Universal-Job AG • Kasinostrasse 32 • 5000 Aarau

Medical device Technical Expert - Risk management

00024655

Company profile

Our client is a successful company in the pharma industry.

Work location

Basel

Main duties

- Ensure timely completion and quality of the assigned risk management files.
- Lead specific risk management activities within projects, as agreed with project leaders
- Facilitate development and completion of risk assessments.
- Ensure compliance with ISO 14971 in all development projects assigned
- Conduct and provide guidance on the use of risk analysis for Use, Products, Components and Processes.
- Ensure compliance with regulatory and normative guidelines focusing on medical device risk management
- Guide internal and external functions on creating, reviewing and approving medical device Risk Management Files.
- Work with device development team to incorporate and complete Risk Management during all design phases for new and/or product enhancements.
- Apply FDA CFR 820, ISO13485, and ISO 14971 Risk Management in assigned projects
- Author the documentation in the medical device risk management file

Start of work

Immediately / by agreement

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Education

An ideal candidate would have at least 5 years of experience in device development of parenteral delivery systems, e.g., drug/device combination products with main focus on medical devices for parenteral administration. The ideal candidate would have experience generating DHF documentation.

Experience

- Excellent technical writing skills (e.g., Design Controls)
- Good understanding of medical device regulations (FDA 21CFR 820, EU Medical Device Directive) and of combination products (US)
- Experience in Product Design and Design for Manufacturing
- Good technical knowledge of primary containers development
- Good technical knowledge of auto injector development
- Good communication skills
- General understanding of Human Factors Engineering and Risk management
- General understanding of clinical trial processes and requirements
- General understanding of pharmaceutical development
- Support DRA to prepare Medical Device/Combination Product pre-registration documents and answer health authority questions.

Languages

Englisch: fluent
German: would be an advantage

Are you interested? Please send your complete application documents by email.

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