

Reducing Risk Earlier: Why the Future of Biopharma Development Demands Smarter CDMO Partnerships

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Katie Edgar, Chief Business Officer at KBI Biopharma, discusses AI-driven development, analytical excellence, commercialization readiness, and the evolving role of CDMOs in accelerating complex biologics.



As biologics become increasingly sophisticated and development timelines continue to shrink, the role of Contract Development and Manufacturing Organizations (CDMOs) is evolving beyond manufacturing support to strategic lifecycle partnerships. **In an interaction with BioSpectrum Asia during BIO International Convention 2026, Katie Edgar, Chief Business Officer at KBI Biopharma,** shares insights on how artificial intelligence, advanced analytics, and integrated development strategies are reshaping the industry. She also discusses the growing importance of analytical characterization, commercialization readiness, ADC manufacturing, supply chain resilience, and the capabilities sponsors should prioritize when selecting long-term development partners.

AI, automation, and predictive analytics are increasingly being integrated into biopharmaceutical development workflows. How do you see these technologies reshaping development and manufacturing over the next five years, and where is KBI already seeing measurable impact?

Over the next five years, the most successful organizations will use AI, automation, and predictive analytics to reduce development risk, improve speed to clinic, and increase confidence in commercial readiness.

As biologics become more complex and development timelines continue to compress, organizations will increasingly rely on data-driven tools to reduce uncertainty, improve decision-making, and accelerate programs toward the clinic and commercialization.

One of the most significant shifts will be the move from reactive to predictive development. Rather than identifying issues after they occur, advanced analytics will enable drug developers and CDMOs to anticipate process variability, optimize development strategies, and identify potential manufacturing or quality risks earlier in the lifecycle. This is particularly

important as companies seek to reduce technical, regulatory, and operational risk while maintaining speed.

At KBI, we view these technologies through the lens of de-risking development. Advanced analytics and digital tools are helping to generate a deeper understanding of processes across cell line development, process development, analytical characterization, and manufacturing. The ability to leverage data more effectively supports smarter decision-making, stronger CMC foundations, and improved readiness for scale-up and commercialization.

Automation is also improving operational efficiency and consistency by reducing manual interventions, strengthening data integrity, and generating richer datasets that support continuous improvement. At the same time, innovations in cell line development technologies and analytical sciences are creating opportunities to accelerate timelines while maintaining quality and compliance.

While AI offers tremendous promise, its success will ultimately depend on the quality of the underlying data and the scientific expertise used to interpret it. At KBI, we believe the future lies in combining advanced digital capabilities with deep scientific knowledge to help clients reduce risk, accelerate development, and bring innovative therapies to patients faster. The true value of AI in biopharmaceutical development will ultimately depend on access to high-quality data, robust governance frameworks, and scientific expertise capable of translating insights into action.

Analytical characterisation has become increasingly important as biologics grow more complex. Why is analytical expertise emerging as a key differentiator for CDMOs, and how can it influence programme success from early development through commercialisation?

One of the biggest challenges in our industry is the commercialization readiness gap—the disconnect between achieving clinical milestones and building the robust analytical, process, and manufacturing foundations required for successful commercial supply. As biologics continue to evolve beyond traditional monoclonal antibodies into increasingly complex modalities, analytical characterization has become one of the most critical drivers of development success. Today, analytical expertise is no longer simply a supporting function—it is a strategic capability that influences decisions throughout the entire product lifecycle.

Robust analytical characterization provides the foundation for understanding a molecule's critical quality attributes, stability profile, manufacturability, and regulatory readiness. Early in development, analytical insights help establish product knowledge, identify potential risks, and guide process optimization. As programs advance, those same analytical methods become essential for demonstrating comparability, supporting technology transfers, validating manufacturing processes, and meeting regulatory expectations.

At KBI, we believe analytical excellence plays a central role in helping clients close the commercialization readiness gap. Drawing on more than 30 years of experience supporting biologics development and manufacturing, KBI has seen firsthand that early investments in analytical strategy and scalable process design significantly improve long-term outcomes.

Many companies focus heavily on reaching the clinic but underestimate the analytical and CMC requirements needed to successfully scale and commercialize a product. Strong analytical strategies implemented early can significantly reduce development risk later by supporting process scalability, regulatory submissions, and long-term manufacturing consistency.

The importance of analytical expertise becomes even more pronounced with complex modalities such as ADCs, bispecific antibodies, and other next-generation biologics, where sophisticated characterization methods are required to assess attributes that directly impact product safety and efficacy. Strong analytical foundations also facilitate regulatory interactions by providing the product and process understanding necessary to support comparability assessments, lifecycle management, and evolving global regulatory expectations.

As a result, drug developers are increasingly evaluating CDMOs not only on manufacturing capabilities but also on the depth of their analytical expertise. The ability to generate actionable insights, support informed decision-making, and build robust control strategies can ultimately determine how efficiently a program advances from development through commercialization.

ADCs and other complex biologic modalities continue to attract significant investment. What are the most common development and manufacturing challenges associated with these therapies, and how should sponsors prepare for them?

ADCs and other advanced biologic modalities continue to generate significant interest due to their potential to deliver highly targeted therapies and improve patient outcomes. However, with increased innovation comes increased complexity, creating unique development and manufacturing challenges that must be addressed early.

One of the biggest challenges is the molecule's complexity. ADCs require the successful integration of multiple components while maintaining product stability, consistency, and efficacy. Small variations in manufacturing can have meaningful impacts on critical quality attributes, making process control and analytical characterization especially important.

Manufacturing these therapies also requires expertise across multiple disciplines. Sponsors must manage antibody production, conjugation processes, purification, analytical testing, containment considerations, and scale-up activities while maintaining product quality and regulatory compliance. As programs advance, demonstrating process consistency and comparability becomes increasingly important.

At KBI, we often emphasize that many development risks associated with complex modalities can be mitigated through stronger planning and earlier investment in commercialization readiness. Too often, companies focus primarily on achieving clinical milestones without fully considering the process scalability, analytical strategies, and CMC foundations needed for long-term success.

Success with complex modalities increasingly depends on integrating analytical, process, manufacturing, regulatory, and supply chain considerations much earlier in development. Biotech companies should seek development partners that can provide integrated expertise across analytical sciences, process development, manufacturing, and regulatory support. Establishing robust analytical methods, scalable manufacturing processes, and clear development strategies early can help reduce risk, avoid costly delays, and improve the likelihood of successful commercialization.

Ultimately, success with complex biologics requires a holistic approach that balances scientific innovation with manufacturability, quality, and long-term development objectives.

KBI recently announced a partnership with MilliporeSigma. Together, we can now offer an integrated service package to advance innovation in ADCs and further accelerate life-changing therapies for patients around the globe.

As drug developers evaluate potential outsourcing partners, what capabilities should they prioritise when selecting a CDMO in today's rapidly evolving market environment?

The criteria used to evaluate CDMOs have evolved significantly over the past decade. While manufacturing capacity remains important, today's biopharmaceutical companies increasingly seek strategic partners that can help reduce risk, accelerate timelines, and support programs from early development through commercialization.

One of the most important capabilities to prioritize is scientific expertise. As biologics become more complex, companies need partners that can provide guidance on process development, analytical characterization, CMC strategy, and manufacturing readiness. A strong scientific foundation can help identify challenges earlier and support more informed decision-making throughout development.

Companies should also look to a CDMO for integrated lifecycle support. The traditional transactional outsourcing model is giving way to long-term partnerships where CDMOs support multiple stages of development. Organizations increasingly value partners that can seamlessly connect cell line development, process development, analytical services, manufacturing, technology transfer, and commercial support.

At KBI, we see growing demand for lifecycle partnerships that evolve alongside the client. Our full-service offerings reflect this shift by enabling customers to leverage integrated expertise across the product lifecycle while maintaining flexibility and responsiveness.

Additionally, drug developers should evaluate a CDMO's quality systems, regulatory experience, supply chain resilience, and ability to support future growth. The strongest partnerships are built on transparency, collaboration, and a shared commitment to achieving program objectives.

In an environment defined by scientific complexity and increasing development pressures, the most valuable CDMO partners are those that help clients navigate uncertainty, reduce risk, and position programs for long-term success.

Supply chain resilience and manufacturing security have become strategic priorities across the industry. How is the growing demand for U.S.-based manufacturing influencing investment decisions, customer expectations, and long-term capacity planning?

Supply chain resilience has become a defining priority for the biopharmaceutical industry. Geopolitical uncertainty, evolving regulatory requirements, and global supply chain disruptions have prompted sponsors to reevaluate how they select manufacturing partners and where critical development and manufacturing activities take place.

As a result, demand for U.S.-based manufacturing continues to grow. While cost and speed remain important considerations, sponsors are increasingly prioritizing reliability, quality, operational continuity, and manufacturing security. Many organizations are seeking partners that can help reduce geopolitical risk while providing greater visibility and control throughout the supply chain.

This shift is influencing investment decisions across the industry. Companies that outsource are placing greater emphasis on domestic manufacturing capabilities and geographically diversified supply networks that can better withstand disruptions. CDMOs are responding by investing in infrastructure, workforce development, technology, and commercial manufacturing capabilities that support long-term resilience.

Customer expectations are also changing. Organizations expect CDMOs to demonstrate robust quality systems, supply chain transparency, and proactive risk management strategies. In today's environment, resilience is no longer viewed as a differentiator—it is a requirement.

Looking ahead, we believe supply chain strategy will remain a central component of development planning, with U.S.-based manufacturing continuing to play an important role in helping organizations reduce risk and strengthen operational confidence. Sponsors are increasingly seeking geographically diversified supply strategies and CDMO partners capable of supporting flexible manufacturing networks as programs transition from clinical to commercial stages.

That all said, manufacturing location is only one component of resilience. Sponsors are increasingly evaluating the strength of a CDMO's supply network, sourcing strategies, quality systems, operational continuity plans, and ability to scale with future demand.

Looking ahead, what major trends do you believe will define the next generation of CDMO partnerships, and how is KBI positioning itself to support emerging therapeutic modalities and future client needs?

The next generation of CDMO partnerships will be defined by deeper collaboration, greater scientific complexity, and a stronger focus on helping sponsors navigate risk throughout the product lifecycle. As therapeutic innovation accelerates, biopharmaceutical companies will increasingly seek strategic partners that contribute expertise, insights, and long-term value—not simply manufacturing services.

One major trend will be the continued shift from transactional outsourcing to lifecycle partnerships. Companies are increasingly looking for organizations that can support programs from cell line development and analytical characterization through manufacturing and commercialization. This integrated approach helps reduce handoffs, improve efficiency, and create stronger pathways to approval and launch.

We also expect commercialization readiness to become an even greater focus. As more advanced biologics move through development, companies will need partners that can help establish scalable processes, robust analytical strategies, and strong CMC foundations much earlier in the development lifecycle.

Digital transformation will be another defining trend. AI, automation, and advanced analytics will enable more predictive, data-driven decision-making, helping organizations improve development efficiency while maintaining quality and compliance. We also expect greater emphasis on platform technologies and standardized development approaches that can accelerate timelines while improving reproducibility across increasingly diverse therapeutic modalities.

We are positioning ourselves at KBI to support these evolving needs through continued investment in scientific expertise, analytical excellence, integrated development and manufacturing capabilities, and innovative technologies. We are committed to supporting clients throughout their entire journey, while our 30-year history provides a strong foundation of experience and industry knowledge.

Ultimately, the most successful CDMO partnerships of the future will be built on trust, collaboration, and a shared commitment to reducing risk and accelerating the delivery of innovative therapies to patients. But the future of biopharmaceutical development is not simply about moving faster—it's about reducing risk earlier.