Validation Engineer GEM (m/f/d)

Temporär Jobregion: Rotkreuz Stellenprozente: 100%

BERATER

Kristof Wildmann
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Seniority Level
Mitarbeiter

Berufskategorie
Elektro & Mechanik

Stellenprozent
100%

Jobtyp
Temporär

Referenz-Nr.
KWI-EM-T-52770

Jobregion
Rotkreuz

Beschreibung

As a first-tier supplier to our renowned business partner **Roche Diagnostics in Rotkreuz**, we are currently looking for a motivated and dedicated **Validation Engineer Global External Manufacturing (GEM)** for a temporary assignment of 12 months, with high probability of extension.

This is more than just a validation engineer position. The job holder acts as a reliable quality partner, auditor, supplier developer, technical expert, and diplomat. As an expert in validation, the successful candidate will work together with suppliers in qualification and validation projects. With sound knowledge about quality regulations (e.g., IVDR / MDR, ISO 13485, 21 CFR 820), qualification and validation, and various production technologies, this role ensures that high-quality products are manufactured in compliance with the company's standards and external regulations. The main task is the supervision of qualification and validation activities with suppliers. This encompasses process risk analyses, qualification and validation documentation, and the corresponding documented evidence.

Tasks & Responsibilities

- Review and evaluate qualification and validation documents and process risk analyses provided by suppliers
- Oversee the assessment of deviations related to qualification and validation activities, ensuring they meet the company's rigorous standards
- Meticulously document the outcomes of evaluations in compliance with established quality standards
- Actively engage in the continuous improvement of processes, providing support in technical matters and performing statistical data analyses
- Offer expert advice to suppliers on quality and compliance, ensuring adherence to all relevant quality standards and specifications
- Thrive in cross-departmental collaboration, working effectively within squads to achieve common goals

Must-Haves

- Bachelor's Degree in engineering, scientific/technical field, or equivalent work experience
- At least 10 years of related experience (Q&V, Auditing, or Quality functions) in the Pharma or medical device industry
- At least 5 years of experience with external manufacturing business
- Profound understanding of applicable standards and norms, along with expertise in injection molding, blow molding, or other automated

production technologies
- Demonstrated continuous desire for learning and improvement for oneself and the team members
- Excellent communication skills in English and German (written and verbal)

Nice-to-Haves

- Knowledge of computerized systems validation and controlled environment qualification (ISO 14644)
- Familiarity with product risk management according to ISO 14971
- Certified Lean Six Sigma Green Belt / Black Belt

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

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