Senior Engineer, Design Assurance

Department: Design Assurance	**Reports To:** Director, Device Development	
Location: Vectura Cambridge	**Band:** C	**Level:** P3

Why

Job Summary:

- Responsible for the verification and validation testing of our combination products and medical devices
- Ensures that the device fulfils all design input requirements
- Overall responsibility for design history file

What

Principal Accountabilities:

Planning, implementation, and documentation of the product verification and validation

- Leading the development and documentation of Design Inputs (Requirements Specifications)
- Managing the traceability matrix
- Overall responsibility for the Risk Management process
- Creation of verification plans and protocols and review of validation plans and protocols to cover all aspects in the traceability matrix according to applicable standards and guidance
- Implementation of device verification, internally or with external test houses
- Reporting of results and conclusions of individual tests and of the plan as a whole, and communication of these outcomes within project team meetings and design phase reviews
- Management of project documentation in support of the project governance policy, leading to the creation and management of the Design History File

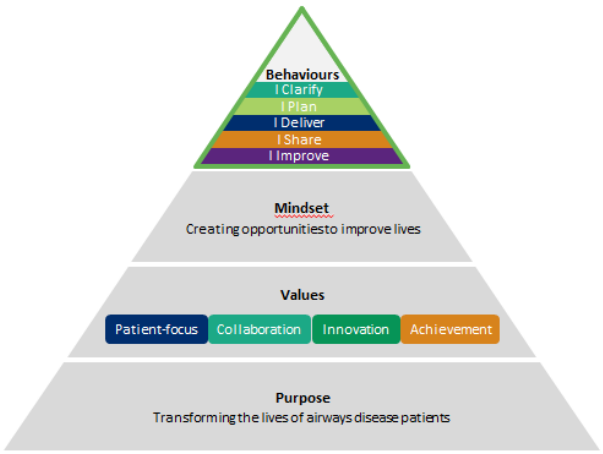
Example standards and guidance to follow

- 21 CFR Part 820, QMS
- ISO 13485, QMS for Medical Devices
- Medical Devices Directive, 93/42/EEC → Medical Device Regulation (EU) 2017/745
    - Articles and annexes relating to CE-marking
- EN 60601, Electrical Safety
- BS EN ISO 20072:2013, Design Verification Testing
- ISO 27427:2014, Nebulising Systems
- EN 14971, Risk Management
- ISO EN DIN 10993, Biocompatibility

Career Track Descriptor:

- Requires in-depth knowledge and experience in own discipline and basic knowledge of related job disciplines
- Uses best practices and knowledge of internal or external business issues to improve products or services
- Solves complex problems; takes a new perspective using existing solutions where available, but often required to identify solutions from first principles using own body of knowledge and the analysis of multiple sources of information
- Works independently, receives minimal technical/professional guidance
- Acts as a resource for colleagues with less experience, explaining difficult or sensitive information
- May lead work packages with manageable risks and resource requirements, gaining support from peers/the wider organisation
- Impacts a range of customer, operational, project or service activities within own team and related teams.

How

Our culture	Our behaviours
	**I clarify**, by asking appropriate questions, setting clear priorities, demonstrating openness to new ideas and adapting the way I communicate to make sure I'm understood.
	I plan, by creating clear actions, considering past learnings, identifying key milestones and stakeholders and revising the plan to address risks and opportunities.
	I deliver, by agreeing defined dates and times for my commitments, completing tasks on time to the required standard, adapting to unforeseen circumstances and helping others to achieve our goals.
	I share, by considering the needs of others in how I communicate, explaining the reasons behind my decisions, testing and challenging and sharing my learnings for the benefit of others.
	I improve, by giving and seeking constructive feedback, taking actions from the feedback received and seeking out opportunities to learn.

Context

Interfaces:

Internal	External
• Mechanical and SW/Electronics Design Teams, Regulatory, Project Team(s)	• Suppliers, contractors, partner organisations

Scope:

Financial (impact/budget)	People (Direct/Indirectly Manage)	Resources (Equipment/Facilities)
• According to project budget	• Leads/directs activities in own specialist area	• Office equipment • Wet / Dry Lab • Workshop

Environment:

Work (Office, Home …)	Travel (% of time away from prime site)	Hours (Office, Shift, etc)
• Office / lab based	• Partner organisations, licensees, Vectura HQ, meetings/conferences <20%	• 37h per week • Mon-Fri

Education and Experience

- Degree in relevant discipline (e.g. sciences and engineering)
- >5 years of experience in verification testing of combination products and medical devices
- Know-how of device development process of combination products and medical devices
- Working knowledge of all or the majority of the standards and guidance listed above
- Good communications skills (accurate and concise)
- Experience in managing internal or external test resources
- Preferred experience
  - Human Factors Engineering / design validation
  - Being audited by notified bodies, licensees, regulatory authorities
  - Understanding of aerosol therapy of respiratory diseases