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“APAC now leads global clinical development of multi-specific antibodies, accounting for over 40% of trials”

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According to market projections, the biologics sector is expected to grow from $451 billion in 2024 to $938 billionby 2034, reflecting a CAGR of 7.6 per cent. While biologics, including vaccines, gene therapies, and monoclonal antibodies, offer targeted, effective treatments for cancer, autoimmune disorders, and rare conditions, these can be complex and costly to produce. Focusing on this market trend, India-headquartered contract research, development, and manufacturing organisation (CRDMO) Syngene International has recently announced the acquisition of its first biologics site in the USA, fitted with multiple monoclonal antibody (mAbs) manufacturing lines. The overall investment in the US facility is estimated around $50 million, including the cost of acquisition ($36.5 million) and expenses to make the facility operational. To find out more about the company’s plans for this acquisition and the current challenges facing the biologics market, BioSpectrum Asia spoke to Alex Del Priore, Senior Vice President – Development & Manufacturing Services, Syngene International.

What are the major plans in store after this acquisition? Is there a phase-wise plan?

Following the acquisition, Syngene has several major plans in store, many of which are already underway. The acquisition significantly expands our manufacturing capacity, increasing the total single-use bioreactor capacity to 50,000 L for large molecule discovery, development, and manufacturing. Hiring for the site is underway.

By adding a US-based facility to its global network, Syngene strengthens its geographic footprint and offers clients greater flexibility. The new facility complements Syngene's two existing biologics sites in India and its extensive bio-discovery services, providing an end-to-end solution from early development through to commercial manufacturing.

There is a clear phase-wise plan. Currently, the focus is on undertaking site enhancements and qualifying equipment, along with all necessary activities to make the site GMP compliant for mAbs. In the summer, Syngene will host key customers, stakeholders, and the press, with the facility expected to become fully operational for GMP manufacturing in the second half of 2025.

Additionally, the US site enables Syngene to offer domestic supply for animal health products, which is a regulatory requirement for approximately 50 per cent of products approved in the US. More broadly, it opens up Syngene to partnerships with innovators that require a US-based CDMO manufacturing option.

With this addition, Syngene is now equipped with one of the largest biologics R&D teams and commercial-scale manufacturing capabilities operating across India and the US.

What are the current challenges facing the biologics market globally and in India?

Advances in biotechnology, particularly in cell and gene therapies like CAR-T and CRISPR-Cas9, are revolutionising treatment for complex conditions, offering the potential for long-term remission or cures. Next-generation biologics, including antibody-drug conjugates, bispecific antibodies, and fusion proteins, are expanding the therapeutic landscape, especially in oncology and rare diseases. Regulatory support from bodies such as the FDA and EMA has also played a vital role, with streamlined approvals accelerating market penetration. Additionally, the shift toward personalised medicine is enhancing the demand for biologics that are more precisely tailored to individual patient profiles.

However, the global biologics industry faces certain challenges. Chief among them are the high costs and complexity associated with biologics development and manufacturing. Unlike traditional small-molecule drugs, biologics are derived from living cells, necessitating sophisticated manufacturing infrastructure and strict regulatory compliance. This complexity increases the risk of contamination and quality issues, adding to the overall cost and difficulty of production.

One of the most promising segments within the Indian biologics market is biosimilars, driven by their affordability and the expiration of patents on major biologic drugs. Indian pharmaceutical companies are capitalising on this opportunity by developing cost-effective biosimilars for both domestic and global markets. Strong government support through initiatives like "Make in India" and the BioE3 policy, along with upgraded regulatory frameworks and increased funding for infrastructure, is further accelerating the sector's expansion. Innovations in biomanufacturing, including advanced cell culture methods and AI integration, are enhancing production quality and efficiency, reinforcing India's position as a competitive global player.

What strategies have been earmarked to strengthen the company's business in the biologics space, for FY 25-26?

We identified biologics as a strategic growth priority several years ago and have since made sustained investments to strengthen both capability and capacity across discovery, development, and manufacturing. These investments are enabling us to support global clients through integrated, science-led solutions aligned with evolving needs in the large molecule space.

Syngene has one of the largest biologics R&D teams in India, with over 700 scientists dedicated exclusively to this segment. Our capabilities span the full biologics development spectrum: from early-stage research, including the discovery and optimisation of monoclonal antibodies, to cell line and process development, analytical sciences, and clinical-to-commercial-scale manufacturing.

With biologics manufacturing capacity across sites in India and the US, we are well-positioned to support programmes of increasing scale and complexity. Our focus now is on operationalising this expanded capacity and driving utilisation to unlock the next phase of growth. In parallel, we continue to invest in automation, digital tools, and quality systems that reinforce efficiency, compliance, and global delivery standards.

How do you view the current scenario of mAbs, and what is the future?

Monoclonal antibodies (mAbs) have emerged as a leading therapeutic modality, especially in oncology, infectious diseases, and autoimmune disorders. Offering higher specificity, fewer side effects, and longer half-lives, mAbs are a compelling alternative to traditional drugs. Their expanding role in immunotherapy, particularly for solid tumours and blood cancers, is driving demand for scalable manufacturing and advanced delivery technologies.

Asia Pacific now leads global clinical development of multi-specific antibodies, accounting for over 40 per cent of trials. This shift highlights the need for strong regional development capabilities, faster tech transfers, and agile manufacturing networks to support IND filings and localised supply.

With over 100 new experimental antibodies entering development each year, improving upstream yields, refining purification, and ensuring stability across formats like bispecifics and fragments are critical. AI/ML tools are accelerating molecule design, process prediction, and QC optimisation, while innovations like inhalable or oral delivery are expanding therapeutic options.

Contributing to this momentum, we are actively investing in the mAb space. Recently, we launched a proprietary cell line development platform that integrates transposon technology, high-throughput clone screening, and single-cell imaging to significantly enhance protein production. This platform can reduce development timelines by up to 10 weeks and deliver titers of up to 10 g/L, with broad applicability across mAbs, biosimilars, bispecific antibodies, ADCs, and recombinant proteins—helping accelerate the development and manufacturing of complex biologics.

As therapies grow more complex, better tools for immunogenicity assessment, ADE mitigation, and long-term safety are essential. Companies that combine speed, flexibility, and scientific excellence will lead the next generation of antibody development.

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