QA Manager - Hybrid working

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.

The role:
he 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 he/she will be a key member in cross-functional project teams ensuring measures for product safety, product quality & cGMP compliance are implemented.

Key accountabilities and duties

- 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.
- Trains and mentors junior Lonza employees to better accomplish and perform in their duties as quality professionals. Supports cGMP training programs to ensure staff is being trained.

Qualification and Skills required

- Bachelor, Master degree or PhD in chemistry, biotechnology, life science or related field.
- 5 years of experience in the GMP regulated pharmaceutical industry; preferable in a QA role.
- General knowledge of biopharmaceutical manufacturing processes and analytical methods.
- Experienced in the interaction with health authorities (Swissmedic, FDA etc.).
- Solution-oriented; Strong fact based decision maker.
- Ability to oversee project execution to identify non-compliance from quality standards. Ability to prioritize and manage work to critical project timelines in a fast-paced environment.
- Structured, focused and well-organized working attitude; open-minded for new ideas and suggestions; agile, highly motivated and dynamic drive.
- Strong team orientation with excellent verbal, written and interpersonal communication skills.

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.