



Product Regulatory Lead R&D

The Product Regulatory Lead R&D is in charge of writing technical documentation to support Clinical Study Approvals, CE marking and FDA submissions and registrations. She/He ensures compliance of product technical documentation with regulatory and industry standards and ensures that Regulatory Standards are met as part of the Product Development Process.

Reports to VP R&D

Function

- Own technical/non-clinical product-related documentation according to Design Verification and Validation plan
- Write technical documents including Investigator Brochures, Product Risk Analysis, Verification & Validation Reports, and others as required
- Coordinate cross-departmental activities needed for successful technical document creation and submission
- Prepare technical documentation to support Clinical Study Approvals, CE-Mark applications, FDA regulatory submissions, and product registrations
- Work closely with Quality Assurance, Quality Engineering, and Quality Control in manufacturing to support validation strategies (processes and test methods)
- Maintain technical documentation to ensure compliance with internal QMS, regulations, and standards
- Prepare and present technical documentation in audits (internal and external, i.e. by Notified Bodies).
- Manage Product Lifecycle Management activities, re-submissions and amendments
- Support product registration processes

Profile required

- Master's degree, preferably Ph.D. degree in Science, Engineering or similar
- Strong technical writing skills in English (Investigator Brochures, Risk Management Reports, Technical Reports)
- Previous experience (5+ years) supporting or in Regulatory Affairs for Medical Devices Class, preferably IIb or III,



- Experience with and knowledge of applicable standards and regulation, such as ISO13485, Medical Device Regulations (MDR), FDA guidance documents, etc.
- Experience with Design Controls
- Fluent in English, written and spoken. Knowledge of another language is beneficial
- Good knowledge of Microsoft Office applications
- Excellent presentation skills