An Integrated State-of-the-Art Site for ADC DS and DP, from IND to Commercial Supply

Antibody-Drug Conjugates (ADCs) represent one of the most powerful and complex classes of cancer therapies ever developed – combining the precision of a monoclonal antibody with the potency of a cytotoxic payload.

Their multi-step, hazardous manufacturing process has made specialist ADC CDMO manufacturing one of the fastest-growing and most technically demanding segments in pharmaceutical outsourcing – and a critical strategic priority for both large pharma and emerging biotech sponsors.

The global ADC contract manufacturing market reached an estimated USD 11.08 billion in 2026 and is projected to expand to approximately USD 29.65 billion by 2035, at a CAGR of 11.56%, according to Towards Healthcare (2026).

The market is expanding steadily, fuelled by rising oncology therapies, expanding clinical pipeline, sustained commercial revenue from approved products, increasing R&D investment from both large pharma and emerging biotech, and the emergence of next-generation ADC technologies – including site-specific conjugation, bispecific ADCs, and novel payload classes – that demand more advanced CDMO platforms.

The availability of CDMOs that genuinely understand protein engineering, conjugation technologies, and next-generation ADC formats is far more limited than general-purpose biologics capacity – and that scarcity is what positions specialist CDMOs as strategic partners rather than commodity suppliers.

The complexity of ADCs creates several manufacturing challenges. Traditionally, producing an ADC required multiple CDMOs, multiple quality systems, multiple technology transfers, and multiple regulatory inspections – across different sites, different countries, different standards.

As the first CDMO in the world to offer a fully integrated supply chain for ADCs under a single roof and a single quality system, BSP delivers Drug Substance and Drug Product manufacturing in seamless operational continuity.

At its Latina, Italy site, BSP Pharmaceuticals has addressed a significant industry bottleneck in ADC manufacturing: a fragmented supply chain. The site co-locates drug substance (DS) conjugation and drug product (DP) fill-finish within a single facility under one quality system. This eliminates multiple inter-site transfers, reduces cold chain risks, improves traceability, accelerates batch release and regulatory preparedness, enhances worker safety when handling highly potent compounds, and shortens time to market. The result is a more resilient and efficient supply chain that supports the production of life-saving oncology therapies.

Consolidating Conjugation and Fill-finish at One Site

Founded in 2006, BSP Pharmaceuticals is an Italian contract development and manufacturing organization (CDMO) specialising in the production of oncology, cytotoxic, and immunotherapy drugs for pharmaceutical and biotechnology partners. It operates from investigational new drug to commercial supply. The company currently manufactures 13 of the 19 ADCs approved for the commercial market and provides service support for more than one hundred bioconjugated clinical programmes.

Traditionally, the critical steps needed to manufacture an ADC are managed in separate, often geographically distant sites, resulting in a highly fragmented supply chain. Monoclonal antibodies are shipped from one facility, the linker-payload complex is shipped from another, and conjugation occurs at a third site. This DS is shipped again to a fill-finish facility to produce the DP. Each handover runs the risk of cold chain interruption, transportation problems, and delays that affect product integrity and delivery to patients.

The Latina facility consolidates conjugation and fill-finish operations within a single facility, which represents a fundamental shift in the structure of ADC supply chains. It is unusual to have a fully integrated supply chain for commercial-scale DPs as complex as ADCs, making the Latina unique in the industry. Monoclonals, cytotoxin-linkers, and intermediates are protected from exposure risks, handling complexity, and extended storage. Cold chain logistics are streamlined, while on-site storage as low as -80°C eliminates the need to move temperature-sensitive materials between sites. All critical components are received at one site, which means fully packaged DP is produced and shipped through a unified supply chain.

"Inter-site transfers of highly potent, cytotoxic intermediates introduces exposure risk, cold chain challenges, and the potential for quality deviations during transit," said Aldo Braca, Chief Executive Officer and President. *"By housing both steps at Latina, end-to-end integration compresses the overall manufacturing cycle, strengthens batch traceability, and gives us a unified point of accountability for the entire ADC production process."*

A Single Quality System for DS and DP

A single quality management system (QMS) across the entire manufacturing process delivers full traceability, improved compliance, and faster batch release, while harmonised documentation reduces complexity and drives higher quality outcomes.

"Co-locating drug substance and drug product operations creates a continuous quality oversight loop that simply isn't achievable when the two steps are separated," said Aldo Braca. *"QC teams can monitor critical quality attributes – conjugation efficiency, drug-to-antibody ratio, aggregation levels – and immediately apply those insights to the downstream fill-finish process without the delays inherent in inter-site communication."*

Any out-of-trend result detected at the DS stage can trigger a real-time review before the material advances, preventing quality risks from propagating. Shared analytical infrastructure also avoids the need to repeat or transfer testing between sites, reducing variability in results.

"Ultimately, the proximity of drug substance and drug product operations fosters a culture of integrated quality ownership, where every team member

understands how their work connects to the final product delivered to patients," said Aldo Braca.

Accelerated Regulatory Pathway

When DS and DP operations are split across multiple sites, regulatory agencies must inspect and approve each location separately. Each site requires its own set of manufacturing authorisations, SOPs, and QMS. Coordinating across those different regulatory frameworks adds considerable overhead and risk. By integrating DS and DP manufacturing, the Latina facility streamlines regulatory pathways for fast-track approvals, reduces post-approval changes, and speeds commercial readiness.

"At Latina, inspectors can assess the full manufacturing journey in a single visit, from conjugation through final fill-finish," said Aldo Braca. *"There is one integrated quality system, one unified set of batch records, and one accountable manufacturing team. This transparency simplifies the inspection process for authorities, accelerates responses to queries, and reduces the likelihood of cross-site inconsistencies being flagged. It also streamlines CMC dossier preparation and post-approval change management, since changes affecting both drug substance and drug product can be addressed in a single regulatory submission."*

Safety by Design

The cytotoxic payloads used in conjugation are among the most hazardous substances handled in pharmaceutical manufacturing, and those handled at the Latina site have an occupational exposure limit (OEL) below 10 nanograms per cubic meter. Every transfer of these materials between facilities introduces occupational exposure risk, packaging complexity, transport hazards, and emergency response challenges across multiple jurisdictions.

"The design of the Latina plant confines the handling of HPAPI-conjugated intermediates to one containment-engineered environment with a highly trained workforce operating under a unified safety management system," said Aldo Braca. *"There is one containment strategy, one spill response protocol, one set of engineering controls – all optimised for ADC-specific hazards."*

This consolidation dramatically reduces the number of touchpoints where exposure incidents could occur and enables a more proactive, coherent approach to occupational health across the entire production chain.

Accelerated Time-to-Market

One of the most significant timelines in ADC drug development is the period between clinical batch release and first patient dosing, or between regulatory submission and commercial launch. Any inefficiency in manufacturing, such as delays at batch handover, inter-site shipping, redundant QC testing, and misaligned release schedules, directly compounds patient wait times. The resilience of the Latina supply chain reduces these delays and has meaningful impacts on time to market.

"Thanks to Latina's integrated supply chain, we have eliminated many of these points of inefficiency," said Aldo Braca. *"Batch release decisions are made with full visibility across both drug product and drug substance, without waiting for material to arrive from a remote site. This allows a faster, more agile response to demand fluctuations or clinical trial schedule changes. For innovative oncology therapies where urgency is critical, the ability to reduce cycle time without compromising quality is not just a competitive advantage, it is a patient-centred imperative."*

BSP Pharmaceuticals has shown that the production of complex ADCs can be dependable and efficient while addressing one of the most critical challenges in oncology manufacturing.

"The expansion of the Latina site establishes a new standard for supply chain resilience and rapid product delivery," said Aldo Braca. "For patients and partners alike, it means a more reliable, predictable supply of complex, life-saving therapies."

What makes BSP truly unique is the design and operation of its fully integrated manufacturing site, which combines integration, flexibility, scalability, and technological depth in a way that is unparalleled in the industry.

The site offers an integrated system that ensures seamless coordination between development, drug substance manufacturing, conjugation, drug product manufacturing, fill finish, storage, cold chain management and quality control. This integration delivers multiple benefits: optimised material flows, enhanced product safety, and significant reductions in working capital, allowing clients to achieve faster, safer, and more cost-efficient pathways to market.

The co-location of development laboratories, quality control facilities, and GMP manufacturing at multiple scales allows for a smooth scale-up process. Scientists and technical experts work in close collaboration, ensuring that every step of the journey from formulation development to commercial supply is aligned and optimised. This integrated approach minimises handover gaps, quickens FDA approval, one inspection for DS and DP, reduces costs, accelerates timelines, and increases the probability of success for complex bioconjugates and next-generation modalities.

Flexibility of scale is another cornerstone of BSP's offering, which provides a broad range of capacities that can adapt to the evolving needs of its partners. For conjugation, BSP has implemented scales from 40 grams up to 15 kilograms of mAb, enabling both small-scale clinical projects and large-scale

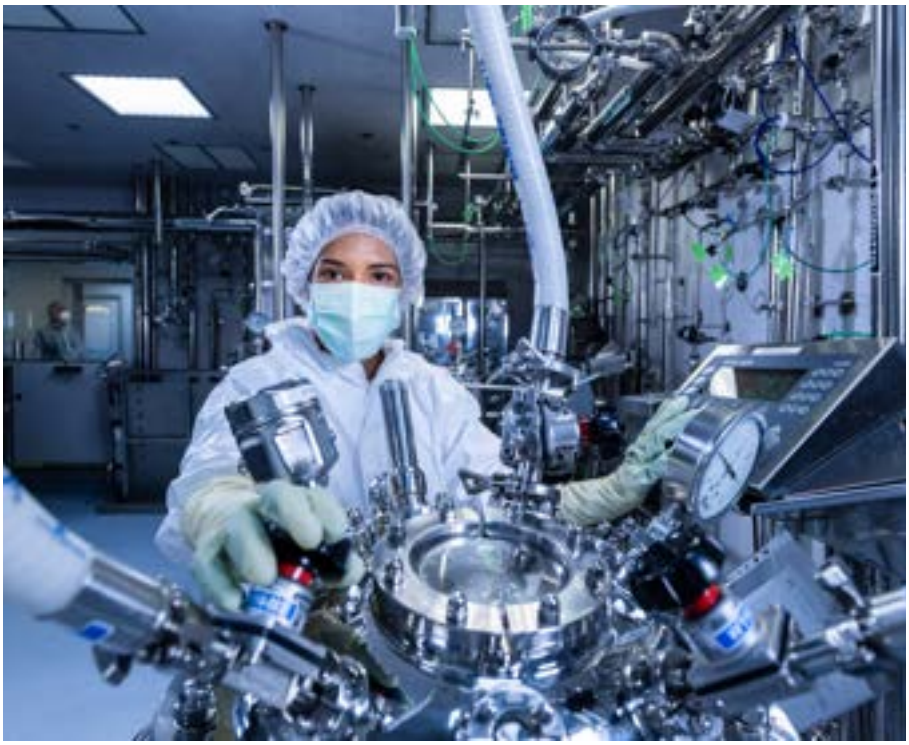


commercial production under one roof. This range of options demonstrates BSP's ability to serve projects at every stage from early clinical batches to global commercial launches without requiring technology transfers to multiple facilities, optimising both timelines and budgets for clients. Whether a customer requires toxicology batches, small-scale GMP-equivalent runs, or full commercial production, BSP provides a continuum of services that ensures consistency, quality, and speed.

A critical enabler of this success is BSP's internal technology transfer structure. Dedicated teams oversee projects from early development through PPQ, ensuring that knowledge, processes, and quality standards flow seamlessly across phases. This reduces the risk of scalability issues that often arise when products move from early to late stages, protecting both clients and patients from delays or failures.

The company's commitment to innovation is also evident in its approach to risk-sharing in product development. By lowering the barriers to entry for promising therapies, BSP ensures that more breakthrough products can advance to clinical testing and ultimately to patients: a tangible support from BSP to projects that carry high levels of scientific and financial uncertainty. BSP not only fosters innovation but also strengthens long-term partnerships built on trust, transparency, and shared objectives.

To back this vision, BSP's Board has approved a €700 million financed expansion plan, adding four new conjugation suites and 4 drug product filling lines. By 2030, DS capacity will increase (to over 4,700 Kg mab/year), while DP capacity will reach over 155 million units annually. These investments will support ADCs, liposomes, RNA-based onco-vaccines, and advanced polypeptides, reinforcing BSP's role as a global leader in oncology, immunotherapy, CNS and type 2 diabet therapeutics.



BSP Pharmaceuticals combines scientific excellence, operational flexibility, and a collaborative spirit. Its fully integrated and scalable site, extensive technical capabilities, innovative risk-sharing approach, and unwavering commitment to patient safety clearly set BSP apart. By enabling faster, safer, and more efficient development and commercialisation of critical oncology and specialty medicines, BSP not only advances the biopharmaceutical industry, but also contributes to the global mission of improving patient outcomes.

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Aldo Braca

Aldo is the President and founder of BSP Pharmaceuticals since 2006, year of the incorporation of the company. He is a member of the Advisory Board of "PM & Partners", a private equity firm specialised in investing in small and middle-sized companies. Aldo has been President of Patheon Europe, a subsidiary of Patheon Inc., since 2010 and developed the company in Europe starting from 1999. Aldo is trained as an Industrial Chemist. He is a graduate of Advanced Management Program at the Harvard Business School.