Lonza

# Senior Manufacturing 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.

Key accountabilities and duties

- Responsible for the generating, managing and reviewing documentation for Drug Product manufacturing campaigns in compliance to cGMPs, SOPs and applicable guidelines. Securing each batch is manufactured safely, on time, in compliance with the batch instructions and quality requirements
- Generating, managing and reviewing the logbooks for Drug Product Operations in compliance to cGMPs, SOPs and applicable guidelines.
- Provides front line technical and procedural support, working with the manufacturing teams (operators), plant engineers and QA operations.
- Lead process related investigations and critical deviations and assists in decision making on production issues
- Lead process changes, CAPAs, and CAPA effectiveness checks related to manufacturing documentation within required timelines and through GMP systems (e.g. Trackwise, MES, training, etc.)
- Supports the execution of process validations, liaising with all the relevant parties at shopfloor to ensure accurate execution
- Use scientific, process and statistical knowledge to analyze data to provide process understanding, and to identify root causes of product and process failures
- Provide training for assigned areas of responsibility, including documentation use and review.
- Acts as Subject Matter Expert during customer audits and visits, maintain their processes at inspection readiness level and to provide the necessary support
- Executes innovation and improvement projects comprising general manufacturing aspects for the production plant.

Qualifications and skills required

- Bachelor / Master Degree
- Preferred area of study: Pharmaceutical Technology, Chemistry, Pharmacy or equivalent scientific degree
- 5-10 years of experience in Sterile Manufacturing on the shopfloor and/or QC/QA preferred
- Fluent in both German and English
- Familiarity with GMP requirements, quality procedures and SOP execution
- Good communication skills and interaction with a variety of interfaces within the organization and on the shopfloor
- Structured, focused and well-organized working attitude; open-minded for new ideas and suggestions
- High motivation and dynamic drive; solution-oriented
- Proven IT knowledge, knowledge in ERFP (SAP) or MES (Syncade) is an asset
- Prepared to work flexible working hours