CoNCERT Pharmaceuticals Inc.®

Title: Analytical Chemistry Quality Control Scientist II

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 and motivated scientist to join our Pharmaceutical Development Analytical Chemistry team. Working closely with the Concert Quality Assurance group, you will be responsible for ensuring the integrity of analytical data generated both by Concert and by our partner CMOs.

Job Summary:

Reporting to the Principal Investigator, Analytical Chemistry, the QC Scientist II will ensure that CMC scientific data is of high quality from a technical, integrity and compliance perspective. This includes overseeing analytical data generated as part of process characterization, method validation, stability studies and regulatory filings. The qualified individual, working within the Analytical Chemistry group, will closely collaborate with Concert's Process Chemistry, Formulation and Quality Assurance groups as well as with our partner CMOs to ensure the integrity of scientific data. In time, responsibility will be undertaken for quality risk management, yearly project reviews, investigations, stability commitments, CMO technical audits etc.

Attention to detail is a critical skill for this role. At Concert we value a team approach to problem solving, therefore strong organizational, communication, and collaboration skills are also required.

Responsibilities:

- Perform QC data review from a technical, integrity and compliance perspective for CMO product release, stability studies, validation reports and in-process controls
- Review Concert Pharmaceutical Development scientific reports and regulatory filings
- Tracking and trending of development and commercial batch data including yearly product reviews
- Oversee stability programs to support clinical development and commercialization
- Perform review and manage sign-off for product specification changes
- Support investigations (e.g. Out of Specification/Out of Trend events)
- Act as analytical Subject Matter Expert for CMO/CRO audits
- Summarize data and scientific findings in presentations and reports
- Contribute to Concert CMC regulatory filings
- Drive ongoing analytical Quality Risk Management
- Keep abreast of relevant USP and EP method compendial changes

Qualifications:

- Bachelor's or Master's degree with 3+ years of related industrial experience
- Demonstrated knowledge and experience with analytical instrumentation including HPLC and GC
- Drug substance and/or drug product analytical method development, validation and method transfer experience
- Demonstrated experience working with Document/Quality Management Systems
- Experience with both drug substance and drug product analysis is preferable
- Ability to work across functional groups and with external manufacturing organizations.

If you would like to be considered for a job on the Concert team, send your resume to: careers@concertpharma.com.

Concert provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.