

Validation Engineer

Global External

Manufacturing

m/f/d, Zug

This is more than just a validation engineer position. You act as a reliable quality partner, auditor, supplier developer, technical expert and diplomat. As an expert in validation you will work together with our suppliers in qualification and validation projects. With your sound knowledge about quality regulations (e.g. IVDR / MDR, ISO 13485, 21 CFR 820), qualification and validation, and various production technologies you will ensure that our high-quality products are manufactured in compliance with our standards and external regulations. Your main task is the supervision of qualification and validation activities with our suppliers. This encompasses process risk analyses, qualification and validation documentation and the corresponding documented evidence.

Your responsibilities:

- * Review and evaluate qualification and validation documents and process risk analyses provided by our suppliers
- * Oversee the assessment of deviations related to qualification and validation activities, ensuring they meet our rigorous standards
- * Meticulously document the outcomes of your 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

Your experience:

- * A Bachelor's Degree in engineering, scientific/technical field, or equivalent work experience, with at least 10 years of related experience (Q&V, Auditing, or Quality functions) in Pharma or the medical device industry

Job Profil

-  Life Sciences - Engineering
-  Zug
-  Contracting
-  Vollzeit
-  Validation, Quality, Medizintechnik



Klingt interessant?

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- * 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
- * Demonstrate a continuous desire for learning and improvement both for yourself and your 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

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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