



Batch Record Review and Support 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.

Ibex® Solutions (www.ibex.lonza.com) is a modular build complex to develop and manufacture biological products. It enables companies to get access to a complete solution, gaining speed and achieving a simplified value chain. The Ibex® Complex is our contribution to the medicine of tomorrow and possibly the next step in your career? Start your career with Lonza today.

Key responsibilities:

- Review of the executed Batch Records (e.g. cleaning logs, production documentation review, temperature reports, test procedures (HEPT, FIT), Autoclave and Washing machine protocols, used material, calibration records, sample results recorded in LIMS, logbooks, etc.)
- Support preparation of 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
- Initiate and support accomplishment of Deviations and investigations for Batch Record review related observations
- Support the initiation of CRs and TCRs

Key requirements:

- 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
- Structured, focused and well-organized working attitude
- Open-minded for new ideas and suggestions; solution-oriented
- Agile, highly motivated and dynamic drive
- Ability to produce reliable results under stress

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.