Lead QA Manager - Process and Cleaning Validation

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:

The site in Visp, Switzerland is growing for our Biologics organization.

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 Lead QA Manager operates in close cooperation with the Manufacturing Science and Technology (MSAT) and Production departments and with customers and ensures that all manufacturing processes and cleaning processes for manufacturing equipment throughout their lifecycle are performed and validated in compliance with cGMP requirements and internal/external quality standards.

Key responsibilities:

- Defines the Process Validation strategy in conjunction with MSAT.
- As a Quality and Compliance representative, you will be a key member of cross-functional technical project teams.
- Defines the Cleaning Validation strategy, and process specific cleaning validation activities in conjunction with MSAT.
- Coordinates Quality and Compliance objectives during the different project phases with regard to the Process and Cleaning Validation activities.
- Supports and approves Quality Risk Analysis related to manufacturing processes and equipment cleaning (e.g. FMEA).
- Review and approval of Process and Cleaning Validation related documents (plans, protocols, reports).
- Review and approval of periodic reports related to the process and cleaning lifecycle (Continued Process Verification (CPV) / Annual Cleaning Review).
- Ensures accuracy of data detailed within process and cleaning validation reports.
- Supports specific projects in process and cleaning validation area of expertise to develop further the quality standard.
- Review and approval of Process and Cleaning Validation related to Deviation, OOS Investigations, Change Requests, and CAPAs.
- Supports internal, stakeholder, and regulatory audits and inspections.

Experience and skills:

- BSc, MSc, or PhD in Biotechnology, Pharmacy, Microbiology, Chemistry, Engineering, or related field.
- 5+ years experience in the area of biopharmaceutical manufacturing, preferably in a QA/qualification/validation/MSAT function as well as a strong background in cGMPs.
- Good communication skills and interaction with all kind of interfaces within the organization, with customer representatives, and with regulatory agencies (Swissmedic, FDA etc.).
- Fluency in English, and German would be an advantage.

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.