# Employee Position Description Template

**ST-081**

Job Title: Scientist & Validation Specialist

Employee Name:

Department: Science, Design & Development

Reports To: Science, Design & Development Manager

| **Summary of Position** |
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| Validation of equipment/processes and technical support to the manufacture department to the ISO 13485 standard, the 21CFR part 820 regulation and any other identified standards/regulations that are applicable. Provide technical support to all departments within Canterbury Scientific. |

**Essential Duties and Responsibilities**

- Create and refine the Validation Master Plan (VMP) and User Requirement Specifications (URS) as part of a team within the S, D&D dept.
- To continuously implement the VMP within the company (to include introduction of new equipment through the IQ/OQ/PQ process and any other identified tasks associated with the VMP).
- Transfer of equipment/processes into manufacture; including training of Bioprocess Technicians and updating of their training records (to complete any required competency checks).
- Continuously update the risk management plan for the company.
- Ensure all laboratory and production facility operations under this position's control are performed to the ISO 13485 standard, the 21CFR part 820 regulation and any other identified standards/regulations that are applicable.
- Target process improvements for existing products/processes with a focus to improve efficiencies and lower failure rates.
- Audit duties.
- Liaison between S, D&D, Quality and Operations.
- Day to day technical support of existing processes in manufacturing, providing advice, direction and troubleshooting including the generation QMS documentation.
- Update DHF/DMR documents as part of design control.
- Carry out other duties as required.

**Supervisory Responsibilities**

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| As per training procedures and individual competency level. |

| **Authorities for Position** |
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| Follow the principles in the Quality Manual and all associated documentation within the QMS system.<br>Delegated authorities as defined in the Company Policies. |

| **Competency and Qualifications Required for Position** |
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| • Minimum of a science or engineering-based degree (BSc, MSc or appropriate diploma)<br>• Experience in a diagnostics laboratory or a manufacturing GMP environment or equivalent.<br>• Demonstrates an understanding of Protein chemistry<br>• Experience in operating Analytical Equipment.<br>• Computer literate.<br>• Technical knowledge and keeps abreast of current developments.<br>• Problem-solving ability and approach.<br>• Ability to evaluate information & data to reach a sound conclusion and present the facts effectively.<br>• Sets high standards of performance for self.<br>• Planning & organising skills<br>• Ability to effectively use time and equipment to meet deadlines and schedules.<br>• Demonstrates flexibility in changed requirements.<br>• Effectively communicates to all levels of the organisation.<br>• Understands the critical importance of adhering to the Quality system. |

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| **Employee Signature:** | **Date:** |
| **CEO Signature:** | **Date:** |