

## **Job Specification**

### **Design Assurance Lead / Design Quality Lead (Contract)**

**Department:** Quality

**Location:** Onsite – Bray, Ireland

**Type:** Contract

**Reporting To:** Quality Director (functional) & PMO Director (day-to-day programme activities)

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### **Role Overview**

The Design Assurance Lead will serve as the quality representative within the product development programme, ensuring robust quality oversight across the full product lifecycle. This role will take ownership of end-to-end design assurance activities for a Continuous Glucose Monitoring (CGM) solution, ensuring compliance with global medical device regulations and standards.

You will play a critical role in minimising organisational risk across product design and development, while ensuring that design controls, documentation, and verification activities meet the requirements of international regulatory frameworks including 21 CFR 820, EU MDR, and ISO 13485.

This position requires a hands-on design quality leader with proven experience delivering medical device New Product Introductions (NPI) from concept through to commercialisation.

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### **Key Responsibilities**

- Establish and maintain Quality System requirements across the Medical Device Product Lifecycle
- Lead the creation and review of design documentation to ensure compliance with global regulatory standards
- Own and maintain Design History Files (DHF), Device Master Records (DMR), and related product documentation
- Ensure traceability across the V-model including requirements, risk management, verification, and validation
- Provide technical guidance on Design Verification & Validation protocols, statistical analysis, and testing strategies
- Train project teams on Design Controls, V&V processes, and good documentation practices

- Support internal and external audits, as well as regulatory submissions
  - Oversee design transfer to manufacturing, ensuring process validation and product quality readiness
  - Collaborate closely with Regulatory Affairs teams on submission preparation and responses to regulatory authorities
  - Provide supplier quality support and act as a Subject Matter Expert across hardware and/or software components
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### **Qualifications & Experience**

- Bachelor's degree in Biomedical Engineering or a related regulated technical discipline (Master's preferred)
  - 8–10 years' experience in medical device quality engineering, design assurance, or related roles
  - Proven experience delivering multiple medical device NPIs from concept through commercialisation
  - Strong working knowledge of key regulatory standards including:
    - ISO 13485
    - ISO 14971
    - IEC 62304
    - IEC 62366-1
    - FDA QSR 21 CFR 820
    - EU MDR
    - MDSAP
  - Experience with CGM technologies or wearable medical devices is highly desirable
  - Professional certification (e.g. ISO 13485 Lead Auditor) is an advantage
  - Strong communication skills with experience collaborating across global cross-functional teams
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### **Quality Engineering Ownership**

The successful candidate will take ownership across the following areas:

- Medical Device V-Model lifecycle and traceability management
- Phase-gated design reviews and compliance readiness
- Design Inputs and Requirements Management
- Risk Management processes
- Verification & Validation protocols and testing reports
- Defect tracking and resolution management
- Maintenance of DHF, DMR, and regulatory submission documentation