Risk Analysis Engineer

SHL Medical is the world-leading solution provider in the design, development, and manufacturing of advanced drug delivery systems with more than 5000 employees worldwide. Our customers include top pharmaceutical and biotech companies from around the globe that require innovative devices such as auto injectors or pen injectors to effectively deliver their drugs. Headquartered in Switzerland, SHL has sites in Sweden, Taiwan, and the Unites States.

Job Overview

The role requires application of engineering knowledge and ingenuity to deliver risk analysis related to medical device manufacturing processes using tools such as - Failure Mode and Effect Analysis (FMEA). The candidate will work with cross-functional teams to ensure processes development, control planning and qualification of manufacturing processes are aligned with risk-based approach and meets ISO 14971:2019 requirements.

Main Responsibilities

- Develop Assembly Risk Assessment document from Assembly Guidance of product to ensure control plan and process development are done according to product risk levels
- Participate in process and equipment design review activities and conduct comprehensive Failure Mode and Effect Analysis (FMEA) of manufacturing processes and related equipment to ensure risk exposure to product and end used is reduced as far as possible at design stage.
- Attend relevant project meetings to ensure all information required to develop, update, and maintain risk management documents for related projects are captured and utilized effectively.
- Participate in relevant product lifecycle management activities to provide/collect information and ensure FMEAs are updated accordingly – e.g., NCMR & complaints, CCB meetings, MPQ meetings, deviations meeting etc.
- Ensure periodic review and update of FMEAs according to comply with procedural and compliance requirements.
- Cascade information and actively participate to propose risk control methods in control planning, process development and equipment development stages through use of ARA and FMEA.
- Where needed, participate and contribute on end-to-end processes risk management in SHL including material handling, transportation, packaging, sterility and testing of final combination product.
- Organize cross-functional meetings with project team members to communicate all open items from FMEA reports and derive solutions to mitigate the risks. This includes active engagement with AMSD and external equipment suppliers where needed.
- Escalate potential issues and progress blockers on risk management work to team leaders and ensuring resolution is achieved with minimal impact to project timeline.

Skills and Qualification

- Masters in Life Science Engineering discipline (or) Degree with 2 years of work experience. Exposure to medical device, pharmaceutical or biotechnology industry is added advantage.
- Trained on Quality System Regulation, Process Validation, Risk Management or Design Control course.
- Demonstrated and applied a broad knowledge in quality management assignments and risk management approaches.
- Good communication and interpersonal skills and demonstrate ability to participate in inter-departmental projects and resolve quality-related issues in a timely and effective manner.