Quality Engineer (IVD/Medical Device)

Permanent Opportunity

Location – Stirling, Scotland

Are you currently working within Assay development in the IVD/Medical Device sector and have an interest in moving into Quality?

My exciting, energetic, growing client are currently recruiting for a full time Quality Engineer who will be responsible for the development of quality engineering activities associated with IVD sensors (assays) development through the R&D phase and the verification and validation phase.

Role Responsibility

- Quality representative for project teams throughout product lifecycle and product realization activities
- Creation and management of documentation forming the Design History File and Device Master Record.
- Assess, control and coordinate changes to Design History File and Device Master Record.
- Coach and support in the writing of design requirements and specifications.
- Coach and support in the writing of Verification and Validation plans and protocols
- Creation and management of traceability matrices.
- Organize, host and facilitate risk management related activities and design reviews with the project teams and ensure compliance of such activities to the applicable standards and regulations.
- Ensure compliance of documentation for design partners (and suppliers) within the supply chain.
- Support clinical processes for assays in development
- Review and approve as Quality representative on project teams and QMS.
- Review and approve Device History Records and final product release.
- Support the QMS day to day activities, such as CAPA, Change Control, Supplier management, complaints investigation, audits and other routine quality activities.

About You

Essential Skills:

- Knowledge and experience of working to the appropriate quality and regulatory standards including ISO13485, FDA 21CFR Part 820.
- Experience of working in an IVD or medical device environment with a strong quality focus and in-depth experience through development and verification and validation activities.
- Experience of post launch IVD or medical device activities including minimum 2 products
- Scientific background.
- Excellent organizational skills for working on multiple projects.
- Ability to use problem solving tools and methodologies.

- Influence internal project team and external parties to maximize success opportunities

Further Details

Our client is offering a competitive salary in a great working environment therefore if you are looking to further develop your career with a thriving and growing company, this could be the role for you. Please contact Suzi at Entrust People on 01224 608988 for more details or to discuss further.