QA Operations Manager (m/f/d) Biotech

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.

Ibex® Solutions (www.ibex.lonza.com) is a modular build complex to develop and manufacture biological products. It enables companies to get access to a complete solution, gaining speed and achieving a simplified value chain.

The QA Operations Manager (m/f/d) Biotech will be part of a team that is currently established to setup the Quality Operations processes for a brand new large scale mammalian cell culture facility.
He/ She 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 he/she will be a key member in cross-functional project teams ensuring measures for product safety, product quality & cGMP compliance are implemented.

Key responsibilities:

- Owns all quality related responsibilities for the manufacturing processes of biopharmaceutical products for clinical and commercial supply
- Represents 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, Material Specifications, Deviations, Change Requests, Effectiveness Checks, Testing Protocols & Reports etc.
- Performs assessments for all product-related changes, assesses relevance to regulatory filings, decides to implement and provide change controls for approval to customers where required
- Ensures all deviations are appropriately investigated and recorded, directs the investigations of customer product complaints and assures the completion of the appropriate documentation
- Identifies emerging QA relevant topics, communicates to the IBEX QA organization and works actively on their development into new or already established Quality and Compliance strategies and/or standards

Key requirements:

- Bachelor, Master degree or PhD in chemistry, biotechnology, life science or related field
- Sound experience in the GMP regulated pharmaceutical industry in QA or Operations role
- Strong experience in the area of process improvement and technical operations
- Great knowledge of biotech manufacturing processes and analytical methods
- Ability to oversee project execution to identify non-compliance from quality standards
- Fluency in English

Structured, focused and well-organized working attitude; open-minded for new ideas and suggestions; agile, highly motivated and dynamic drive
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.