Lonza

Quality Assurance Project Manager Ibex™ (m/f/d)

Job Description Summary

Quality Assurance Manager Ibex™

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:

- Own all quality related responsibilities for the manufacturing processes of biopharmaceutical products for clinical and commercial supply
- Represent QA in project/ tech transfer organizations for new biotech manufacturing processes
- Responsible for review and final release of records like Standard Operating Procedures (SOPs), Master Manufacturing Batch Records/ Batch Records, Material Specifications, Deviations, Change Requests, CAPAs, Effectiveness Checks, Testing Protocols & Reports etc.
- Perform assessments for all product-related changes, assess relevance to regulatory filings, decide to implement and provide change controls for approval to customers where require
- Perform internal and external audits
- Identify emerging QA relevant topics and work actively on their development into new or already established Quality and Compliance strategies and/ or standards
- Train and mentor junior Lonza employees to better accomplish and perform in their duties as quality professionals

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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.