SECURECELL AG
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INNOVATION IS OUR PASSION

Securecell is the trusted partner for biopharma, enabling them to bring new therapies to patients in a safe, efficient, and economical way. We innovate ground-breaking measuring and control engineering technologies to radically improve bioprocessing, medical treatment, and patient health. For more than 25 years, we have been delivering innovative solutions in bioprocess control for biotech, pharma, and academia. This expertise and experience provided the foundation for the technology transfer into the MedTech space and the development of Seraccess, a truly disruptive diabetes therapy. Continuing steadily on our sustainable innovation path and growth journey, we are looking for talented

QUALITY ENGINEER

for our Quality Assurance and Regulatory Affairs department

You develop, implement, and maintain the quality management system across the entire product lifecycle, ensuring compliance with applicable standards and regulatory requirements. You define and oversee quality processes, methods, and tools to ensure consistent product and process quality. You contribute to verification and validation activities, ensuring that all deliverables meet defined requirements and specifications.

You act as a key interface between stakeholders, including project management, R&D, manufacturing, suppliers, and regulatory bodies. You facilitate quality-related communication, drive issue resolution, and ensure alignment on quality objectives. You create, review, and maintain the necessary quality documentation, including procedures, reports, and records, and support audits (internal and external).

You lead root cause analyses, implement CAPAs, and drive continuous improvement initiatives. You assess risks, hazards, and non-conformities, ensuring appropriate mitigation strategies are defined and implemented. You ensure that lessons learned are captured and integrated into ongoing and future projects.

You monitor relevant standards, regulations, and industry best practices, incorporating them into the quality framework. You support business development and product strategy by providing quality-related insights, ensuring that products meet market and regulatory expectations.

YOUR TASKS

- Act as the Quality Assurance specialist in biotech projects.
- Coordinate and moderate risk management activities and ensure that defined risk control measures have been implemented.
- Perform CR, CAPA, and NC activities in accordance with quality procedures.
- Drive, create, and maintain the technical and end-user documents for our hardware products through the entire product lifecycle.
- Write the relevant information in a form fulfilling the legal and normative requirements
- Organize and coordinate documentation deliverables at the end of each project phase by interacting with document owners to define, create, and publish required deliverables to ensure that quality targets, timelines, and regulatory requirements are respected.
- Lead the eDMS system, contributing to the continuous improvement of documentation tools, including validation, user training, and serving as the key contact person.
- Gather, compile, and consolidate the information needed for technical writing by collaborating closely with departments, teams, suppliers, experts, and other third parties (both locally and globally).
- Support Quality Control activities in production.
- Create new processes relevant to the Quality department.

- Support the maintenance of the Quality Management System (QMS).
- Act as a trainer for the documents created as an author or for other general training related to product documentation or compliance.

YOUR PROFILE

- Min. bachelor's degree in engineering, sciences, or similar with relevant proven experience in a technical area, preferably in Biotech, MedTech, or other highly regulated environment
- 3-5 years of experience in a quality role, preferably in a highly regulated industry
- Interpersonal, autonomous, flexible, and organized with an analytical and critical mind
- GMP knowledge and strong affinity for technology
- Excellent spoken and written command of English (native speaker or equivalent level), ideally good German knowledge
- Candidates must have the legal right to work in Switzerland. Please indicate your current work authorization status.

OUR OFFER

Securecell offers a highly diverse international working environment and the opportunity to collaborate with highly skilled individuals from various disciplines. Partnership and interdisciplinary collaboration are at the core of our company, our research activities, and the commercialization of our marketed products. We nurture true innovation and creative thinking to advance our research projects as well as to continuously improve our marketed products. At Securecell, you will discover a challenging job, inspiring colleagues, and a true purpose. We are looking forward to hearing from you!

Please submit your detailed curriculum vitae and additional documentation to hr@securecell.ch

Only direct applicants (not via third parties such as recruitment agencies) will be accepted.

JOB LOCATION

Securecell headquarters are in Urdorf (Zurich), Switzerland.