

QA Project Manager Ibex™

Job Description Summary

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 <u>Ibex™ Solutions</u>, our recently launched unique biological manufacturing and development concept in <u>Visp, Switzerland</u>, 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
- 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
- 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
- Participate in and support regulatory inspections and customer audits

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
- Good communication skills and experience in interaction with all kind of interfaces within the organization and with regulatory agencies (Swissmedic, FDA etc.)
- Fluency in English, German would be an advantage

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.