Quality Engineer

Assistance in implementation of a quality management system in compliance with ISO 13485:2016 and FDA requirements
Support Design and Development activities in different stages: design input, output, V&V
Updating the DHF
Assistance in V&V planning and execution (Biocompatibility, performance, packaging, transportation, shelf life and sterilization validation)
Participation in risk management (DFMEA, AFMEA, PFMEA)
Design transfer and DMR
Incoming inspection
Suppliers' evaluation
Document control
Preparation for external audits
Support ECO's
Support CAPA's
Support clinical trials
Assistance in bench tests, validation testing and prototypes manufacturing

Qualifications
3years of QA experience in the medical device industry (design control experience is an advantage)
BSc in Bio-Medical/ Mechanical /Biotechnology Engineering /Exact Sciences

Strong written and verbal communication skills in English

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