Lonza

Senior QA Manager

Job Description Summary

Today, Lonza is a global leader in life sciences operating across three continents. While we work in science, there's no magic formula to how we do it. Our greatest scientific solution is talented people working together, devising ideas that help businesses to help people. In exchange, we let our people own their careers. Their ideas, big and small, genuinely improve the world. And that's the kind of work we want to be part of.

We are looking for a Senior QA Manager (f/m/d) who will support our DPS (Drug Product Services) Organization in Visp, Switzerland. Apply today for this exciting opportunity and join us to enable a healthier world.

Key responsibilities:

General QA functional responsibilities:

- Represent Quality Assurance in cross-functional teams, establish and maintain interfaces with the Manufacturing teams, QC, Support Functions, Project- and Site Engineering project / technology transfer to effectively execute tasks related to Drug Product processes
- Assess, review and approve quality records e.g. deviations, change control, CAPAs, investigations, effectiveness checks, extensions in line with current local SOPs
- Author, review and approve GMP-relevant documents and SOPs
- Organize DPS Quality Councils
- Responsible to present Drug Product QA topics during the conduction of all customer audits and regulatory inspections within DP
- Participate in internal audits as required by the organization.

Project-specific QA functions within Drug Product:

- Act as point of contact for Drug Product QA related questions and issues related to the manufacturing operations
- Support and approve project / product specific risk assessments
- Review and release product specific documentation such as process descriptions and workflows, recipes, manufacturing protocols, transfer documents, test plans, parameter lists, etc
- Review and approve executive batch records, prepare batch release for the responsible person (FvP), including recommendation on disposition status

Key requirements:

- Bachelor, Master degree or PhD in Biology, Chemistry, Biotechnology, Life Science or other related field
- Significant work experience in a quality function within a GMP regulated area
- Several years of experience in aseptic processing for Drug Product and associated installations is desired (but not a requirement) including:
    - e.g. filling line / isolator / depyrogenation tunnel / lyophilizer/Media Fill / Aseptic Process Simulation
    - Environmental Monitoring (microbiological background/experience) and associated Cleanroom classifications
    - Requirements for Visual Inspection/Container Closure Integrity Testing CCIT of Drug Product
    - Moist Heat & Dry Heat Sterilization e.g. autoclave / SIP sterilization-in-place, depyrogenation experience and biological challenge with BIs/endotoxin
- Language skills: English is a must, German would be desired

Every day, Lonza's products and services have a positive impact on millions of people. For us, this is not only a great privilege, but also a great responsibility. How we achieve our business results is just as important as the achievements themselves. At Lonza, we respect and protect our people and our environment. Any success we achieve is no success at all if not achieved ethically.

People come to Lonza for the challenge and creativity of solving complex problems and developing new ideas in life sciences. In return, we offer the satisfaction that comes with improving lives all around the world. The satisfaction that comes with making a meaningful difference.