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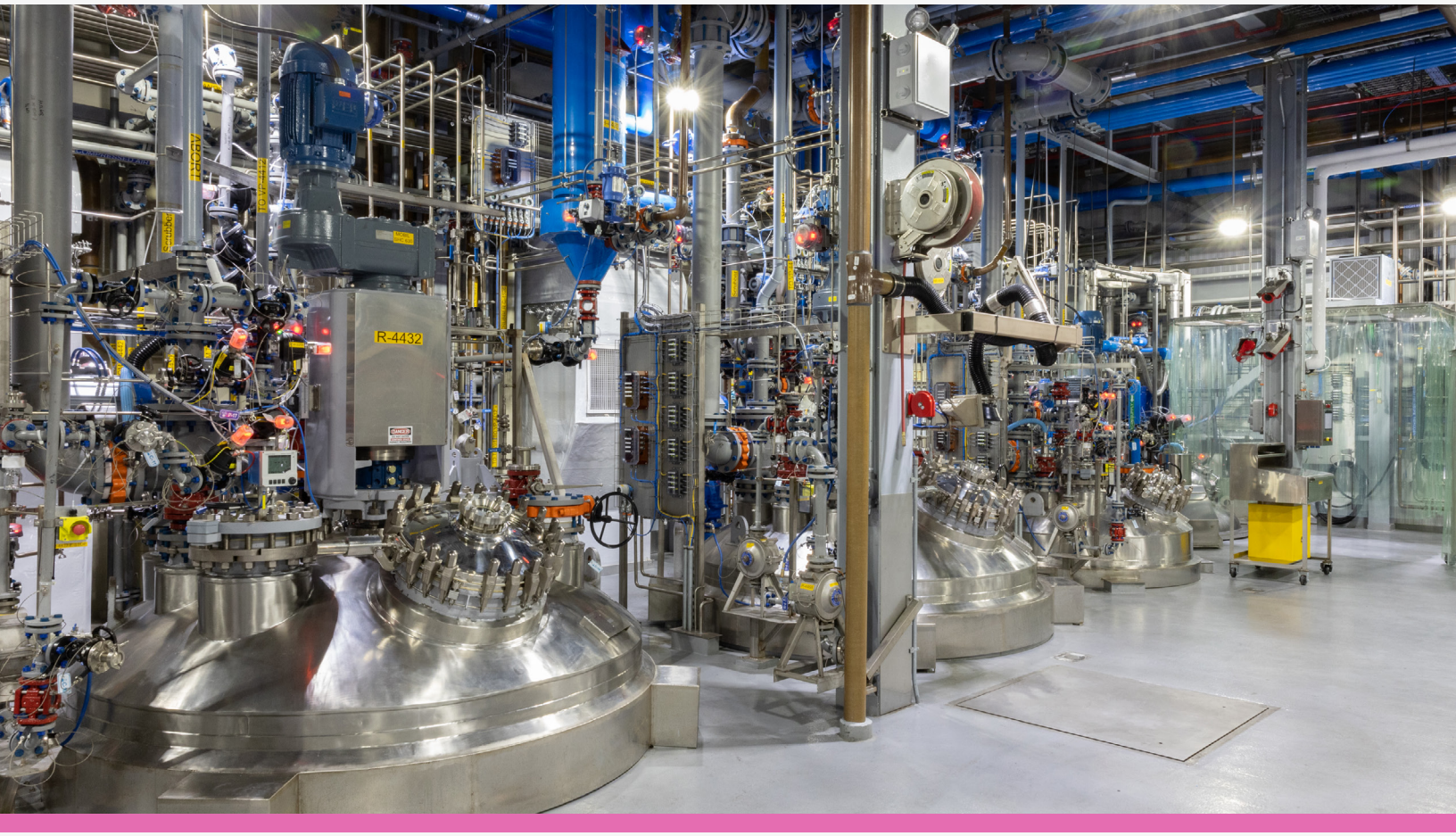
AUGUST 2025



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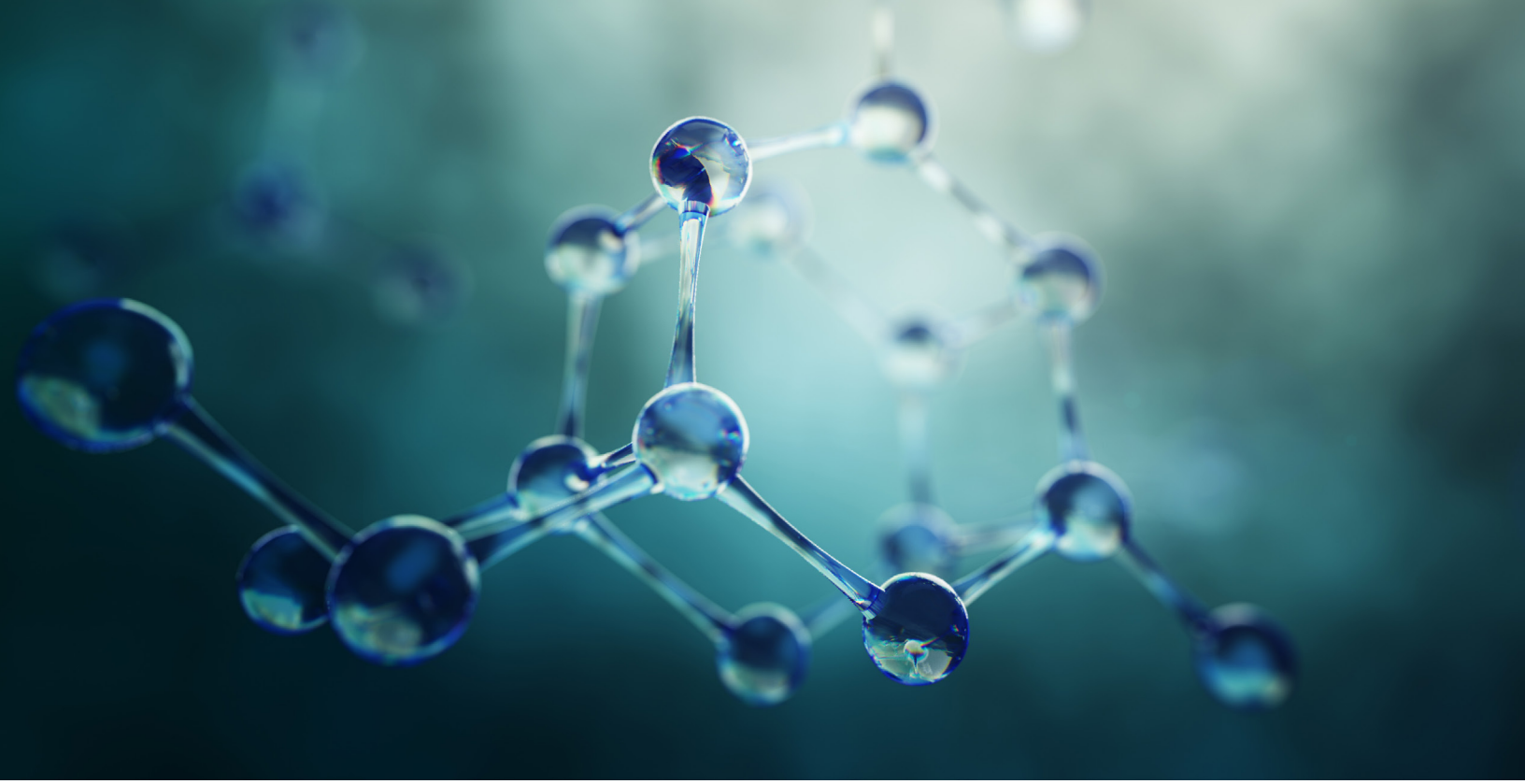

How Automation, Sustainability, And Geopolitical Foresight Are Reshaping Outsourcing Priorities

Amid rising geopolitical risks and tightening sustainability mandates, pharmaceutical companies are redefining outsourcing strategies. This article explores how automation, environmental commitments, and multi-regional manufacturing are reshaping Contract Development and Manufacturing (CDMO) partnerships.

The U.S. pharmaceutical supply chain faces an unprecedented challenge: an estimated 88% dependency on imported active pharmaceutical ingredients across all drug types, with domestic production covering only about 15% of innovator (brand-name) medicines and roughly 12% for generics.[1]

In early 2025, new tariffs of up to 245% on Chinese imports drove API costs for basic generics up 12–20%. While these tariff-driven cost increases have so far primarily impacted the generics sector, prompting immediate reassessment of procurement strategies, the resulting market volatility has heightened risk awareness and triggered supply chain reviews for innovator manufacturers as well.[1-3]

These supply chain pressures are coinciding with two other significant trends reshaping CDMO partnerships. First, the EU's Corporate Sustainability Reporting Directive will require detailed ESG disclosures from large pharmaceutical companies, elevating environmental performance as a procurement criterion.[4-5] Second, advancing molecular complexity and shrinking development timelines are pushing traditional tech transfer processes to their limits.[6-7]

Procurement decisions increasingly prioritize supply chain resilience, process innovation capabilities, and integrated service delivery across multiple regions. For industry executives, the challenge now is to build CDMO relationships that are not only cost-effective, but also resilient, innovative, and environmentally aligned.

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Supply Chain Security Drives Procurement Strategy Shifts

Recent tariff implementations have accelerated a trend already visible in post-COVID procurement strategies: the move away from single-source, cost-optimized supply chains toward diversified, risk-adjusted approaches. But industry experts suggest the changes run deeper than geographic diversification alone.

"I think there are a lot of companies that are interested in changing their supply chains to address supply chain security and diversification," said Matthew Bio, PhD, chief scientific officer at Cambrex.

The strategic implications extend beyond immediate tariff calculations. "We're seeing a strong desire from clients to manufacture materials in the same regions where they plan to commercialize them. So, Europe for Europe, US for US, and Asia for Asia is now a strategy that we've heard from a number of our larger clients, and we're seeing it play out in the RFPs that we receive and the proposals that are won," he added.

This regional alignment strategy reflects a broader recalculation of risk factors. Companies are incorporating regulatory predictability, intellectual property security, and supply chain stability into procurement decisions previously dominated by unit cost comparisons. The shift suggests that CDMOs with robust multi-regional capabilities and integrated cross-site operations may capture disproportionate market share as clients prioritize supply security alongside cost efficiency.

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Process Innovation Becomes Competitive Differentiator

As pharmaceutical companies navigate supply chain restructuring, they're simultaneously confronting development timeline pressures that traditional CDMO service models struggle to address. The industry has responded with significant investment in process automation and real-time analytics capabilities.

Leading CDMOs are implementing closed-loop optimization systems that fundamentally change development economics. Cambrex, for example, has

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implemented closed-loop optimization systems wherein automated reaction systems with real-time analytical monitoring can be connected to an optimization algorithm to enable rapid screening of reaction conditions. The system can independently identify optimal reaction conditions.

The timeline improvements are substantial. "What could have taken weeks is now on the order of days to solve a problem of identifying the starting conditions for a commercial process," Bio said.

Analytical capabilities are evolving in parallel. Erik Feldmann, PhD, principal technical advisor at Cambrex, described a systematic approach to method development that integrates high-throughput screening with automated workflows. "We've implemented more semi-automation of analytical development workflows. High-throughput and data-rich method development using multi-column and multi-solvent screening in our development labs," he explained.

These technological capabilities appear to be reshaping client expectations around tech transfer timelines and cross-site process reproducibility. CDMOs that can demonstrate integrated automation and analytics capabilities may find themselves better positioned for larger, more complex development programs.

Sustainability Requirements Drive Process Innovation

Environmental regulations are creating new technical challenges that some CDMOs are turning into competitive advantages. The EU's Corporate Sustainability Reporting Directive requires pharmaceutical companies to disclose Scope 3 emissions—about 80% of their carbon footprint—with phased compliance beginning mainly from 2025 through 2027 and beyond for different company categories. This makes supplier environmental performance an increasingly material consideration in procurement decisions.[4-5]

Regulatory pressure is driving innovation in manufacturing processes, particularly for complex molecules such as peptides. Traditional solid-phase peptide synthesis (SPPS) generates significant waste,

whereas alternative approaches can dramatically reduce this environmental impact.

"The motivation for developing liquid-phase peptide synthesis (LPSS) technology was really about the environmental impact of SPPS," Bio explained. "We're routinely seeing two orders of magnitude or more improvement on the process mass intensity of those reactions when we're using LPPS versus SPPS. Where solid-phase synthesis might generate 10,000 kilos of waste to produce just one kilo of peptide, we can now achieve the same outcome with as little as 100s of kilos of waste using liquid-phase synthesis."

Similar innovations are being applied to solvent recovery and energy consumption. Cambrex has reduced the environmental footprint of high-volume processes by internally recycling solvents, significantly lowering overall solvent use.

Infrastructure investments are also supporting sustainability objectives. Facilities are increasingly powered by renewable energy sources, with some manufacturing sites achieving 90-95% wind energy or 100% renewable steam, according to Bio.

The integration of environmental considerations into early-phase development decisions appears to be creating new evaluation criteria for CDMO selection, particularly for programs advancing toward commercial manufacturing.

Cross-Site Integration Addresses Multi-Regional Demands

As pharmaceutical companies seek multi-regional manufacturing capabilities, operational integration of multisite CDMOs has emerged as a critical differentiator. The challenge extends beyond simply having facilities in multiple geographies to coordinating complex development and manufacturing activities across time zones and regulatory jurisdictions.

Jim Graham, director of drug substance development and manufacturing at Cambrex Longmont, describes how integrated site coordination can compress overall development timelines: "Tight internal coordination helps streamline scheduling and information flow across our sites to better support clients. The close collaboration and cooperation between sites reduces overall timelines by removing months' worth of administrative, shipping, and project management time."

"The ability to run parallel development tracks while maintaining information flow and quality standards across sites appears to be creating competitive advantages for CDMOs with mature cross-site integration capabilities."

This coordination becomes particularly complex when combining early-phase development with the preparation for commercial-scale manufacturing. The ability to run parallel development tracks while maintaining information flow and quality standards across sites appears to be creating competitive advantages for CDMOs with mature cross-site integration capabilities.

"It's this time often found in the margins that adds up to significant time and cost savings for clients of all sizes," Graham added.

The operational complexity extends to specialized capabilities, such as biocatalysis, where institutional knowledge and proprietary platforms can provide significant advantages. Some CDMOs have developed extensive enzyme libraries over decades, creating capabilities that competitors cannot easily replicate.

For example, Cambrex's team in Wiesbaden, Germany, has developed a large library of wild-type enzymes covering a broad range of chemistries that support route development across the organization.

These specialized capabilities, combined with advanced manufacturing platforms, represent the kind of deep technical assets that become increasingly valuable as molecular complexity continues to increase.

"Cambrex is also expanding analytical infrastructure to meet the growing demands of complex modalities."

Cambrex is also expanding analytical infrastructure to meet the growing demands of complex modalities. "We conduct extractables & leachables studies for a wide variety of drug product formulations," Feldmann said. "We use advanced tools like GC-MS with ECM MassHunter and BioConfirm software on our HRMS LC-Q-TOF system to characterize unknowns—including peptides and oligos."

Market Implications and Strategic Considerations

The convergence of supply chain security concerns, sustainability requirements, and product complexity is creating new competitive dynamics in the CDMO market. CDMOs that effectively integrate advanced technologies, multi-regional manufacturing, and specialized expertise are well-positioned to support pharmaceutical manufacturers developing complex products, navigating evolving outsourcing strategies and intricate supply chain dynamics.

"We continue to see an increase in molecular complexity and the types of synthetic modalities that are being advanced," Bio said. "For any organization whose primary activity is chemical synthesis and manufacturing of chemical entities, I think it's still a really strong area of growth for the future."

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