Quality System Engineer with DHT Technical Capabilities (m/f/d)

Temporär Jobregion: Basel Stellenprozente: 100%

Beschreibung

As a first-tier supplier to our renowned business partner F. Hoffmann-La Roche Ltd. in Basel, we are currently looking for a motivated and dedicated **Quality System Engineer with DHT Technical Capabilities** for a temporary assignment of 12 months.

Tasks & 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 Roche’s global standard operating procedures (SOPs)
- Ensure compliance with Roche’s internal quality standards and global standard operating procedures (SOPs) for medical devices, including

BERATER

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Seniority Level
Mitarbeiter

Berufskategorie
Elektro & Mechanik

Stellenprozent
100%

Jobtyp
Temporär

Referenz-Nr.
AFE-EM-T-54604

Jobregion
Basel

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 Roche 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

Nice to haves

- Cybersecurity experience - relevant ISO for products
- Past experience leading training for ISO 14971, ISO 62304/SDLC
- Past experience working with the Roche Group

Benefits

- Become part of one of the most prestigious pharmaceutical companies and actively shape the future of healthcare
- Experience a work culture that promotes diversity and inclusion and where all employees feel valued.
- Work on a state-of-the-art campus featuring green spaces, meeting areas, and an inspiring atmosphere
- Work with modern and up-to-date tools in an innovative work environment
- Start with a professional onboarding process and a thorough introduction to your new role during the Welcome Days
- Benefit from financial support for your professional development plans
- Enjoy a selection of high-quality meals in modern staff restaurants

- As part of a sustainable mobility concept, on-site parking spaces are available to you (subject to eligibility criteria)
- Take advantage of unbeatable, year-round discounts at renowned retailers and over 200 top brands
- Benefit from fleet discounts when purchasing new cars or receive constant fuel discounts with our fuel card

Are you interested? Do not hesitate and submit your complete application documents online today. We look forward to hearing from you!

Wir wertschätzen Vielfalt und begrüssen daher alle Bewerbungen – unabhängig von Geschlecht, sozialer Herkunft, Religion, Alter und Identität. Zur leichteren Lesbarkeit und besseren Verständlichkeit verwenden wir nur eine Gender-Form. Selbstverständlich sind im jeweiligen Kontext alle Genderformen gleichermassen gemeint.

Unser Bewerbungsprozess