

## **Production Quality Manager**

## **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 seeking a Production Quality Manager at our Visp site. The successful candidate will be accountable to manage and conduct batch reviews of executed Electronic Batch Records. Ensuring that all control parameters for intermediates and biological drug substances are checked for compliance with defined specifications before a batch is dispatched. A vital part of this role is the responsibility to identify GMP events requiring a Deviation, authoring Deviation reports including managing of related investigation and CAPAs and to manage changes related to batch processes and EBRs.

## Key responsibilities:

- Review of the executed Batch Records (e.g. cleaning logs, production documentation review, temperature reports, test procedures and washing machine protocols, used material, calibration records, sample results recorded in logbooks)
- · Prepare a complete documentation package to enable fast release by QA
- Review comments added to the executed Batch Records, clarify with the operations team and evaluate with the responsible QA Manager
- Lead the initiation and accomplishment of Deviations and investigations for Batch Record review related observations
- · Lead the initiation of CAPAs out of relevant Deviations
- · Collect and evaluate KPI data on a regular basis
- · Managing and approval CRs and TCRs and corresponding CAPEX projects
- · Write and revise SOPs in his/her area of expertise
- Support presentation and documentation of department specific activities in audits and inspections
  Key requirements:
  - Bachelor degree or equivalent Chemistry, Chemical Engineering, Biotechnology, Bioengineering or related disciplines
  - · A good understanding of the Biologic drug substance process
  - Previous experience of working with automation systems such as DeltaV or MES is highly desired along with SAP knowledge
  - Previous experience in GDP and GMP regulated pharmaceutical / API industry is an advantage
  - · Ability to identify non-compliance and gaps from quality standards
  - Very good communication skills and interaction with all kinds of interfaces within the organization;
    strong team orientation
  - Solution-oriented

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.

#LI-AM4