Lonza

Quality Risk Manager, Ibex[™] Solutions – R19900

Job Description Summary

Today Lonza is a global leader in life sciences. We are more than 15,000 employees in more than 100 locations around the world. 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 <u>lbex[™] Solutions</u>, our recently launched unique biological manufacturing and development concept in <u>Visp</u>. <u>Switzerland</u>, we have multiple openings. Become part of this exciting opportunity and join our team by applying for the position as Quality Risk Manager (QRM). As QRM you will be part of the QA department and be responsible - under the guidance of the Quality Management Systems Group Lead - for the implementation of a QRM concept, the planning, realization and oversight of the risk management activities related to our new lbex[™] Solutions facility and the associated processes.

Thereby, you will ensure that all Quality Risk Management activities meet the requirements of internal instructions, regulatory expectations and industry standards.

Key responsibilities:

- Organization and oversight in the Quality Risk Management process, ensuring that risk management principles are embedded throughout the Ibex[™] organization
- · Provide support, advice and guidance on all aspects of risk management
- Close cooperation with other Quality experts and cross-functional collaboration with subject matter experts of other departments, such as Development, MSAT (Manufacturing Science & Technology), Manufacturing and Engineering
- · Represent QA in interdisciplinary, technical project teams
- Assist leaders to ensure that all areas of the organization understand, own and are accountable for risk management systems that are applied in operational practice and ensure that processes and defined strategies are more robust and continuously improved
- Train and coach staff on QRM principle and tools
- Ensure that internal / external GMP standards and regulatory requirements related to QRM are adhered to in projects
- · Moderate cross-functional risk analysis/ assessments or coach moderators
- Develop a concept for the structured documentation of risk analyses/ assessments, issues, reviews or approves related documents

Key requirements:

- Bachelor, Master degree or PhD in chemistry, biotechnology, life sciences or related field
- Significant experience in the GMP regulated pharmaceutical industry; preferable in a role within the Quality Unit
- · Knowledge in biotechnological manufacturing processes is an advantage
- Strong background in QRM operations: fully familiar with the use of Risk Management tools (like FMEA, FTA, PHA, etc.) and processes (moderation of Risk Assessment sessions) and with related Guidelines (ICH Q9)
- · Structured, focused and well-organized working attitude
- Open-minded for new ideas and suggestions
- Capability to negotiate with different stakeholders for the implementation of Risk Management tools
- · Excellent communication skills in English, German would be an advantage

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.