Product Development and Quality Coordinator - Vacancy Details

Vacancy Overview

We have an immediate position for an experienced medically focussed Product Development and Quality Coordinator to join our successful team in Edinburgh.

You will get the opportunity to work with a wide range of US & EU based clients, with a focus in the pharmaceutical and medical device sector. The role will be to coordinate medical device development projects using both client and internal processes as part of our overall service to customers, delivering new and innovative devices to market.

The successful applicant will receive a competitive salary, great benefits package and the opportunity to contribute to a stimulating and varied project mix, all within a fantastic working environment.

Primary Roles

Quality Assurance

- Quickly adopt and work within established client processes and QMS creating project documentation, ensuring document control and approvals through client systems.
- Establish effective and efficient project documentation including, D&D plan, user and product requirements, risk management plans, V&V plans etc.
- Provide medical device quality assurance across multiple client projects; giving guidance and direction internally and externally.
- Coordinate with input from the technical team, the risk management programme for medical device projects in accordance with ISO 14971.
- Create and manage Design History Files, Device Master Records and compliance technical files for CE marking.
- Contribute to the review, management and update of medical device quality systems, SOPs and processes.

Project Management

- Working alongside client R&D Device Lead to arrange and lead sub-team meetings with clients, consolidate team input, manage actions, timelines and tracking of all development process and project deliverables.
- Identification and management of design and development activities ensuring tasks are executed on time according to clients project plan.
- Work with key personnel internally and externally to ensure documentation procedures and processes are efficiently followed and delivered.
- Lead meetings with clients, present and communicate ideas and concepts, manage actions and deliverables.

Requirements / Skills

- The ideal candidate will have certified quality training and significant experience in taking medical device projects through the development, using design controls from concept up to design validation, design transfer and product launch.
- Have a detailed working knowledge and experience managing compliance with ISO 13485, ISO 14971, FDA CFR21 part 820 QSR and GMP for the development, validation and manufacture of disposable and durable combination products and medical devices, including software.
- Working knowledge of statistical tools, including sample size rationales for V&V protocols and design of experiments.
- Excellent communication skills and the ability to work with multiple client based document authors, reviews and approvers, helping them work within the QMS smoothly and efficiently.
- Self-motivated, versatile performer experienced in a fast moving environment, managing and achieving short timescale deliverables.

How to Apply

If you are interested in applying to join our team, please send your full CV and examples of any recent work to,

jobs@shore-group.com quoting reference **QC0518**

Please note, due to the high number of enquiries we are unfortunately only able to respond to shortlisted candidates.