

QA Manager: Process Validation Specialist

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 Process Validation Manager for the expansion of our team here at our site in <u>Visp</u>. In this role, you will QA responsible for manufacturing process validation in the biopharmaceutical plants, including process characterization, validation activities at scale, continued process verification and Product Quality Reviews (PQRs).

Key responsibilities:

- Ensure the manufacturing processes: APIs and Intermediates are in a validated state during their whole lifetime according to Lonza procedures, and in compliance with regulatory guidance
- Preparation of comprehensive process specific Validation Master Plans, describing the individual studies required for process validation
- · Leading the process validation teams including communication with customers
- · Support R&D teams during the process design phase
- Preparation of the validation protocols and reports for the studies performed at manufacturing scale
- · Assessment of changes and deviations during manufacturing for their impact on validation
- · Preparation and maintenance of a documented continued process verification plan

Key requirements:

- Master Degree in Chemistry or Biotechnology (PhD preferred)
- · English/German both fluent
- · Proficiency in writing scientific reports in English
- · Experience in GMP manufacture preferred
- Excellent communication skills
- Challenges the status quo and looks for opportunities to make improvements in his/her area of the business and beyond
- · Managing internal and external customer relations professionally and effectively

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.