

Quality Assurance Compliance Manager

South San Francisco, CA

Position Summary

Quality Assurance Compliance Manager/Sr. Manager needed to manage the Quality Assurance-Compliance group in a biopharmaceutical company. The position is responsible for oversight of compliance and lot disposition. The candidate should have an excellent understanding of cGMP requirements. The position requires an individual who works independently and in a team environment and who is experienced in managing staff and group responsibilities. Position is highly visible and requires leadership, collaboration, and excellent communication with other functional areas and sites.

Responsibilities

- Responsible for oversight of Compliance programs and activities:
 - Product Return
 - Product Complaints
 - CMO Oversight
 - Internal and External Audits
 - Vendor Quality
 - Inspection Preparation and Facilitation
 - Manage Annual Product Review Reporting
- Responsible for oversight of Lot Disposition program
 - Dispositions manufacturing supplies, raw materials, intermediates and product
 - Responsible for QA role in the handling and disposition of manufacturing supplies and raw materials
- Manage QA responsibilities toward support of equipment calibration, equipment/utility validation and preventive maintenance, facility shutdown/restart processes,
- Lead Investigations into compliance and product quality issues
- Facilitate Material Review Board meetings
- Determines and assembles information and metrics to support Management Review program
- Provide guidance to Operations staff regarding compliance and product quality issues
- Identify trends and implement improvements
- Provide intra- and inter-departmental GMP training.
- Write and revise standard operating procedures and forms.
- Provides operational support for other QA functions.
- Manage and develop staff

Skills

- Knowledge and experience in US and EU cGMP, preferably in a commercial biopharmaceutical organization. Experience in Japanese and Korean cGMP requirements, desirable.
- Able to provide technical solutions to difficult issues
- Excellent organization and documentation skills.
- Detail oriented.
- Computer skills, including Microsoft Word, Excel, and Access

Requirements

- BA or BS in a scientific discipline. 8-10 years in Quality Assurance (minimum 3 years of supervisory or managerial responsibility) in a commercial cGMP environment, preferably in a pharmaceutical/ biotechnology company. Experience in interacting with Regulatory Agency Investigators.