

European Biotechnology

Autumn 2026



CROs & CDMOs

SPECIAL



Europe rethinks the CRO-CDMO model

OUTSOURCING Should a biotech hand its molecule to a single integrated partner, or build a network of specialists around it? Manufacturers and clinical providers are answering in both directions at once: some are adding capabilities and integrating more of the development chain, while others are narrowing their focus and relying on specialist partners. Whichever it picks, the biotech answers for what happens between its suppliers.

A drug application is judged on the medicine and, separately, on the manufacturing site that makes it. Xspray Pharma learned that the hard way when it signed a manufacturing and supply agreement with NerPharMa in December 2017. The Milan contractor would make both the drug substance and finished product for HyNap-Dasa, a reformulated version of the leukemia drug dasatinib, from clinical supply through to worldwide commercial sale. The Swedish company Xspray Pharma aimed to launch in the United States in 2021.

Nine years on, the product is still not on the market. The U.S. Food and Drug Administration (FDA) turned the application down in 2023 over dosing information and again in 2024 over label comprehension and concerns at the contract manufacturer's site.

In October 2025, the FDA issued another complete response letter, this time citing good manufacturing practice observations at the contractor's site. Xspray said none of the observations concerned the production line used for its product. "It is unfortunate that manufacturing-related issues beyond our control are delaying our launch," then chief executive Per Andersson said. On Aug. 19, 2026, Xspray disclosed that the FDA had rejected the application again. The agency pointed to unresolved observations at NerPharMa and requested data from additional consecutive commercial-scale batches. Xspray says responsibility for closing them now rests with the site's new owner, the Benta Group.

Despite those setbacks, Xspray says the FDA has raised no questions about the drug's clinical data, bioequivalence or stability. What it does not control is the factory. Few biotechs do. They own a molecule, a data package and a set of contracts, but whether the drug reaches the market can depend on how well those external partners perform.

Clinical trials stop for the same reason. In January 2025, the FDA placed Atara Biotherapeutics' active investigational new drug applications on clinical hold after a pre-license inspection found GMP compliance failures at one of the company's third-party manufacturing sites. The impact extended beyond products made there directly. One affected program used drug product manufactured at a separate, compliant facility, but its starting material came from the site cited by the FDA. The holds were lifted in May.

The problem is not outsourcing itself. It is that regulatory responsibility cannot be outsourced with it. Sponsors remain accountable for the quality and reliability of their manufacturing network even when they do not own the facilities, employ the operators or control how quickly deficiencies are corrected. Xspray's experience shows how that dependence can delay a launch; Atara's shows that the same risk can reach further upstream and stop clinical development altogether. That dependence has also changed in nature: sponsors are no longer outsourcing capacity alone.



Why outsourcing became strategic

What sponsors buy through those contracts has changed. Outsourcing began as a way to get capacity more cheaply than building it. Today, increasingly, it is a way to access capabilities that a biotech cannot realistically maintain under one roof.

EUCROF, the European CRO Federation, whose member associations span twelve European countries, says CROs “were originally largely a solution to cost; today they are increasingly a solution to complexity and part of Europe’s operational infrastructure for clinical research, not just execution partners.” By its account, trials have gone global, patient populations have narrowed and data and technology requirements have grown, so sponsors need judgment: where to place a trial, where the patients are, which sites can deliver, and which technologies earn their place.

The same logic runs through manufacturing. Few developers can justify owning every capability required across the lifetime of a drug, particularly as modalities become more specialized. Outsourcing therefore gives sponsors access to expertise and infrastructure they may need only at particular stages of development.

Where outsourcing breaks down

The risk sits at the handoffs. Drug development does not divide neatly into independent work packages, and decisions made by one provider can shape what the next one is able to do.

“Cell line development affects upstream productivity; upstream conditions influence downstream purification; process decisions affect analytical strategy, formulation, comparability and ultimately cost of goods,” says Cornelius Klöck, vice president for strategy and technology at Rezon Bio, a Polish CDMO. Divide that chain among vendors and a decision can be right for one work package and wrong for the program. There is an organizational argument too. Each new team reconstructs a process it did not develop, context is lost as data changes hands, and accountability blurs when several companies contribute to one outcome.

Clinical development creates the same tension. “Too many specialist vendors create complexity and interfaces, while too much reliance on one large provider can reduce flexibility and create dependency,” says Martin Krauss, co-founder of FGK Clinical Research and president of Germany’s CRO association BVMA.

Advanced modalities make those trade-offs harder still. An antibody-drug conjugate needs three largely separate industrial disciplines before sterile fill-finish: mammalian cell culture, high-potency payload and linker chemistry and conjugation under containment. Very few sponsors own all three. Similarly, an autologous cell therapy ties one patient’s material to a manufacturing slot and an appointment; a radiopharmaceutical decays while it ships; and for RNA medicines, delivery chemistry is part of the therapeutic itself.

The more tightly those steps depend on one another, the more consequential every handoff becomes. A formulation decision can reshape a clinical protocol, while missing process knowledge or incomplete data transfer may not become visible until a regulatory review years later.

Providers try to close the gaps

Providers are responding to those risky handoffs by bringing more capabilities together – either under one roof or through tighter partnerships.

Samsung Biologics is pursuing the first route. The South Korean CDMO is bidding CHF 1.46 billion (€1.6 billion) in cash for PolyPeptide, which would add peptide APIs to a business built around antibodies and ADCs. The move would give Samsung another manufacturing capability in a field where demand, particularly for GLP-1 drugs, has strained peptide capacity.

Lonza has arrived at greater integration from the opposite direction. In March 2026, it agreed to sell control of its Capsules & Health Ingredients division to Lone Star Funds at a CHF 2.3 billion (€2.5 billion) enterprise value while keeping 40%. The deal completes Lonza’s shift to a pure-play CDMO and releases CHF 1.7 billion (€1.8 billion) for growth, acquisitions and share buyback. Samsung is broadening its manufacturing capabilities; Lonza is narrowing its focus. They are arriving at the same destination – a greater emphasis on contract manufacturing – but from opposite directions.

Alignment can also be contracted. In December 2025, the Czech cell-therapy CDMO SCTbio and the global CRO Fortrea formed an alliance intended to match GMP manufacturing readiness to clinical logistics from the start of development, addressing the kind of manufacturing-to-clinical interface that Atara’s hold exposed.

Specialists choose their limits

Smaller providers are often moving in the opposite direction: narrowing their focus rather than trying to offer every capability themselves. Rentschler Biopharma announced in January 2025

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that it would leave cell and gene therapy and close its Stevenage site, saying growth in that market had been slower and demand lower than it expected, less than 18 months after the site received its cGMP certificate. The exit came alongside a renewed concentration on cell-culture biologics at Laupheim and Milford.

Rezon Bio arose from a different narrowing. Polpharma Biologics split in September 2025 into a Swiss biosimilars developer that kept the original name and a standalone Polish CDMO trading as Rezon Bio. Its Warsaw-Duchnice facility won FDA approval for commercial biosimilar manufacturing in February 2026. Rezon says it separated the CDMO from the proprietary pipeline specifically so that it would not develop products in competition with its clients.

Neither company presents that focus as a retreat from integration. “The future is not integration versus specialization,” Klöck says. “It is intelligent integration,” by which he means keeping tightly coupled work together where continuity improves speed, cost of goods and accountability, while using specialist partners where they add capabilities that would be inefficient to build internally. Asked the same question, Krauss answers it almost identically: the key, he says, is to combine specialization with integration.

His company, FGK, keeps the core of clinical development in-house but uses specialist technology providers where they offer stronger capabilities or expertise, allowing it to stay “flexible in selecting the most suitable partner for each project, especially in fast-moving technology areas.”

Both CDMOs make drug substance in-house and reach outside for the GMP drug-product step, Rezon developing formulations itself but coordinating manufacture through qualified partners; Rentschler using Coriolis Pharma for formulation and its Xpert Alliance with Vetter for aseptic filling. Patrick Meyer, Rentschler’s global head of business development, treats that as a feature. Requirements increasingly “demand a higher level of specialization which cannot always be provided by integrated partners,” he says.

What the client still carries

Every configuration returns the risk to the developer. A vendor network produces coordination cost and fragmentation; a single integrated partner replaces that with concentration. Regulators have already settled where the exposure sits. ICH’s good clinical practice guideline lets a sponsor transfer trial activities but not responsibility for participant safety or data reliability, and requires oversight of work vendors subcontract onward. EU GMP rules put the parallel duty on the contract giver: assess the contractor, supply the knowledge it needs, keep access to the records. Klöck’s answer to the concentration problem is knowledge retention. Integration can reduce complexity, he says, but if designed poorly, it swaps many vendors for dependence on one. “Outsourcing should never result in a sponsor becoming disconnected from its own molecule. The moment outsourcing leads to a loss of knowledge, the model is not working as it should.” In practice, that means holding the development data, analytical methods, batch and validation history, reference standards and the reasoning behind critical decisions, and audit trails held in the contractor’s validated systems.

Krauss puts the same requirement in contract terms. That is where a sponsor can act on it in advance. Sponsors should keep control of their data, know-how and strategic decisions, he says, and make sure systems and contracts allow activities and data to be moved if necessary. “Outsourcing should extend internal capabilities, not create lock-in.”

The same record now has to serve models as well as people. Process data can feed predictive tools and digital twins, but only where provenance is traceable and definitions stay consistent across sites, and if the process moves, the question is whether the structured dataset moves with it.

Klöck treats a move as routine. Transferability is “part of responsible process development and an important way of managing vendor dependence risk,” he says, and the usual trigger is growth, since a process built for early supply may later need

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Rezon Bio is a **science-driven, price-competitive** European CDMO specializing in the development and manufacturing of mammalian biologics. Headquartered in Poland, we provide fully integrated solutions from cell line development to commercial supply. With state-of-the-art facilities, world-class teams and a legacy of biosimilars development and global commercialization, we bring together deep scientific expertise, digital transparency and cost-to-value efficiency to help clients move their biologics programs from concept to market with confidence.



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more capacity than its site has. Keeping the same CDMO does not eliminate the work. Rentschler began supporting VarmX's VMX-C001 at Laupheim in 2022, and in January 2026 the companies said Phase 3 supply and process validation would move to Milford. A transfer runs through equipment, training, analytical procedures, validation batches and comparability. And if the transfer happens after approval, the sponsor may also need to submit the appropriate post-approval regulatory filing.

Geography stops being procurement

Then there is politics. "Geopolitics has moved from being primarily a procurement consideration to becoming an important part of CMC and manufacturing strategy," Klöck says.

U.S. trade policy is adding another variable. On April 2, 2026, President Donald Trump imposed new pharmaceutical tariffs under Section 232 of the Trade Expansion Act, after a Commerce Department investigation concluded that dependence on imported drugs and active ingredients posed a national security risk. Covered patented pharmaceuticals and APIs face a headline tariff of 100%, while qualifying EU products are capped at 15%. Certain categories, including cell and gene therapies and antibody-drug conjugates, can qualify for zero tariffs under specified conditions. That can change the economics of a manufacturing route without necessarily changing which route is technically viable. Scientific fit, available capacity and familiarity with the target regulator still determine where a product can realistically be made.

U.S. policy is also starting to determine which suppliers companies can safely rely on. The BIOSECURE Act, enacted in December 2025, will restrict federal agencies from procuring biotechnology equipment or services from companies designated as national security concerns, and will also affect entities that use those suppliers in federally funded work. The Office of Management and Budget has until December 2026 to publish the initial list of covered companies.

WuXi AppTec shows how the commercial impact can begin before those restrictions formally bite. The Pentagon added the Chinese life sciences services group to its separate Section 1260H list of Chinese military companies in June 2026, although a court temporarily blocked the designation in August. Even without an immediate BIOSECURE prohibition, the uncertainty around a supplier's future eligibility can be enough to make sponsors reconsider where they place work.

The clinical side faces a different set of pressures. "In the CRO business, this is less about manufacturing and more about the resilience of a development program," Krauss says. Patient access, quality, timelines and cost still determine where a trial goes, but sponsors now weigh political stability, sanctions, data sovereignty and dependence on any single region alongside them. He stops short of advocating regional trials. Geographic concentration has become a risk factor in its own right, and a multi-country strategy gives sponsors room to shift if

conditions change. It also supports the case for a CRO structured like his own.

"The disruptions of recent years have demonstrated that a technically strong supply chain is not necessarily a resilient one," Klöck says. Rezon says some companies manufacturing outside Europe are now looking to qualify a second European manufacturing site while their products are still in development, rather than waiting until a disruption forces them to find an alternative. Building that redundancy is costly. It can require technology and analytical method transfer, qualification of the new site and, depending on the stage of development, comparability studies and regulatory filings. For a small biotech, that work can absorb capital that might otherwise have funded the next clinical or development milestone. "Regionalization should not be confused with complete localization," Klöck says. "Biopharmaceutical supply chains are global and will remain so."

Where the seams belong

Europe is trying to make that network easier to operate. The Critical Medicines Act covers shortages rather than every innovative biologic, and the broader European Biotech Act remains a proposal. EUCROF, which works with the European Medicines Agency on the Act, backs its ambition and says faster authorization and greater harmonization would reduce fragmentation. But regulation alone will not be enough, the federation argues: Europe also needs investment in clinical research infrastructure, digital capability, sites and people. "Europe's diversity is an asset; fragmentation is not."

For sponsors, however, there is no regulatory fix for the central design question. Neither an integrated partner nor a network of specialists solves the design problem alone, and providers on both sides of the industry say so. Integration creates value where continuity across tightly coupled work reduces delays, and a specialist justifies the added handoff when its expertise outweighs the coordination it requires.

The sponsor ultimately decides where those seams belong. It also has to retain the process knowledge, data, financing runway and transfer options that keep the network workable. Even a very small biotech therefore needs someone internally who owns the integrated schedule, CMC and quality, the link between clinical operations and product release, and access to the underlying data.

Xspray shows what happens when that control reaches its limits. The company says it plans to resubmit in 2026 and is prioritizing the additional commercial batches requested by the FDA. Whether its drug reaches U.S. patients next year now depends in part on how quickly an Italian manufacturing site under new ownership can satisfy an American regulator. That dependence traces back to a manufacturing agreement signed in 2017. ■



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ADVERTORIAL Perfusion is here, and it is rewriting the rules of biologics and biosimilar manufacturing. What was once experimental has become industrial reality: scalable, robust, regulatorily accepted, and commercially proven. As global demand for high quality, cost competitive biosimilars accelerates, perfusion stands ready as the technology built for this moment.

For years, “N Reactor” full perfusion was viewed as an intriguing but demanding technology – admired for its potential yet approached cautiously. Concerns persisted around scalability, operational robustness, and regulatory acceptance. Today, those questions have been answered. Advances in cell retention systems, single use technologies, automation, and process analytics have transformed perfusion into a reliable, commercially viable platform. Successful GMP campaigns across the industry show that perfusion can deliver consistent performance at scale, with

quality attributes aligned to regulatory expectations.

Meeting the critical challenges

Biosimilars stand to benefit most from this transformation. Their commercial reality is defined by intense price pressure, narrow margins, and the need to deliver originator level quality at significantly lower cost. Developers must achieve high productivity, stable CQAs, and predictable supply while operating within constrained budgets and competitive timelines. Perfusion

directly addresses these constraints: it reduces COGs per gram, compresses seed trains, stabilizes product quality, and enables commercial output from smaller reactors. For biosimilars, perfusion is not simply an alternative manufacturing mode – it is a strategic lever for long term competitiveness.

Regulators have modernized frameworks to support intensified and continuous manufacturing. ICH Q13 provides harmonized guidance on continuous and hybrid processes, including explicit recognition of time, volume, and mass based batch definitions. For perfusion, this removes ambiguity around how batches should be defined and justified. With ICH Q13, manufacturers can confidently establish batch boundaries aligned to process design – whether based on cumulative harvest volume, defined duration, or total mass – while maintaining full regulatory compliance.

Next wave of biosimilars

The broader market context reinforces this shift. Biosimilars are entering a decisive acceleration phase. Analysts forecast that the global biosimilars market will grow at a solid double digit pace through 2036, driven by patent expiries, payer pressure, and expansion into oncology, immunology, ophthalmology, and rare diseases. Europe remains the most mature market, but the steepest growth curves are expected in the United States and emerging regions. As biologics pipelines diversify and biosimilar competition intensifies, manufacturing



The latest-generation Sartorius Ambr® 250 HT 24 Perfusion-Enabled Bioreactor system at Celonic's Biologics Development Center (BDC) in Basel, Switzerland, supports high-throughput process development and optimization for biologics manufacturing.

models must evolve. Perfusion enables that evolution.

The 2026 BioPlan Annual Report captures this transition clearly: 42% of survey respondents stated they will be evaluating upstream continuous processing and perfusion at their facilities this year. This reflects a structural pivot toward technologies that deliver higher productivity, greater flexibility and lower cost. Samanta Cimitan, CEO of the Celonic Group, sees this shift as both inevitable and overdue. “The economics of biologics and biosimilars have fundamentally changed. Perfusion-based manufacturing is moving from a technical option to an essential strategic capability!”

Perfusion boosts productivity

Perfusion unlocks capabilities that directly address modern biologics and biosimilar constraints. High density cell culture enables dramatically higher volumetric productivity, allowing commercial output from 1,000 L–2,000 L single use reactors rather than 10,000 L fed batch systems. Continuous media exchange stabilizes product quality and reduces variability – critical for biosimilar comparability. Compressed seed trains free up facility time and reduce labor intensity. Smaller bioreactors reduce CAPEX and allow CDMOs to support multiple programs without expanding footprint. Perfusion aligns cost, quality, and scalability in a way fed batch cannot.

Supported by automation

A major enabler of modern perfusion development is high throughput perfusion screening, now possible with the latest generation Sartorius Ambr® 250 HT 24 bioreactor system. This platform allows developers to evaluate dozens of clones, media strategies, and perfusion rate profiles in parallel under true perfusion conditions. For innovators, it compresses development timelines, increases data richness, and ensures that only the most robust candidates advance into pilot and GMP scale. For CDMOs like Celonic, it strengthens process predictability and reduces scale

up risk – critical advantages in competitive biosimilar and biologics programs.

Equally important is the ability to scale perfusion reliably to commercial volumes. Modern single use systems such as the Cytiva Xcellerex™ X platform bioreactors have addressed historical concerns around perfusion scalability, particularly oxygen transfer at large volume. The latest X platform designs deliver significantly higher oxygen transfer capacity, enabling stable perfusion operation up to 2,000 L. With robust mass transfer performance, consistent mixing, and proven integration with ATF based cell retention systems, Cytiva bioreactors make high density perfusion not only feasible but reliable at commercial scale. Perfusion is compatible with modern control strategies, including enhanced PAT, automated perfusion rate algorithms, and predictive culture management.

From niche to new standard

Celonic recognized perfusion’s potential long before it entered mainstream biomanufacturing conversations. The company made early strategic investments in perfusion technologies, process intensification, and the operational capabilities required to run high density cultures reliably. These investments now position Celonic as one of the few CDMOs with true industrial perfusion expertise. Celonic offers not only access to perfusion technology, but also the accumulated process knowledge, operational discipline, and development to GMP integration required to implement it successfully.

Celonic is not alone in recognizing the strategic value of perfusion. Leading biosimilar and biologics manufacturers – including giants like Sandoz – are actively evaluating or implementing intensified upstream strategies to reduce COGs per gram and increase facility agility. Sandoz’s 2024 acquisition of Evotec’s biologics manufacturing site publicly underscored this trend, adding state of the art capacity with perfusion ready and intensified upstream capabilities. As biologics pipelines expand and biosimilar competition intensifies, perfusion is becoming a



Celonic, Heidelberg, Cytiva Xcellerex™ XDR-1000 Perfusion-Enabled Bioreactor

central pillar of next generation manufacturing strategies.

Expertise to rely on

Perfusion is no longer a niche technology. It is a commercially proven, regulatorily accepted, economically compelling manufacturing platform that aligns with the next decade of biologics and biosimilar growth. For biotech innovators and biosimilar developers, perfusion offers a way to scale smarter, move faster, and compete more effectively. Cimitan frames Celonic’s commitment clearly: “Biosimilars and next generation biologics deserve modern manufacturing. Perfusion is the technology that finally aligns cost, quality, and scalability. At Celonic, we’re committed to making intensified bioprocessing the new standard for our industry.” ■

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AI in clinical research: hype vs. reality

ADVERTORIAL AI can already reduce administrative work, improve decision-making and streamline parts of clinical development. But its impact is often overstated. Evidenze's Raphaela Schnurbus explains where AI is delivering measurable value today, where human expertise remains essential and what biotechs should ask before buying in.

European Biotechnology: Where is AI delivering value today?

Raphaela Schnurbus: AI is already creating value by simplifying processes, reducing administrative workload, and supporting more efficient decision-making. At Evidenze, for instance, the Fast-TrIAI platform can generate study protocols from a draft synopsis, flag potential issues and operational bottlenecks, and recommend suitable sites through predictive analysis of historical trial data.

That said, some of the industry's most ambitious expectations have yet to be fully realized. Patient recruitment is a good example. While AI can help refine recruitment strategies and identify potential participants, it has not produced the step-change in enrollment performance that is often suggested. Recruitment outcomes still depend on a combination of clinical, operational, and human factors that technology alone cannot address.

EB: Can AI address delays in clinical development?

Schnurbus: The most significant delays in clinical trials are mostly driven by organizational and clinical challenges. Fragmented coordination among stakeholders, overstretched site personnel, lengthy contracting processes, and the availability of investigational medicinal products at study sites often have a large impact on timelines. AI can support these efforts by providing insights and improving efficiency across individual steps of the process, but its greatest contribution lies in enabling better-informed decisions rather than replacing human expertise.



DR. RAPHAELA SCHNURBUS, International Business Operations and Country Manager Italy at Evidenze is an experienced business leader and pharmacology expert with +20 years in drug development.

EB: How are you using AI?

Schnurbus: Fast-TrIAI is Evidenze's proprietary AI platform, developed to streamline study processes and accelerate timelines across the clinical development journey. This year the platform has been primarily used for protocol drafting and amendments, literature reviews, and document generation. All activities are performed within a secure, controlled environment that ensures consistency, traceability, and compliance throughout the process. Right now, after summer break, Fast-TrIAI is releasing support for statistical activities, and next release for

feasibility assessments, site selection, and regulatory intelligence is following shortly, further broadening its value across the clinical research landscape.

Based on Evidenze's experience to date, timelines for several key activities can be reduced by 30% to 50%, allowing teams to work more efficiently without compromising quality but trained experts retain full responsibility for the final output and every critical decision throughout the process.

EB: What should biotechs ask about AI?

Schnurbus: Focus on the problem being solved, clinical impact, workflow integration, human oversight, transparency, auditability, regulatory and data-privacy compliance, implementation effort and time to value. There are also several clear warning signs that should prompt caution. One of the biggest is when the conversation focuses more on the technology itself than on the clinical or operational outcomes it is expected to deliver. Other red flags include manual validation or process duplication, disconnected workflows, standalone tools, limited explainability, auditability, or oversight, reactive compliance approach.

Ultimately, biotech companies should look beyond the AI label and focus on outcomes. The best solutions are often those that work quietly in the background, helping teams make better decisions, reducing operational burden, and improving execution.

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WuXi AppTec bets on expansion in Europe

INTERVIEW Global science, local innovation: In an interview with European Biotechnology, WuXi AppTec Co-CEO Steve Yang explains why Europe remains a key source of scientific innovation, why the company continues to expand its Munich site despite geopolitical tensions, and why trust, quality and international collaboration are essential for the future of drug discovery.

WuXi AppTec, the Chinese life sciences services company, is one of the world's largest providers of research, development and manufacturing services (CRD-MO) for the pharmaceutical and biotechnology industries. The company supports customers across the entire value chain – from early drug discovery through pre-clinical and clinical development to commercial manufacturing.

WuXi AppTec has maintained a presence in Europe since acquiring Munich-based Crelux in 2016. Since then, the site has been continuously expanded and today represents a key component of the company's European research activities. At the same time, WuXi AppTec operates in an increasingly complex geopolitical environment. In the U.S., the company has recently been at the center of national security debates concerning the role of Chinese biotechnology companies. Although some of the originally proposed regulatory measures have since been softened, many pharmaceutical companies are scrutinizing their supply chains and development programs more closely than they did just a few years ago. In response, WuXi AppTec is placing greater emphasis on regional operations while pursuing a strategy that combines global integration with a strong local presence.

European Biotechnology: Dr. Yang, WuXi AppTec offers virtually every technology and scientific capability one could ask for today. How do you view the landscape of the many highly specialized German companies?



STEVE YANG, Co-CEO. Before joining WuXi AppTec, Dr. Yang was Vice President and Head of Asia and Emerging Markets at AstraZeneca, Vice President and Head of Asia R&D at Pfizer and Executive Director and head of Pfizer's global R&D strategic management group. He received his Ph.D in Pharmaceutical Chemistry from the University of California, San Francisco.

Steve Yang: Europe generates outstanding science. The challenge is transforming that science into drug candidates, development programs and ultimately medicines. Anything that accelerates that translation process creates value. That is where we believe we can contribute.

EB: Is that also why you expanded your Munich site?

Steve Yang: Exactly. When we acquired the Munich company Crelux, the team consisted of about 30 employees working in approximately 700 square meters. Today, roughly ten years later, the site has grown to more than 100 employees. Around 70 percent hold a Master's or PhD degree. The laboratory and office space has expanded to about 3,000 square meters, and we continue to invest. Our goal is to develop the site into a global center of excellence for discovery biology.

EB: How important is it for you to be physically close to your European customers? Couldn't you simply say, "Come to our facilities in China, we can do everything there and ship the products back to Europe"? Or has the situation changed to the point where development and manufacturing capabilities are now also required in Europe?

Steve Yang: We believe globalization and localization are two sides of the same coin. By operating facilities across multiple regions, we can offer customers greater flexibility and a more secure supply chain. Although these facilities are geographically distributed, they all operate under the same global quality standards and are managed by the same global organization.

EB: Speaking of customer relationships and trust: Do you still have to earn your customers' trust every day, or has your reputation reached the point where customers already know what to expect?

Steve Yang: *Trust is never something you achieve once and then keep forever. It has to be earned continuously. Science evolves, and customer needs evolve as well. Our focus is therefore on continuous improvement and on earning our customers' trust again and again.*

EB: Can you give us a concrete example?

Steve Yang: *Certainly. Last year alone, we underwent 741 audits by customers and regulatory authorities. That included more than 50 inspections by regulatory agencies, as well as approximately 60 information security audits. None of those audits resulted in critical findings. Maintaining that level of performance requires constant effort. Every year we must demonstrate once again that our quality systems, our data protection, our intellectual property protection and our manufacturing standards continue to meet the highest expectations.*

EB: Let's talk about one of today's most exciting scientific fields: targeted protein degradation and molecular glues. These technologies are rapidly becoming major areas of drug discovery. It almost seems as though conventional antibodies could one day appear old-fashioned compared with degraders, proximity-inducing compounds and other approaches that enable entirely new ways of manipulating proteins.

Steve Yang: *I completely share that enthusiasm. Today, we have one of the largest scientific teams in the industry working on heterobifunctional molecules, what most people simply call degraders. Every stage of development presents its own scientific challenges, and we aim to provide solutions along that entire journey.*

EB: Imagine your ideal future. Would it be a world in which everyone simply follows the science? One in which

researchers choose the best partner regardless of where that partner is located?

Steve Yang: *Yes, very much so. Our vision is simple: every drug can be made, and every disease can be treated. Achieving that requires solving countless scientific, technical and operational challenges. Healthcare is fundamentally different from many other industries. Diseases do not recognize national borders. There is no German version of cardiovascular disease, and there is no American version of cancer. Patients everywhere deserve access to high-quality medicines. Science also has no borders. Researchers publish their discoveries, and knowledge spreads around the world. That exchange of knowledge is one of the greatest strengths of science.* ■

Georg Kääb



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From development to commercial reality

ADVERTORIAL Helping biopharmaceutical innovators build scalable, manufacturable, and commercially viable processes from the start.

Biopharmaceutical companies face increasing pressure to advance innovative therapies rapidly while ensuring scalability, manufacturability, and commercial viability. Decisions made during early development often have a lasting impact on regulatory readiness, manufacturing efficiency, supply security, and time to market.

As part of SK bioscience, IDT Biologika supports pharmaceutical and biotechnology companies in translating scientific innovation into robust manufacturing solutions. With expertise spanning vaccines, recombinant proteins, viral vectors, gene & immune therapies, oncolytic viruses, biosimilars, and sterile injectables, we help customers navigate the path from development to commercial supply.

Commercialization starts during development

Manufacturing success is often determined long before commercial production begins. Process robustness, scalability, material strategies, product stability, and cost of goods should be considered early to avoid delays and costly redesigns later in development.

By integrating commercial thinking into CMC and manufacturing strategies from the outset, developers can establish a stronger foundation for long-term success.

Using platform knowledge effectively

Platform technologies can reduce uncertainty and accelerate development, but successful programs require more than standardization.

Their value lies in identifying which technologies, materials, analytical meth-

ods, and unit operations can be transferred effectively while maintaining the flexibility required for product-specific needs. This supports more predictable timelines, stronger scale-up strategies, and informed development decisions.

Managing product-specific complexity

Advanced biologics often build on established manufacturing technologies while introducing unique challenges. Oncolytic viruses, viral vectors, and other complex therapies require careful alignment of dose, potency, concentration, process recovery, manufacturability, and commercial requirements.

Addressing these factors early helps establish scalable processes that maintain product quality and support future clinical and commercial supply.

Connecting development and manufacturing

Successful technology transfer requires more than reproducing an existing process. Development, manufacturing, analytics, quality, and regulatory considerations must work together to ensure process robustness and commercial readiness.

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The handover: Making technology transfer work

COWORKING Technology transfer is an often underestimated step in biopharmaceutical manufacturing. Technical hurdles are only part of the challenge: information gaps, unclear expectations and weak collaboration can derail even robust processes. Two experts explain why successful transfers depend as much on people, planning and communication as on science.

Technology transfer is a key milestone in the journey of many molecules, but also a high-risk inflection point in biopharmaceutical development. Often perceived as a purely technical handoff, technology transfer frequently falters due to organizational challenges rather than scientific hurdles, causing delays that affect timelines, costs and patient access.

Melanie Jawerka, Senior Director of Manufacturing Science and Technology (MSAT) at Rentschler Biopharma's German site in Laupheim, and Dante Lepore, Laboratory Head of Downstream Process Development at the company's U.S. facility in Milford, MA, spoke with EUROPEAN BIOTECHNOLOGY MAGAZINE about the organizational habits that determine whether cross-continental tech transfer succeeds or fails.

The pair agree that successful technology transfer, whether from one CDMO to the other or between one CDMO's sites, relies on deep expertise, clearly defined processes and a culture of transparency.

Transfers don't begin at the kickoff meeting

Successful tech transfers begin with early collaboration between sponsor and CDMO. Jawerka, whose MSAT function bridges process development and manufacturing at Rentschler Biopharma's headquarters, is clear on what that means in practice.

"Tech transfers often struggle not because of technical limitations, but because of information gaps," she says. "A



MELANIE JAWERKA, PhD, is Senior Director, Manufacturing Science and Technology at Rentschler Biopharma, where she bridges process development and manufacturing.

well-organized development package from the sending site includes process understanding, historical data and analytical readiness in order to create a solid foundation. Throughout the process, maintaining open communication and fostering a truly collaborative one-team mindset is key."

Lepore emphasizes the operational side. "Clear planning and expectation management are key differentiators," he says. A CDMO should set expectations early: complete parameter uniformity across two sites is unlikely. What matters more is a strong scientific rationale and deep process understanding to improve

efficiency without compromising product quality.

Process robustness: Stress-testing before scale

Bench-scale success does not always translate to GMP manufacturing. Lepore advocates an almost adversarial approach. "The mindset should be trying to make the process fail for a certain quality attribute while working within your design space," he says. "If the process stands up to whatever creative forms of disruption you can conceive, it is ready for GMP." The trade-off in time and resources, he argues, is worth it: the rigor invested before scale-up is less costly than the deviations caught afterwards. Jawerka underlines the scientific foundation. "A robust and well-characterized process is fundamental because it ensures a product can be reliably reproduced when moving from development to production scale," she says. "When a process is thoroughly understood across relevant operating ranges, teams can define critical parameters, identify sources of variability and establish strong control strategies."

Facility fit: A cross-site conversation

Rentschler Biopharma's cross-continental dual-site model allows for different technology transfer models. In one case, the development can take place in Germany with late-stage and commercial manufacturing in the U.S. In other cases, a process

might be developed at one site and subsequently be validated and manufactured by both. Flexibility is built into the model.

"Starting the facility fit early helps to identify risks, understand the process and close any gaps that we might identify to align the process within our environment. Doing this thoroughly helps teams from both sites understand how equipment, automation, utilities and operational practices will interact with the process long before batches are scheduled," says Jawerka.

The pitfalls that still catch teams off guard

Among the most persistent blind spots, Lepore identifies the loss of process experience when know-how doesn't fully make it into documentation. "Every process carries unique nuances and historical learnings that the originating site has adapted to over time," he says. "The rationale behind



DANTE LEPORE, PhD, leads the Downstream Process Development laboratory at Rentschler Biopharma.

specific decisions, often rooted in past troubleshooting, can be overlooked." That gap triggers unnecessary investigations at

the receiving site, often without the context that would resolve them immediately.

"In the end, successful tech transfer isn't just a technical exercise, it's a people-centered one," says Jawerka. "The strongest outcomes result from both sides committing to transparency, shared problem-solving and a willingness to revisit assumptions as real data emerges."

The competitive advantage is organizational

Smooth GMP execution starts with rigorous planning, and timing is everything. Digital tools accelerate the work: bioreactor modeling adds confidence at scale, and AI can help surface the knowledge that gets lost between sites or CDMOs.

As biopharmaceutical manufacturing networks become increasingly global, technology transfer is becoming a strategic lever for supply chain resilience. ■

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Geopolitical shifts in trial outsourcing

DIVERSIFYING CLINICAL TRIAL RISK Three developments over the past year have changed what “outsourcing” a clinical trial actually means. New U.S. tariffs on patented pharmaceuticals, a revised Chinese trial standard, and faster approval rules in Europe, the UK and Australia are all forcing sponsors to look again at where trials run and who runs them.

Start with Washington. In April 2026, the U.S. used Section 232 to put tariffs on patented pharmaceuticals and their active ingredients: 100% on standard imports, up to 120% for companies without an approved U.S. manufacturing plan, in force from July 31, 2026 (Crowell & Moring, 2026). Generics, biosimilars and cell and gene therapies are exempt. For sponsors, the practical point is that a supply chain built around a low-cost API source or contract manufacturer now needs a second look, and outsourcing contracts should spell out who carries tariff risk if a product’s status changes.

China tightens oversight

China moved too. Its revised Good Clinical Practice rules, in force from September 1, 2026, adopt ICH E6(R3) but keep the sponsor fully responsible for outsourced work, including CROs and oth-

er vendors. A new chapter on data governance requires validated systems, audit trails and tighter access controls, and ethics committees can now intervene further into how a trial is run (Cisema, 2026). China still accounts for roughly a fifth of drugs in global development, so this is not a reason to leave; it is a reason to check that contracts clearly assign quality obligations, and that data systems can withstand an audit.

Europe fights back

Meanwhile Europe, the UK and Australia are competing harder for the trials that might otherwise go to Asia. The EU’s Joint Clinical Assessment allows one review across member states instead of several, part of a push toward 11% more trial volume by 2030 (Clinical Trials Arena, 2026). The UK has cut median trial setup time from 169 to 122 days under a new 150-

day rule, and Australia offers a 43.5% refundable tax offset on eligible trial costs through Phase 3 (Clinical Trials Arena, 2026). None of this reverses a decade of share loss to Asia-Pacific on its own, but it does mean cost is no longer the only reason to look outside the traditional hubs.

Risk joins cost and speed

Put together, these three shifts point to the same conclusion: location decisions and CRO selection now carry trade and regulatory risk that didn’t exist a year ago, and that risk needs to sit next to cost and speed on the same checklist, not after it. Sponsors should ask any CRO how a contract handles a tariff change or a new data rule mid-trial, not just how it handles a missed enrollment target. CROs that can run comparable quality systems across two or three regions at once, and show it on paper, will have an easier conversation with sponsors than those that can only point to being cheap or being big. ■

*Lumis International GmbH
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hs@lumisinternational.com*

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Picture: © Lumis International



CDMO: How to find a reliable partner

ADVERTORIAL Every biopharmaceutical company reaches the same crossroads when selecting a contract development and manufacturing (CDMO) partner. The temptation is to optimize for the lowest quote or the shortest lead time, or both. But the most consequential question is rarely asked directly: which partner will actually carry your program from early-phase clinical through commercial launch without a single avoidable disruption?

At Richter BioLogics, nearly 40 years of serving the global pharmaceutical and biotechnology industry have taught us that several questions deserve a clear answer.

“Won’t a large, global CDMO give us more security than a specialist?”

Company size can be reassuring, but it is not the same as reliability. Larger providers often spread capacity across a broad range of modalities and a fairly large number of clients, which can mean your program competes for attention and expertise. Richter BioLogics offers something better: deep, focused specialization in microbial manufacturing. Your program, whether it’s a protein, an antibody (VHH/nanobody, ScFv-fragment, pDNA, or a vaccine, benefits from teams whose expertise is concentrated, and from an organization small enough to remain genuinely responsive while mature enough to withstand any regulatory scrutiny.

Consistent quality outcomes require consistent people, processes, and leadership rather than reactive management. Our stability on all three fronts is a direct advantage to the programs we support.

“What does a quality mindset actually change in daily operations?”

Quality in CDMO manufacturing is not simply a matter of passing audits. The real measure is whether that rigor is embedded in day-to-day work: in how deviations



are investigated, how processes are validated, and how knowledge is preserved across teams.

At Richter BioLogics, quality is an operating philosophy that runs through every function, and every client engagement. For your program, that means fewer surprises, more predictable timelines.

“Why does a CDMO’s regulatory record matter?”

Because a clean regulatory record signals several things about a prospective partner:

- Process robustness: Systems that satisfy multiple regulatory bodies across multiple inspection cycles rest on sound scientific and procedural foundations.
- Documentation integrity: Zero findings in an FDA inspection reflect a documentation culture that is both thorough and accurate.
- Risk mitigation: Every regulatory finding creates downstream risk for timelines, submission dossiers, and commercial supply continuity. A strong inspection record reduces that risk materially.

Your partner’s regulatory credibility directly strengthens the integrity of your dossier. Beyond our recent FDA inspection

with zero observations, our quality standards are continuously confirmed by the EMA, ANVISA, PMDA, MFDS, and others, among the most stringent regulatory environments in the world.

“Can a quality-first partner still move at the pace we need?”

Yes, and this is the central point. Quality is not a constraint on speed but it is the foundation that makes it possible. That continuity is reflected in several years of revenue growth at Richter BioLogics, sustained by maintaining the standards that keep clients engaged for the long term. The right partnership delivers both quality and pace, because one enables the other.

Let’s continue the conversation

If you are evaluating partners for your next protein, antibody, vaccine, or pDNA program, we welcome the discussion. Meet our team at CPhI Milan 2026, Hall 12, Booth F65 (#12F65) taking place October 6-8.



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European CDMOs follow pharma west

RELOCALIZATION European drug manufacturers are putting more steel, reactors and filling lines on U.S. soil. From Evonik and Vetter to Lonza and Siegfried, recent investments show how CDMOs are adapting to a pharmaceutical supply chain increasingly organized around regional production — without abandoning their European base.

For decades, pharmaceutical outsourcing was largely about finding the right technology, quality and price wherever those capabilities happened to be, but nowadays geography is becoming harder to ignore.

The pressure is becoming more concrete. U.S. efforts to reshore pharmaceutical manufacturing, including new tariff exposure for imported patented drugs and ingredients, are giving manufacturers another reason to put capacity closer to the American market. For European CDMOs, that turns a long-term supply-chain trend into a more immediate investment question.



Evonik's Tippecanoe Laboratories in Lafayette, Indiana, where the German company is investing \$100 million.

In July, Germany's Evonik committed \$100 million over five years to modernize its Tippecanoe drug-substance facility in Indiana. The company explicitly described strengthening its U.S. business as a "strategic necessity," citing surging demand for U.S.-based CDMO services and the need for a more balanced global manufacturing footprint.

Evonik is far from alone. Swiss CDMO Siegfried completed the acquisition of two U.S. drug-substance sites in May: Noramco's commercial facility in Delaware and Purisys' clinical API operation in Georgia. The deal gives the company additional U.S. capacity from early development through commercial manufacturing.

Germany's Vetter is going further. It is investing about \$285 million in a new clinical manufacturing facility in Des Plaines, Illinois, expected to be ready by the end of 2029. The site will nearly double its U.S. clinical-service capacity and eventually replace its existing Skokie operation.

A transatlantic network

For some European CDMOs, the U.S. build-out started earlier but is now becoming central to their strategy. Rentschler Biopharma's expanded Milford, Massachusetts, site — the largest expansion in the German company's history — added four 2,000-liter single-use bioreactors. Seven new products have been introduced there over the past two years.

Sweden's Recipharm has meanwhile announced another multimillion-dollar

investment in U.S. sterile fill-finish capacity for biologics and advanced therapies.

And Lonza is using scale to offer customers something increasingly valuable: optionality between continents. The Swiss group said in July that an expanded agreement with a major U.S. biopharma company would use all of its U.S. commercial biologics sites alongside development and manufacturing capacity in Europe. In September it added plans for a new commercial spray-drying facility in Oregon.

Europe stays in the network

The shift does not necessarily amount to a migration of pharmaceutical manufacturing out of Europe. Vetter, for example, is simultaneously building a new German manufacturing site as part of a €1.5 billion investment program spanning Europe and the U.S.

Instead, the emerging model looks increasingly regional: manufacture closer to the final market where that reduces tariff, supply-chain or technology-transfer risk, while keeping specialized capacity distributed across several regions.

That puts European CDMOs in an unusual position. Their manufacturing expertise was built largely at home. Increasingly, part of their competitive advantage may depend on how successfully they export that expertise — and the factories that come with it — across the Atlantic. That balance may define the next phase of European CDMO growth.

Joachim Eeckhout

Northway Biotech opens 4th facility

A MAJOR STEP IN CELL THERAPY Building on more than 22 years of CDMO experience, Northway Biotech has opened a €61 million, 3,500 sq. m facility dedicated to cell therapy and personalized medicine. Designed with up to 20 independent cGMP manufacturing lines, the center begins operations with its first customer programs already secured.

Located in Vilnius, Lithuania, the Innovative Cell Therapy and Personalized Medicine Center is the first dedicated center of its kind in the Baltic States and the fourth facility developed by the Group.

The investment adds significant development and cGMP manufacturing capabilities for advanced and personalized therapies to Northway Biotech's established CDMO platform spanning mam-

malian and microbial biologics, cell therapy and gene therapy.

Leadership built over 22 years

Northway Biotech comprises seven biotechnology companies across Lithuania, the United Kingdom and the United States, supported by more than 200 highly qualified professionals. The company works with more than 100 partners across Europe, North America and Asia.



More than two decades of scientific expertise, continued investment and service to global biotechnology and pharmaceutical companies underpin Northway Biotech's position today. The company is a member of the Lithuanian consortium for cooperation with MIT and received an Outsourced Pharma 2025 CDMO Leadership Award in the global biologics CDMO category.

The new center, part of the wider BIO CITY development, adds another dimension to Northway Biotech's established CDMO platform — combining biologics expertise with the infrastructure to deliver increasingly complex cell and advanced therapy programs worldwide. ■

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Designing biologics for commercial success

ADVERTORIAL Justyna Adamczyk, Associate VP Integrated MS&T at Rezon Bio, discusses why integrating development and manufacturing strategies is key to improving late-stage efficiency and commercialization readiness.

The path from biologics development to commercial manufacturing is becoming increasingly complex. Developers must balance accelerated timelines, evolving regulatory expectations, and increasing pressure to reduce cost of goods while maintaining product quality and supply reliability.

While early development often focuses on achieving the desired biological outcome, manufacturing success depends on far more than molecule performance. As programs advance toward GMP manufacturing and commercialization, scalability, reproducibility, process robustness, and operational efficiency become critical determinants of long-term success.

Late-stage challenges

Late-stage development brings together process validation, technology transfer, analytical comparability, manufacturing readiness, and regulatory compliance under compressed timelines. Decisions made at laboratory scale can become significant operational constraints at manufacturing scale, increasing complexity, extending timelines, and reducing manufacturing efficiency.

For many organizations, these challenges emerge too late to be addressed without additional development work or manufacturing delays. The ability to anticipate potential risks and design processes with commercial execution in mind is becoming an essential component of successful biologics development.

An integrated approach

Late-stage efficiency starts with early collaboration between process devel-

opment, analytical development, Manufacturing Science & Technology (MS&T), manufacturing, quality, and regulatory teams.

Integrating these functions early enables organizations to establish stronger process understanding, identify manufacturing risks sooner, and design processes that are scientifically robust and operationally practical. The result is greater manufacturing readiness, improved process robustness, and increased confidence as biologics programs transition from development to commercial supply.

Technology transfer also benefits from this integrated model. When development and manufacturing teams work within a connected framework, process knowledge, analytical methods, and operational experience transfer efficiently across functions, reducing variability and supporting smoother implementation at GMP scale.

As biologics grow in complexity, successful commercialization will increasingly depend on development strategies that embed manufacturability from the early stages. Integrating scientific expertise with manufacturing knowledge throughout the product lifecycle reduces development risk, improves operational efficiency, and establishes a stronger foundation for long-term commercial success.

Integrated biologics services

Rezon Bio supports biotech and biopharma companies across the entire biologics product lifecycle.

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 - Clinical & commercial manufacturing
 - Regulatory CMC support
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Meet our expert

Justyna Adamczyk,
Associate VP Integrated MS&T



Justyna specializes in biologics manufacturing, process scale-up, tech transfer, and MS&T, with 15+ years of experience across mammalian and microbial systems. She supports multidisciplinary teams in scaling processes, validating manufacturing, and ensuring efficient transfer from development to GMP production while ensuring regulatory compliance.

ADC boom drives European CDMO investment

SCALE-UP The rapid growth of antibody-drug conjugates is reshaping the European CDMO landscape, pushing manufacturers to invest in the specialized chemistry, containment and conjugation capabilities needed to make the increasingly complex drugs.

Swiss CDMO Lonza became the latest example in June, announcing an expansion of payload-linker manufacturing at its Visp site. The investment will add commercial-scale capacity for highly potent active pharmaceutical ingredients and ADC payload-linkers, part of an effort to offer customers more of the ADC manufacturing chain under one roof.

The expansion reflects a wider shift. ADCs combine an antibody with a highly potent drug payload through a chemical linker, creating manufacturing challeng-

es that range from handling toxic compounds to controlling the conjugation process. As more ADC programs move toward late-stage development, CDMOs are being asked to provide not only development expertise but also larger-scale commercial capacity.

Switzerland's HAS Healthcare Advanced Synthesis is investing more than CHF 100 million across its Biasca and Lugano sites, with ADCs and highly potent APIs among the priorities. Europe already has an established base to build

on. Piramal Pharma Solutions' Grange-mouth site in Scotland has manufactured ADCs since 2004 and commercial products since 2012. The facility expanded its capacity by 70% in 2023.

The result is an increasingly competitive European manufacturing niche. As ADC pipelines mature, the advantage may shift toward CDMOs that can connect payload production, conjugation and drug-product manufacturing while minimizing the technology transfers between them. ■

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ADVERTORIAL For CDMOs, flexible upstream platforms can help streamline process development while maintaining reproducibility and continuity across scales.

When every client process comes with its own demands, contract development and manufacturing organizations (CDMOs) need upstream bioprocessing solutions that are flexible and make process development more efficient and reproducible. Teams must develop a thorough understanding of each process, reproduce performance across scales, and establish a clear path to production, often within demanding timelines.

Orchestrated hardware and software tools increase process development efficiency

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- Tailor process control to meet the specific needs of the cell type of interest

- Automate process control, sampling, and data management to save time and reduce manual work
- Transform experimental results into actionable process knowledge

Platform continuity simplifies technology transfer

The Eppendorf upstream bioprocess solutions can support a process from research and development through clinical and commercial manufacturing. They help teams:

- Reduce variables by maintaining a consistent bioprocess platform when scaling up from R&D to bench-scale manufacturing
- Reduce user training requirements by using the same bioprocess platform across scales and for various cell types

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consistent software environment. This allows the same vessel geometry and process control strategy to be applied across scales, reducing equipment-related variables and simplifying technology transfer.

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The CDMO partner for next-gen medicine

ADVERTORIAL As advanced therapies and vaccines reshape healthcare, Wacker Biotech is emerging as a CDMO partner of choice. With decades of experience and integrated expertise spanning pDNA, RNA, LNP formulation, GMP production, and targeted LNP conjugation, the company offers end-to-end support to accelerate cell and gene therapies, RNA-based medicines, and next-generation vaccines from development through commercialization.

As advanced therapies move from R&D to clinical trials and commercialization, developers increasingly need a contract development and manufacturing organization (CDMO) that can provide integrated expertise across nucleic acids, formulation technologies, analytics, process development, and GMP production. Wacker Biotech has strategically built exactly this combination of capabilities with an end-to-end manufacturing platform spanning plasmid DNA (pDNA), RNA, lipid nanoparticle (LNP) formulation and delivery, analytical development, and GMP manufacturing. This comprehensive approach allows customers to work with a single partner rather than coordinate multiple vendors across different stages of develop-

ment and manufacturing, with the accompanying delays and transfer risks.

End-to-end nucleic acids

Unlike many companies that entered the nucleic acid space only after the success of COVID-19 mRNA vaccines, Wacker Biotech invested in RNA technologies and nucleic acid manufacturing well before the pandemic. In the last decade from facilities in Germany and the Netherlands, it produced clinical supply for two RNA candidates at the Phase III stage – a COVID-19 mRNA vaccine and an mRNA infectious disease vaccine. With the backing of parent company Wacker Chemie AG, it has continued investing in state-of-the-art

RNA-based infrastructure, including building a dedicated RNA competence center in Halle, Germany that also serves as a critical pandemic preparedness partner for the German government. And it has expanded its capabilities beyond mRNA to circular RNA, self-amplifying RNA, siRNA, and other emerging RNA modalities.

Meanwhile, Wacker Biotech's pDNA center of excellence in San Diego, USA has been producing plasmid DNA for more than two decades — and for multiple applications including direct applications like DNA vaccines and as starting material for RNA and viral vector (AAV- and lentivirus-based) medicines. It has produced 120+ GMP batches of pDNA using a diverse range of *E. coli* strains including a high-performing, proprietary *E. coli* strain that forms the basis of the industry-leading PLASMITEC® platform. Given the importance of plasmid DNA as a template for RNA production, such long-standing expertise in plasmid manufacturing provides customers with a secure and reliable foundation for end-to-end development programs. Nucleic acid therapeutics and vaccines require tightly controlled production processes. By integrating these capabilities under one roof, Wacker Biotech reduces supply chain complexity, shortens project timelines, and minimizes technology transfer risks.

In 2026, Wacker Biotech strengthened this end-to-end offering even further with the launch of Contract Research Services from the WACKER R&D Biotechnology Center in Munich, Germany. R&D scien-



Lipids that are used to formulate lipid nanoparticles for RNA-based medicines are stored in large stainless steel tanks at Wacker Biotech's state-of-the-art RNA Competence Center in Halle, Germany.

tists at this facility can help customers optimize nucleic acid candidate molecules – for example through capping strategies and finetuning of nucleotide UTRs (untranslated regions) — while also cost-effectively producing very small quantities of pDNA and RNA at R&D grade. Because these R&D scientists work closely with colleagues at the manufacturing sites, they ensure that a nucleic acid construct is designed from the beginning with efficacy, safety, manufacturability, and scalability in mind.

Enabling the future of vaccines

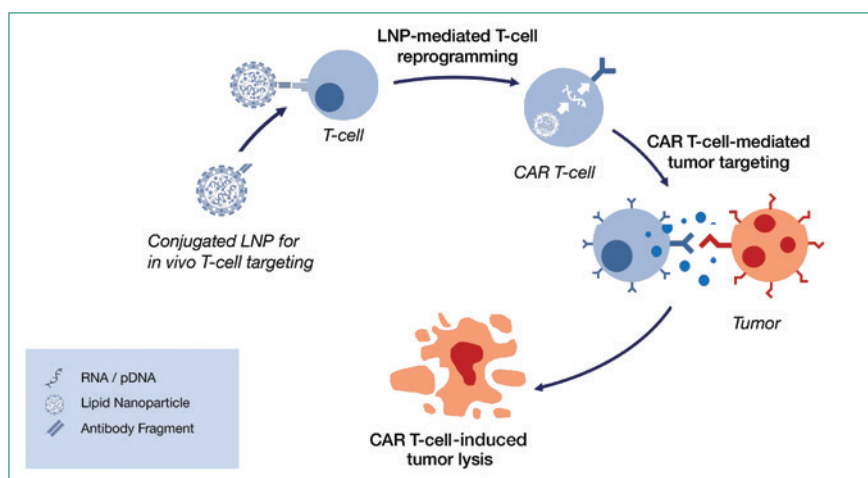
The success of mRNA vaccines for COVID-19 and now their FDA approval in 2024 and 2026 for RSV and influenza, respectively, has demonstrated the efficacy of nucleic acid-based technologies. However, the future vaccine landscape will extend beyond infectious diseases. Personalized cancer vaccines, therapeutic vaccines, and next-generation prophylactic vaccines are expected to become increasingly important components of modern healthcare.

Wacker Biotech is ideally positioned at the center of this transformation. Its experience includes the production of pDNA and RNA as well as the formulation technologies required to deliver these molecules effectively. With 750+ GMP batches produced across all vaccine modalities, including two commercial products, the company supports both traditional vaccine developers and innovators pursuing entirely new paradigms. Wacker Biotech guides clients step-by-step through the complete vaccine development lifecycle.

More precision

Lipid nanoparticles have emerged as a leading platform for delivering nucleic acid medicines safely and efficiently. Wacker Biotech has therefore invested heavily in LNP formulation expertise and analytical methods as a core component of its advanced therapy offering.

A particularly exciting area is the development of targeted or decorated LNPs. While first-generation LNPs successfully deliver cargo to broad tissue popula-



Wacker Biotech provides solutions for *in vivo* CAR T-cell therapies, such as RNA delivered with targeted precision via LNPs conjugated with antibody fragments. Once injected into the body, LNPs find and bind to T cells, releasing their nucleic acid cargo to program the T cells to recognize cancer tumor antigens and destroy the cancer cells.

tions, next-generation products increasingly require precise targeting to specific cell types or tissues. This is especially important for advanced therapies, where delivery efficiency can directly influence safety, efficacy, and dosing requirements.

And this is where Wacker Biotech's even more extensive three decades of experience in microbial-based protein production and conjugation becomes another critical asset.

By attaching targeting ligands such as peptides, antibodies or antibody fragments, sugars, or other functional molecules to nanoparticle surfaces, Wacker Biotech can create decorated LNPs designed to enhance uptake by selected cell populations. Conjugation approaches can help improve biodistribution profiles, increase potency and safety, and enable entirely new classes of precision medicines. They can even prime T cells *in vivo* for the fight against cancer or other rogue cells. Such technologies provide a powerful platform for future RNA therapeutics, gene-editing applications, and targeted vaccines.

The regulatory landscape

Scientific excellence alone is not enough in advanced therapeutics. To gain the support of funders and regulatory authorities, developers must also navigate scale-up,

regulatory expectations, supply reliability, and commercial manufacturing readiness. Wacker Biotech's operational maturity in these areas for proteins, vaccines, nucleic acids, and conjugates provides customers with confidence that processes can be seamlessly scaled up into commercial manufacturing workflows.

A partner for tomorrow

The future of medicine will be shaped by advanced medicines capable of addressing disease at its genetic roots. From cell and gene therapies to RNA medicines, personalized vaccines, and targeted nucleic acid therapeutics, innovation is accelerating at an unprecedented pace. With its integrated capabilities, proven manufacturing expertise, dedicated infrastructure, and long-standing commitment to innovation, Wacker Biotech is uniquely positioned to help bring these breakthroughs to patients. Its end-to-end platform encompassing plasmid DNA, RNA production, and advanced LNP technologies, including opportunities for targeted and conjugated nanoparticle delivery, makes Wacker Biotech a compelling CDMO partner for companies seeking to transform scientific potential into clinical and commercial success.

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Beyond monoclonals: Multispecific antibodies

ADVERTORIAL New biologic logic – Multispecific antibodies extend targeted therapy beyond one antigen or pathway. By combining binding sites, cell recruitment and defined valencies within one molecule, they enable mechanisms that conventional monoclonal antibodies or their combinations cannot reproduce with the same spatial and pharmacological control.

Multispecific antibodies recognize two or more antigens or epitopes and connect functions that would otherwise remain separate. Established examples are T-cell engagers that bind a disease-related antigen and CD3 expressed on T cells to induce MHC-independent cytotoxicity. Other concepts recruit NK cells or macrophages, combine checkpoint modulation with tumor targeting, or bring enzymes and substrates into proximity.

Other bi- and multispecifics act without immune-cell redirection. Dual-receptor antibodies can block compensatory signaling, while biparatopic antibodies bind two epitopes on the same target to increase avidity, promote clustering or accelerate internalization. Multispecificity can also improve tissue selectivity by requiring co-expression, antigen density or a defined spatial arrangement.

Format defines function

Today, more than 100 multispecific antibody formats are under clinical investigation. The field comprises IgG-like, fragment-based and hybrid architectures. This diversity reflects a central principle: binding domains alone do not define activity. Geometry, valency, flexibility, affinity, half-life and Fc function jointly determine biological activity.

Fc-containing formats offer prolonged exposure and adjustable effector functions. Fc-free formats are smaller and may improve tissue penetration, but often require half-life extension. VHH, Fab and scFv modules allow additional specificities at defined positions. The optimal architec-



Choosing the right therapeutic antibody format. A diverse toolbox of multispecific formats enables the selection of the right biologic for each target and therapeutic strategy.

ture depends on the intended mechanism rather than on a universal platform.

Beyond oncology

Clinical development of bi- and multispecifics has been led by oncology, particularly CD3-based T-cell engagers for hematological malignancies. The same engineering logic is expanding into solid tumors, inflammatory disease and autoimmunity.

Mechanisms include dual cytokine neutralization, selective depletion of pathogenic immune cells and simultaneous modulation of receptor pathways.

Engineering remains decisive

Greater functional control comes with increased molecular complexity. Chain pairing, expression, aggregation, stability, product heterogeneity and manufacturability must be considered early. Safety also depends on affinity, valency,

target distribution and activation geometry. Conditional activation, Fc engineering and tuned binding kinetics can improve therapeutic windows.

Outlook

Multispecific antibodies represent a conceptual evolution from passive targeted blockade to active, programmable biologics. As computational design matures and safety-by-design engineering further refines toxicity profiles, these molecules have the potential to become a foundational backbone of targeted biological therapy.

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Europe's complex trials fuel CRO demand

MULTICOUNTRY TRIALS Europe may have simplified the way multinational clinical trials are authorized, but running them across multiple countries still creates a substantial operational burden. New analyses of Clinical Trials Information System (CTIS) data suggest that this complexity is translating directly into demand for CRO support.

The pattern is particularly clear in late-stage and multinational studies. An analysis by Trial Agents of 352 European Phase 3 orphan-drug trials found that 84.7% listed at least one CRO or outsourced provider. Among trials running in seven or more countries, that share rose to 93.6%.

The same relationship appears across therapeutic areas. In 887 European Phase 3 oncology trials, CRO or specialist-provider support was identified in 49.9%

overall, but in 90.4% of studies spanning at least 10 countries. Among Phase 2 and 3 colorectal cancer trials, CRO involvement rose from just 7.4% for single-country studies to 100% for the 16 trials conducted in seven or more countries.

CTIS has made Europe easier to access on paper: sponsors can submit a single application covering up to 30 EU/EEA countries. But national authorities remain responsible for trial assessment and over-

sight, and multinational applications still involve country-specific requirements and multiple Part II sections.

For sponsors, that leaves a familiar problem behind the harmonized front door: site activation, contracting, translations, monitoring and local execution still have to work country by country. The larger the European footprint, the stronger the case for outsourcing that coordination.

Joachim Eeckhout

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