

## Scaling Smarter: The New Blueprint for Next-Generation ADC Development

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As ADC modalities become more complex, integrated development strategies, site-specific conjugation technologies and APAC's expanding innovation ecosystem are redefining the path from discovery to commercial manufacturing.



ADCs continue to represent a major growth area for drug developers, with the market projected to reach \$69B by 2029<sup>1</sup>. As the category matures and clinical pipelines expand, increasing molecular complexity is introducing new challenges across early development, scale-up, and manufacturing. These dynamics underscore the importance of partnering with a fully integrated CDMO that can support end-to-end bioconjugate development, from discovery through IND and beyond.

In this exclusive conversation with **BioSpectrum Asia**, **Marcel Scheepstra, Director, Organic Chemistry, Bioconjugates Research at Lonza Advanced Synthesis**, shares insights from **World ADC Asia 2026** on how CDMOs are partnering with biotech companies to advance and scale complex ADC modalities, and how emerging APAC hubs are enabling the next generation of targeted therapies.

**The ADC landscape continues to evolve rapidly. How do you see the next generation of ADCs differentiating themselves from current therapies in terms of efficacy, safety, and commercial scalability?**

The ADC and bioconjugates field continues to grow rapidly, including next-generation modalities such as antibody-oligonucleotide conjugates (AOCs), degrader-antibody conjugates (DACs), and more recently, targeted lipid nanoparticles (LNPs). With a projected market value of \$69 billion by 2029<sup>1</sup>, ADCs are increasingly being developed with the rigor applied to established biologics.

One big shift is that ADC innovators are moving away from one-off molecules to repeatable platform approaches for linker-payload and conjugation strategies, improving speed, comparability, and predictability across development programs.

Manufacturing has evolved in parallel, from basic capability to control and consistency. Advances such as site-specific conjugation, bispecific formats, and both high and ultra-low drug-antibody ratio (DAR) strategies are enabling more precise design. These innovations aim to address tumor heterogeneity, overcome acquired resistance, and speed adoption of the emerging next-generation modalities. Some innovators are also developing ADCs with immunostimulatory or

immunosuppressive payloads. The category's growing maturity is enabling the next wave of innovation, while also introducing new technical and manufacturing challenges.

**Lonza's GlycoConnect® and HydraSpace® technologies have supported several partnered programmes. What key clinical and development insights have emerged from these collaborations so far?**

ADC design and development pose significant challenges due to their complex structure: a biologic, the antibody, and a chemical moiety, typically a high-potency linker-payload. This requires a high level of quality control, impurity removal, and tight DAR management, thus making the development of safe, efficacious ADCs time-consuming and costly.

Technologies such as the Synaffix GlycoConnect® platform help to address these challenges through precise, site-specific conjugation. In partnered programmes, this approach has helped alleviate issues such as premature linker-payload release, thereby minimizing off-target toxicities, while preserving antibody structure and ensuring consistent drug attachment.

HydraSpace®, a hydrophilic spacer technology, further improves conjugation, pharmacokinetics, and the balance between efficacy and safety. When combined with GlycoConnect® technology, HydraSpace® technology enhances tolerability and predictable performance compared with conventional ADC architectures.

By integrating these ADC technology platforms into development pipelines, drug developers can de-risk and accelerate a bioconjugate's path to Investigational New Drug (IND) status or Investigational Medicinal Product Dossier (IMPD) filing whilst mitigating potential hurdles in the process, shortening time to clinic.

**High DAR and dual-payload ADCs are attracting significant industry attention. What manufacturing and development challenges must be overcome to enable broader commercial adoption of these advanced modalities?**

Indeed, recent literature highlights ADCs with high DAR (8-16) and a few examples of ADCs with very high DAR (up to 30) and using up to six different payloads<sup>2</sup>. This increased complexity introduces challenges across development, analytics, and manufacturing.

Heterogeneity is becoming a central challenge. With higher DARs or multiple payloads, controlling species distribution becomes significantly demanding, directly impacting safety and efficacy. Strategies such as site-specific conjugation and well-defined payload ratios are critical to maintaining consistency. As highlighted in case studies presented at the World ADC Summit in Seoul, South Korea, integrated conjugation approaches that combine site-specific technologies with tailored linker-payload systems can effectively control DAR and payload distribution, enabling better consistency and manufacturability for high-DAR and dual-payload ADCs.

Analytics must evolve at the same pace as molecular innovations. Traditional ADC analytics are no longer sufficient; developers need deeper insights into subpopulations, payload distributions, and stability over time, or risk losing critical insights as complexity increases.

These challenges are amplified at Good Manufacturing Practice (GMP) scale, particularly in downstream processing, where aggregation, heterogeneity, and yield losses pose risks. A sustainable approach is to apply quality by design, where critical quality attributes are clearly defined and tightly linked to process parameters. This level of control is essential to translate molecular complexity into scalable, reliable manufacturing processes.

**As ADC pipelines become increasingly complex, how is the role of CDMOs evolving beyond manufacturing to support innovation, development strategy, and accelerated timelines?**

As the ADC modalities and formats diversify, standard chemistry, manufacturing, and controls (CMC) development may not apply fully. There may also be a need for tailored solutions to de-risk and accelerate the path to IND, particularly for increasingly sophisticated ADC formats.

A successful platform requires a holistic view of the bioconjugate product lifecycle, incorporating CMC and development considerations into the molecule's initial design and process. This helps mitigate downstream challenges as programs move into clinical development. Striking the right balance between CMC readiness and risk mitigation is critical to enabling both speed and robustness.

Collaborating with an experienced partner is essential for developing these novel medicines and bringing breakthrough treatments faster to patients. Today, an estimated 70-80% of ADC projects are outsourced to CDMOs<sup>3</sup>. This trend is likely to persist in the coming years given the complexity of the ADC development process, especially given the challenges surrounding handling of cytotoxic substances.

For example, containment remains a critical requirement, adding layers of complexity in both infrastructure and operations. Lonza's purpose-built containment suites and on-site incineration capabilities allow safe handling of cytotoxic materials while reducing reliance on external partners. For most biotech companies, replicating this capability internally is not practical. Partnering with an integrated CDMO enables access to end-to-end capabilities, helping to accelerate timelines, manage risk, and streamline development across the ADC lifecycle.

**From an Asia Pacific perspective, what trends are you observing among biotech and pharmaceutical companies investing in ADC research and development?**

Asia-Pacific has constituted itself over the past 3-5 years as a global innovation hub in the biotech ecosystem, gaining momentum in next-generation modalities including ADCs, AOCs, biospecific antibodies, and in vivo CAR-T. As early-stage innovation faces pressure<sup>4</sup> in the US, global pharma companies and CDMOs<sup>5</sup> are increasingly partnering with biotech and pharma from Asia Pacific and are expanding their R&D footprint locally.

The region is experiencing rapid growth<sup>6</sup> in ADC and advanced therapy activity, particularly across North Asia. South Korea, Japan, Singapore, and China are seeing high levels of ADC-related investment, partnerships, and infrastructure buildout, while Singapore continues to strengthen its role as a regional hub through targeted investments in drug product manufacturing, ADC infrastructure, and advanced therapy capabilities.

We are also seeing increased collaboration across academic and industry sectors throughout APAC. This is driving not only investment but also access to novel platforms and technologies and a greater focus on differentiated payloads and linker technologies. The region is prioritizing both innovation and scalability, with many companies now leveraging strategic CDMO partnerships to address rising development costs, accelerate timelines, share risk, and reduce complexity. For biotech and pharma companies, these partnerships provide access to enabling technologies, including conjugation and payload platforms, as well as to integrated, end-to-end capabilities.

Overall, the increasing partnership activity reflects a broader structural shift across APAC, from cost-driven manufacturing toward globally integrated, innovation-led ecosystems, where companies compete through technological sophistication, partnerships, and advanced manufacturing capabilities.

**Looking ahead over the next five years, which technological advancements or market developments do you believe will have the greatest impact on the future of targeted therapies and ADC innovation?**

The manufacturing paradigms built for ADCs are becoming the blueprint for these emerging bioconjugate modalities. ADCs forced the industry to learn how to integrate biologics with complex, potent, or sensitive cargoes, and that same logic now applies to AOCs and other novel conjugate modalities.

Moreover, in addition to new types of conjugates, we can expect to see these modalities help treat diseases other than cancer, including autoimmune disease, cardiac disease, fibrosis or genetic alteration-induced diseases.

High-DAR constructs and novel architectures may still feel experimental today, but if they demonstrate improved efficacy, pharmacokinetics, tolerability, and manufacturability, they could enable entirely new classes of therapeutics, some of which may resemble non-traditional formats such as "bottlebrush"-like structures.

Targeted LNPs, particularly those carrying messenger RNA (mRNA), represent another emerging area of innovation. Functionalizing LNPs with ligands to target specific cell types effectively creates a new class of bioconjugates, expanding the potential applications of targeted delivery.

Above all, technological advances must serve patients' needs. Collaborating with CDMOs is a proven pathway for drug developers to turn their breakthrough innovations into viable therapies and manufacture the medicines of tomorrow.