

Title: Sr. Scientist II/Associate Director, CMC Technical Operations

At Concert Pharmaceuticals we use our industry-leading expertise in deuterium chemistry to create and develop innovative drug products that address important patient needs. We are seeking an enthusiastic, motivated and organized person to join our Pharmaceutical Development team. You will be responsible for technical operations supporting our small-molecule CMC development programs.

Job Summary

This is a highly visible role facilitating CMC development activities for Concert's clinical candidates. You will be working with a team of scientists at Concert where you will have responsibility for building our vendor relationships. This includes selection and management of CMOs who are responsible for GMP drug supply, process optimization, stability studies and validation of methods. Any experience with late-stage programs and process validation would be advantageous.

Experience in the pharmaceutical industry is required. A good understanding of GMP quality systems, ICH guidances, and FDA regulations would be important. Project management skills are required for efficient execution of the role and a strong aptitude for meeting both budgets and timelines.

Responsibilities:

- Lead technical interactions with CMOs for process development and technical supports for external GMP Manufacturing
- Authoring RFPs and managing transfer of technology to external CMOs
- CMO management that helps to build trust and maintain strong productive relationships
- In partnership with Concert's Quality organization ensure risks with external manufacturing is mitigated and that CMO quality documents are of high standard
- Enable teams to develop robust and appropriate processes, methods and data packages supporting regulatory filings
- Experience with validation and regulatory filings is preferred
- Provide post-approval planning support and commercial scale estimates for new products in partnership with Pharmaceutical Development and Commercial stakeholders
- Contribute to the development of product specifications
- Demonstrate technical proficiency and making problems visible then solving them
- Highly organized and motivated

Qualifications:

- PhD in Chemistry, chemical engineering or related field with 4+ years of industrial experience or Master's/Bachelor's degree with 5+ years of industrial experience
- Experience working with external CMOs
- Strong interpersonal and organizational skills.
- Good communicator and a team player
- Ability to work across functional groups and with external organizations (i.e. CROs and CMOs)

If you would like to be considered for a job on the Concert team, send your resume in the body text of an e-mail (no attachments please) to: careers@concertpharma.com.

Concert is an Equal Opportunity Employer (EOE). M/F/D/V