Lonza

CQV Group Lead Ibex™ Operations

Job Description Summary

Key responsibilities:

- Responsible for all required CQV activities of production equipment's, utilities, clean room and small devices during the life cycle of the plants
- Act as an interface between the investment-engineering organization and operations
- Responsible for delivering all input required for the use of CQV tools for construction, commissioning and qualification of Ibex biopharma facilities
- Act as decision-maker if new or changed CQV strategies or standards are identified e.g. during the Engineering-Phase of a project
- Support all Quality and Compliance related responsibilities for the commissioning, qualification and validation of facilities, equipment, utilities and systems (incl. Computer System Validation) related to the cGMP manufacture in multiple plants
- Support the future operation units and project teams in all questions of CQV
- Train and supervise staff and work cooperatively with Ibex™ Leadership to achieve quality and compliance goals
- Responsible for and support the preparation of GMP risk assessments and introduce expertise into these risk analysis's
- Write, review and approve CQV documents
- Write, review and approve SOPs (in your area of Subject Matter Expert (SME)), act as owner of such documents and assure that all CQV documents and activities follow approved SOPs and existing standards
- Review technical change requests during the different phases of a project and during the life cycle and assesse their relevance to the CQV activities of facilities, equipment, utilities and systems
- Represent specific areas as SME and provide guidance's and recommendations in these areas to internal or external customers
- Lead or support specific projects in your area of SME to develop further CQV standards
- Represent CQV topics during customer audits and regulatory inspections
- Support continuous improvement programs to establish an effective CQV System
- Ensure a thorough information exchange from other management levels to your team and the other way around through regularly team meetings and escalation of production issues
- Ensure and manage the respective interfaces to the Manufacturing teams, QA, QC, Support Functions, Project- and Site Engineering teams
- Support the implementation of Lonza culture via openness for change and new ideas, cooperative teamwork and continuous improvement even outside the own area of responsibility

Key requirements:

- Bachelor or Master Degree (University for Applied Science, Technical University), preferred area of study: Mechanical Engineering, Chemical- or Biological Process Engineering
- Extensive experience in GMP and CQV activities of biopharmaceutical plants; recognized expert in the area of CQV activities for biopharma production units
- Deep experience with CQV activities according to V-Model and the science and risk-based process
- Good knowledge of engineering and manufacturing processes
- Strong leadership skills and team orientation
- Ability to communicate internally and externally at higher levels; strong business understanding
- Open-minded for new ideas and suggestions
- Structured, focused and well-organized working attitude
- Agile, highly motivated and dynamic drive, solution-oriented
- Fluency in German and English, very good knowledge regarding MS Office especially Excel, Word

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.