

# Quality Director Job Description



<b>Job Title:</b>	Quality Director
<b>Reports To:</b>	VP of Operations
<b>FLSA Status:</b>	Exempt
<b>Department:</b>	Quality

## Job Purpose:

The Quality Director is Responsible for the Implementation, Deployment, and Management of the ISO 13485 Quality Management System.

## Duties and Responsibilities

- Assigned as Management Representative.
- Provide key leadership, direction, and supervision for all Quality Assurance and Quality Control activities.
- Evaluate and report on the performance of the quality system to management for review and as a basis for improvement of the quality system.
- Ensure the promotion of awareness of customer and regulatory requirements throughout the organization.
- Liaison with external parties on matters relating to the quality management system.
- Responsible for:
  - Documentation control activities for Quality System documents to assure conformity with regulatory and quality system requirements.
  - The records management system.
  - Equipment, process and software validation activities.
  - The risk management program.
  - Company internal and external (vendors/subcontractors) audit activities and performance.
  - ISO training and assure company compliance.
- Manage electronic quality systems.

## Supervisory Responsibilities:

- Manages Quality Staff.
- Develops and maintains an effective organization through the selection, training, compensation, motivation, termination and review of all assigned employees.
- Develops and maintains a program for sound employee relations with assigned employees.
- Provides guidance and direction to employees to assist them in their professional development.

## Key Skills and Competencies:

- Oral Communication Skills
- Technical Communication
- Customer Service
- Organization
- Project Management
- Professionalism

## Quality Director Job Description



- Time Management
- Written Communication Skills
- Customer Relations
- Diplomacy
- Planning
- Math Aptitude
- Reading Skills
- Computer Skills

### Education / Experience:

- Bachelor degree or equivalent experience. A minimum of 5 years ISO 13485 quality management experience.

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**Employee Signature**

**Date**

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**Management Signature**

**Date**