European Biotechnology

Summer 2025

(Bio)Engineering

SPECIAL

Higher and higher: labspace goes skyscraping

REAL ESTATE AND CAMPUS EXPANSION The EU Commission's call for evidence marks a positive step towards the proposed new European Biotech Act, signalling a significant prioritisation of the biotech sector in the EU. The direction of travel in the EU acknowledges the potential of biotechnology. In anticipation, the life sciences real estate sector grows – literally upwards.

Innovation patterns across key life sciences hubs can be seen from Boston's Center for Life Science to Europe. The US mentality to build up high in the sky pioneered also high-rise laboratory development at Kendall Square and in many other quarters in the life sciences hubs at the US east and west coast. The establishing principles now transform London's skyline through Euston Tower and One North Quay developments.

The European landscape reveals convergences with four innovation facilities across Limerick, Leeds, Leiden, and Harlow. The Biotech Campus Delft secures €500m for expansion. Meanwhile, Spain's emerging presence grows through Javier García Cogorro's SOKAI HUB España developments in San Sebastián (shown in photo), Madrid, and potentially Granada.

From Boston's pioneering verticality to San Sebastián's strategic positioning, these developments illustrate how global life sciences infrastructure responds to similar pressures whilst adapting to local contexts. Understanding these patterns provides essential intelligence for navigating an increasingly connected innovation landscape and makes the life sciences real estate an ever more attractive asset class for fund managers.

London's vertical development

Two significant tower projects are highlighting London's growing focus on high-rise laboratory space to meet increasing demand. British Land is seeking investment partners for Euston Tower's comprehensive redevelopment into a life sciences hub. The redeveloped tower will provide approximately 570,000 sq ft of commercial space, including 215,000 sq ft of lab-enabled and flexible workspace, after securing planning consent in March.

Construction has commenced on One North Quay at Canary Wharf, which will become Europe's tallest purpose-built commercial laboratory building. The 23-storey, 823,000 sq ft development is scheduled for completion in 2027 and will address London's shortage of level 2 wet laboratory space.

Canary Wharf now houses over 30 specialist life sciences tenants, reflecting the area's established cluster. Both developments demonstrate London's strategic approach to accommodating sector growth through vertical expansion rather than traditional campus models. This approach maximises prime urban locations whilst delivering the specialist infrastructure that London's growing life sciences sector requires.

Birdview of One North Quay at London´s Canary Wharf

Spain gains momentum

The life sciences real estate sector in Spain is gaining significant momentum, as evidenced by our latest newsletter featuring an above-average concentration of Spanish deals. SOKAI HUB España's launch stands out as a major development, with Quercus Investments and Columbus Venture Partners securing €100 million to develop life sciences facilities across Spain. Their flagship San Sebastian asset, requiring €80m investment, has already pre-leased 75% of its gross leasable area according to sources.

Other significant moves include i+Med's 4,300 sqm research centre opening in Vitoria, Colonial's €200m strategic investment in Deeplabs, and Euroespes' sale-and-leaseback in Galicia. Notably, the Basque country features prominently in two of these four deals.

More to come

There is more on the way, also in Germany. In Mainz – the hometown of mRNA pioneer BioNTech – a new laboratory quarter is being developed in collaboration with Kadans and other technology partners. But also in Berlin, Cologne and Leipzig, huge areas are under construction or in planning, albeit rather broadly. ■

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Bayer Berlin develops a life sciences campus

OPEN INNOVATION It all began with a view from the window of the 15th floor of Bayer's site in Berlin, reminiscent of Boston before it became one of the most important biotech hotspots in the world. This inspired the vision of developing the Bayer Campus into "Boston an der Spree" – a vibrant healthcare campus that fosters collaboration and innovation.

Bayer campus in Berlin-Wedding with a rendering of a future building

Picture: Bayer AG

Bayer is undergoing a major transformation of its research, production and administration site in Berlin. The goal: to create an internationally renowned life sciences campus that brings together diverse companies and ecosystem players. Through close partnerships with institutions such as Charité and the state of Berlin, the aim is to develop innovative therapies and digital healthcare solutions, making them available to patients more quickly.

Berlin Center for GCT

A central component of this transformation is the Berlin Center for Gene and Cell Therapies (BC-GCT), which is being established in a public-private partnership with Charité - Universitätsmedizin Berlin. The centre will offer a unique combination of infrastructure in Europe, including an incubator and a GMP-certified manufacturing facility. The aim is to accelerate the development of innovative cell and gene therapies and represents a significant step forward in the field of regenerative medicine, addressing critical healthcare needs.

The centre will serve as a beacon for research and development, attracting top talent and fostering a culture of innovation. It will provide essential resources for startups and established companies alike, helping them navigate the complex regulatory landscape for cell and gene therapies. By facilitating collaboration between academia and industry, the centre aims to accelerate the translation of scientific discoveries into clinical applications, ultimately benefiting patients who are in dire need of effective treatments.

Bayer Co.Lab Berlin

Launched in November 2024, Bayer Co.Lab Berlin is a key element of Bayer's external innovation strategy. As part of a pioneering global network of life science incubators – including Cambridge (US), Shanghai (China), Kobe (Japan) – Bayer Co.Lab connects entrepreneurs with world-class expertise, resources, and global networks. By identifying Europe's top scientists and entrepreneurs, Bayer Co.Lab Berlin supports early-stage life science companies bringing their brilliant ideas to life.

Startups remain independent through a no-strings-attached agreement while receiving invaluable mentoring from Bayer experts and industry leaders, along with access to state-of-the-art laboratory and office facilities. The community is designed to nurture entrepreneurial spirit and drive disruptive innovation.

Bayer Co.Lab focusses on breakthroughs in cutting-edge fields aligned to Bayer's global research strategies. Two companies are already part of the Berlin community. MyoPax, a clinic-ready startup specialising in stem cell and gene editing technologies to develop muscle regeneration therapies, is the first resident company and was recently awarded a prestigious European Innovation Council Accelerator grant. Captain T Cell, developing potentially best-in-class autolo-

gous and first-in-class allogeneic T cell therapies to fight cancer, is the latest addition to the community.

In the future, Bayer Co.Lab Berlin will co-locate with the BC-GCT to empower more startups, expand the offering, and cultivate a strong entrepreneurial community all under one roof. By creating a vibrant ecosystem, Bayer supports the next generation of healthcare innovators, transforming groundbreaking ideas into viable products and services that can significantly impact patient care.

The Supply Center Berlin

The Supply Center Berlin is Bayer's excellence centre for manufacturing of parenteral dosage forms. The GMP manufacturing facility enables supply of high-quality medicinal products to patients around the globe, whether it is an aseptically manufactured biotechnological or terminally sterilised small molecule product. Being fully embedded in the Berlin Campus, the Supply Center offers integrated cutting-edge manufacturing solutions for the Bayer portfolio as well as contract and development manufacturing services to external partners. Bayer experts support all stages of the product life cycle from clinical to commercial, including complementary services such as supply chain management, procurement, quality and beyond. For further information please send an email to info@bayer.com.

Strengthening Berlin and Bayer

The planned campus development is a clear commitment to Berlin as the global headquarters of Bayer's Pharmaceuticals Division. This initiative aims to create new jobs and foster a robust network of employees from various sectors within the healthcare ecosystem. Additionally, the project may have a positive influence on the local labour market, potentially contributing to the economic vitality of the Berlin region.

The development will include state-of-the-art facilities that meet the highest standards of research and production. By investing in cutting-edge technology and infrastructure, Bayer is positioning itself as a key player in the life sciences industry, ready to tackle the challenges of tomorrow's healthcare landscape. The site already offers rental options for chemical and biological laboratories of 300 square meters or more as well as office space of various sizes. For more information please contact info@bayer.com

Myopax introduces themselves to Kai Wegner, the Governing Mayor of Berlin, and Stefan Oelrich, President of Bayer Pharmaceuticals, at the Bayer Co.Lab Berlin Grand Opening in November 2024

Sustainable urban development

The Life Science Campus will not only promote research and development but also contribute positively to urban development. The campus will be partially open to the surrounding urban space, support the development of neighboring districts, and align with Bayer's commitment to sustainable development. Extensive green spaces and meeting zones will be designed to ensure a high quality of stay and contribute to the overall well-being of the community. Additionally, sustainable energy supply and mobility concepts are being planned to promote environmentally friendly transportation.

Integrating green infrastructure will improve the campus's aesthetic, air quality, and biodiversity. Bayer's commitment to sustainability extends beyond the campus itself, as the company aims to set an example for responsible corporate practices in the life sciences sector. By prioritising eco-friendly practices, Bayer is working to minimise its environmental footprint while maximising its positive impact on society.

A vision for the future

The Life Science Campus embodies a vision for the future of healthcare. By fostering collaboration among academic institutions, startups, established companies, policy makers and more, Bayer aims to create a dynamic environment for innovative ideas. This collaborative approach is vital to address the complex challenges faced by the healthcare industry today.

The campus will also serve as an educational hub, providing opportunities for professionals to enhance their skills and knowledge. By investing in human capital, Bayer is contributing to the growth of the entire healthcare ecosystem, ensuring a workforce ready to meet the demands of a rapidly evolving life sciences industry.

Bayer is committed to realising this vision, keeping Berlin at the forefront of the global life sciences landscape. By building a robust ecosystem that supports innovation and collaboration, Bayer is poised to make a lasting impact on the future of healthcare. ■

Picture: Bayer AG / Steffen Kugler

Scale-up facilities are crucial to success

ENGINEERING BIOLOGY Following the publication of recommendations for Engineering Biology in the UK from the House of Lords Science & Technology Committee, European Biotechnology Magazine spoke to Duncan Lugton, Head of Policy & Impact at the Institution of Chemical Engineers (IChemE), who submitted evidence to the committee, to find out more about the current landscape in the UK.

EuroBiotech_What were the primary motivations behind the £2bn investment in Engineering Biology announced in late 2023?

Lugton_*This investment was primarily driven by the UK Government's recognition of the field as a major opportunity for economic growth. This initiative aims to stimulate job creation, enhance industrial processes and support the transition to more sustainable practices. Additionally, the investment responds to recommendations from the House of Lords Science and Technology Committee, which included many of IChemE's recommendations. The report highlighted the need to improve access to scale-up infrastructure and to develop the skills necessary to support innovation in this rapidly evolving sector – something we believe is pivotal for the sector to thrive in the UK.*

EuroBiotech_What progress has been made since the announcement, and how is the current Government enacting the strategy?

Lugton_*Since the announcement, progress has been limited. Following its election in July last year, the Government has not specified its funding commitments in this area, with more detail only expected once the spending review process concludes in June 2025. While there has been positive rhetoric suggesting support for the strategy, detailed plans are still awaited. The UK Government has been working with the Engineering Biology Advisory Panel and others to understand how innovation infrastructure might be improved, but this has not yet fed through to action. The Government's Industrial Strategy is due to be published shortly, and we hope that some aspects of that can help support the sector, including funding but also the fundamentals including upskilling and reskilling our current workforce.*

EuroBiotech_How would you assess the UK's standing globally in engineering biology infrastructure?

Lugton_*The UK has broad and deep strengths in engineering biology – including a world-class academic base, strong existing infrastructure and a skilled workforce – but it also faces several challenges that impact its global standing. One of the key issues is limited access to scale-up facilities, which significantly hinders the ability to translate innovation into com-*

mercial success. This constraint contributes to a talent drain, as skilled professionals often move to countries like Belgium and the Netherlands, where better scale-up capacity exists – and they take their exciting new innovations with them. In comparison, economic heavyweights such as the United States and China offer attractive conditions for engineering biology, further highlighting the UK's relative lag in infrastructure.

While the UK remains a strong player in foundational research and innovation, its position is undermined by infrastructural gaps that affect both talent retention and commercial competitiveness.

EuroBiotech_What are IChemE's key recommendations to enhance the UK's competitiveness?

Lugton_*IChemE feels that focus on strengthening innovation, skills and collaboration can help the UK become more competitive. This includes improved access to scale-up infrastructure through Government-subsidised innovation centres, brokering of access deals and the development of new facilities in underserved regions. Prioritising the training of chemical engineers is essential, alongside adjusting the academic syllabus for our scientists and engineers to include entrepreneurial skills. In addition, tax relief measures to support startups and a shift in the emphasis of Government research funding towards applied research could help.*

Finally, we emphasise the importance of promoting stronger industry-academia collaboration through exchanges, mentoring initiatives and the creation of communities of practice - making sure that engineers have the business and communication acumen can help bring innovations to market.

EuroBiotech_How has IChemE communicated with the Government and influenced policy?

Lugton_*We have a unique role as a Professional Engineering Institution, and we have served as a bridge between science, industry, and Government, for instance through submitting evidence to the House of Lords' inquiry. In addition, IChemE supports its members through networks, events, mentorship programs, and training resources that further contribute to its policy engagement and influence.*

DUNCAN LUGTON is Head of Policy & Impact at IChemE. He helps take the insights, skills and wisdom of chemical engineers and applies them to some of the biggest problems facing the world today. This includes producing materials and input to help policymakers make better decisions.

EuroBiotech_What steps are critical for commercialising sustainable tech (e.g., HutanBio's algae biodiesel)?

Lugton_*Several factors are crucial for this. First, access to scale-up facilities is essential to move innovations from lab to market. Collaboration with industry partners helps ensure that the technology meets real-world demands and has a clear path to adoption. Entrepreneurial training equips innovators with the skills needed to navigate commercial landscapes, while applied research ensures that practical challenges can be overcome and that technical development and refinement happens at pace. Timely funding from both Government and private sectors plays a key role in bridging the gap between innovation and implementation. Finally, mentorship and strong academic-industry connections provide invaluable*

Picture: IChemE

guidance and networks that can accelerate successful commercialisation.

EuroBiotech_Based on international models, what should the UK adopt, and what are its unique strengths?

Lugton_*Fostering stronger integration between industry and academia (such as placement or exchange schemes), would be a good place to start. The UK should also prioritise developing a robust scale-up infrastructure that allows it to retain new innovations at risk of being lost to neighbouring European countries such as Belgium, the Netherlands, as well as the US. The Fraunhofer model is one that we think is particularly worth learning from in this area. At the same time, the UK benefits from unique strengths such as its world-class science base, well-established organisations, an emerging bioeconomy strategy and significant public policy focus. The previous Government committed to invest £2 billion in this area and it would be welcome if the current Government follows through on this in the forthcoming Industrial Strategy.*

EuroBiotech_Which countries are serious competitors to the UK?

Lugton_*Serious competitors to the UK include the United States, China, Belgium and the Netherlands. These countries are specifically mentioned because the UK has seen its talent and promising innovations move to these countries, given their attractive environments for scale-ups.*

EuroBiotech_What are the next steps and principal challenges for UK scale-up efforts?

Lugton_*The UK needs to make the most of the Industrial Strategy to put in place the infrastructure needed to support innovation, and to develop a robust plan to ensure that the country has the workforce needed to deliver it. More specifically, we look forward to the Government developing and implementing its plans in response to the House of Lords inquiry on engineering biology. The principal challenges include talent retention, bridging the gap between academic and commercial cultures, improving accessibility to infrastructure, increasing funding for applied research and addressing the limited commercial acumen among scientists.* ■

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Engineering biology

Engineering Biology or Synthetic Biology is the application of engineering principles to biology. It involves designing, building, and modifying biological systems – such as cells, enzymes, or genetic circuits – to perform specific tasks or produce useful products, like medicines, biofuels, or materials. Not all bioeconomy strategies place as much emphasis on engineering biology as the British approach. The EU's current bioeconomy strategy has largely focused on enzymatic and microbial conversion of biomass from agricultural, forestry, and industrial waste streams, rather than on the photosynthetic fixation of excess atmospheric CO_2eq. A strong example of engineering biology in action comes from HutanBio Ltd, a spin-out from Cambridge University, UK. In May, the British/Malaysian start-up announced that the production process for its proprietary HBx microalgal biofuel achieved net-negative carbon emissions. According to independent Life Cycle Analyses (LCAs), HutanBio's salt-water microalgal closed bioreactor system removed up to 1.48 tonnes of CO_2eq per tonne of biofuel produced across all three planned production sites: Morocco, the Middle East, and Western Australia. The LCA addressed all production stages – including raw material inputs, inbound transport, production and refinery processes, and waste handling. ■

It is time to rethink biotech scaling

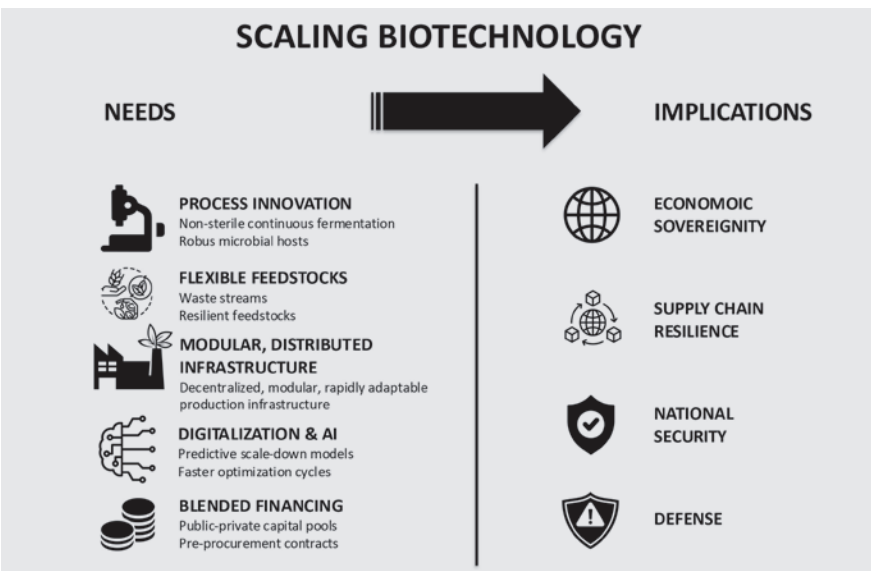
DEEPTECH BIOECONOMY Biomanufacturing promises domestic, sustainable, sovereign and resilient production. Capacities are trapped in outdated scale-up processes. SPRIND urges investment and disruptive innovation to propel biomanufacturing. Demands are decentralised, non-sterile & continuous biomanufacturing capabilities.

› Dr Nicolas Krink, Senior Business & Research Analyst, German Federal Agency for Breakthrough Innovation SPRIND, Berlin, Germany

Biotechnology, empowered through advanced synthetic biology tools, has matured. And yet today's capacity remains trapped in outdated scale-up processes. It still follows fine-chemical paradigms: sterile, low-volume, high-value production, locked into single feedstocks and products, with non-production chassis. This model fails to meet bulk industrial needs long promised but not yet delivered.

Pharma logic limits biotech

Fermentation processes require a rethink. Incremental innovations have sufficed for pharma but not for large-scale industrial biomanufacturing. The future lies in robust non-sterile fermentation, Needs and Impacts of biotech scaling robust hosts, and continuous fermentation processes. Scaled biomanufacturing must be feedstock-flexible, resilient, and incorporate scale-down models to better predict large-scale outcomes. The only certainty ahead for markets and manufacturing is unpredictability. Bioprocesses must be designed with industrial end-use in mind to avoid the infamous 'valley of death' so many are unable to bridge. Digitalisation and AI can dramatically accelerate optimisation. Most challenges are engineering, not scientific; they can be solved in years, not decades. Sustainability is just one benefit; sovereignty and resilience are now paramount. In a shifting geopolitical landscape, domestic supply chains and production independence are critical for national security.



Needs and Impacts of scaling biotechnology

Security and sovereignty

Decentralised, modular, rapidly adaptable production infrastructure will strengthen resilience against pandemics, trade conflicts, and geopolitical shocks. SPRIND's deep-tech bioeconomy strategy (*www.sprind.org/en/words/magazine/position-bioeconomy*) calls for targeted scaling infrastructure. Biotech, green chemistry, and traditional chemical engineering must converge to create integrated, hybrid value chains built for resilience. Regulatory frameworks must evolve. Genetic engineering should be treated as a tool for chemical manufacturing, not subjected to pharma regulations. Industrial biotech represents the next phase of the chemical industry and needs streamlined approval, flexible hybrid processes, and differentiated risk assessments. Rapid, unbureaucratic public funding, venture capital, tax incentives are required. SPRIND uses its procurement driven tools to unlock economic potential, exemplified by the Curricular Biomanufacturing Challenge. One initiative is not sufficient to drive change. Many more such initiatives are urgently needed to tackle the real challenges in biomanufacturing. Investments in biotech scaling are investments in future security, economic independence, and technological sovereignty. ■

Unlocking *Pichia* for industry

Pichia pastoris (syn. Komagataella phaffii), a methylotrophic yeast, is a proven platform for pharmaceutical protein production. However, its potential reaches far beyond. As a reliable, scalable, and cost-efficient platform for recombinant protein expression, *Pichia* is equally suited for industrial enzymes, food & feed, diagnostics, and biomaterials.

Key advantages include secretion of target proteins into the culture medium, and compatibility with chemically defined media. These streamline downstream processing and enable cost-effective scale-up. *Pichia* also supports efficient folding and disulfide bond formation, making it suitable for more complex proteins.

Tailored Expression Strategies

While *Pichia pastoris* offers a strong foundation as an expression host, its true potential is realised through advanced engineering. VALIDOGEN's proprietary UNLOCK PICHIA® system is one of the most flexible and powerful Pichia platforms available, designed to overcome expression bottlenecks across diverse applications. Importantly, its support for both methanol-based and methanol-free processes adds flexibility for varied safety and regulatory needs.

Picture: © VALIDOGEN

Their molecular toolbox includes a novel library of strong promoters (methanol-induced and methanol-free), synthetic secretion signals, native co-expression factors, and host strains optimised for robust performance. These modular components can be systematically combined and screened using high-throughput workflows to identify the best-performing expression strategies for each target protein.

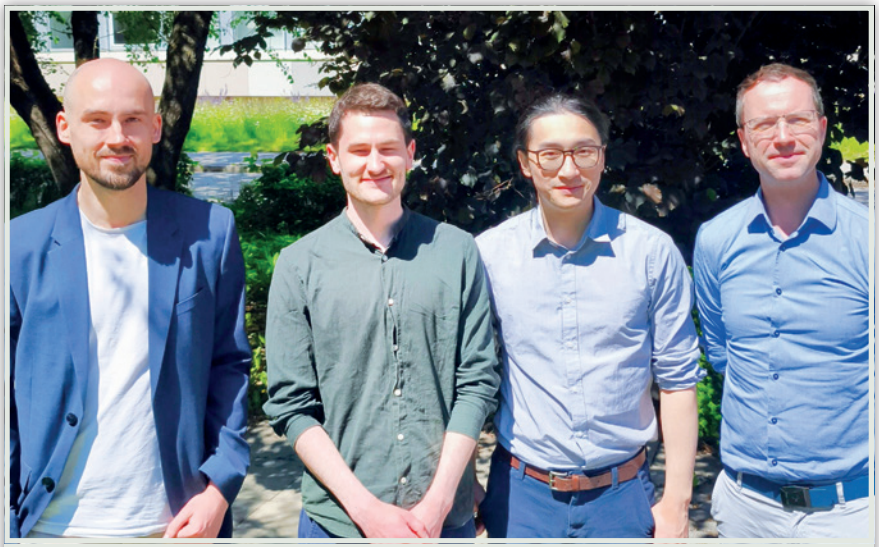
UNLOCK PICHIA® in Practice

By combining rational design with process-level optimisation, VALIDOGEN transforms *Pichia pastoris* into a precision tool for recombinant protein production. Proven scalability to industrial volumes of up to 100,000 L underscores its readiness for commercial deployment. In an era demanding sustainability and efficiency *Pichia* offers a robust and scalable solution across industrial biotechnology. ■

Rosie Maddock, PhD, VALIDOGEN GmbH

Programmable next-gen gene editor delivery

GENE EDITING DELIVERY A Munich-based team located at Helmholtz Munich and the Technical University of Munich recently introduced ENVLPE, a platform designed for efficient, safe, and versatile delivery of virtually all CRISPR-based therapeutics for somatic gene therapies. European Biotechnology spoke with Dong-Jiunn Jeffery Truong, lead inventor of ENVLPE, to discuss how this innovative approach is setting a new benchmark for gene editor delivery.



Dong-Jiunn Jeffery Truong (3rd from left) is currently a group leader at the Institute for Synthetic Biomedicine, headed by Prof. Gil Gregor Westmeyer (right), located in Helmholtz Munich. Together with Julian Geilenkeuser (left) and Niklas Armbrust (2nd from left), they are actively pursuing opportunities to advance their technologies towards practical application and commercialisation.

EuroBiotech_What exactly is ENVLPE, and how does it compare to existing gene delivery platforms?

Dr Truong_*ENVLPE is a novel, highly modular delivery platform based on virus-like particles (VLPs) derived and engineered from HIV-1. It inherits all the key strengths of lentiviral vectors, notably highly efficient delivery and proven low immunogenicity, without the drawbacks of integrating the genetic payload randomly into the genome, which poses a risk for insertional mutagenesis.*

Lipid nanoparticles (LNPs), which excel in mRNA delivery, such as in vaccine applications, and liver targeting, remain limited in their ability to deliver ribonucleoproteins (RNPs) and suffer from poor programmability of tissue tropisms. Although we previously contributed to developing the first AAV-based split-Cas9 system, recognising that while adeno-associated viruses (AAVs) are excellent for long-term expression of intact gene copies, we realised that they are not optimal for gene editing due to prolonged expression increasing immunogenicity risks and reducing editing precision with increased off-targets.

ENVLPE addresses these challenges effectively, offering a transient, precise delivery with a modular "hit-and-run" capability, i.e., the cell receives a load of pre-assembled gene editors (hit) and after having performed their job, they disappear quickly due to the cell's natural protein turnover (run). By quickly changing ENVLPE's surface proteins as easily as plug-and-play, we can reprogramme its tissue tropism without re-engineering the entire system or payload. For example, our recent study in Cell successfully demonstrated selective targeting and prime editing of the mutated Rpe65 gene in retinal pigment epithelium (RPE) cells in mouse models of retinitis pigmentosa.

EuroBiotech_CRISPR pioneers like David R. Liu, Jennifer Doudna, and Feng Zhang have also developed virus-like particles (eVLPs, EDVs, PNPs), with companies securing significant funding. What specific technological advantages does ENVLPE offer compared to these technologies?

Dr Truong_*Virus-like particles themselves aren't new, but previous implementations have struggled with efficiently delivering advanced, potent, yet unstable gene editors like prime editors. Any modification to the gene editor typically necessitates complete re-*

Picture: © Helmholtz Munich

optimisation of packaging components, creating significant development bottlenecks.

ENVLPE resolves these issues through its highly modular design by packaging gene editors via non-covalent interaction as opposed to protein-fusion design from other systems that strictly rely on release by viral proteases, encompassing cargo protection modules and logistical packaging improvements. Our approach delivers significantly higher editing efficiencies per particle in diverse in vitro and in vivo models, surpassing current leading platforms such as nChromaBio by more than 10-fold in in vivo settings. This means we achieve superior clinical outcomes with drastically reduced particle titers, minimising required dosages and optimising therapeutic efficacy.

EuroBiotech_What are your next steps to bring your technology closer to translation? What are your next steps towards commercialisation?

Dr Truong_*Having successfully established the core ENVLPE architecture, we will next expand our capabilities by building a comprehensive library of glycoproteins, including engineered variants, using traditional protein engineering and AI-assisted minibinder designs, enabling us to achieve selective targeting of various cell types relevant to therapeutic applications.*

We are currently also integrating ENVLPE with our other complementary proprietary technologies to enhance efficient CAR expression cassette knock-ins. Leveraging our immunogene-free selection method that couples CAR integration with cell survival upon exposure to an otherwise lethal compound without using additional foreign selection markers, we can produce highly enriched and pure engineered CAR-T cell populations with uniform CAR expression. We actively seek partnerships with developers working on novel CARs or synthetic TCRs for high-value therapeutic indications who can benefit significantly from our delivery, knock-in, and selection technologies without relying on lentiviral random integrations.

Scaling is usually a major hurdle, but ENVLPE's full compatibility with established industrial lentiviral vector manufacturing simplifies this challenge. We are currently exploring collaborations with partners with experience in lentiviral vector production to accelerate the scale-up and GMP-grade manufacturing processes.

Additionally, we are actively pursuing translational grants and industry partnerships to drive ENVLPE towards clinical application and commercialisation, ensuring that our gene editor delivery platform can rapidly benefit patients. ■

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Ensuring flexibility and resilience

SUPPLY CHAIN In today's rapidly evolving world, adapting to demand volatilities while ensuring uninterrupted supply of biological medicines is more critical than ever. At Boehringer Ingelheim, our global biopharmaceutical network delivers flexibility, resilience, and reliability. By leveraging harmonised procedures, standardised setups, and innovative logistics, we ensure the biologics we produce reach those in need – even during unexpected challenges.

› Dr. Rebekka Wuester, Communication Lead BioXcellence, Biopharmaceutical Contract Manufacturing Business, Boehringer Ingelheim Biopharmaceuticals GmbH

Boehringer Ingelheim BioXcellence™ operates large-scale cell culture facilities strategically located in the United States and Europe (Austria and Germany). This global footprint provides robust and reliable solutions to meet the evolving needs of the biopharmaceutical industry.

Strength of our global network

Our European facilities in Biberach, Germany and Vienna, Austria feature similar technical setups, ensuring positive technical comparability and thus consistent product quality. This harmonisation is key to maintaining the highest standards across our network. Even slight differences between our U.S. facility in Fremont, California, and the European sites – such as stirrer or sparger configurations – are seamlessly managed thanks to our experience and operational excellence. This expertise in the network allows us to predict and address potential variations, ensuring smooth process transfers both for client-specific processes into our network and in case an additional supply node is requested by our customers also within our network.

Figure 1: Our four large-scale cell culture facilities feature 28 bioreactors, each with a capacity of 15,000 liters, distributed across the United States and Europe.

One key idea is to develop robust and easily transferable production processes for large-scale manufacturing. This approach might offer the option to skip engineering runs, enabling us to immediately proceed with process performance qualification (PPQ) runs after completing small-scale runs, *in vitro* comparability studies, gap and risk assessments, as well as simulations and modeling.

By streamlining the manufacturing process, this method could save valuable time and resources. Not only does this approach enhance flexibility in supply for our customers, but it also accelerates the delivery of critical medicines to patients in need. This idea of 'portable' production processes exemplifies our commitment to innovation and efficiency.

Standardisation drives flexibility

Whether responding to demand fluctuations or timeline variability, our global manufacturing network setup enables interchangeability and a reliable supply without compromising quality. This consistency is achieved by a high level of process standardisation, thorough planning and execution, ensuring that every product meets the highest standards, regardless of the manufacturing site.

To further strengthen operational resilience for our customers, we offer access to our cryovessel pool and our newly

established Global Vessel Management Center – developed in collaboration with a trusted logistics partner to deliver seamless, reliable, and expert solutions. Designed for technical excellence, the Global Vessel Management Center offers validated cleaning processes, secure storage conditions, and comprehensive maintenance programs to support operational efficiency and regulatory adherence.

Resilience amid uncertainty

The COVID-19 pandemic and ongoing geopolitical uncertainties have underscored the importance of robust supply chains. That is why we have implemented a comprehensive Business Continuity Management (BCM) system designed to anticipate and mitigate risks, ensuring that our operations remain reliable under any circumstances.

Key pillars of our BCM framework

Our business continuity management framework is built on three dimensions.

1. Enhancing production continuity for patient supplies: Our commitment to business continuity ensures uninterrupted operations, allowing us to reliably meet our customer's needs and deliver on time, even in the face of unexpected challenges.

2. Managing contractual obligations: Customer requirements for BCM systems are integrated into our contracts, and regular audits ensure the effectiveness of our measures. This proactive approach builds trust and accountability with our partners.

3. Maintaining customer trust: Reliable delivery is essential to preserving our reputation and relationships with clients. Our BCM system mitigates the risk of disruptions that could impact trust, ensuring that our partners can rely on us.

Advantages for our customers

Our global biopharmaceutical manufacturing network offers several key benefits that make Boehringer Ingelheim BioXcellence™ the partner of choice for large-scale cell culture contract manufacturing.

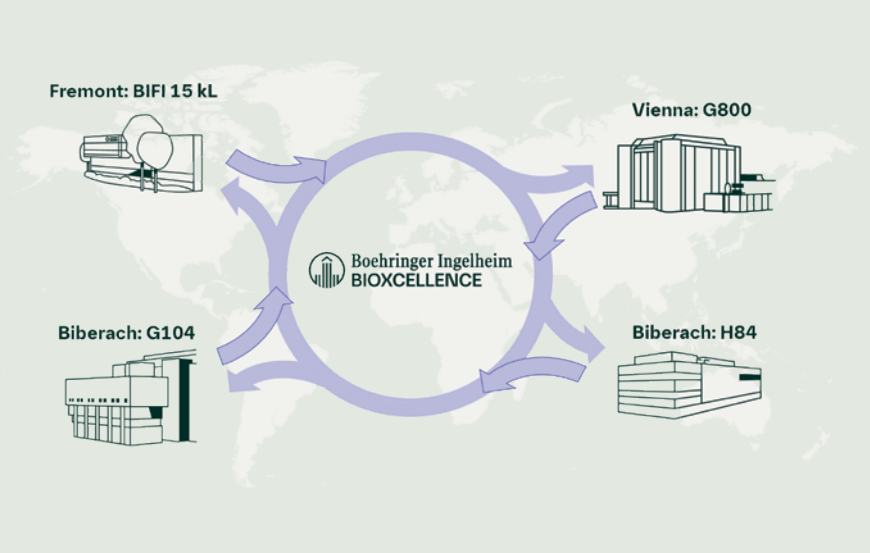

Figure 2: The standardised setup of bioreactors and harmonised procedures across our large-scale cell culture facilities offer interchangeability, providing high flexibility and reliable supply security for our partners.

First, our network ensures resilient supply chains, even in times of geopolitical uncertainty. By leveraging our distributed facilities, we minimise risks and maintain a reliable delivery of critical medicines. This capability is particularly valuable for customers seeking stability and consistency in their supply strategies.

Second, we offer enhanced flexibility in responding to demand volatilities. With multiple sites registered for production, we can shift manufacturing runs between facilities to align with clients' supply strategies. This adaptability allows us to meet changing market demands while maintaining high standards of quality and efficiency.

Third, our streamlined oversight processes reduce the complexity for clients. Customers with multiple sourcing supply security strategies can combine in-house production capabilities with various sites at one contract manufacturing organisation (CMO). This approach simplifies oversight efforts, allowing customers to focus on their core operations while trusting us to manage the complexities of manufacturing and logistics.

Finally, our harmonised setups and standardised processes ensure consistent product quality across all sites. Customers can trust that their products will meet the highest standards, regardless of where they are manufactured within our network.

Many of our customers have established their products at more than one site within our network, enabling us to discuss and adopt production schedules and jointly optimise supply strategies. This flexibility is a critical advantage in today's dynamic market environment. By working closely with our partners, it is our ambition that their needs are met with precision and care, fostering long-term relationships built on trust and reliability.

At Boehringer Ingelheim BioXcellence™, we're committed to leveraging our global biopharmaceutical manufacturing network to its fullest potential. By combining harmonised procedures, logistics systems, and business continuity management, we deliver for our partners and patients.

As the world continues to face challenges, our large-scale mammalian cell culture production network stands as a testament to the power of collaboration, innovation, and operational excellence. ■