Senior QA Specialist, Operations Drug Substance (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.

For Ibex® Solutions (www.ibex.lonza.com), our unique biological manufacturing and development concept in Visp, Switzerland, we have an opening. Become part of this exciting opportunity and join our team by applying for the position of Senior QA Specialist, Operations Drug Substance (f/m/d) for one of our Ibex® manufacturing plants.
The Senior QA Specialist, Operations Drug Substance (f/m/d) will be a member of a small QA team that will ensure the quality oversight of the facility and drug substances produced therein. You 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:

- Responsible for defining the bill of materials and involved in all activities required to qualify raw materials
- Facilitate discussions within internal cross-functional teams such as MSAT, Manufacturing and QC
- Review and approve manufacturing recipes and perform batch record review and approval in the Manufacturing Execution System
- Review and approve Discrepancy Records and Change Requests
- Support the definition of preventive and corrective measures (CAPAs), approve them and track their timely implementation and effectiveness
- Support the release of Drug Substance batches
- Review and approve SOPs and project related documents; support and approve quality risk analysis (e.g. FMEA); write or revise SOPs in own area of expertise
- Involved in customer audits as well as in regulatory inspections and support all activities to ensure inspection readiness of the department

Key requirements:

- Master of Science in natural sciences – preferred in Biology or Biotechnology
- Significant experience within the GMP related environment and preferably within a QA role
- Proficient in usage of MS Office. Beneficial is experience in TrackWise, LIMS, SAP
- Fluent English language required, German language a plus

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.