Quality System Engineer (Digital Health Technologies)

m/f/d, Basel-Stadt

For our client from the Pharma Industry, we are looking for a Quality System Engineer with in-depth knowledge and experience with Digital Health technologies, with a focus on regulatory aspects

Responsibilities:

- Serving as the single point of contact: for technical conversations with third party device manufacturers regarding design controls, risk management, and agreements. Act as the Subject Matter Expert (SME) on device requirements and technical nuances; also ensure these elements are appropriately integrated into study protocols and documentation.
- Compile and maintain the "Asset List" (Technical Documentation), perform technical reviews of manufacturer data, and author or review technical content for submission documents.
- Digital & Regulatory Identity: Co-lead the regulatory characterization of DHTs with the Product Management & Design Leaders, which involves providing input into Roche's internal Device Regulatory Assessment and supporting updates.
- Change Control: Act as the intake point and primary assessor for changes during a study, rigorously evaluating the impact on technical accuracy, documentation, and overall study integrity. Work will also help inform third party manufacturers of updates needed in their design control documentation.
- Evaluation: Support manufacturer qualification activities with Quality, Product Managers, Business Strategy & Operations and Procurement teams to evaluate vendor capabilities and identify technical gaps to inform viability of use as a third party manufacturer.
- Remediation: Oversee the manufacturer's delivery and lead any needed remediation efforts (when needed) to address updates to documentation.
- Review Manufacturer Design History Files (DHFs) and product development documentation: from the third party DHT product manufacturers
- Conduct Risk Management and computer systems validation (CSV) for products not classified as medical device, when necessary and per global standard operating procedures (SOPs)

Job profile

- Engineering - Quality Management
- Basel-Stadt
- Contracting
- Full Time
- ASAP (latest 1st of September) - 12 months
- Quality Management Systems

Sounds interesting?

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- Ensure compliance with internal quality standards and global standard operating procedures (SOPs) for medical devices, including sourcing, clinical investigation, risk management, and clinical performance procedures.
- Draft or support product managers, clinical scientists, or other clinical teams with drafting technical documentation or risk management plans to meet the company specific SOP, ISO standards or Health Authority Requirements.
- Support upskilling: activities and plans to train team members new to medical device development, design control, regulatory assessment and quality documentation activities.

Must haves:

- BA/BS degree in Computer Science, Software Engineering, Informatics, Biomedical, related technical field or equivalent practical experience. Masters or advanced degree in Engineering, Quality Management, or related field.
- 7+ years' experience in the medical device or pharmaceutical industry
- In-depth knowledge and experience executing ISO 13485, ISO 14971, IEC 62304,IEC 82304, IEC 60601-1, 21 CFR 820, 21 CFR Part 11, Annex 11, and GAMP 5, with a strong emphasis on medical device regulations and quality management systems
- Experience conducting ISO 14155 compliant clinical investigations for medical devices, ensuring regulatory and ethical standards are met
- Experience executing ISO / IEC 27001 and cybersecurity aspects related to development of medical device products
- Software Validation & Testing: Expertise in Computerized System Validation (CSV) and software quality assurance, with an ISTQB Test Manager certification
- Experience with GCP / GxP practices and GMP
- Experience in working with the Center for Devices and Radiological Health (FDA), EU Health Authorities/MDR, and Notified Bodies
- Track record of effectively working in a matrix environment with global team members
- Fluent in English, German is of advantage

Sounds like a great job?
Then we look forward to receiving your complete application

documents through our online application form.

When applying by email, the sender agrees that his or her data will be used in accordance with our data privacy policy.

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