Senior Design Assurance / Quality Engineer

Job ref: 1113

Are you a talented Design Assurance or Quality Engineer with experience of taking medical products to market? Do you want to be an integral member of multidisciplinary teams, developing innovative medical products? If so then please read on…

Main purpose of the job

As a Design Assurance / Quality Engineer at Cambridge Consultants, you will make a significant contribution to major medical technology development projects. You will translate regulatory requirements into product requirements for innovative medical products, and ensure compliance to relevant standards and regulations throughout, with a particular focus on risk management and design verification.

Type of work undertaken by division

The Medical Technology Division undertakes the development of innovative medical products and equipment from concept to manufacture. The projects often involve considerable technical challenges.

The Division's activities fall into four focus areas:

- Drug Delivery Devices
- Surgical and Interventional Products
- Medical Diagnostics and Instrumentation
- Wireless devices / eHealth

We combine highly creative lateral thinking with excellent technical skills and a broad base of industry experience to form powerful development teams. Our work ranges from undertaking complete product developments from concept to market, to providing consulting services for our clients on their technology, strategy, quality system requirements or development processes.

Specific responsibilities

As a Design Assurance Engineer at Cambridge Consultants, you will be involved in a wide range of projects, from requirements capture through to manufacture. You will apply your regulatory knowledge to device development projects across any of the Division’s four focus areas, liaising with scientists, engineers and Quality Assurance personnel both within Cambridge Consultants and within our client organisations.

Your specific responsibilities are likely to include:

- Take an active role in Design Reviews to assess quality and compliance
- Review requirements for traceability and testability
- Lead product risk management activities according to ISO14971 (including creation of Risk Management Plan, FMECAs, Fault Tree Analysis and Risk Management Report)
- Plan verification programmes, including interpretation and implementation of relevant standards, and establishment of acceptance criteria
- Perform analysis and interpretation of test data, including statistical analysis where necessary
- Help clients optimise their medical development processes
- Supporting creation of Technical Files / Design History Files
- Including review of client’s Technical File / DHF
- Perform gap analysis against quality system and regulatory requirements
- Creation of essential requirements checklists
Minimum requirements

To meet the requirements of this role, you will have:

- A good degree in Engineering or related technical discipline
- Experience of working in multi-disciplinary teams in at least one of the Division’s four focus areas
- Significant experience of risk management with regard to Medical Product development (according to ISO14971)
- Excellent understanding of medical device directive 93/42/EEC, ISO13485 and FDA QSR
- Experience of Design Verification
- Excellent communication skills
- Ability to review the work of others

The following would also be beneficial:

- Knowledge and experience of implementing IEC 60601
- Knowledge and experience of implementing IEC 62304
- Experience of liaising with the US FDA with regards to device submissions
- Experience of Design Validation
- Experience of design and development of, and regulatory submission for combination products / borderline products
- Experience of regulatory requirements regarding testing of pharmaceuticals
- Experience of manufacturing line qualification processes
- Experience of other applicable European directives including the in vitro diagnostic directive (98/79/EC), active implantable directive (90/385/EEC) and medicinal product directive (2001/83/EC)

Full Details

Benefits

- Good salary, based on merit and reviewed annually
- Company profit share scheme in addition to basic salary
- Pension scheme
- Life assurance plan
- Private medical insurance
- Travel insurance
- Disability insurance plan
- Free canteen - lunches and refreshments
- 25 days annual holiday plus public holidays
- Relocation assistance if applicable
- Excellent career development and training opportunities
- Flexible working hours
- Social committee

FUTURE PROSPECTS

Cambridge Consultants is committed to developing its employees careers and has a flexible policy for individual capabilities and preferences. Promotion is linked to merit.

Location

United Kingdom