SYNER-G BIOPHARMA GROUP

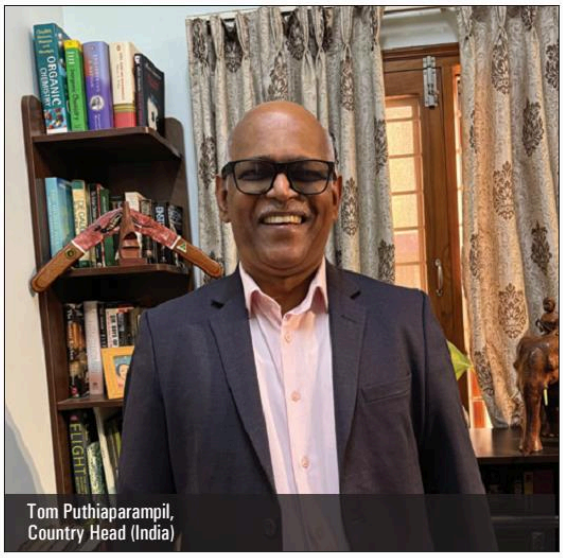
FACILITATING INNOVATION AND COMPLIANCE IN GLOBAL PHARMA REGULATORY AFFAIRS

Today, the pharmaceutical industry is witnessing noteworthy evolution in global regulations, regional variations, and the increasing complexity of drug development. With this, navigating the shifting compliance standards, managing the growing demand for faster market entry, and addressing the unique needs of biologics, gene therapies, and personalized medicine have become more challenging than ever.

Perfectly understanding these impending challenges, SYNER-G Biopharma Group offers comprehensive solutions across regulatory strategy, functional outsourcing, medical writing, and more. The group brings unparalleled expertise in medicinal and process chemistry, scale-up, quality, and commercial production, ensuring seamless interdisciplinary collaboration. Having experts from diverse pharmaceutical domains, it aligns every development stage with regulatory requirements. Furthermore, the group's integrated approach supports innovators through all regulatory stages, including NDAs and lifecycle management, across 180+ countries like the EU, LATAM, and APAC.

Adding to this, SYNER-G Biopharma Group combines scientific and regulatory expertise to deliver end-to-end support by specializing in small molecules, biologics, cells and gene therapy, and virology. It ensures compliance, innovation, and strategic value, positioning itself as a trusted partner in global pharmaceutical development by applying quality-by-design principles.

While SYNER-G Biopharma Group doesn't manufacture drugs, it helps clients integrate quality by design (QbD) principles early to ensure consistency across batches, scales, and regions. This reduces risks, streamlines regulatory submissions, and accelerates timelines. For example, it helped a biologics client overcome scalability and batch variability issues, avoiding regulatory delays by addressing root causes early. Also to note, navigating regulatory landscapes is another core strength of SYNER-G Biopharma Group. Its team, including RAC-certified professionals, stays updated on global trends. In one case, SYNER-G Biopharma Group helped a client with an orphan drug by crafting a tailored regulatory strategy, expediting approvals and addressing queries with scientific precision. This highlights its blend of expertise, ensuring successful outcomes and reduced timelines.



Tom Puthiaparampil,
Country Head (India)

Devising Tailored Solutions

SYNER-G Biopharma Group's functional outsourcing model prioritizes close client collaboration, tailoring solutions to specific needs, especially during early-stage outsourcing. At this stage, critical studies like toxicity and efficacy are conducted, and drug quality is defined. It bridges the gap between clients and Contract Development and Manufacturing Organizations (CDMOs) through its deep expertise in drug development and commercialization.

"Acting as a facilitator, we ensure seamless communication and alignment between client requirements and CDMO capabilities. We focus on quality, timelines, and compliance while addressing technical and regulatory challenges. With a 50-member team in India, a key outsourcing hub, we offer local expertise in technology transfer, real-time troubleshooting, and regulatory compliance. This approach streamlines outsourcing, allowing clients to focus on innovation while we handle development and manufacturing complexities. Also, by combining global regulatory insights with local expertise, we deliver efficient, compliant, and client-focused outsourcing solutions", highlights Tom Puthiaparampil, Country Head (India), SYNER-G Biopharma Group.

The success and impact of SYNER-G Biopharma Group's outsourcing partnerships are measured by clear, outcome-driven metrics aligned with client goals and regulatory standards. Here, key indicators include timely delivery of high-quality outputs, adherence to specified quantities, and compliance with phase-appropriate development requirements, whether for early-stage (Phase 1/2) or late-stage (Phase 3) programs. SYNER-G Biopharma Group ensures that all processes and documentation meet GMP standards and regulatory expectations.

Moreover, success is also evaluated based on the seamless integration of outsourcing activities with the client's broader development strategy, ensuring alignment with scientific, regulatory, and business objectives. When deliverables meet quality, timeline, and compliance benchmarks, the company considers the partnership successful. This results-oriented approach not only supports clients in achieving their mission-critical goals but also strengthens trust and collaboration, driving long-term value in global drug development programs.

Syner-G Biopharma Group combines deep scientific expertise with regulatory precision, delivering innovative solutions that drive successful drug development and ensure global compliance

Fostering a Competitive Edge

Medical writing is a key strength at SYNER-G Biopharma Group, driven by the company's blend of scientific, technical, and regulatory expertise. The team, composed of experienced professionals, delivers high-quality documentation that meets strict regulatory standards. The company's specialized verticals, namely Regulatory Affairs, Quality, and Technical Services, are led by subject matter experts, ensuring seamless collaboration and a holistic approach to documentation. With a goal-oriented management system focused on metrics and outcomes, SYNER-G Biopharma Group ensures all documents, including clinical, regulatory, or technical, are accurate, compliant, and aligned with global requirements. By integrating scientific rigor with regulatory precision, it consistently produces documentation that supports successful drug development and approvals, highlighting its commitment to quality and excellence.

Innovation drives SYNER-G Biopharma Group's growth and success. Since 2006, the company has expanded from

small molecules to biologics, cell and gene therapies, and personalized medicine. Additionally, collaboration with academia and industry leaders enables it to address challenges and integrate advancements like next-generation therapies and scale-up techniques into its services. This approach ensures forward-thinking solutions and a competitive edge in pharmaceutical development. Furthermore, it has always promoted sustainability by encouraging clients to adopt green chemistry, reduce waste, and use efficient technologies like flow chemistry. Its experts stay updated on sustainable practices aligned with global guidelines. Internally, the company minimizes its environmental footprint through flexible work models that reduce energy use and emissions. These initiatives reflect the company's commitment to eco-friendly practices, helping clients and operations achieve a greener future.

A Noteworthy Journey

SYNER-G Biopharma Group is proud to foster a culture that has earned accolades, including recognition as one of the 'Best Places to Work 2024' in the U.S. With a team of over 400 skilled and motivated employees worldwide, its people-first approach emphasizes employee satisfaction through industry-leading compensation and a high happiness index, driving exceptional performance and client loyalty. Also to note, SYNER-G Biopharma Group was selected as a Best Place to Work by BioSpace, Boston for 2024 and 2025, consecutively.

"Going forward, we plan to further strengthen its global presence, enhance its services, and uphold its reputation as a trusted partner in pharmaceutical development and regulatory consulting. By adhering to its core values of technical excellence, employee empowerment, and client-focused solutions, we aim to solidify our position as an industry leader over the next decade", concludes Tom. PO