyen criticized the US funding reductions as a "gigantic miscalculation" and emphasized Europe's commitment to scientific freedom and diversity.

The EU's strategy also includes reducing bureaucratic hurdles and enhancing collaboration between science and industry, positioning Europe as a global hub for research and innovation.

What are your thoughts? Will the US see an exodus of researchers to Europe and other territories? Let me know: *stephanie.vine@conexiant.com*

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# The Shingles Vaccine and Dementia

*Studies have suggested that the RZV shingles vaccine can lower the risk of dementia; GSK is now investigating further*

Credit: Rawpixel.com

GSK is collaborating with the UK's Dementia Research Institute and Health Data Research UK to explore a potential link between GSK's RZV shingles vaccine and a reduced risk of dementia.

Data from several observational studies appears to suggest a link may exist, with the latest study being published at the start of April in *Nature*. In this study, research used health data from Wales, where eligibility for the shingles vaccine is based on a person's exact date of birth. This allowed researchers to compare people who were just old enough to miss out on the vaccine (born before September 2, 1933) with those who were just young enough to qualify (born on or after September 2, 1933).

By analyzing health records, the researchers found that people who were eligible for the vaccine were 20 percent less likely to be diagnosed with dementia over the following seven years. In addition, the protective effect appeared stronger in women than in men. To check their results, the researchers also looked at death records from across England and Wales and saw a similar pattern: people who had been vaccinated were less likely to have dementia listed as a cause of death.

"There has been evidence for some time that older people who receive their vaccinations in general are less likely to develop dementia. This is the best evidence yet to show this," commented Henry Brodaty, Scientia Professor of Ageing and Mental Health and Co-Director of the Centre for Healthy Brain Ageing at the University of New South Wales. "Future research will determine whether the newer non-live virus, Shingrix, will provide the same benefit and whether immunization at younger ages may be just as effective."

The GSK collaboration will draw on UK health data to examine links between vaccination and disease risk at the population level. A statement from GSK says: "There are around 1.4 million 65 and 66 years olds in the UK and their eligible electronic health records are expected to give a robust and comprehensive dataset which will account for factors such as RZV vaccination, age, sex and co-existing medical conditions. The research will take 4 years to complete."

But how exactly could the shingles vaccines lower dementia risk? Anthony Hannan, Group Head of the Epigenetics and Neural Plasticity Group at the Florey Institute of Neuroscience and Mental Health, suggests that it could be down to an effect on brain immune cells. "We now know that, despite the blood-brain barrier, the brain has its own immune cells, which serve many roles including removal of specific toxic molecules that accumulate with age (particularly in the most common form of dementia, Alzheimer's disease)," he says. "It is possible that the vaccine had direct effects on these brain immune cells, but it is also possible that the vaccine acted indirectly, for example, by slowing brain aging and/or enhancing brain resilience to the ravages of age."

## Building for Business

Almac Pharma Services opens its £65 million commercial manufacturing facility in Craigavon, Northern Ireland. GMP manufacturing commenced in March.

*Credit: Almac Group*

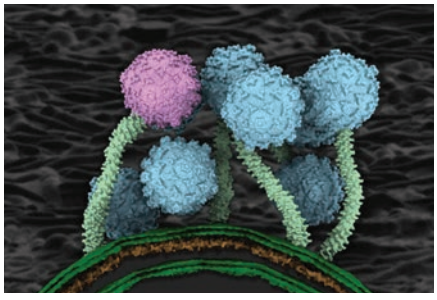
**QUOTE** *of the month*

*"Those who defend science and act decisively will shape the future of biopharma. This is a time to protect progress, not retreat from it."*

Power Lister Audrey Greenberg (Founder and CEO at AG Capital Advisors) speaks about the disruption facing the industry and scientists in the US. Read more on page 20.

## Cracking the Code of Phages

*How new structural insights captured in high-res could help fight TB*



*Credit: Scripps Research*

Scientists at Scripps Research and the University of Pittsburgh have captured the first high-resolution structural images of a virus that infects mycobacteria, the bacterial genus responsible for TB. They hope their work could pave the way for phage-based therapies targeting drug-resistant strains of TB.

The team used imaging techniques, including single-particle cryo-electron microscopy (cryo-EM) and cryo-electron tomography (cryo-ET), to visualize the mycobacteriophage Bxb1 at near-atomic resolution during various stages of infection. The images revealed how Bxb1 attaches to mycobacteria, injects its genetic material, and initiates infection.

Contrary to expectations, Bxb1 does not form a channel through the bacterial membrane to deliver its DNA, suggesting a unique genome translocation mechanism distinct from other known phages. Additionally, the study revealed significant structural changes in the phage's tail tip upon binding to the bacterial surface, indicating a dynamic infection process.

By elucidating how Bxb1 overcomes these defenses, researchers hope to better understand phage-host interactions and find a way to use that knowledge against TB.

# The Surge in Demand for Sterile Manufacturing

*How prefilled syringes, blow-fill-seal technology, and innovations in vials are transforming sterile manufacturing*

By Vincenza Pironti, head of Business development at Recipharm

The pharmaceutical and biopharmaceutical industries are experiencing a surge in demand for sterile manufacturing, driven by the rise of injectable drug products including vaccines, cell and gene therapies, and complex biologics.

As part of the production of sterile therapeutics, careful consideration of container formats is needed to ensure their safe and effective delivery. Selecting the appropriate container format is crucial for maintaining product quality and minimizing risks while optimizing patient outcomes. Factors such as patient safety, convenience, cost-effectiveness, and sustainability must be carefully considered when deciding the most suitable container format.

The landscape of therapeutic packaging is undergoing a significant shift, driven by several key factors. Changing demand, a focus on patient centricity, and enhancements in various container formats, including pre-filled syringes (PFS), blow-fill-seal (BFS) technology, and vials, are all playing key roles in this evolution.

First, let's look at PFS. By eliminating manual measurement and drug withdrawal, PFS helps minimize medication errors and contamination risks. The ready-to-use format streamlines administration, saving valuable time in clinical settings and improving efficiency, especially during mass vaccination campaigns.

Beyond these inherent benefits, advancements in PFS packaging have further expanded their applications and enhanced their usability. Innovations in kitting and design, such as easier-to-grip syringes, clearer instructional packaging, and an expanded range of sizes to accommodate larger volumes and more viscous products, are making PFS more compatible with self-administration in a greater range of patient groups.

These advancements are driving the increasing adoption of PFS for a wider variety of therapeutics. With the rising prevalence of chronic diseases requiring regular injections and the increasing preference for self-administered treatments and home healthcare, PFS will continue to play a prominent role in the future of drug delivery.

Meanwhile, BFS technology represents a significant advancement in aseptic manufacturing because it can be used to produce a variety of pharmaceutical products. In the BFS process, container formation, filling, and sealing occur in a single, continuous, and automated operation within a sterile environment. This integrated approach minimizes human intervention and the risk of contamination.

While BFS has traditionally been employed for ophthalmic solutions, respiratory medications and other sterile liquids, its applications are rapidly expanding beyond these traditional uses. The automated nature of BFS also streamlines production, reducing manufacturing costs and improving efficiency, making it particularly well-suited for large-scale manufacturing of injectables, where even minor cost savings per unit can have a significant impact. Additionally, the flexibility of BFS allows for the production of custom-shaped containers tailored to specific applications, such as those requiring precise integration with inhalation devices, ensuring accurate and consistent drug delivery.

Moving onto vials; these have long been a cornerstone of injectable drug delivery, offering a versatile and reliable container format for a wide range of therapeutic products. However, traditional glass vials present certain limitations, such as the risk of breakage and potential interactions between the drug product and the vial material.

One notable advancement in vial technology is the introduction of vials made from cyclic olefin polymers (COP). These plastic vials offer increased durability, reducing the risk of breakage during transport and handling, a crucial safety aspect for both healthcare providers and patients, especially in self-administration scenarios. COP vials also exhibit enhanced drug compatibility and stability, minimizing potential interactions between the drug product and vial material, which is essential for sensitive biologics and complex formulations.

Specialized vial types for specific applications, such as lyophilized products or those with advanced closure systems, further demonstrate the continuous innovation in vial technology, providing enhanced options for drug containment and delivery. These advancements in vial formats signal a promising future for injectable drug delivery, with the industry's ongoing commitment to innovation evident in the development of vials that prioritize safety, compatibility and performance.

The future of drug delivery lies in selecting the optimal container format for each therapeutic product, a crucial decision that requires careful evaluation of factors such as drug modality, route of administration, formulation compatibility and patient preferences.

As therapeutic modalities continue to evolve, so too will container formats. We can anticipate ongoing innovation in materials, design, and functionality, driven by a growing emphasis on patient-centricity and personalized medicine. This continuous evolution will ensure that drug delivery systems meet the complex and ever-changing needs of patients, leading to improved treatment outcomes and a brighter future for healthcare.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# POWER *List*

*Amplifying the innovators of tomorrow – today*

Innovation in pharma isn't just about molecules and machinery; it's powered by people. Visionaries, disruptors, and dedicated minds drive the next wave of medicine, transforming bold ideas into life-changing therapies for patients around the world.

Once again, The Medicine Maker community answered the call to spotlight those shaping the future of drug development. Through your nominations, we've curated this year's Power List: 30 standout pioneers accelerating progress across drug development in traditional small molecules, biologics, and advanced therapies.

In a world defined by rapid change, unprecedented challenges, and incredible new scientific advances, these trailblazers don't just adapt – they lead through their influence to ignite innovation, inspire action, and push boundaries. Welcome to the 2025 Power List: a celebration of the minds moving medicine forward.

Be the first to find out about nominations for our 2026 Power List by subscribing to our newsletter

# *Advanced Medicine*

## Alan Boyd

*CEO and Founder, Boyds*

Alan is a pioneer in cell and gene therapies, having led the development of Cerepro, the first gene therapy submitted to the EMA for approval. Although not approved, Cerepro's application set a precedent in establishing the standards required. Ultimately, Alan's work demonstrated the potential to turn DNA into an approvable medicine.

In 2005, he established Boyds to support the translation of ideas into medicinal products and treatments. His work has resulted in the development of multiple approved medicines for a variety of indications. Of the 26 approved cell and gene therapy products on both sides of the Atlantic, the team at Boyds has worked on 11 of them at some stage.

## Daria Donati

*Chief Scientific Officer of Genomic Medicine, Cytiva*

Daria is an active influencer in key industry organizations, including the Alliance for mRNA Medicines, and in science-driven networks dedicated to advancing innovative therapies. She is also a passionate advocate for the representation of women and gender equality in life sciences, particularly through the championing and mentorship of young women pursuing STEM careers.

*"The most important advice I can give any scientist is to follow your passion and curiosity each day, whether it is in academia or industry. If you do that, I believe you are more likely to have a fulfilling career."*

## Miguel Forte

*President, ISCT and CEO, Kiji Therapeutics*

A member of the European Advisory Board with the Alliance for Regenerative Medicine, as well as a professor at the Faculty of Pharmacy, University of Lisbon, Miguel has been leading and championing the cell and gene sector for decades in academic, regulatory, and industry CEO roles.

He earned his PhD in Medicine, Immunology, and Infectious Diseases at the University of Birmingham, UK, and now heads up Kiji Therapeutics while sitting on the board of many other biotechs, including Swarm Oncology, Stembond Technologies, and mC4Tx. Miguel, a Power List veteran since 2016, returns following a successful 2024 and promising pipeline with Kiji Therapeutics.

## Fabian Gerlinghaus

*CEO and Co-Founder, Cellares*

In his role with Cellares, Fabian focuses on automated manufacturing platforms. In 2024, he oversaw the launch of the Cell Shuttle, attracting partnerships with industry leaders Bristol Myers Squibb and Kite, a Gilead Company, to automate CAR-T cell therapy manufacturing.

*"A few decades from now, we will eradicate cancer entirely. Patients will be diagnosed by AI; we will sequence the tumors and produce an individualized treatment of CAR-T cells, armed against neoantigens found specifically on that patient's tumor, alongside individualized mRNA therapeutics that target the neoantigens found in the outpatient's tumor. In other words, we'll have a generalized approach to eliminating cancer."*

## Audrey Greenberg

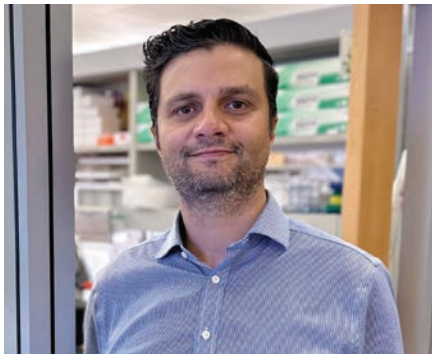
*Founder and CEO, AG Capital Advisors*

Audrey founded and led the Center for Breakthrough Medicines (CBM) as it established itself as a global leader in cell and gene therapy, earning accolades such as Employer of the Year and DEI Initiative of the Year. Under her leadership, CBM achieved multi-billion-dollar valuations and resulted in an acquisition by SK pharmteco. A champion of collaboration between academia, industry, and government, she is committed to mentoring the next generation of leaders through organizations such as Women in Bio and the Healthcare Businesswomen's Association.

## John Maher

*Founder and Chief Scientific Officer, Leucid Bio*

A consultant immunologist at Eastbourne Hospital and King's Health Partners, as well as a clinical academic at King's College London (KCL), Maher founded the CAR Mechanics group at KCL in 2004, focusing on adoptive immunotherapy using CAR-engineered and gamma delta T cells. Maher has spent over 25 years advancing CAR T-cell therapy for solid tumors and led the first academic CAR-T trial for head and neck cancer in 2015. He now oversees the AERIAL trial, evaluating Leucid's lead candidate, LEU011, in patients with relapsed or refractory solid tumors.



## Samir Ounzain

*CEO and Co-founder, HAYA Therapeutics*

Samir focuses on a new area of drug development focused on the regulatory genome, previously known as "the Dark Genome." He was the first to publish how the regulatory genome controls key biological functions in the diseased heart – and identified a way to change it – leading to the formation of HAYA Therapeutics. Through HAYA, Samir has helped develop a platform to identify long non-coding RNAs (lncRNAs) that control the regulatory genome – "the software of the cell"– and thereby develop medicines capable of reprogramming sick cells into healthy ones.

## Jonathan Rigby

*CEO, Sernova Biotherapeutics*

At 18, Jonathan was diagnosed with Type 1 diabetes (T1D) after surviving a lifechanging episode of diabetic ketoacidosis. He used his frustration with the diagnosis as motivation to compete in triathlons and Ironman races to raise money for the T1D community – against his doctor's orders! – all while navigating a career as a biotech industry executive. He has founded, taken public, and sold four companies and has made meaningful contributions to the commercialization of five new treatments. In August 2024, Jonathan was appointed CEO at Sernova, where he now leads the advancement of a bio-hybrid organ, the insulin-producing Cell Pouch.

## Stella Vnook

*CEO, Likarda*

Stella joined Likarda in 2023 to oversee a rapid pivot and expansion into multiple areas after recognizing a broad list of applications for the company's Core Shell Spherification technology. From humble beginnings in Belarus, Stella arrived in the US as a teenager, and has now founded, led, and sat on the board of numerous biopharma companies. She is also a regular keynote speaker and Penn State University-based mentor.

## Claudia Zylberberg

*Board Chair and Co-Founder, Kosten Digital; Board Chair and Co-Founder, Arscience Biotherapeutics; Foundation Board Member, Alliance for mRNA Medicines*

Claudia innovates across the cell and gene therapy space, and throughout biopharma more broadly. Her latest endeavor is co-founding and launching Kosten Digital to leverage AI technologies that can optimize cell and gene therapy development and manufacturing. Other roles include CEO at Akron Bio, board member of Canada's Centre for Commercialization of Regenerative Medicine, Alliance of Regenerative Medicine (ARM) and the ARM Foundation, International Society for Cell & Gene Therapy, Standards Coordinating Body, Octomera, and Arscience Biotherapeutics (which she also co-founded).

# *Biopharma*

## Hesham A. Abdullah

*Senior Vice President and Global Head of Oncology Research and Development, GSK*

Hesham has more than 20 years of experience leading R&D teams at global pharmaceutical companies. He has led the development of 12 novel precision oncology therapies and currently leads a team of 300+ global researchers at GSK focusing on novel technologies and precision medicine to develop innovative cancer treatments. Using advanced technologies such as artificial intelligence, digital pathology, and tumor modelling, Hesham champions approaches that help facilitate the identification of modalities with a higher probability of success, with a focus on patient populations with significant unmet needs.

Credit: EPNAC.com

## Charlotte Allerton

*Head of Preclinical and Translational Sciences, Pfizer*

In nearly 30 years at Pfizer, Charlotte and her team have been instrumental in discovering and developing breakthrough treatments. She currently leads an R&D organization of 3,000+ team members, focused on advancing research in areas of critical unmet need. Charlotte's work has led to the approval of several key medicines, including Paxlovid to combat COVID-19; Litfulo for alopecia; Cibinqo for eczema; and Lorbrena for non-small cell lung cancer. She and her team have also significantly improved phase II success rates in drug development by leveraging molecular design and innovative clinical development paradigms.

## Jayasree K. Iyer

*CEO, Access to Medicine Foundation*

Jayasree first appeared on our Power List in 2016 as a managing director of the Access to Medicine Foundation (AMF). Today, she leads the organization by striving for health equity and justice. She developed the AMF into a research hub and influential organization that tracks industry progress in reaching people who need lifesaving medicines, as well as influences the policies and practices of companies and governments.

*"I do what I do because health equity is within our reach; it is in the hands of people who choose whether to act or not. We can save lives when people choose to integrate early access plans in drug development, push boundaries, and work with the right partners in the right way. It's about challenging organizations to not only do better, but to collaborate strategically and ensure innovations reach those who need them most."*

## Maik Jornitz

*Principal Consultant, BioProcess Resources LLC*

Maik says that his purpose has always been saving patients' lives, which encourages him to think outside of the box and always think about what is new and better for patients. A technical expert with over 35 years of experience, Maik's career spans Sartorius, G-CON, and numerous board member and advisory roles. He is a subject matter expert in sterilizing grade filtration, with over 100 scientific articles and books published on both facility design, and bioprocess-related issues. He has also served as a former Chair of the PDA board of directors and contributed to multiple PDA task forces.

## Beatrice "Bea" Lavery

*Vice President and Regulatory Strategy Senior Leader, Genentech, a member of the Roche Group*

Bea oversees Genentech/Roche's global regulatory development strategies and execution for the pharmaceutical portfolio across all disease areas and platforms. With Bachelors and Masters degrees from the University of Calgary, specializing in Microbiology and Infectious Disease research, Bea joined Genentech in 2001. She has held a number of leadership positions in regulatory affairs, including Global Head of Oncology Regulatory Affairs. In 2017, she was recognized as a "Rising Star" by the Healthcare Businesswomen's Association.

## Hanns-Christian Mahler

*CEO (Chief Enablement Officer) & Board Member, ten23 health*

After studying pharmacy at the University of Mainz and pursuing a PhD in toxicology, Hanns-Christian wanted to contribute in a more practical way to developing medicines, particularly injectable biologics. After his father passed away from lung cancer, he says that his motivation to develop medicines to treat serious diseases such as cancer "became unstoppable." He previously worked as head of pharmaceutical supplies and development at Roche, and led the Drug Product Services Business Unit at Lonza. He launched ten23 health in 2021 as a CDMO with a strong focus on sustainability.

## Kiran Mazumdar-Shaw

*Group Chairperson, Biocon Group*

Kiran has shattered glass ceilings at every stage of her career, leaving strong footprints in traditionally male-dominated environments. The first woman to become a brew master in India, Kiran used her knowledge of fermentation technologies to build a multi-billion-dollar company, Biocon, which has put the nation on the global biopharmaceuticals map. Her name in India is synonymous with the biotechnology industry and the success that women entrepreneurs can achieve.

*"I was driven with the purpose to harness the power of science to create meaningful benefits for society. I was inspired to work in drug development because I saw inequities in global healthcare as medicines were out of reach for those who needed them most. This was unacceptable to me."*

## Niven Narain

*President and CEO, BPGbio*

Niven has developed and championed an AI platform that integrates patient biology with causal AI to accelerate drug discovery. Having driven the development of over 100 drug candidates so far, Niven seeks to challenge traditional pharma approaches and emphasize a systems medicine framework to ensure biology-first AI applications are grounded in patient-centric data and comprehensive biological insights. Elsewhere, and in his capacity as a trusted advisor to NASA and the US Department of Defense, Niven remains an astute advocate for global health equity.

## John V. Oyler

*Co-Founder, Chairman, and CEO, BeiGene*

At BeiGene, John created a model in which internal teams run clinical trials, leveraging custom-built technologies to improve efficiency and the quality of execution.

Under John's leadership, more than 1.5 million patients have been treated with BeiGene's medicines, to date. Now in its fifteenth year, BeiGene will rename to BeOne Medicines and redomicile to Switzerland in 2025.

## Mike Rea

*CEO, IDEA Pharma*

IDEA Pharma's annual Pharmaceutical Innovation & Invention Indices records, tracks, and charts the ingenuity progress inherent in the industry to determine how companies establish value through their pipelines. Mike's 2024 index accurately predicted a huge power shift in favor of Novo Nordisk and its GLP-1 pipeline. He is also a Senior Fellow, FasterCures, at Milken Institute; an advisor at BioEthics International and OneHealth/FidoCure; and the owner and Chief Musical Officer of indie record label Medical Records. He can be found on the stage at many events throughout the year, or otherwise reading a book.

# Small Molecules



## Christine Allen

*Professor, University of Toronto; Co-founder and CEO, Intrepid Labs*

With a career spanning research and entrepreneurship, Christine's work has helped advance the development of new drug delivery systems, including nanotechnologies and novel formulations that enhance the performance of therapies. Her integration of machine learning and robotics into drug formulation design has enabled a data-driven approach that minimizes reliance on traditional trial-and-error methods. She is also a fellow of the Canadian Academy of Health Sciences with more than 170 publications and numerous patents.

## Jeremy Bender

*CEO, Day One Biopharmaceuticals*

Under Jeremy's leadership, Day One Biopharmaceuticals obtained its first FDA approval in April 2024. Ojemda (tovorafenib) is a targeted therapy for children living with pediatric low-grade glioma. Jeremy is committed to closing the innovation gap between adult and pediatric therapies by addressing the urgent unmet needs of people of all ages with cancer. His work at Day One aims to fundamentally shape the way pediatric diseases are studied and treated.

## Lawrence Blatt

*Chairman, President, and CEO, Aligos Therapeutics*

A veteran of the hepatology and virology space, Lawrence is a key and proven expert in both sectors. He has successfully progressed drugs from the bench to the market, and is on track to do so again with Aligos' portfolio of potential best-in-class drugs for liver and viral diseases. Many of his team members have been with him at multiple companies, including Janssen. He says that he aims to inspire those around him through the provision of the tools and mentorship that turn bold ideas into transformative technologies.

## Ann Cleves

*VP of Application Science, BioPharmics Division, Optibrium*

A 3D molecular design, predictive pharmacology, and lead discovery/optimization expert, Ann focuses on the challenges of complex macrocyclic ligand optimization, an increasingly important area of drug discovery because of the potential of macrocycles against previously "undruggable" targets. She has collaborated with many pharmaceutical and agrochemical organizations to improve 3D design.

*"A natural consequence of meeting with such seemingly diverse groups is that the groups learn each other's contributions to the project. In fact, those individuals who see the whole picture tend to matriculate to leadership positions. This has been a constant in my experience."*

## Lee Cronin

*Founder and CEO, Chemify; Regius Professor of Chemistry, University of Glasgow, UK*

Lee has published over 450 papers, given over 600 lectures, and written extensively on all aspects of science, including the origin of life. His goal is to revolutionize drug discovery through the combination of chemistry, robotics, and AI at scale – known as "chemputation" – to digitally design, discover, and make small molecules. With an interest in electronics and chemistry since childhood, Lee's work at the University of Glasgow on the digitization of chemistry has resulted in a new programming paradigm for matter and organic synthesis and discovery, which uses the world's first domain-specific and universal programming language for chemistry.

## Faye Feller

*Executive Vice President and Chief Medical Officer, Geron*

Faye says she is driven by her prior experience as an attending hematologist at Memorial Sloan Kettering Cancer Center, where she learned that less than 50 percent of patients characterized as having a lower-risk of progression respond to frontline therapies. Of those who do, most relapse within two years. Faye thus sought and seized opportunities to play a lead role in clinical development aimed at advancing new treatment options. As a result, Geron's Rytelo (imetelstat) was granted FDA approval in 2024 for the treatment of adult patients with transfusion-dependent anemia.

## Edward Hæggström

*CEO, Nanoform*

Edward worked with Jouko Yliruusi, a professor in pharmaceutical technology, at the University of Helsinki to develop a novel particle engineering technology, which led to the founding of Nanoform. The Controlled Expansion of Supercritical Solutions technology can create nanoformulations with higher drug loading, improved bioavailability, and better release profiles. Edward has previously held the role of visiting professor of physics at Harvard Medical School, visiting scholar (assistant professor) of physics at Stanford University and project leader at CERN.

## Kevin Kreutter

*Senior Vice President, Drug Discovery, Empress Therapeutics*

Kevin has over 20 years of experience in drug discovery, and was co-inventor of several clinical and developmental candidates, including safimaltib and lorpucitinib during his tenure at J&J/Janssen. He is interested in streamlining drug discovery by using AI to identify drug-like small molecules from genetic data. Under his leadership, Empress has discovered 15 promising drug leads in 24 months. Kevin also has over 30 patents and 20 publications in diverse therapeutic areas.

## Tara Rheault

*Chief Development Officer, Verona Pharma*

Tara has dedicated her career to advancing respiratory disease treatment after noting the lack of progress compared to other fields. Inspired by patients with respiratory conditions, her work led to the first FDA-approved novel inhaled COPD treatment in over 20 years in 2024. She first entered the industry as a PhD organic chemist, where she excelled at interpreting large data sets to solve scientific problems.

*"My advice to the next generation is to continue investigating known disease drivers in novel ways and persisting until curative therapies are uncovered, especially for chronic progressive diseases. The potential to have a large impact on patients' everyday health and wellbeing remains."*

## Ali Tavassoli

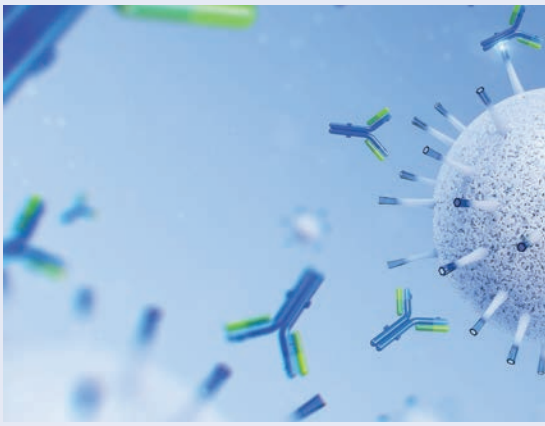
*CSO and Co-Founder, Curve Therapeutics; Professor of Chemical Biology, University of Southampton, UK*

Ali developed the technology behind Curve's microcycle discovery platform. His research focuses on developing screening platforms to discover protein-protein interaction inhibitors and converting cyclic peptide hits into new therapeutics. He was also President of the Royal Society of Chemistry's Chemistry and Biology Interface Division (2020-2023) and previously served as the Chair of the RSC's Chemical Biology and Bioorganic Group (2012-2015). He has won a number of awards, including the European Association for Chemical and Molecular Sciences' medal for European Young Chemist (2008), the RSC's Protein and Peptide Science Award (2017), and the European Peptide Society's Leonidas Zervas Award (2020).

# Building Better Biologics – While Being Sustainable

*Helping biopharma manufacturers to accelerate their time to market, with sustainable practices; here's how Ecolab is making a difference*

Hayley Crowe
Executive Vice President and General Manager
Ecolab Life Sciences



"Working in research, I felt that I was constantly on the cusp of a discovery, but often missing the right tools to optimize the job. I'd think, 'If only I had this instrument, or if only this tool could do that…'"

Hayley Crowe initially trained as a bench scientist and has years of experience in drug discovery research, including at Novartis and Pfizer. After shifting her career to innovation-based scientific solutions, product marketing and business development, she found a passion for developing tools that would help many companies to accelerate drug development.

Today, she is Executive Vice President and General Manager of Ecolab's Global Life Sciences sector. "Ecolab caught my interest because of its mission to protect what's vital, including both human and environmental health. This is not just a slogan on a wall, but something the company truly lives."

We caught up with Crowe to learn more about Ecolab and how it helps both patients and the planet through a focus on innovation in contamination and biomanufacturing, as well as its commitment to sustainability.

**How has Ecolab evolved to stay at the forefront of the life sciences industry?**

Ecolab has been around for over 100 years. Once you know the name you can never unsee it. One of our mottos is: we're everywhere it matters. You'll find us in places such as Marriott and Walmart, as well as in manufacturing plants and industrial facilities globally.

A key part of our approach has always been to have experts in the field working directly with customers. Our life sciences division started with critical contamination control solutions – ensuring pharmaceutical manufacturing environments were clean, contamination free, and compliant with strict regulations. Through acquisitions, we've expanded our capabilities. We acquired Bioquell, which specializes in environmental control, isolators, and sterilization units, across critical processes like sterility testing and brings us into emerging areas such as cell and gene therapy manufacturing. Our contamination control programs focus on reducing cleaning time through innovative automation technology. Bioquell's technology helps with efficient startup and shutdown processes, helping to ensure clean environments with minimal downtime.

More recently, we acquired Purolite, which provides purification resins, including protein A and ion exchange, using their patented Jetting technology – making them easier to manufacture, more efficient, and capable of producing higher yields in less time.

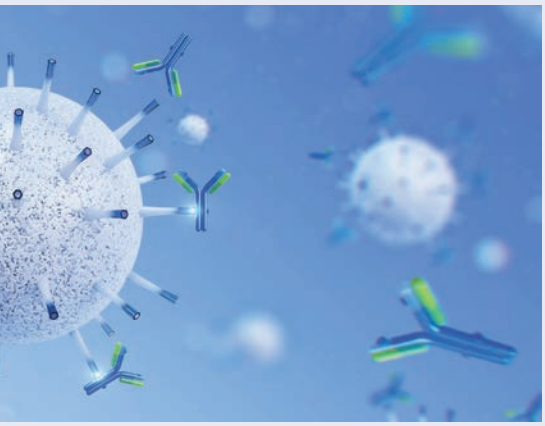
**Drug complexity and advanced modalities require specialized solutions. How is Ecolab different from competitors when it comes to new modalities, and what specific advances have you made?**

I'll break this into two sides.

On the drug complexity side, the growing diversity of drugs, from fragments to Fabs to ADCs, means there is no longer a one-size-fits-all approach to purification. One drug may purify beautifully with a specific feedstock and purification method, while another drug sees virtually no yield.

Ecolab has built a toolbox of resins that offer better yield and productivity, depending on the specific molecule and how it binds. We've also invested in a new and specialized bioprocessing applications lab based in King of Prussia, PA, so that our team can partner directly with customers to develop the best purification protocol for their specific molecule. Our scientists test different resins and conditions before making recommendations. We become an extension of our customers' development teams.

On the cell and gene therapy side, we're tackling



a different set of challenges. Bioquell's fully enclosed isolators allow for production inside a completely contained unit with automated decontamination, which is a game changer. Growing cells is a very delicate process. One contamination event – just one stray spore – and you've lost five weeks of work and incurred a lot of costs. I've been there in my own lab days, and it's painful.

Bioquell isolators keep everything ultra-clean and safe, minimizing contamination risks. We can also assist customers with recommendations when it comes to securing the environment around the unit too.

**What approaches has Ecolab implemented to decrease manufacturing costs associated with traditional biologics development?**

We focus on what we call "Total Value Delivered." Every time we introduce a new solution, we look at what customers are spending today, and how much water, waste, energy, and labor are involved.

From there, we calculate the potential savings and efficiency gains from implementing our solutions. We don't just analyze a single step in the process; we evaluate the total impact of a process change and package this into a Total Value Delivered report. For example: "This solution will save you 15 hours of production time, reduce water usage by 25 percent, and lower your overall costs by X percent." We also outline exactly how to achieve these results.

Purification is one of the most expensive steps in biomanufacturing, but with our Jetted resins and new ligand innovations, we can significantly reduce costs for our customers. As many customers are discovering, our chromatography solutions have the potential to significantly increase drug purity in a single step. Combined with improvements in productivity, this can impact the total cost of a drug, thereby expanding patient access and increasing manufacturer revenue.

Often, we start with a pilot to test a new approach and then adjust as needed. This tailored approach is where we excel. We're able to adjust and create solutions that fit each facility's unique needs. We have multiple manufacturing facilities ourselves, and we're constantly optimizing for efficiency, just like we do for our customers. This hands-on experience makes a huge difference.

**Digital technologies and AI are transforming industries everywhere. What is Ecolab doing in this space?**

Ecolab has been working in the digital space for over 30 years. Today, we have a full cloud platform with AI-enabled applications designed for specific markets. One of our latest innovations is CLEEN, which automates cleaning validation, logbooks, and batch manufacturing processes. Operators follow an automated checklist on a tablet, and the system generates a time-stamped batch release at the end that integrates directly into regulatory systems ready for auditing.

CLEEN is a system that can be configured very quickly for our customers. At a single plant, CLEEN saved 60 hours of QA time and eliminated 12,000 reams of paper, translating to improved efficiency, reduced costs, and significant sustainability benefits.

Of course, implementing digital solutions isn't just about technology; a cross-functional approach is required. You need buy-in from quality teams, plant heads, operations leaders, and digital teams. Change management is always a challenge, but once teams see the benefits in time savings of the system, momentum builds quickly.

Looking ahead, AI will take things further. I imagine a future where AI-driven agents provide real-time feedback and recommendations for process improvements. We are actively working in this area by partnering with Microsoft – bringing together world-class AI technology with Ecolab's deep expertise in applying solutions to manufacturing and life sciences. Look out for exciting things on the horizon!

**What are the key initiatives Ecolab has undertaken to promote environmental responsibility?**

Ecolab was one of the early contributors to the Water Coalition and continues to play a major role in shaping water conservation strategies. We actively measure water savings across the world – from both our customers and us – and there's a live tracker on our website. So far, we've saved a total of 827 billion gallons of water. We also measure savings in energy, waste and greenhouse gases.

These metrics show customers what's possible when they work with us. The pharma industry is on a sustainability journey, but companies are at different stages – and we can help. We have processes that involve a plant assessment, allowing us to analyze a given plant's sustainability metrics, and provide consultative guidance and practical steps to help build their sustainability roadmap.

We don't just hand over a report and walk away. We will be there every step of the way, working alongside teams in plants to implement real change. People often love ideas on paper, but do not know how to get from where they are now to where they want to be. That's where Ecolab's expertise and partnership have really made a difference over the last few years. We'll continue to play that role as new solutions emerge as part of our long term commitment to pharma.

ECOLAB

CELL AND GENE

# The Trump Effect on Cell and Gene: Science Versus Shockwaves

*Audrey Greenberg on FDA staffing cuts, Peter Marks' resignation, CDMO pressure, IP migration, AI acceleration, and what CGT needs now to stay on track*

With regulatory turmoil, NIH funding caps, AI strategy pivots, sweeping leadership resignations, and unprecedented restructuring across US healthcare agencies, the cell and gene therapy (CGT) sector finds itself in a pressure cooker. Audrey Greenberg, CEO of AG Capital Advisors and Founding Co-Host of the Advanced Therapies Think Tank, discusses how the industry can protect progress, and where we go from here.

**How would you describe the current environment for CGT in the US?**

This is a recalibration moment. The science is delivering, but the commercial model is straining. Cell and gene therapies are pushing medicine forward in ways that were unimaginable a decade ago. But the business challenges – scale-up, reimbursement, global regulatory fragmentation, and manufacturing complexity – are still significant.

What investors are watching now isn't just the science, it's the economics. Can we reduce the cost of goods? Can we streamline autologous manufacturing? Can we make in vivo delivery real? The capital markets want more than potential; they want predictability.

At the same time, global regulators are moving at different speeds, and access remains uneven. CGT still represents a once-in-a-generation shift in how we treat disease, but getting from innovation to impact now requires a very deliberate strategy.

**What impact could a second Trump administration have on the future of CGT?**

It depends which version shows up. The first Trump term saw deregulation, accelerated pathways, and pro-business rhetoric, but also volatility, agency churn, and science politicization.

For CGT, the risk isn't about red versus blue – it's about stability versus uncertainty. This field needs regulatory clarity, consistent leadership at agencies like the FDA and HHS, and investment in infrastructure and workforce. If we see renewed disruption – especially if leadership turnover slows progress at the Center for Biologics Evaluation and Research (CBER) or undermines trust in the approval process – it could set the field back.

That said, there's also an opportunity: a new administration could double down on American biomanufacturing, genomic innovation, and AI integration. But the

industry will need to advocate loudly and stay laser-focused on facts, outcomes, and patient impact – not headlines.

**What's happening at CBER, and what's at risk if that progress stalls?**

The resignation of Dr. Peter Marks is a huge loss for the field. He's been a tireless advocate for advanced therapies and a steady hand during moments of incredible scientific and political turbulence. His leadership helped drive forward platform-based regulatory models, accelerated review processes, and strengthened CBER's CGT infrastructure.

CBER made tremendous strides under Marks, who had led the center since 2016 and deeply understood the complexities of CGT. One of the most promising developments is the exploration of platform-based regulatory frameworks, which could allow modular approvals across similar products, reducing duplication and time to market.

Fortunately, strong internal leadership remains. Dr. Nicole Verdun, Director of the Office of Therapeutic Products, continues to bring deep hematology and regulatory expertise, with a focus on improving review efficiency and industry engagement. Her presence offers important continuity.

Still, the loss of Marks underscores how vulnerable scientific progress can be to political instability. It's a clear signal that the industry must double down on speaking with one voice, standing up for regulatory independence, and protecting the infrastructure and leadership that enable innovation.

If CBER loses momentum, whether due to budget constraints, political pressure, or internal turnover, that progress could evaporate.

**HHS has cut 10,000 jobs, including 3,500 at the FDA. How serious is this for CGT?**

Very serious. Even if direct drug reviewers are "protected", CGT depends on an ecosystem of regulatory support – everything from compliance and inspections to data infrastructure and project coordination.

With a therapy class this complex, delays in FDA meeting minutes, IND responses, or BLA reviews aren't just inconvenient – they're existential. Companies may face unpredictable timelines, and smaller biotechs in particular could suffer.

We need the FDA to be stronger, not leaner. Efficiency doesn't come from slashing staff – it comes from stable funding, clear mandates, and partnership with industry.

If there are regulatory slowdowns, CGT companies should plan for turbulence. Build buffers into timelines. Over-resource your regulatory teams. Engage early and often with the FDA, and make sure your CMC and clinical documentation is bulletproof.

Also, invest in policy literacy. The smartest companies right now are the ones mapping out how changes at the FDA, CMS, NIH, and even AI policy will impact development and commercialization two to three years out.

**There's been talk of CGT IP being developed in China and licensed to the US. Is this a real trend?**

Yes – and it's accelerating. Chinese companies, many with government subsidies, are developing CGT platforms that are now being licensed into the US. It's a reversal of the historic model, where US biotech was the IP engine for global markets.

I'm all for collaboration, but we need to protect American innovation. That means incentives for domestic R&D, manufacturing infrastructure, and fair trade practices. If we don't secure our ecosystem, we risk becoming a secondary market for therapies we should be leading.

**Are global regulatory standards diverging? What's the impact on CGT?**

There's growing divergence in how regulators handle CGT globally. The EU, UK, and Japan's agencies are experimenting with new frameworks. The US still leads, but if we don't modernize consistently, we risk becoming less competitive. Companies may start designing trials for faster-to-approve jurisdictions. That's a wake-up call: regulatory leadership isn't a given, it's earned.

**What does the CGT industry need to prioritize over the next 12-18 months to maintain investor confidence under the current administration?**

With the Trump administration back in office, we're seeing a return to pro-business rhetoric, agency reshuffling, and potential deregulation. For investors, that creates both tailwinds and turbulence. CGT companies need to stay focused on execution.

That starts with three things:

- Platform-first thinking – Investors are looking for scalable, repeatable technology, not one-time therapies that are hard to commercialize.
- Manufacturing transformation – The field needs to shift from bespoke processes to cost-efficient, scalable models – whether through automation, in vivo delivery, or allogeneic platforms.
- Reimbursement strategy – Demonstrating early payer engagement and economic value is now table stakes.

Beyond the boardroom, however, we need to unify as an industry. That means a coordinated message to policymakers around regulatory clarity, manufacturing incentives, and reimbursement innovation. It also means investing in workforce development because CGT doesn't scale without people trained to build and run these platforms.

Finally, we need to lead the narrative. CGT is delivering hope and cures. That message has to rise above the politics. The companies that do this well – those who balance scientific rigor with commercial realism – will continue to earn capital and drive impact.

BIOPROCESSING

# The Era of Antibody 2.0?

*We asked over 100 industry professionals for their views on the future of pharma: "Looking ahead to the next 5–10 years, what will be the key disruptors and/or what can be improved upon in the pharma industry?"*

Here's what two experts have to say about the future of antibody therapeutics.

Top: Sebastian Arana
Bottom: Jeng Her

Response from: Sebastian Arana, Head of Process Solutions, Merck

The key disruption in the pharma industry has been the rise of biologics and their increasing relevance compared to small molecules. The first generation were protein-based therapies like monoclonal antibodies, which have demonstrated their therapeutic potential in a variety (and growing list) of indications – from oncology to immunology and several rare diseases.

This wave created a variety of blockbuster molecules and gave rise to the bioprocessing industry, as therapeutic manufacturers were in need of purpose-built products to effectively manufacture these therapies. In particular, the emergence of single use as a technology fundamentally changed the manufacturing paradigm. The next wave of innovation created cell and gene therapies in the 2010s. During COVID, mRNA, another new modality, demonstrated its potential in the rapid design and production of vaccines.

Over the next 10 years, we will see this trend continue, rooted in deep pipeline funnels and sustained R&D spend and funding. mAbs will maintain the lion's share of the biologics market, but a variety of novel modalities will continue to grow, effectively complementing the treatment options for patients. From a manufacturing perspective, two trends will likely continue: (i) increasing adoption of intensified processing for a more robust, cost-effective way of producing mAbs without compromising on quality, and (ii) the establishment of new manufacturing templates that are needed to make novel modalities more broadly accessible.

Response from: Jeng Her, CEO, AP Biosciences

We've witnessed antibody-based therapeutics transform the treatment landscape for patients across autoimmune disease, infectious disease, and especially cancer. Monoclonal antibodies have drastically improved patient outcomes in oncology and become the backbone for a range of therapeutic strategies. Their ability to bind specific targets continues to offer near limitless applications across drug development.

We're now entering the "antibody 2.0" era, wherein the field has begun to overcome the initial limitations of antibody-based therapeutics, such as efficacy and resistance. We've seen the adoption of new strategies in the form of antibody-conjugates, which are quickly becoming the norm, and now bispecific antibodies are emerging as another breakthrough drug class. These drugs can function as a combination treatment in a single molecule, simultaneously reducing toxicities associated with multidrug regimens and decreasing the likelihood of resistance. The high specificity of bispecifics can be combined not only with ADCs, but an array of other treatment modalities to enhance on-target activity and reduce side effects. The incredible flexibility of this approach is already creating new therapeutic strategies and improving on existing approaches.

With the growing number of applications, I foresee a concurrent rise in investment and collaboration aimed at streamlining antibody design and manufacturing, enabling us to treat patients with safer, more potent therapeutics.

Want to read more views on the future of pharma? Check out: themedicinemaker.com/the-multifaceted-future-of-pharma

# Packaging for Biologics: Complexity with Flexibility

*Understanding the role of ready-to-use solutions and flexibility when it comes to primary packaging for biologics*

By Daniel Martinez, Head of Product Management DCS & Analytical Services, Stevanato Group

The biologics market is evolving rapidly, and so are expectations around drug delivery. Many new biologics are high-concentration formulations intended for subcutaneous injection, which introduce challenges around viscosity and delivery. At the same time, there is also growing preference from patients for at-home administration. Each of these trends adds pressure on primary packaging to perform reliably.

Choosing the right primary packaging for a biologic drug product can be a more complex task than expected. Biologics are inherently sensitive molecules and stability is paramount, from understanding leachables to potential container interactions – but that's just one piece of the puzzle. Packaging decisions must align with every stage of a product's lifecycle, including manufacturing constraints, fill-finish capabilities, injection route, patient experience, and regulatory compliance

There's no such thing as a one-size-fits-all solution. Drug developers must consider all aspects of their drug's needs – and keep in mind that these may change during development. Vials are typically used in preclinical or phase I development because they are easier to handle in the lab. As the product progresses, however, there tends to be greater adoption of more patient-friendly solutions, such as prefilled syringes or auto injectors. Smaller biotech firms might not have the infrastructure for syringes early on and may choose to stick with vials, but the ultimate goal should always be flexibility throughout development.

**Ready-to-use formats and flexibility**

With many different aspects to consider, packaging flexibility is a strategic imperative. At Stevanato Group, we strongly advocate for a platform-based approach that gives pharmaceutical companies flexibility across development and manufacturing. To this end, our ready-to-use (RTU) solutions are designed to provide container flexibility by allowing manufacturers to process multiple formats, including vials, syringes, or cartridges, using the same fill-finish line. This approach supports the transition from one container type to another as a drug evolves, while maintaining regulatory compliance and improving operational efficiency.

RTU solutions offer many advantages. The increasing stringency of regulatory guidelines – such as EU GMP Annex 1 – underscores the importance of minimizing contamination risks at every stage. RTU containers reduce human intervention by arriving prewashed, siliconized (if needed), and sterilized. This supports both compliance and operational efficiency, while also improving line uptime and product yield.

Even materials we often consider inert, such as glass, can interact with sensitive biologics under certain conditions. pH shifts, delamination, silicone particulates, and protein absorption are all real concerns. To address these concerns, we offer the EZ-fill® Platform, a fully integrated pre-sterilized containment solution for pharma companies' aseptic manufacturing.

In EZ-fill® syringe systems, Alba® represents the best-in-class solution for biologics. Alba® features an internal cross-linked silicone coating that preserves drug stability over time and de-risks the development of sensitive drugs.

We've also innovated around particulate reduction in collaboration with partners such as Gerresheimer. Our EZ-fill Smart® platform eliminates the Tyvek lid from traditional nest-and-tub formats, replacing it with a heat-sealed film. This significantly reduces particulate generation – by 90 percent in some tests – when opening the tub, addressing a known challenge with standard packaging.

Operationally, the benefits of RTU extend beyond compliance. With fewer line components – no washers or tunnels – manufacturers save on validation, water, and energy and by eliminating time-consuming steps like sterilization and washing, they achieve significant reductions in production time and costs.

**Ready for agility**

Faster changeovers and reduced downtime also allow for more agile production, with modern RTU lines able to operate at speeds comparable to traditional bulk lines, without compromising quality or throughput. Contract manufacturers, in particular, benefit from RTU's scalability. With a single flexible line, a CMO can support a diverse portfolio of clients and container types, improving scheduling, responsiveness, and further improving cost-effectiveness.

For companies with existing infrastructure, integrating RTU is still an option. Older fill-finish lines can often be retrofitted – by removing or bypassing washers and tunnels – to accommodate RTU containers. While these setups may not support multiple formats on the same line, they still offer the benefits of lower contamination risk, better compliance, and improved efficiency.

Ultimately, selecting primary packaging for a biologic product isn't just about the molecule. It's about the full context in which that drug will be used. Will it be injected at home or in a hospital? What's the viscosity at commercial concentration? Is the delivery device compatible with the container and the patient? All of these questions matter. That's why we pride ourselves on being "nosey" with our partners – asking the right questions early so we can help guide them toward the best packaging strategy for their drug, their process, and most importantly, their patient.

RTU isn't a silver bullet, but it offers a compelling way to simplify the complexity of biologics packaging. With the right approach, it can support stability, compliance, operational agility, and patient access to life-changing therapies.

Stevanato Group

Credit: AdobeStock.com

SMALL MOLECULE

# AMF's 2026 AMR Strategy, Revealed

*The new benchmark evaluates 26 companies across three core research areas: R&D, responsible manufacturing, and appropriate access and stewardship*

By Rob Coker

Drug-resistant infections could contribute to 8.22 million deaths annually by 2050. Recognizing the urgency of this issue, the Access to Medicine Foundation (AMF) has developed the 2026 AMR Benchmark, an analytical framework designed to track the contributions of pharmaceutical companies in keeping antimicrobial resistance (AMR) under control.

Since the WHO declared AMR a global threat in 2014, progress has been made in raising awareness and initiating preventive measures. However, challenges – particularly in low- and middle-income countries (LMICs) – persist. These regions bear the highest burden of AMR-related deaths (more than 80 percent). Without decisive action from pharma companies, the global burden of drug-resistant infections will continue to rise, with devastating health and economic consequences. The economic cost of inaction is projected to reduce global output by $1.7 trillion annually by 2050, making investment in AMR mitigation a necessary priority.

New antimicrobial treatments are needed, but big pharmaceutical investment in antibiotic innovation has declined, leaving smaller players to drive innovation with minimal support. The 2026 Benchmark evaluates the R&D pipeline of both large and SME pharmaceutical companies, focusing on their contributions to developing effective antibacterial and antifungal medicines and vaccines. Key updates include:

- A focus on the WHO's Priority Pathogen Lists for identifying urgent R&D needs.
- An assessment of innovation based on the WHO's innovation criteria, such as new targets, modes of action, and classes of antibiotics.
- Greater emphasis on companies' access and stewardship plans to ensure broad availability and appropriate use of newly developed drugs.
- A stronger pipeline for new antimicrobials, with SMEs leading development but facing significant financial and market challenges.
- New incentives and collaborations to sustain large pharma interest and innovation.

## Responsible manufacturing

Antibiotic waste released during pharmaceutical manufacturing contributes to environmental contamination, accelerating AMR development. To counteract this, the AMF calls on companies to adopt sustainable manufacturing practices that minimize environmental risks. The 2026 Benchmark evaluates:

- The implementation of waste management strategies at company-owned and supplier facilities.
- Compliance with discharge limits based on predicted no-effect concentrations for resistance selection.
- Transparency in reporting waste treatment practices and antibiotic discharge levels.
- Timely and publicly shared raw surveillance data.
- Enhanced expectations for standardized surveillance methodologies to improve data reliability.
- Transparency in monitoring resistance trends.

The Benchmark also assesses company efforts in expanding access to both on- and off-patent antimicrobials in LMICs, ensuring that critical medications are available where they are needed most. Updates for 2026 include integrated assessment of access and stewardship at the product level, new indicators tracking patient reach and the effectiveness of access strategies, and expanded registration of essential medicines, using collaborative mechanisms to streamline approvals.

With AMR now a high-priority issue on the global political agenda, pharmaceutical companies must align with international efforts, such as the United Nations' pledge to reduce AMR-associated deaths by 10 percent by 2030. While it will be interesting to see how the US withdrawal from the WHO will affect these targets, the 2026 AMR Benchmark serves as both a tool and a roadmap that aims to give pharmaceutical companies the skills and support to adopt best practices, and innovate responsibly.

# Streamlining Biologics from IND to Commercial Scale with Continuous Manufacturing

*Leveraging its data-driven, fully integrated design capability and continuous manufacturing technology platform (J.DESIGN), Just – Evotec Biologics aims to deliver the highest product quality and cost efficiency to its partners.*

By Nick Hutchinson, Associate Vice President, Business Development

At Just - Evotec Biologics, our goal is to help customers bring their antibodies and next-generation biologics to market faster, reliably, and with a more efficient process that will reduce production costs. A central component in this mission is our comprehensive J.DESIGN service, which integrates AI/ML-driven antibody selection and optimization, high-expression cell lines, and continuous manufacturing infrastructure to support every phase of biologics development – including design, optimization, and commercial production.

For example, at the earliest stages we can select and optimize antibody variants with favorable manufacturability profiles, which helps to smooth the path to process development. Our manufacturing platform – built on an intensified, continuous process and using our proprietary J.CHO™ High Expression System – is highly robust and allows us to bypass many aspects of traditional process development by confirming product fit rather than building a new process from scratch. Because this platform is highly productive, we can consistently generate more than enough material for first-in-human studies. However, our customers are also welcome to integrate their own cell line.

**Supporting greater efficiencies**

Integrating cell line development and process development has a huge impact on minimizing inefficiencies. By integrating development activities, we can initiate process development, formulation and analytical work even before cell line development is complete, shaving weeks – even months – off development timelines.

Another powerful advantage of our manufacturing platform is that scale-up is unnecessary. Unlike fed-batch processes that often require facility and equipment changes in late-phase or commercial production, our approach relies on running the same process for longer, or at slightly higher volumes. We typically move from a 500 L to a 1,000 L perfusion bioreactor and extend the production duration – without changing facilities, equipment, or operating teams. This continuity also streamlines the path to filing because data collected during early clinical manufacturing can support commercial submissions.

Perfusion technology supports higher product quality by minimizing residence time in the bioreactor, reducing the risk of enzymatic or chemical degradation. The continuous process maintains cell health and product stability throughout, making it particularly advantageous for complex or fragile molecules, such as bispecific antibodies. Downstream, material flows continuously through purification steps with minimal hold times, further preserving product integrity.

Continuous product collection through perfusion enables highly efficient downstream processing. Our multi-column protein A capture systems run a high number of cycles per campaign, significantly reducing resin consumption compared to the 5 or 10 cycles typical in fed-batch. This level of intensity applies across the downstream process, supporting both cost-efficiency and facility compactness.

**Integrated and de-risked approach**

Our regulatory affairs team will engage from day one to align development work with each client's investigational new drug (IND). We've filed our own INDs, including Modules 1 through 5, so we understand the full scope of regulatory expectations. Clients can lean on us for as much – or as little – support as they need. Some prefer a hands-on approach; others want us to act as their de facto regulatory department. The choice is yours.

Our J.POD® facilities were purpose-built for continuous biomanufacturing, and can support first-in-human and early phase clinical, late phase clinical, and commercial production. By controlling cell line development, process development, and manufacturing under one roof, we can detect and mitigate issues earlier. This tight integration minimizes risk and supports faster, more reliable development, with fewer handoffs, faster timelines, and a more seamless experience for partners. Competitors with less integrated approaches may only catch problems later, which can delay timelines and increase costs.

We have J.POD® facilities in both the US and Europe, allowing us to manufacture close to key markets and patient populations. However, we can also work with clients to integrate our platform into their own infrastructure. We provide design, intellectual property, and technical expertise to help clients achieve the same operational efficiency we see in our sites.

The future of biologics manufacturing isn't just faster; it's smarter, more connected, and built for agility at every stage.

www.just-evotecbiologics.com

Just EVOTEC BIOLOGICS


*"Being part of the cell and gene therapy field is an incredible privilege."*

# Maintaining Momentum

*Sitting Down With… Frank Mathias, CEO, Oxford Biomedica (OXB)*

**What drew you to the pharma industry?**
Like most children, I had many dreams, but I was influenced by my father, a pharmacist. I was fascinated by his ability to help sick people through the medicines he prepared. Watching him mix formulas in his pharmacy left a lasting impression on me.

Ultimately, I chose to study pharmacy. To be completely honest, the decision was partly practical – my university was just a few kilometers from home – but it's a choice I've never regretted. That early exposure to pharmacy shaped my path and sparked my passion for healthcare.

I've always been driven by the desire to do something meaningful for others. During the early 1980s, when I began studying in Paris, the field was witnessing groundbreaking advancements, such as the emergence of monoclonal antibodies and the rise of biopharma. I became fascinated by the biotech industry and how it was improving our understanding of diseases.

Pharmacy was, and still is, a beautiful profession. It allows you to directly help people who are very sick by providing the right therapies. But biotech, with its potential to not only improve lives but also cure diseases, captured my imagination. I'm deeply convinced of the value of this industry. It offers meaningful, rewarding work for highly qualified individuals, while driving life-changing innovations.

**Are there any career moments that stand out as particularly memorable?**
I've been fortunate to work with incredible leaders who shaped my understanding of leadership and business. I've experienced diverse cultures, and worked in companies of different sizes. One of the defining moments came early at the age of 32. I was entrusted with my first general management role at Servier, overseeing more than 250 people. At the time, I had no real idea what it meant to run a company – I was too young! But the trust placed in me, combined with the support I received, allowed me to grow into the role. The experience taught me the importance of leadership and the value of helping others to succeed.

Later, my time at Amgen in the US was equally formative. I gained valuable insights into leadership, storytelling, and the ability to inspire teams to tackle big challenges. Another pivotal experience was serving as Chairman of the German Biotech Association. Leading a group of general managers and CEOs from different companies required strong persuasion skills and collaborative leadership. These roles underscored for me that success ultimately comes down to people, passion, commitment, and willingness to work toward a common goal.

**How did you come to join OXB?**
I was approached by a headhunter. As I researched OXB, I became intrigued by its unique focus and expertise in cell and gene therapy. At the time, I was with another CDMO called Renschler Biopharma, where things were going exceptionally well. I hadn't planned to leave. However, the opportunity at OXB was so compelling that I decided to make the leap. I'm grateful to my previous employer, who graciously allowed me to exit my contract early to pursue this new challenge.

**What would you say are the greatest challenges of being a CEO?**
There are several challenges, but for me, the most significant is creating an environment where employees can thrive. I believe a CEO's primary role is to build a culture in which people are inspired to perform at their best, grow professionally, and have fun while doing so. The key is to bring together teams that share a vision and mission, enabling them to collaborate effectively.

Talent is irreplaceable, so I focus on hiring the best people – and being present, understanding their needs and supporting their efforts. Beyond that, a CEO must also balance the interests of various stakeholders, including employees, shareholders, clients, and the broader community.

At OXB, the biggest challenge we face is the complex transformation from a product development company to a CDMO. This requires entirely different skills, processes, and systems. Aligning all these elements while maintaining momentum is no small task.

**What are the most rewarding aspects of your role?**
Being part of the cell and gene therapy field is an incredible privilege. These therapies have the potential to cure life-threatening diseases, offering new hope to patients who previously had none. It's deeply rewarding to witness the progress being made in clinical programs and to hear directly from patients about how these therapies have transformed their lives.

On a personal level, I find great satisfaction in seeing my team succeed. Watching people implement a shared vision and grow into their roles is immensely fulfilling. At OXB, I feel proud to work alongside such a talented and passionate group of individuals.

**What industry trends are you keeping an eye on?**
The increasing number of FDA approvals is a strong signal that the cell and gene field is maturing. Another significant trend is the shift toward outsourcing, as companies increasingly rely on CDMOs for their specialized expertise and facilities. Additionally, there's growing interest in using multiple types of viral vectors, as no single vector can meet all therapeutic needs. This trend aligns well with our capabilities, as we work with a wide range of vectors.

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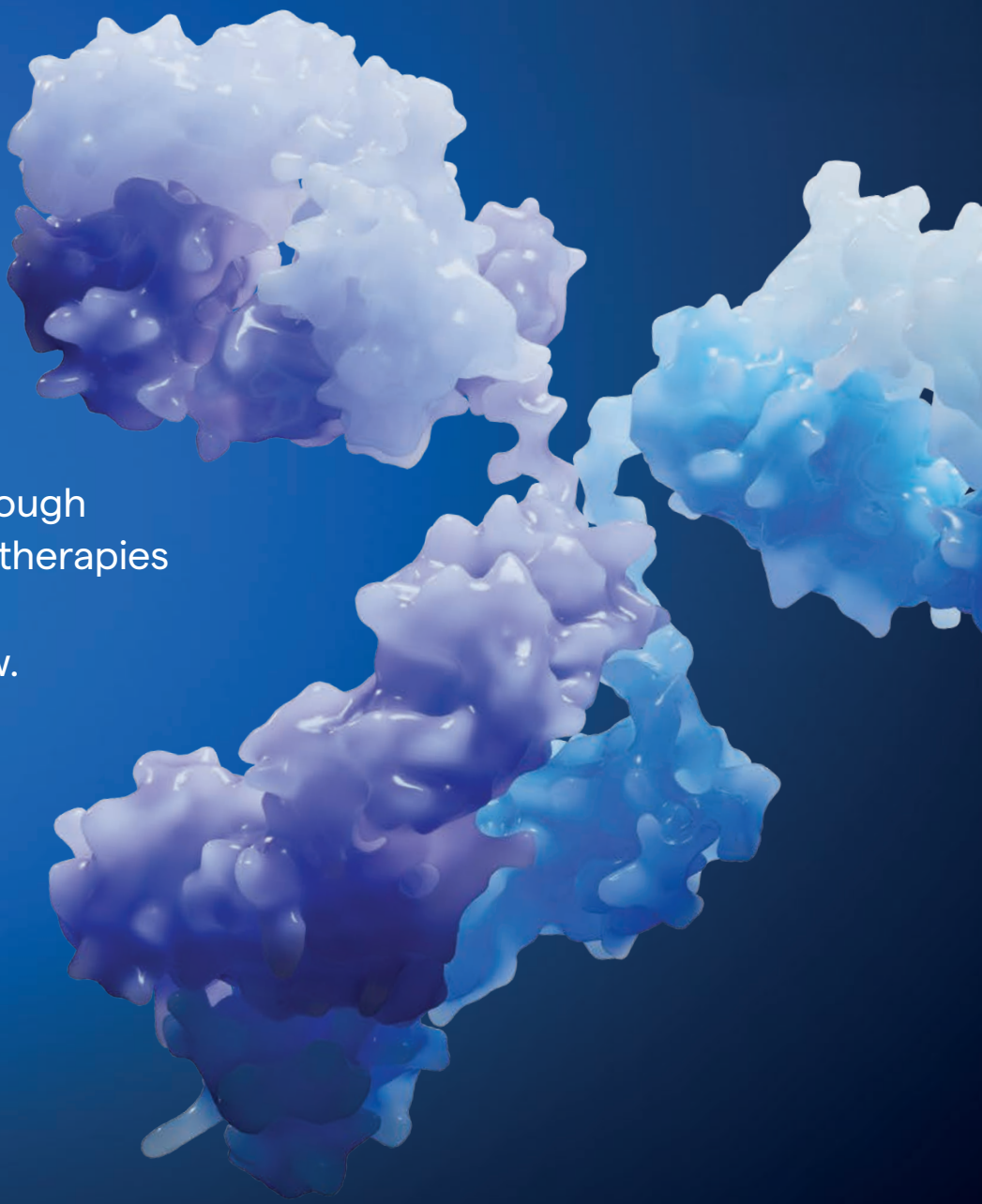

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