Syner-G Job Description: CMC Regulatory Affairs (Manager/Associate Director)

The Company:

- A young, dynamic and entrepreneurial regulatory and technical consulting firm providing specialized consulting and contracting services in the areas of Chemistry, Manufacturing and Controls (CMC) for biopharmaceutical companies (small molecule and therapeutic proteins).
- We are adept in developing risk-based CMC strategies in accordance with cGMP for 21st Century initiatives and QbD principles.
- We distinguish ourselves by our passion for creativity and innovation.
- We are growing and looking for the "right" people to join our team.
- We offer flexible work environment allows for on-site, off-site and virtual-office scenarios.
- Our clients include national and multinational pharma companies, so domestic and international travel assignments to client sites can be expected.
- Opportunities exist for both full-time and part-time professionals.

The Candidate:

- An aspiring regulatory science professional driven by learning and applying scientific principles to solve CMC regulatory challenges
- Has a passion to help patients by enabling the expeditious development and approval of high-quality, life-saving medicines
- Has a MS or Ph.D. in bio/chemistry, pharmacy or related engineering subjects with 5 to 10 years of industry experience in pharma/biopharma settings
- Familiar with FDA, ICH and other relevant CMC/Quality and cGMP guidance documents
- Has at least 3-5 years of experience in CMC regulatory activities in supporting IND/CTA/NDA/MAA applications (small molecules and/or biologics)
- An "outside the box thinker" who is not limited by dogmas but have a passion for applying current scientific and regulatory principles to design innovative strategies and solve regulatory CMC challenges.
- Should be diligent in paying attention to details and take pride in delivering high quality output within defined timelines.
- Should be fluent in MS Office (Word/Excel/PowerPoint) suite of products and familiar with CMC documentation in the CTD format.
- A great team player with leadership qualities to work with cross-functional teams.
- Has excellent written and verbal communication skills.

Additional desired qualification/experience:

- *Graduate degree or certification in Regulatory Affairs*
- *Experience in managing projects and timelines*

Critical success factors:

- Knowledge and experience in pharmaceutical development or technical operations (combination of drug substance, drug product development or manufacturing under cGMP conditions and/or analytical chemistry and quality control)
- A strong appreciation for science-based quality and regulatory compliance
- Ability to work in an entrepreneurial environment and take responsibility and ownership for the deliverables
- Independent thinker and self-motivated
- Has a sense of urgency to help clients bring life-saving medicines to market
- Enjoys learning and applying problem solving skills in a fast paced setting.
- Comfortable and confident in presenting ideas to large audiences and in smaller client settings.

Interested candidates, please submit your resume with a cover letter to RegulatoryCMC@SynerGPharma.com

Note: Currently, we only accept responses directly from the candidates. No agencies please.

You can make a difference. As a Team WE can make it BIG. Let us do it!