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ASIA EDITION

“ASEAN has become an important fulcrum in the global pharmaceutical production supply chain”

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Asia-based BioDlink, a full-service Contract Development and Manufacturing Organisation (CDMO) specialising in biologics and antibody-drug conjugates (ADCs), has built a strong track record over the past decade, offering integrated solutions from early-stage R&D to commercial manufacturing. With globally compliant quality systems and high-potency Occupational Exposure Bands (OEB)-5 facilities, the company has supported over 100 projects and passed nearly as many GMP audits, including a zero-defect European Union, Qualified Person (QP) inspection. Recently, BioDlink strengthened its global compliance credentials with GMP certifications from Argentina and Brazil. Dr Jun Liu, CEO and Executive Director, BioDlink shares insights into the company’s capacity expansion plans, the role of continuous manufacturing in its long-term strategy, and key trends shaping the CDMO landscape, etc.

What are your plans for capacity expansion in biologics and ADC manufacturing?

We are already among the largest biologics CDMO providers within China, and our capacity infrastructure reflects this leadership. Currently, we operate with a combined bioreactor capacity of 20,000 litres for antibody drug substance, with two independent production centres for antibody stock solutions and another three for ADCs, delivering more than 100 clinical projects worldwide, including European and the US, in the past three years.

We also have four complete commercial drug production lines — two for antibody-based manufacturing and another two for ADCs. These production lines are outfitted with international world-class equipment, fully validated for antibodies and ADC drug substance and drug product production, compliant with US, EU and China standards. This strong foundation gives us the flexibility to seamlessly transition projects from development to full-scale commercialisation.

We run one of the most advanced ADC production lines in the region, including a 40-square-meter liquefaction unit — a critical and often capacity-limiting step in ADC manufacturing, with up to 150 batches per year.

Looking ahead, we will further enhance our production capacity to cater to our clients' diverse and customised requirements. As of May 2025, we're actively supporting multiple pre-FDA Biologics License Application (BLA) projects — producing clinical material, executing Process Performance Qualification (PPQ) runs, and preparing for regulatory inspections.

How do you leverage presence in Asia-Pacific to differentiate from global CDMO players?

Our roots in Asia-Pacific afford us a distinct advantage to meet the diverse needs of our clients: proximity to the world's fastest-growing pharmaceutical markets and a nuanced understanding of regional regulatory landscapes.

We leverage this by offering compliance with global quality standards and flexibly allocating resources, offering a combination of antibody and XDC CDMO platforms to realise faster delivery and cost effectiveness. Moreover, our bilingual, cross-cultural scientific teams enhance collaboration and reduce communication friction for our multinational clients. It's a combination of speed, compliance, and cultural competence that sets us apart.

How do emerging technologies like continuous manufacturing fit into your growth strategy?

We see continuous technological innovation as a core pillar of our strategic growth, focusing on building distinctive, customiable technology platforms designed to address specific customer needs. By advancing and personalising these cutting-edge solutions, we strengthen our competitive edge and enhance our ability to support a broad spectrum of customer projects with flexible, high-impact technical capabilities.

The continuous manufacturing approach we employ—Perfusion Fed-batch—is not just an incremental process improvement; it's a paradigm shift. This technology significantly lowers manufacturing costs while enhancing efficiency. We've integrated Perfusion Fed-batch into our large-scale commercial production.

Meanwhile, BioDlink continues to advance its technology platform, accelerating innovation cycles to more effectively meet the evolving and diverse needs of our clients. We incorporated the GL-DisacLink technology, a competitive solution for next-generation XDC (xenobiotic drug conjugate) bioconjugation. The platform stands out with its precision and efficiency, enabling a single-enzyme, one-step reaction with rapid turnaround and high completion rate.

Which key practices have enabled BioDlink's regulatory success across multiple markets?

Our regulatory strategy is built on proactive alignment with global standards. We engage early and often with regulatory agencies, ensuring our data packages meet or exceed expectations. Internally, we've established robust quality systems and a culture of continuous improvement. Transparency, traceability, and technical rigour are the cornerstones of our compliance model. With ISO 27001 certification in Information Security Management Systems, we also provide excellent customer information security.

Quality is our core, with extensive global compliance experience. Our facilities and processes have consistently met the rigorous standards of the National Medical Products Administration (NMPA), and we've successfully passed EU QP inspections four times in the past two years— a rare feat that underscores our operational excellence. Recently, we passed our first-ever on-site PIC/S (Pharmaceutical Inspection Co-operation Scheme) audit conducted by Brazil's National Health Surveillance Agency (ANVISA). Our quality system is now GMP-compliant in the six key markets of Brazil, Indonesia, Egypt, Colombia, Argentina and Nigeria.

Could you share BioDlink's strategic goals for the next 5–10 years?

Looking ahead, our vision is to establish BioDlink as a global, top-tier CDMO specialising in biologics, including bispecific antibodies, XDCs, and others. We're actively expanding our footprint in global markets with local partners, strengthening international operational capabilities while accelerating our adoption of digital manufacturing technologies and AI-driven process optimisation to elevate service quality and efficiency.

We see ourselves not merely as a service provider, but as a trusted partner that grows alongside our clients. Long-term strategic partnership is the key to further growth, and we are actively exploring a milestone-based model beyond traditional fee-for-service to establish a longer-term strategic partnership to complement and empower our clients, such as leading global pharmaceutical companies and biotech companies with strong innovative capabilities.

What key trends are you seeing in the CDMO space, particularly in Asia-Pacific?

Asia-Pacific, especially ASEAN, has become an important fulcrum in the global pharmaceutical production supply chain. As the APAC pharmaceutical market is diverse, biopharma brands adopt a flexible strategy in the region while minimising some of the problems caused by cultural differences and geopolitical factors.

In addition, these brands seek to increase efficiency, enhance speed to market, and achieve cost efficiency. Therefore, we see an increase in demand for one-stop CDMO services with segmented production capabilities. The challenges with this model are to control the quality risks, industrial safety, and other factors.

At BioDlink, we address these pain points with consistent quality and possess a strong track record with a one-stop, one-site production platform. By providing biopharma brands with a seamless and traceable solution, from cell line development to process optimisation to commercial production, we accelerate speed-to-market while better managing the production value chain and implementing quality management more smoothly.

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