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ASIA EDITION

# “There are talent shortages in specialised modalities such as ADCs, peptides, and computational biology”

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**As the Asia Pacific (APAC) contract development and manufacturing organisation (CDMO) sector continues to expand rapidly due to rising R&D investment, strong biotech formation, increased demand for Investigational New Drug (IND) - enabling and early Chemistry, Manufacturing, and Controls (CMC) services, and national incentives for biomanufacturing, KBI Biopharma is focused on targeted expansion into Japan, Korea, Taiwan, and Australia, for improving local engagement and enhancing access to global network. BioSpectrum Asia spoke to Katie Edgar, Chief Business Officer, KBI Biopharma to learn more about the company’s growth plans in 2026, and about the growth opportunities in store for the CDMO market within the APAC region.**

**How would KBI Biopharma highlight its achievements in 2025? Which key projects strengthened the company’s global CDMO presence?**

2025 has been a pivotal and transformative year for KBI Biopharma, with breakthroughs across scientific platforms, digital capabilities, customer experience, and strategic partnerships. We completed significant platform upgrades to ensure speed, consistency, and robustness for early-stage programmes heading toward IND. These improvements have positioned KBI as a top choice for biotechs seeking reliable, high-quality IND-enabling support. A major milestone this year was the build-out of an integrated, end-to-end development and manufacturing model, including a strategic partnership with Argonaut Manufacturing Services for Drug Product (DP). This partnership streamlines vendor management, strengthens supply chain reliability, and gives our clients a more seamless, unified experience from cell line development (CLD) through DP release.

We currently offer GMP antibody drug conjugate (ADC) testing at our Geneva site, and plan to expand this service to our Boulder and North Carolina sites in 2026.?In addition, we are in the design phase for building a state-of-the-art ADC process development lab at one of our North Carolina sites.

**What are the major plans lined up for 2026? Are there any new investment plans? How much growth is anticipated in 2026?**

2026 will be a year of strategic expansion and deeper integration across our technology, digital, and commercial capabilities. A few key priorities include the launch of a peptide development offering, which will expand KBI's modality coverage and strengthen our competitive position for next-generation therapeutics; continued upgrades to mammalian CLD, including platform automation, predictive stability analytics, and enhancements focused on IND quality and reproducibility; further expansion of ADC capabilities, with targeted analytical and process development investments to support the next wave of conjugated and targeted biologics; and more around strengthening our digital and artificial intelligence (AI) integration, network enhancements, and scaling our end-to-end ecosystem. We anticipate solid double-digit growth in 2026, driven by a few key factors, some of which include a rebounding funding cycle that we're seeing in the current market dynamic, which is enabling early-stage clients to restart IND-enabling programmes – a sweet spot for KBI and a large portion of our portfolio of customers. Additionally, there is rapid ADC and XDC market segment growth, and targeted biologics market expansion, particularly in the ability to meet the needs for complex monoclonal antibody (mAb) development; and our investment in growth within the APAC region, enabled by KBI Japan?and additional resources to support the region.

**Please elaborate upon the company's strong moves in the Asia Pacific region?**

KBI is purposefully expanding across the APAC region, recognising its rapid scientific growth and increasing demand for global-quality CDMO partners. We're focused on the formal launch and staffing of KBI Japan, providing local language and cultural alignment; targeted expansion into Japan, Korea, Taiwan, and Australia with technically fluent commercial teams; integration of APAC programmes into global digital and quality systems for seamless cross-site execution; and partnerships with key regional innovation hubs and institutions. We feel these steps will further enable APAC innovators to access world-class IND-enabling, development, and manufacturing pathways without geographic barriers.

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**How is KBI Biopharma exploring the area of AI-based drug discovery? What opportunities do you foresee?**

KBI has established a dedicated AI governance and innovation task force to ensure responsible application of AI across biologics development. Specifically, we have predictive modeling for CLD, media optimisation, and yield improvement. We are currently exploring AI-enhanced analytics for complex data interpretation, automation of data capture, documentation, and quality workflows, and secure AI frameworks that protect IP and ensure global regulatory and quality compliance. Looking ahead, we foresee AI helping with faster, higher-quality IND-enabling packages, improved process predictability and fewer experimental iterations, reduced development risk and stronger comparability packages, and more. We expect AI to further become a competitive differentiator when applied in a scientifically rigorous and secure manner.?Our job is to provide the framework and protections for the ability to provide this in a way that maintains the regulatory and quality scrutiny that patients deserve.

**What are your thoughts on the key trends & challenges for the global CDMO sector, including the APAC region, in 2026?**

As far as trends, we know there is continued rebound in early-stage biotech funding, which is both opportunistic and promising for the biologics industry as a whole, there's strong momentum in ADC and targeted biologics, and onshoring in the US and supply chain resilience are top of mind for all of us in the industry.

As noted, an expansion of microbial, peptide, and biosimilar platforms?is something to watch, particularly in the APAC region given incentives by certain municipalities on regulatory opportunities for acceleration pathways. Digitalisation and AI as critical enablers of speed, quality, and transparency continue to drive discussions around innovation and change. And a growing preference for end-to-end service models with unified DS-DP-analytics frameworks?continues to be on trend; but more important with this, is proof of concept. Anyone can announce a partnership, but satisfied customers and meaningful impact are the true KPIs we all need to be striving for.

When it comes to challenges for CDMOs, capacity constraints at late-stage and commercial scales?are always going to be relevant, but with the current regulatory landscape, these are even more top of mind for the late-stage programmes. Rising regulatory expectations for comparability, data integrity, and analytical depth?require very specific expertise. We are fortunate to not only have a robust in-house regulatory team to help facilitate this for our customers, but also partner with A-REG

Solutions to ensure best-in-class solutions to our customers in delivering tailored regulatory support that meets each client's distinct needs based on the specifics of the markets in which they are filing globally.

Additionally, one of the most challenging things to watch is ongoing talent shortages in specialised modalities such as ADCs, peptides, computational biology, and late-stage CMC. We pride ourselves on the technical expertise of our staff, so continuing to provide the best requires us to continue to hire, train, and retain the best. Fortunately, KBI's platform innovations, digital investments, AI governance, growing partnership?portfolio, APAC expansion, and growing late-stage pipeline position the company to meet these challenges with strength and confidence.

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