

CSV Engineer - Biologics (m/f/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.

As a CSV Engineer Biologics (m/f/d) you will be responsible for the generation and execution of the validation of the computerized systems on process engineering equipment and facilities, including MES. You are responsible to follow the planning and implementation of CSV activities resulting from projects and plant adaptations during the system life cycle of the plants, as well as make a contribution to the ongoing optimization of processes, facilities and internal procedures.

Key responsibilities:

- Preparation of commissioning and validation documents for new systems, as well as the supervision of conversion, expansion and new construction projects. This is broken down into CSV activities on new construction projects for critical systems and SLC support for all systems after going live
- Supervision of deviations, changes (GEP and GMP), and CAPAs
- Coordination of CSV executions with internal groups, as well as external service providers and suppliers
- · Responsible for the presentation of CSV documents during audits and inspections
- Scheduling and reporting of CSV activities
- · Following the alignment of the CSV strategy with the QA CSV for all Biologics scope
- · Contribution in the review and amelioration of all CSV documents

Key requirements:

- Bachelor / Master / Diploma from a technical school (HF) / university of applied sciences
 (FH) or university in a technical field
- Significant experience in a regulated environment with regard to Computerized System Validation (CSV)
- · Good knowledge of Microsoft Office and Delta-V is required
- Knowledge of KNEAT, COMOS (plant engineering software solution), DMS, TrackWise and SAP is an advantage
- Fluent in English, German language skills are advantageous

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.

Lonza