Lonza

Senior QA Specialist, Cleaning (f/m/d)

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.

The site in Visp, Switzerland is growing and for our Biologics Quality organization, we are currently looking for a Senior QA Specialist for Large Scale Mammalian in Ibex® Solutions, our recently launched unique biological manufacturing and development concept. The successful candidate will be responsible for QA Operations and will be in direct contact with the key stakeholders in the Manufacturing Team, QA/QC & Project Management teams within the organization.

Key responsibilities:

- Owning all quality related responsibilities for the manufacturing processes of biopharmaceutical products and representing QA in project/tech transfer organizations for new biotech manufacturing processes
- Reviewing and approving the routine cleaning-relevant documents, i.e., routine cleaning plans and reports, MAC plans and cleaning QC plans
- Act as QA Ops cleaning SME in meetings with the relevant stakeholders, customers and audits
- Responsibility for review and final release of records like Standard Operating Procedures (SOPs), Master Manufacturing Batch Records, Material Specifications, Deviations, Change Requests, Effectiveness Checks, Testing Protocols & Reports etc.
- Performing assessments for all product-related changes, assessing relevance to regulatory filings, deciding to implement and providing change controls for approval to customers where required
- Ensuring all deviations are appropriately investigated and recorded, directing the investigations of customer product complaints and assuring the completion of the appropriate documentation
- Identifying emerging QA relevant topics, communicating to the relevant stakeholders and working actively on their development into new or already established Quality and Compliance strategies and/or standards i.e., CAPAs
- Active participation in audits and inspections and following up

Key requirements:

- Bachelor or Master degree in chemistry, biotechnology, life science or related field
- Significant experience in the GMP regulated pharmaceutical industry; preferable in a QA role is required
- General knowledge of manufacturing processes, cleaning procedures and analytical methods
- Experience with TrackWise, SAP, Syncade and Microsoft suite of products is preferred
- Experience in the interaction with health authorities (Swissmedic, FDA etc.) is desired
- Fluency in English, able to communicate in or willing to learn German

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.