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Validation Engineer

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Company: Sotera Health

Location: Belgium

Category: computer-and-mathematical

Validation Engineer **Objective of the function** Responsible for executing equipment requalification, validation and R&D projects according to Sterigenics procedures on agreed validation protocol. Plan, organize and coordinate all validation activities related to assigned validation projects (facility and/or EAS projects). Identify business process improvement and assist in implementing them. **Responsibilities/Duties** 1. Review customer or EAS supplied validation or test protocols for executability within the limitation of the facility's equipment, Sterigenics operating procedures and compliance with current regulatory standards. 2. Handle periodic customer requalification's (protocol and report edition). 3. Organize the execution of validation protocols and technically driven customer and/or EAS projects, which include but are not limited to the following: Planning all validation activities, project runs, ancillary resources, lab testing and sample handling, in order to minimize the risk of errors in the execution, Cycle programming and preparation of necessary process documents (CSA) and safety assessments, Microbiological samples inventory, Data collection and analysis (if applicable), Assuring proper handling, storage and shipping of bioburden, LAL, biological indicators, sterility, engineering or residual samples to the appropriate laboratory. 4. Ensure validation activities are carried out according to the agreed time-schedule and communicate follow up to relevant persons (validation manager, EAS, sales, etc); 5. Organize work of validation operators for load preparation in collaboration with the validation team leader. 6. Writes validation work instructions for production staff and the lab. Make sure it complies with protocol requirements. This includes but is not limited to Creation of validation batch Lab work requests with all relevant information required to perform laboratory analyses and

related purchase orders edition 7. Responsible for annual equipment re-commissioning (sterilization and laboratory); 8. Update validation status in the relevant systems; 9. Maintain the quality and integrity of information required for validation records. Report any deviation to validation manager. 10. Provide support to Maintenance or Engineering department in the performance of IQ/OQ/PQ activities of new or existing facility equipment. **Authority:** The Validation Engineer reports to the Validation Manager. **Requirements: Knowledge/Education and Training:** Industrial Engineer or equivalent Modern Quality Systems & standards ISO, FDA, GMP **Experience:** First experience in the industry is useful Project management First experience in writing and executing validation protocols Fluent in English and French (reading, speaking, writing)**Skills:** Fine organizational skills Efficient, accurate, work according to plan Strong computer skills Relevant standards knowledge**Contacts: Internal:** Validation operators & validation manager EAS, Operations, Laboratory (Nelson Labs), Customer service, Quality, Engineering and Maintenance departments **External:** Customers External laboratories (if needed) External Consultancy Services (if needed) **Deputy:** Equivalent Validation Engineer position or Validation Manager

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