VedTechBio
RESEARCH FOR HUMANITY

Job Title: CMC Process Scientist

Role Overview:

The CMC (Chemistry, Manufacturing, and Controls) Process Scientist will manage the process and assay development needed to advance drug substances and products from development to commercialization. Collaborating with internal stakeholders and contract development and manufacturing organizations (CDMOs), this role oversees the process development, technology and assay transfer, and the scale-up and GMP clinical batch production at CDMOs. This position requires expertise in CMC, formulation, and analytical processes, with a strong emphasis on solid oral formulation development and manufacturing.

Key Responsibilities:

- **Process & Assay Development:** Lead and manage integrated plans for process, formulation, and analytical development, as well as GMP clinical testing and manufacturing activities at external laboratories and CDMOs.
- **Technology Transfer & Scale-Up:** Oversee the transfer, qualification, and validation of analytical methods, troubleshooting, and scale-up of manufacturing processes.
- **Manufacturing Oversight:** Supervise engineering runs, GMP drug manufacturing, labeling, and packaging activities at CDMOs from Phase I through commercialization.
- **Documentation & Compliance:** Review batch records (DS, DP, L&P), author technical memos, and manage manufacturing investigations (deviations, CAPA). Author and review CMC sections for regulatory filings, development reports, and process development records.
- **Cross-Functional Collaboration:** Actively communicate and collaborate with other functional areas to address challenges and achieve project goals.
- **Additional Duties:** Perform other duties as required to support the evolving needs of the company.

Skills & Qualifications:

- M Pharma, PhD in Pharmaceutics, MSc in Biochemistry, Chemical Engineering, Biomedical Engineering, or related field with 6-10 years of relevant experience, or PhD with 4-8 years of relevant experience.
- Proven experience in drug production, upstream and downstream process development, and cGMP manufacturing, including formulation and analytical chemistry. Experience with organic synthesis and solid oral dosage formulation is preferred.
- Extensive knowledge of cGMPs, regulatory guidelines, validation practices, and relevant regulatory requirements.
- Strong judgment, problem-solving, negotiation, and conflict resolution skills. Proven success in managing CDMOs, with excellent verbal and written communication abilities. Ability to effectively collaborate across levels, functions, and companies.
- Can-do attitude, flexibility to adapt in a small company environment, strong interpersonal and organizational skills, and the ability to multi-task.
- Ability to travel up to 10% domestically and internationally.