Syner-G BioPharma Group provides in-depth expertise across the three key elements of Chemistry, Manufacturing, and Controls (CMC): Regulatory Services, Technical Development, and Quality Compliance. We call this CMC 360™. It’s our focus, our passion, and our lifeblood.

We have the skill set and experience to guide your pharmaceutical asset through any development challenges and navigate the ever-changing maze of regulatory filing pathways to a position of full compliance and the highest possible quality. Our CMC expertise spans small molecules, peptides, oligonucleotides, biologics, antibody-drug conjugates, and cell and gene therapy products. Our track record includes successful filing and approval of hundreds of investigational applications and more than 30 new drug applications, including several breakthrough drugs.

**A Holistic, Integrated Approach**

Integrated solutions for science- and risk-based CMC development with complete Project Management support across all activities pre- and post-approval, including:

**Technical**
- Process development and manufacture of drug substance and drug product
- Analytical methods development, validation, and quality control
- Oversight of preformulation/formulation activities
- Identification, selection, and management of contract manufacturing and quality testing sites (CMO/CRO) for clinical and commercial drug substance/drug product
- CMC technical due diligence support for in-license/out-license
- Criticality/risk analysis and development of risk mitigation strategies to minimize the impact of unexpected results on project timelines

**Regulatory**
- Provide phase-appropriate regulatory strategy for global submissions (US, EU, JP, Canada, etc.)
- Identify and manage critical quality and regulatory issues during development
- Regulatory agency meetings (Pre-IND, EOP-2, Pre-NDA, Type C, scientific advice)
- Author eCTD Module 3/CMC sections of IND, IMPD, CTX, NDA, BLA, MAA, and NDS
- Respond to regulatory agency inquiries
- Change management in both investigational and post-approval stages
- CMC regulatory gap analysis and due diligence
- Tactical support: regulatory documentation and submissions; submissions management

**Quality**
- Establish Quality Management Systems (QMS) and Standard Operating Procedures (SOPs)
- GMP, GLP, and GCP audits of contract service providers/GMP training
- GxP documentation review and Data Integrity verification
- PAI-readiness assessment/support
- GMP investigations and deviation reports
- Product complaints and product recalls
- Computer System Validation (CSV)
We Offer More than Typical Consultants

What makes us special is the way we work. From our client’s perspective, it’s like flipping a switch. Just bring us on board and watch us make CMC happen. We know what needs to be done, how to do it, and how to communicate it to the regulators, all while working within the client’s culture. We’re quick, but we don’t hurry. We follow a rigorous approach that delivers scalable and sustainable results. Once you engage Syner-G, you can rest assured that the CMC portion of your drug development program is in the best possible hands.

CMC 360™
We are the go-to firm for an integrated approach that covers all the elements of CMC in technical, regulatory, and quality services.

The Team
Our deep, diverse group of over 80 full-time staff has both academic and hands-on experience in the US and abroad. They are not external affiliates, but rather 100% dedicated and completely committed to our mutual success. Whatever your challenge, it’s likely our team has not only experienced it, but they’ve also conquered it.

The Approach
Always patient safety first, science-based, risk-based and phase-appropriate, we are focused on what’s needed by the regulators – and we don’t spend unnecessary time and resources on what’s not.

Our Culture
Curious, entrepreneurial, eager to learn, and efficient, we offer a superior level of dedication to CMC that’s rarely seen.

Communication
We’re highly skilled at understanding and becoming embedded within the client’s culture. Our team excels at presenting information to regulators in a clear and simple way based on the data.

Intelligence
The combination of critical thinking and the ability to think on-the-fly is consistently manifested in our rigorous approach to problem solving.

Ready to learn more about how Syner-G can support your organization?
Contact Frank Sorce, Senior Director, Business Development
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