Associate Director, Quality Assurance

Position Summary:
The Associate Director (AD) of Quality Assurance will report to the Sr. Director of Quality Assurance Operations. This position is responsible for providing leadership and direction for all drug substance (DS) and active pharmaceutical ingredient (API) Quality Assurance oversight of contract manufacturers (CMOs) and for ensuring compliance with all relevant FDA and EU regulations and guidelines as they pertain to marketed drug products. The AD, Quality Assurance has responsibility for day to day quality oversight activities of the CMO manufacturing, including but not limited to, disposition of DS and API, deviation resolution, CAPA, changes, and documentation supporting the suitability of the batch. The AD is responsible to ensure staff execute the company’s Quality Management System and adhere to policies and procedures.

Responsibilities:

- Provide QA support for the manufacturing and disposition of Portola DS and API. Responsible for release or rejection of GMP DS and API products utilizing trained and qualified QA staff. In addition, collaborate with Supply Chain and Program Management to assure on time delivery of approved products.
- Work directly with operating entities (internal and CMOs) to ensure that Portola products (i.e., drug substance and API) meet all required quality standards and specifications.
- Provide leadership to the DS QA team and influence other functional departments to ensure that CMOs achieve and maintain the appropriate levels of GMP compliance and provide quality services to Portola. In addition, work with CMOs to ensure CMOs’ GMP processes and procedures provide continuous evaluations and improvements to their quality systems.
- Responsible for executing Quality Assurance (QA) programs and activities; this includes assisting with training and auditing programs, as well as the review of SOPs, investigations, specifications, methods, reports and manufacturing records.
- Assist the Portola Quality Management Systems (QMS) team in the development, establishment and maintenance of internal Quality Systems processes and procedures (e.g., change control, training, audit, CMO management, deviation and CAPA) that complies with applicable GMP standards, regulations and guidelines.
- Assist the Quality Compliance team to conduct CMO audits as an SME or lead auditor.
- Provide QA guidance and support for supplier qualification, technology transfer, scale-up, validation and other GMP activities associated with Portola products manufactured by CMOs.
- Facilitate resolution of quality issues with internal and external parties in a timely manner. Coordinate communications with CMOs and internal team for quality issues.
- Review and approve CMC sections of regulatory filings.
Qualifications:

- BA or BS degree in a scientific discipline or comparable experience; advanced degree in sciences or business preferred.
- At least 10 years of experience in Quality Assurance at an operational level supporting manufacturing, quality control in a pharmaceutical or biotech environment.
- Must have excellent verbal, written, interpersonal, and organizational and communication skills.
- Demonstrate ability to manage staff and projects (direct and indirectly) and variable workloads with demanding timelines.
- Position requires 10-20% travel.
- Minimum of 2 years in outsourced manufacturing environment.
- Experience with Phase 3 and/or commercial biologic drug substance manufacturing required.
- Recent experience in preparation of CMC sections of US or EU regulatory approval (e.g., BLAs, NDAs) is desirable.
- Prior experience related to managing technology transfer, scale up and validation.
- In-depth knowledge and full understanding of pharmaceutical GMPs (US and EU)
- Prefer candidate understand standards of practice for the manufacture of API and solid dosage forms.
- Experience with effectively managing FDA inspection, working with regulators, and supplier audits.

Contact Us:

- Our company overview and history: [http://www.portola.com/Company-Overview](http://www.portola.com/Company-Overview)
- Please include a cover letter that highlights your qualifications and matches our requirements and send resumes to [careers@portola.com](mailto:careers@portola.com)