

Junior QA Project Manager Batch Record Review IBEX (f/m/d)

Job Description Summary

Today Lonza is a global leader in life sciences. 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</u>, <u>Switzerland</u>, we have multiple openings. Become part of this exciting opportunity and join our team by applying for the position as Quality Assurance Manager Ibex™. The QA Manager specifies quality requirements for manufacturing processes and ensures that manufactured products comply with national and international requirements and cGMP standards over their entire life cycle. As a Quality and Compliance representative you will be a key member in cross-functional project teams ensuring measures for product safety, product quality & cGMP compliance are implemented.

Key responsibilities:

- · Executed Batch record review
- Represents 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.
- Authoring/approval of SOPs
- Participates and supports regulatory inspections and customer audits
- Actively supports the Quality culture as a role model

Key requirements:

- Bachelor, Master degree or PhD in Chemistry, Biotechnology, Life Science or related field
- Significant experience in the GMP regulated pharmaceutical industry; preferable within Quality Assurance
- · General knowledge of manufacturing processes and analytical methods
- Ability to oversee project execution to identify non-compliance from quality standards
- Experienced in the interaction with health authorities (Swissmedic, FDA etc.)
- · Experience in biological manufacturing environment is an asset
- 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.