Lonza

Quality Assurance Manager

Job Description Summary

Randstad Inhouse Services is looking for a QA Manager (m/f/d) for **Lonza AG** (100%). This is a temporary position for **6 months**.

Today, Lonza is a global leader in life sciences operating across three continents. While Lonza works in science, there's no magic formula to how they do it. Their greatest scientific solution is talented people working together, devising ideas that help businesses to help people. In exchange, they let their people own their careers. Their ideas, big and small, genuinely improve the world. And that's the kind of work Lonza wants to be part of.

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.
- Coordinates QA interests during the different project phases.
- Has the authority to make quality decisions for the respective projects in internal and external meetings.
- 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.
- Supports and approves project/product specific risk assessments.
- Performs internal and external audits.
- Supports and participates in customer audits and health authority inspections.
- Ensures all deviations are appropriately investigated and recorded.
- Directs the investigations of customer product complaints and assures the completion of the appropriate documentation.
- Responsible to drive CAPA and effectiveness check items to completion and timely closing.
- Ensures an efficient cGMP compliant life cycle management of all products manufactured.
- 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.
- Supports cGMP training programs to ensure staff is being trained.
- Trains and mentors junior Lonza employees to better accomplish and perform in their duties as quality professionals.
- Actively supports the Quality culture as a role model.

Key requirements:

- 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.
- Strong background cGMP regulations.
- General knowledge of manufacturing processes and analytical methods.
- Auditing experience.
- 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.
- Excellent verbal, written and interpersonal communication skills.

Every day, Lonza's products and services have a positive impact on millions of people. For Lonza, this is not only a great privilege, but also a great responsibility. How they achieve their business results is just as important as the achievements themselves. At Lonza, they respect and protect their people and their environment. Any success Lonza achieves 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, Lonza offers the satisfaction that comes with improving lives all around the world. The satisfaction that comes with making a meaningful difference.