Quality Assurance Manager

Summary:

The Quality Assurance (QA) Manager will provide QA oversight of drug product manufacturing to assure adherence to the approved master batch record and compliance with cGMPs. The successful candidate will be proficient in the requirements for aseptic manufacturing, investigation and CAPA review, change control, environmental monitoring, batch record review, lot release and in process testing and lot disposition. This position will report to the Senior Manager of QA and will be based in our headquarters in South San Francisco, CA.

Responsibilities:

- Work with the Contract Manufacturing Organization (CMO) as Portola’s Quality Assurance representative
- Serve as QA Person-in-the-Plant during drug product manufacturing
- Partner with Portola Technical Operations to assess changes to batch records and process changes and other required documents such as Bill of Materials, drug product testing requirements and incoming API testing
- Coordinate and perform supplier management qualification and audits as required per SOP
- Be the QA lead for drug product manufacturing and efficiently work with various departments within Portola such as Technical Operations, Supply Chain, Analytical Development and Quality Control
- Manage lot disposition activities and lot disposition standard lead times at the CMO, including:
  - Perform batch record review including investigations, deviations, CAPA and QC testing
  - Communicate lot disposition issues to management in a timely manner to ensure continued supply of drug product
- Prepare lot disposition records
- Provide periodic updates to management of deviations, GMP issues, system issues, non-conforming materials, and CAPAs
- Review and approve equipment qualification protocols and reports
- Review and approve analytical method qualification/validation protocols and reports
- Support regulatory inspections as well as internal audits
- Review technical/ investigation reports as appropriate
- Review and approve proposed changes to systems, procedures, and submissions to regulatory agencies as appropriate
- Provide QA guidance to product development projects and programs
- Gather metric information for use in continuous improvement of areas of responsibility
- Assist Portola QA Management with departmental needs
- Perform other duties as assigned
Qualifications:

- BA, BS or MS degree in Chemistry, Biology or related science field with 6-9 years of experience in Pharmaceutical or biotechnology industry with 5 years in QA
- Demonstrated knowledge of cGMP, ICH and other regulatory requirements for the manufacture and testing of BDS and drug product
- Experience with aseptic manufacturing required
- Ability to effectively partner and negotiate with representatives from contract organizations
- Proven proficiency using MS Word, Excel and PowerPoint
- Excellent written and oral communication and organization skills
- Ability to prioritize and manage several projects and activities simultaneously
- Ability to travel domestically and internationally (25%)

Additional Information:

- 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 along with your resume and send to careers@portola.com
- Recruiters: Please click this link for more information: [http://www.portola.com/Recruiters-and-Vendors](http://www.portola.com/Recruiters-and-Vendors)