QC MANAGER (Ref. QC20/01)

(BIOPHARMACEUTICAL MANUFACTURING PLANT)

Job Summary

The Quality Control Manager for the new Helvetic Biopharma SA facility at Mezzovico, Ticino, Switzerland is responsible for designing, planning, implementation, supervision, control and management of the Quality Control Lab. (Microbiology and Physico-Chemical analytical Laboratory) and directly performs the QC analyses of therapeutic proteins by:

- Managing and performing Microbial and Physico-Chemical testing of raw materials, in-process and final products.
- Managing and performing cleanroom and utilities Microbial monitoring; providing appropriate quality for product manufacture
- Managing and performing Physico-Chemical analytical determinations of the utilities of the plant
- Ensuring the laboratory is operated in a safe manner
- Ensuring an effective quality management system is in place within the laboratory; through appropriate root cause analysis for any deviations and through an appropriate investigation and impact assessment for any out of limits
- Supporting and Coaching of Laboratory Supervisors and Technicians, providing motivation to the team and take appropriate corrective action on individual/team performance where required.

Responsibilities

- Ensuring SOPs and all the documentation are followed and comply with cGMP.
- Ensure testing is completed in line with EP/USP and registered specifications.
- Address, and manage the validation protocols and reports of analytical methods and processes.
- That the environmental monitoring and utility monitoring is supported with environmental monitoring risk assessments.
- Supporting contamination control strategies manufacturing operation.
- Perform assessments of personnel activities versus the SOP to ensure compliance.

- Involved in internal and external audits.
- Work closely with the production management team on site; providing assistance in investigation of OOS events and supporting batch assessment and CAPA.

Key Duties

- Accountable for managing and supporting Microbiology and Physico-Chemical Laboratory Supervisors and Technicians.
- Accountable for Quality System within the laboratory; ensuring timely completion of reports and investigations and written to a high standard.
- Ensuring all testing is performed within defined timelines, is performed as per SOP and SOP is compliant with regulatory requirements.
- Ensuring effective monitoring and control of cleanrooms and utilities and contamination control strategies are supporting therapeutic proteins manufacturing.

Requirements

- Degree in Chemistry, Biology, Biochemistry, Biotechnology or related educational background.
- 7+ years' experience within QC and GMP environment.
- 5+ years' experience in a management role.

Experience

- Strong background in Microbiology and Analytical chemistry operations.
- Extensive knowledge of microbiology/analytical chemistry tasks and associated regulatory standards and guidance.
- Ability to anticipate, understand and address the changing regulatory environment and guidelines of the industry.
- Strong interpersonal and communications skills; written and oral.
- Fluent in English and Italian.
- Broad and experiential knowledge of Pharmaceutical Quality, and GMP practices.