QA Project Manager Ibex™ -

Today Lonza is a global leader in life sciences. We are more than 15,000 employees in more than 100 locations around the world. 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.

For Ibex™ Solutions, our recently launched unique biological manufacturing and development concept in Visp, Switzerland, we have multiple openings. Become part of this exciting opportunity and join our team by applying for the position as QA Project Manager Ibex™. The QA Project Manager owns all quality related responsibilities for the manufacturing processes of biopharmaceutical products for clinical and commercial supply. This includes oversight of QC/logistic/supply chain related activities.

Key responsibilities:

- Represent QA in project/tech transfer organizations for new biotech manufacturing processes
- Coordinate QA interests during the different project phases
- Make quality decisions for the respective projects in internal and external meetings
- Responsible for review and final release of records such as Standard Operating Procedures (SOPs), Master Manufacturing Batch Records, Material Specifications, Deviations, CAPAs, Change Requests, Effectiveness Checks, Testing Protocols & Reports etc.
- Perform assessments for all product-related changes, assesse relevance to regulatory filings, decide to implement and provide change controls for approval to customers where required
- Direct the investigations of customer product complaints and assures the completion of the appropriate documentation
- Ensure an efficient cGMP compliant life cycle management of all products manufactured
- Identify emerging QA relevant topics, communicate to the Ibex™ QA organization and work actively on their development into new or already established Quality and Compliance strategies and/or standards
- Authoring of SOPs, batch record review, involvement in generation of Annual Product Quality Reviews, participate to Quality Risk Assessments
- Enhance the quality knowledge by following the quality standards and by visiting specific training courses/conferences
- Participate in and support regulatory inspections and customer audits
- Support cGMP training programs
- Train and mentor junior Lonza employees to better accomplish and perform in their duties as quality professionals

Key requirements:

- Bachelor's or master's degree in biotechnology, biology, chemistry, life science or related field
- Significant experience in the area of biopharmaceutical manufacturing, preferably in a QA function
- Strong background in cGMP
- Broad knowledge of biotechnological manufacturing processes, validation approaches and risk management
- Sound experience in representing Quality and Compliance in projects
- Good communication skills and experience in interaction with all kind of interfaces within the organization and with regulatory agencies (Swissmedic, FDA etc.)
- Ability to oversee project execution to identify non-compliance from quality standards
- Ability to prioritize and manage work to critical project timelines in a fast-paced environment
- Strong team and solution orientation
- Excellent verbal, written and interpersonal communications skills
- Fluency in English, German would be an advantage

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.