gynesonics

# Job Description

## Job Title: (Sr) Manager, Regulatory Operations

**Department: Regulatory Affairs**

☒ **Exempt** ☐ **Non-Exempt**

### 1. Job Description:

This position is an integral member of the Regulatory and Healthcare Compliance team. The position reports to the Director of Regulatory Affairs.

As Regulatory Operations Manager, this position is responsible for establishing and maintaining Regulatory infrastructure, procedures, documentation, and records to optimize effectiveness and efficiency of the Regulatory function. Additional responsibility includes promotional review and support of Healthcare Compliance audit and reporting.

### 2. Primary Responsibilities:

Regulatory Operations Manager

- Develops, implements, maintains, and trains others on procedures, tools, and infrastructure for effective and efficient regulatory operations, including regulatory information systems; management of product technical documentation; calendaring; tracking and renewals of annual licenses, registrations, listings, and other post-marketing commitments;
- Develops and maintains processes for Regulatory use of Master Control, including identifying means to take most advantage of available functionality for optimal efficiency;
- Compiles and organizes documentation for use in submissions, notifications, and internal filings ("letter to file"). Maintains technical documentation files and authorized representative on-line repositories;
- Maintains regulatory databases, calendar, and correspondence files; tracks preparation and completion of required tasks and projects including submissions, annual licenses, registrations, and listings; generates reports as required;
- Reviews proposed claims, labeling, and promotional materials against established criteria to ensure regulatory compliance;
- Provides regulatory support for inspections and audits as needed;
- Other duties as assigned.

Compliance Manager

- Manages systems to log and track documentation, approval, and expiry of Business Need Justifications, HCP contractual engagements, sponsorships, grants, and other activities related to implementation of the healthcare compliance program;
- Identifies opportunities for, develops, and implements improvements to the Healthcare Compliance Program and its implementation;
- Develops and administers healthcare compliance training , including knowledge assessments, in self-training and/or in-person formats;
- Assists in development and implementation of monitoring plans and reports to ensure compliance with policies and procedures;
- Assists in preparation, conduct, and reporting of health care compliance audits;
- Reviews promotional materials and activities to ensure compliance with healthcare compliance policies;
- Assists in preparation for and facilitation of Healthcare Compliance Committee meetings and activities;
- Other duties as assigned.

**3. Knowledge, Skills, and Experience (check all that apply):**

- Education Level, Required Skills and Experience:
  - Bachelor degree in related field or equivalent education and experience
  - 3+ years medical device regulatory affairs experience.
  - Strong organization skills; detail oriented.
  - Self-starter; able to manage multiple projects and timelines
  - Significant experience with regulatory databases and/or registrations software programs. Experience with MasterControl preferred.
  - Familiarity with contents of regulatory submissions and medical device technical files
  - Excellent written and verbal communication skills including procedure development.
  - Microsoft Excel expertise, including custom automation.
  - Experience in training development and delivery preferred.
  - Direct experience with audit preparation and conduct preferred.
- Familiarity with ISO 13485, 21 CFR 820, and EU MDR
- Practical understanding of Healthcare Compliance policies as related to the OIG *Compliance Program Guidance for Pharmaceutical Manufacturers* and applicable regulations such as Anti-Kickback, False Claims, Foreign Corrupt Practices Act, and transparency reporting regulations preferred.

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- Required Medical Device Experience:
  - ☒ General Medical Devices
  - ☐ Specific or Similar Medical Devices
  - ☐ None Required
- Regulatory Experience:
  - ☒ QSR
  - ☒ ISO 13485
  - ☐ None Required
- Required Risk Management Experience:
  - ☐ ISO 14971
  - ☐ Risk Management Techniques
  - ☒ General Knowledge
  - ☐ None Required
- Required Design Control Experience:
  - ☐ Working with Medical Device Design Control Processes
  - ☒ General Knowledge
  - ☐ None Required
- Required ESD Experience:
  - ☐ Working within ESD Environments
  - ☐ General Knowledge
  - ☒ None Required
- Required Certifications:
  - ☐ Lead Auditor Certification
  - ☐ ASQ Certification
  - ☐ Certified Engineer
  - ☐ Other Certifications: _____
  - ☒ None Required

**Signatures:**

Human Resources: _____ Date: _____

Manager: _____ Date: _____

Senior Management: _____ Date: _____
(N/A if direct manager is member of senior management)