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 fundament 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

VALIDATION MANAGER

for our Biotech Department

In this role, you will be responsible for establishing and owning the validation strategy, procedures, instructions, and related scientific content with an emphasis on risk-based approaches to Validation and Good Manufacturing Practices. You will be part of an international team and report to our Lead of Quality Assurance and Regulatory Affairs. You will coordinate cross-functional activities of the Validation and Qualification program for computer systems and laboratory, development, and manufacturing equipment. You will also be the key contact person to support all Qualification and Validation activities for customers implementing our software and computerized systems. You will lead software compliance during applications and systems development. You will closely collaborate with our interdisciplinary and cross-functional teams. Among your responsibilities, you will:

- Act as a key contact person for all validation activities, including supplier self-assessment and preliminary clarification with customers
- Develop a compliant validation and test strategy based on risk assessment for internal computerized systems, ensure cost-efficient implementation, and set industry standards
- Participate in projects for systems/applications development and create compliance strategies for software from requirements definition to implementation and testing
- Build and maintain the process for Qualification and Validation to ensure compliance, work together with project managers to include activities for qualification and validation in implementation timelines, and act as a coordinator in all projects for validation
- Moderated and documented Quality Risk Assessments concerning the executed validation activities
- Determine validation deliverables and oversee the execution of validation plans and validation documents
- Supervise, review, and document all validation activities (e.g., VPs, URS, FRS, RAs, IQs, OQs, PQs, VRs) upon internal and external needs
- Evaluate proposed changes for both validated processes and computer systems to define the recommended level of validation activities required
- Establish all Quality System related documents, procedures and templates together with the relevant stakeholders
- Create and implement training material and courses for the proper execution of validation documents and coach the teams for the implementation
- Implementation of compliance strategies for Data analysis processes and integrated AI tools (incl. machine learning tools audit)
- Support projects in cybersecurity compliance and assessment
- Collaborate with the IT team to improve IT infrastructure and disaster recovery processes and guarantee business continuity

YOUR PROFILE

- At least a bachelor's degree in engineering, sciences, or similar with relevant proven ten years of experience in Process Validation and Computer System Validation in Biotechnology or Medical Devices
- Proven scientific and technical expertise in qualification and process validation in the Life Science / Pharmaceutical industry as well as corresponding key validation approaches (validation lifecycle, GAMP5, V-Model)
- Proven scientific and technical expertise in commissioning large-scale projects for the bioprocess/pharmaceutical production facilities, including facilitating the compliance process of physical and digital environments (incl. IT infrastructure qualification, computerized systems integration, and digitalization)
- Practical experience in managing and validating laboratory equipment and managing quality control processes
- Experience working in clean rooms and a deep understanding of contamination control strategies in Biotech or pharmaceutical companies
- Evidence in auditing biotech and pharmaceutical manufacturing processes (GxP), software development processes and/or cloud infrastructure suppliers, as well as managing service level and quality agreements with cloud service suppliers (SaaS, PaaS, IaaS)
- Knowledge of GxP, ISO 13485, CSV, GAMP, 21 CFR part 11, 21 CFR 210/211 and/or 820
- Strong MS Office suite and other tools used in state-of-the-art technical documentation; knowledge in using tools based on Large Language Models will be an advantage
- Confident stakeholder management skills and ability to manage tight timelines and scopes
- Ability to collaborate and communicate with subject matter experts from different functional areas
- Very organized and structured workstyle with attention to detail
- Interpersonal and autonomous with an analytical and critical mind
- Excellent spoken and written English (native speaker or equivalent level), ideally with a good understanding of German
- Valid work permit for Switzerland and only direct applicants will be taken into consideration (no agencies)

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 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 to hr@securecell.ch

JOB LOCATION

Securecell headquarters are in Urdorf (Zurich), Switzerland.