Lonza

QA Cleaning Validation Manager (CAPEX)(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.

We are currently looking for a QA Manager Cleaning Validation (CAPEX) (f/m/d). for our recently launched unique biological manufacturing and development concept in Visp, Switzerland. Become part of this exciting opportunity and join our team by applying for the position as QA Cleaning Validation Manager (CAPEX)(f/m/d). In this role, you own all quality related responsibilities for the daily qualification activities of new facilities, equipment, utilities and systems (incl. CSV) related to the cGMP manufacture of pharmaceutical products.

Key responsibilities:

- Ensure QA oversight for site Cleaning Validation activities
- Preparation of validation documents in collaboration with the cleaning teams (study design / protocols and reports) according to Lonza procedure and in compliance with regulatory guidance.
- Technical lead of cleaning validation teams including communication with customers, as appropriate
- Support / review / approve QC cleaning studies.
- Responsible for the cleaning validation assessment by change requests and deviations.
- Maintenance of the cleaning validation matrix to ensure a cleaning validation overview of the plants and the corresponding Products.
- Preparation of periodical cleaning review reports with focus on the summary of relevant issues, identification of potential trends/deficiencies to implement CAPAs and a final validation assessment

Key requirements:

- Bachelor, Master degree or PhD in Analytical Science or related field
- Significant experience in the GMP regulated pharmaceutical industry; preferable in a role within the Quality Unit (QA, QC)
- Good understanding of the applicable cGMP regulations
- Broad knowledge in cleaning validation of biopharmaceuticals
- Sound experience in representing Quality and Compliance in projects
- Experience in interaction with all kind of interfaces within the organization and with regulatory agencies (Swissmedic, FDA etc.)
- Fluency in English, German language knowledge 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.

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