



## Job Description

**Position Title:** Post Market Specialist  
**Report To:** Senior Manager, Quality Assurance  
**Department:** QA/RA  
**Location:** Mountain View  
**FLSA:** Exempt  
**Date:** September 2024

**APPLY**

---

We are changing the standard of care for millions of untreated sufferers of ENT conditions. We improve patient access to life-changing relief through safe, practical, and effective innovation that changes how and where patients are served. Aerin differentiates itself with our commitment to providing straightforward and clinically proven products so that ENTs and their patients can make treatment decisions together without limits.

At Aerin Medical our values show up as: always seeking the collective good, holding ourselves and each other accountable, showing respect with compassion, creation and innovation and being all in.

As a Post Market Specialist at Aerin Medical, you will be an essential part of our mission-driven team, dedicated to transforming the lives of those with untreated ENT conditions. Your role will involve contributing directly to our commitment to innovation and improved patient care.

### **PURPOSE OF JOB:**

This position executes post market surveillance activities, including gathering post market data and submitting appropriate reports to regulatory authorities. The position manages the customer complaint handling program.

### **MAJOR DUTIES AND RESPONSIBILITIES:**

- Lead and manage customer complaint handling activities, including complaint intake, risk assessment, and timely investigation to closure.
- Perform Good Faith Efforts to obtain required information for complaint assessment and evaluation.
- Complete adverse event reporting determinations per geography regulatory requirements for approved devices (US FDA, EU MDD/MDR, etc.) in a timely manner.
- Identify complaint investigators per expertise (R&D, OPS, Regulatory, etc.).
- Coordinate with different internal teams and Contract Manufacturers to ensure complaints investigation are closed in a timely manner.
- Ensure complaint records, documentation, and Regulatory reports are compliant with Good Documentation Practices (GDP), global regulatory standards and internal procedures prior to closure.

- Perform and/or coordinate complaint investigations and gathering of additional information, working closely with other departments to complete investigation reports.
- Evaluate all information from a technical perspective to ensure appropriate analysis and investigation.
- Support and participate in internal and external audits, risk management summaries and health hazard evaluations.
- Escalate potential complaint trends, and product problems supporting the initiation of immediate remedial action, if appropriate.
- Run reports to track status of complaints.
- Support the preparation of reports for management reviews, monthly complaint trend meetings, and other required reports, as requested.
- Manage the documentation of customer feedback.
- Participate in nonconformance and CAPAs investigations.
- Participate in any field safety corrective actions or product recalls.
- Review and identify additional sources of post market surveillance data.
- Gather post market surveillance data per established procedures.
- Author PSUR/PMSR.
- Contribute to product post market surveillance plans and post market clinical follow up plans.
- Analyze quality data and track key quality metrics according to Quality Objectives.
- Maintain trained status for, and comply with, all relevant aspects of the Aerin Quality Management System to ensure product and support regulatory compliance.
- Any other tasks assigned.

#### **EDUCATION REQUIREMENTS:**

- Bachelor's degree and/or a minimum of 2 years of related experience in the medical device industry.

#### **EXPERIENCE REQUIREMENTS:**

- 2-5 years of post market surveillance experience in the medical device industry
- Good understanding of ISO 13485, EU Medical Device Directive/Medical Device Regulation, FDA QSR Part 820 and other applicable standards, specifically, requirements related to post market surveillance.
- Previous experience with complaint handling, event reporting and data collection.
- Ability to understand relevant technical, regulatory, and compliance information to satisfactorily understand product problems and resolutions to perform complaint closure.
- Strong problem-solving skills, critical thinking, and experienced at investigating and resolving complex technical issues.
- Prior experience in medical device manufacturing environment.
- Flexibility to support changing assignments and priorities in an independent and reliable manner while maintaining a positive and collaborative demeanor.

#### **OTHER QUALIFICATIONS:**

- Simploud CRM or applicable database experience.
- Strong technical understanding of medical equipment troubleshooting.
- Excellent interpersonal and communication skills (both verbal and written) that allow for effective communication with all levels of the organization.

- Demonstrated ability to work well with cross-functional departments and stakeholders in a proactive and constructive manner.
- Takes initiative and ownership to drive department and organization goals.

## BENEFITS AND PERKS:



Our culture is rooted in our core values every day, in everything we do.

Our benefits focus on the 5 dimensions of wellbeing: physical, financial, emotional, career and community. Physical benefits include Medical – PPO & HSA with co-contribution, Dental, Vision, Accident Insurance, Critical Illness, Hospital Indemnity, and onsite Tonal & Peloton. Financial benefits include HSA/FSA, 401k with company match, Lifestyle Spending Account, Long Term Disability, Life Insurance, a monthly stipend to cover phone and tech costs, employee discounts, and weekly office lunches. Emotional benefits include Employee Assistance Program, 5 free counseling sessions per issue per year, 80 hours sick leave, 13 holidays, and flexible vacation (exempt employees). Career and Learning & Development opportunities with Aerin led leadership trainings. Community initiatives which include Aerin “give back” week, family days as well as Aerin holiday giving.