

# Manager of Quality & Regulatory

Optimum Imaging Diagnostics – Scarborough, ME

**SUMMARY** – The Manager of Quality and Regulatory role will be responsible for all aspects of OIDx's Quality System, Regulatory pathways, and overall compliance activity.

**ESSENTIAL DUTIES AND RESPONSIBILITIES:** Other duties may be assigned.

- Support manufacturing activity through verification that processes meet necessary regulatory requirements
- Maintain, manage and improve upon existing Quality System elements
- Oversee activity surrounding Preventive Maintenance, Calibration, and IQ/OQ/PQ programs to ensure regulatory compliance
- Act as primary point of contact for all regulatory activity as well as 3rd party and customer audits
- Manage Supplier Approval program, including any necessary vendor audits
- Maintain NCR, CAPA & Process Deviation programs and ensure facility compliance with their parameters
- Implement and Maintain Environmental Control programs within manufacturing
- Manage all aspects of OIDx Risk Management, consistent with US and all respective authorities
- Perform post market evaluation of products in the field
- Continue developing and implementing an Internal Audit program for OIDx
- Oversee Inventory Control to ensure capability of recall/trace-ability functions
- Provide regulatory guidance through the development and tech transfer stages of all products through to commercialization
- Perform training activity associated with OIDx Quality Systems

## **QUALIFICATIONS & COMPETENCIES:**

The following skills and competencies are necessary to perform the essential functions of this position

- Knowledge surrounding ISO 13485 and FDA cGMP regulations
- Knowledge of regulatory requirements for IVD worldwide
- Must possess high-quality communication skills (verbal & written)
- Ability to effectively communicate with executive leadership, as well as other department managers, clearly and persuasively
- Can anticipate and/or identify problems and resolve them in a timely manner
- Is self-directed and able to work effectively in a multi-disciplinary team environment
- Gathers and implements complex or diverse information skillfully

## **EDUCATION & EXPERIENCE REQUIREMENTS:**

- Minimum Bachelor's Degree in a scientific field
- Minimum of 5 years' experience developing and managing Quality Systems, including direct reports
- Experience working in a highly regulated environment (FDA, ISO, or other)
- Experience with diagnostics preferred

- 3 – 5 years' experience working with manual and automated Inventory Control systems

**TRAINING:**

- cGMP Guidelines
- Ability to complete, within the first 30 days of employment:
- Blood borne pathogen training
- Hazardous Waste Handling training
- Chemical Safety training
- DOT chemical training

Job Type: Full-time

Education:

- Bachelor's (Required)

Work authorization:

- United States (Required)

Benefits offered:

- Paid time off
- Health insurance

**HOW TO APPLY:**

- Please include in your cover letter that you found this job posting through biomaine.org
- Apply through Indeed: <https://www.indeed.com/cmp/Optimum-Imaging-Diagnostics/jobs/Manager-Quality-Regulatory-869179ee58fad635?q=optimum+imaging+diagnostics&vjs=3>