Senior QA Specialist, Project Manager (f/m/d)

Job Description Summary

We are looking for a Senior QA Specialist, Project Manager (f/m/d) for our BioAtrium organization. The Specialist, Project 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. You will have full QA oversight of a product and manage the project from Quality perspective.

Key responsibilities:

- Own all quality related responsibilities for the manufacturing processes of biopharmaceutical products for commercial supply. This includes oversight of QC / logistic / supply chain / manufacturing related activities
- 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, Quality Risk Assessments, Deviations, CAPAs, Change Requests, 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 required
- Support the investigations of customer product complaints and assure the completion of the appropriate documentation
- 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
- Involvement in generation of Annual Product Quality Reviews
- Participate 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 and broad knowledge in 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.)
- Experience in the use of the following systems would be preferred: TrackWise, LIMS, DMS and SAP
- Excellent written and spoken English - knowledge of written and spoken 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.