

Lonza

QA Manager Drug Substance

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 QA Operations Manager Drug Substance will be a member of a small QA team that will ensure the quality oversight of a new facility and drug substances produced therein. She/he will be involved in transfers of manufacturing processes, reviews and approves manufacturing SOPs and recipes and release or reject drug substances on behalf of the Responsible Person.

Key responsibilities:

- Ensure the quality oversight of a new facility and drug substances produced therein
- Be involved in transfers of manufacturing processes; maintain contact with customers, facilitate discussions between customers and internal teams such as MSAT (Manufacturing Science & Technology), Manufacturing, Engineering and Quality Control
- Review and approve Discrepancy Records and Change Requests, manage the process for notifying the customer about discrepancies / change requests and assuring the customer's feedback and relevant comments are addressed internally
- Review and approve SOPs and project related documents; support and approve quality risk analysis (e.g. FMEA); write or revise SOPs in your area of expertise and act as Owner of such documents
- Be involved in customer audits as well as in regulatory inspections and support all activities to ensure inspection readiness of the department

Key requirements:

- Bachelor in Biotechnology, Biology, Chemistry or other natural science
- Substantial experience in the area of biopharmaceutical manufacturing
- Broad knowledge of biotechnological manufacturing processes (especially microbiological biotech processes) as well as in cGMP
- Good communication skills and interaction with all kind of interfaces within the organization and with regulatory agencies
- Strong team orientation and solution-oriented working approach
- Structured, focused and well-organized working attitude
- Fluency in English, German 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.