

Form Title: Job Description, Complaint Management Specialist

Job Title:	Complaint Management Specialist		
Job Code:		FLSA:	Salaried Exempt
Department:	Operations		
Reports To:	COO, Regulatory Manager, Regulatory Director, or Regulatory Specialist		

Job Scope and Quality Impact:

Support the required event reporting and investigation of all medical device complaint-related procedures, in accordance with applicable laws and regulations.

General Description and Duties:

To perform this job successfully, an individual must be able to perform each essential job task satisfactorily. The tasks listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Records and evaluates complaint submissions.
- Communicates with health care providers (HCP), HCP staff and/or patient to acquire relevant complaint information.
- Coordinates with internal departments (Customer Service, Regulatory Affairs, Quality Assurance, Medical Affairs, Manufacturing and R&D) to incorporate vital input into medical device event reports.
- Reviews and provides feedback on complaint manufacturing investigation reports.
- Records and provides regulatory reportability decisions on complaints.
- Ensures timely processing of complaints.
- Generates and submits medical device event reports to appropriate authorities and government agencies as requested and as required by applicable laws and regulations.
- Responds to inquiries regarding medical device report submission associated with device malfunction or serious injury.
- Involved in activities to prepare for audits and inspections.
- Performs root cause investigations and is involved in CAPA (Corrective and Preventive Action) activities.
- Receives returned goods and decontaminates if necessary.
- Provides material to support post-market surveillance reports.
- Reviews and closes complaint files.
- Collects complaint case and process metrics to capture and generate trend reports.
- Coordinates with other departments to provide complaint data reports as needed.
- Participates in inter-departmental cross-functional projects.

Projects and Other Duties:

- Perform other duties as assigned by supervisor.

Position Qualifications

- Prior experience as a complaint handler in the medical device industry, performing all duties described above.
- Knowledge of medical terms associated with sacral neuromodulation procedure and Medical Device Reporting regulations.
- Exceptional organizational skills and attention to detail.
- Able to perform job function with minimal supervision and work independently, taking initiative to make independent decisions, where appropriate.

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- Display flexibility and a positive outlook in handling new processes, technology and general change.

Minimum Education:

- Bachelor's degree in technical, scientific, or business-related discipline preferred.

Minimum Experience:

- 3 years related work experience

Specific Skills, Knowledge & Behaviors:

To perform the job successfully, an individual should demonstrate the following competencies:

Core Competencies:

- **Interpersonal Effectiveness:** Actively seeks to understand perspectives and interpersonal needs and expectations of others at all levels, builds self-awareness, flexes personal style appropriately, and works through conflicts constructively and appropriately
- **Communication:** Effectively uses all mediums of communication as appropriate, presents well to groups, actively listens, and continuously identifies opportunities to build communication skills
- **Collaboration & Teamwork:** Actively works together with formal and informal team members to build relationships and achieve team goals
- **Prioritization:** Effectively prioritizes work to ensure timely completion of work within scope
- **Technical Expertise:** Continuously builds functional and technical expertise, and pro-actively applies that technical expertise in progressively broader scope
- **Continuous Improvement:** Learns and uses best practices tools and methodologies to assess, identify, and executes on opportunities to improve; Focus on learning and building new capabilities into self
- **Problem Solving & Problem Prevention:** Learns and uses strong problem-solving methodologies and tools, focuses on root cause analysis, and shows orientation towards problem prevention
- **Accountability:** Focuses on results, takes initiative without direction, takes ownership for all work within scope, builds relationships and works across departments, functions, or areas of responsibility

Equipment Use & Abilities Required:

- **Equipment Use:** Copy machines, fax machines, calculators and personal computers and computer terminals.
- **Computer Skills:** Software proficiency in Microsoft Office Suite.
- **Language Skills:** Ability to read, analyze, and interpret general business periodicals, professional journals, technical procedures, legal documents or governmental regulations. Ability to write reports, business correspondence, and procedure manuals. Ability to effectively present information and respond to questions from groups of managers, clients, customers, and the general public.
- **Mathematical Skills:** Ability to work with mathematical concepts such as probability and statistical inference. Ability to apply concepts such as fractions, percentages, ratios, and proportions to practical situations.
- **Reasoning Ability:** Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists. Ability to interpret a variety of instructions furnished in written, oral, diagram, or schedule form

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Work Environment & Physical Demands of the Job:

The noise level in the work environment is usually quiet. While performing the duties of this job, the employee is regularly required to sit; use hands and fingers; talk or hear. The employee is occasionally required to reach with hands and arms and to move within and between the buildings. A computer terminal is used to access, input, and retrieve data. The employee must occasionally lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision.