

	Product Surveillance Engineer		Page 1 of 2
	Job Description	Rev: A	

QP-005-04 Job Description Template rev A

Department: Quality Assurance

Reports to: VP of Regulatory Affairs and Quality Assurance

Responsibilities:

- Receive, review, and triage incoming complaints and non-conformity reports to determine initial risk, reportability, and investigation scope.
- Conduct thorough investigations of hardware failures, software issues, system performance concerns, and user-reported events.
- Partner closely with Technical Support to obtain device logs, photographs, troubleshooting details, and returned product information.
- Interface with distributors to collect complete complaint information, clarifications, and customer feedback needed for investigation.
- Document all investigative steps, findings, and evidence in the complaint management system with high accuracy and traceability.
- Coordinate cross-functional inputs with Engineering, Field Service, Regulatory, and Operations as needed to determine root cause.
- Perform failure analysis review, including hardware tear-downs, software behavior review, and replication attempts when applicable.
- Determine whether complaints are potentially reportable and escalate promptly to Regulatory Affairs when needed.
- Drive timely closure of complaint files in accordance with internal SOPs and regulatory requirements.
- Recommend and contribute to corrective or preventive actions (CAPA) when investigation findings indicate systemic issues.
- Track complaint trends and support periodic trending, metrics reviews, and management reporting.
- Support audits (internal, external, regulatory) by providing complaint records, investigation summaries, and objective evidence.

Qualifications:

- Bachelor's degree in Engineering or other closely related technical field and five or more years of experience in Quality Engineering in a Medical Device Design and Manufacturing environment.
- Experience in complaint handling, quality, technical support, or failure analysis within a medical device or regulated environment preferred.
- Strong analytical skills with the ability to interpret technical data (logs, hardware behavior, software error states).
- Excellent communication skills for interfacing with distributors, customers, and cross-functional teams.

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NOTE: This job description is subject to modification and may change based on current needs of company.

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- Highly organized, detail-oriented, and capable of managing multiple investigations simultaneously.

Desired Skills / Abilities:

- Fluent in Microsoft Office: Excel, Power Point, and Word
- Statistical Analysis, Pareto Charting
- Root Cause Analysis and implementation of appropriate countermeasures and corrective actions.
- Prepare and present reports by collecting, analyzing, and summarizing data; making recommendations.