QA Project Manager IBEX – Automation Expert (f/m/d)

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 Ibex® Complex is our contribution to the medicine of tomorrow and possibly the next step in your career? Start your career with Lonza today, apply as QA Manager Ibex®

Key responsibilities:

- Owning all Quality related responsibilities for the manufacturing processes of biopharmaceutical products for clinical and commercial supply and representing QA in project/tech transfer organizations for new biotech manufacturing processes
- Development of concepts for ensuring compliance in automation related topics; enhancing automation expertise in the QA Operations team and providing guidance and training to members of the Quality organization
- Responsibility 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.
- Performing assessments for all product-related changes, assessing relevance to regulatory filings, deciding to implement and providing change controls for approval to customers where required
- Ensuring all deviations are appropriately investigated and recorded, directing the investigations of customer product complaints and assuring the completion of the appropriate documentation
- Identifying emerging QA relevant topics, communicating to the IBEX QA organization and working actively on their development into new or already established Quality and Compliance strategies and/or standards

Key requirements:

- Bachelor or Master degree in chemistry, biotechnology, life science or related field
- Significant experience in the GMP regulated pharmaceutical industry and exposure to automated manufacturing processes (MES, DCA, DeltaV, etc.) will be ideal
- General knowledge of manufacturing processes and analytical methods
- Experienced in the interaction with health authorities (Swissmedic, FDA etc.)
- Fluency in English, German is 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.