



Associate Director, Analytical Sciences

Position Code: 23044-18B

Summary Description

The Associate Director, Analytical Sciences is responsible for implementation of efficient systems and management of overall development activities within the Analytical Sciences group. This position is coordinating the effective delivery of analytical data on GLP and GMP studies and CMC sections of regulatory submissions. This position will also ensure consistent use of best and effective processes across the Analytical team. The position will work closely with the heads of the Process Chemistry, Product Development and the CTM departments in the CMC organization.

Key Responsibilities

- Evaluates and leads implementation of new improved processes within Analytical Sciences for delivering high quality CMC information to agreed timelines.
- Represents the Analytical Sciences department on cross-functional teams for all projects.
- Summarizes experimental findings, reviews and interprets study results, assembles analytical data packages. Prepares and reviews development reports, assisting in the preparation of regulatory submissions.
- Interacts with outside testing laboratories and follows up with the release and stability testing schedules; manages timely delivery of the analytical data.
- Manages and is responsible for outsourced GLP/GMP studies within Analytical Sciences.
- Manages method development, validation activities, and sample testing in support of all ongoing development activity.
- Maintains up-to-date knowledge of applicable industry and regulatory guidelines and requirements
- Plans and coordinates laboratory studies. This includes the stability testing of development compounds and formulations, formulation development support.
- Monitors, organizes and prioritizes resources to increase efficiency on a regular basis.
- Implements and supports efficient approaches in using and improving the systems within Analytical Sciences.
- Authors and reviews SOPs related to multiple functions.
- Recruits, manages, trains and mentors Analytical Sciences staff, particularly with respect to new processes and procedures as well as changes in processes and systems

Experience & Education

- Ph.D. in Analytical Chemistry or related disciplines with 3 years relevant industry experience, or equivalent experience.
- Working knowledge of GLP and cGMP requirements.
- Proficient in using various analytical laboratory equipment.
- Strong writing skills and experience in contributing to regulatory filings.
- Proven management experience in the selection, supervision, evaluation and development of employees.