

## R&D ENGINEER AND SENIOR PROJECT MANAGER

We are looking for R&D Manager cum Senior Project Manager to support our medical device client from our office in Basel, Switzerland and requires about 10% travel to client location on a weekly basis.

### Job Responsibilities

- Overview the FMEA team (DCRM-Design clinical risk management and PRM-Production Risk management) and provide the necessary technical support in getting the deliverables completed.
- Analyse and evaluate clinical data gathered and ensure compliance with regulations.
- Responsible for shared service document review, specially to Restricted substances report and Biocompatibility report and comply with regulatory standards.
- Systematic review of different DHF's for the Product line
- Ensure accurate risk benefit analysis cascaded in documents and get reviewed by medical affairs
- Good Experience in Plastic and metal part design, material selection
- Proven track record in R&D functions is a must have
- Previous experience working for a global medical device company and good understandings in ISO 13485 and EU MDR Regulation (EU) 2017/745
- Ensure accurate activity or study budget management, updates for scope changes and reconciliation of assigned studies for out of pocket expense and FTE costs.
- Tracking budgeting and invoicing, working with purchase order preparer

### Qualifications:

- At least 5 years of technical experience and minimum 3 years management experience is must
- Relevant working experience with Mechanical Engineering background is added advantage
- Experience in materials and Plastics and Proficiency in Plastic and metal part design (Proficient with plastic and metal part design, material selection, assembly/machine design, 3D modelling/surfacing of parts/assemblies in CAD software, creation of 2D and process drawings for quoting and material procurement)
- Proven management experience in an Orthopaedic industry
- Good analytical skill, ability to prioritize and plan the multiple tasks.
- Good problem solver and negotiator
- English fluency and German knowledge are expected