

Quality Systems Specialist

Microbiologics, a leading global manufacturer of biological controls and standards, is currently seeking a Quality Systems Specialist to join our team. This position is responsible for supporting Microbiologics Quality Systems efforts to meet applicable FDA regulations, ISO 13485, ISO 17025, ISO Guide 34 and CE Mark conformity.

Essential Responsibilities:

- Plan and lead internal audits
- Train Internal Auditors
- Conduct supplier audits
- Perform document control and CAPA functions
- Mentor employees on the quality system
- Conduct special projects as needed
- Manage the calibration process
- Maintain the Master equipment Listing
- Generate supplier agreements
- Act as backup to Quality Department Administrative Assistant
- Act as backup to Sr. Quality System Manager
- Monitor standards for updates
- Prepare documentation for international submissions
- Review and approve change orders, CAPAs and other records requiring quality system review

Physical Requirements and Environmental Attributes:

- Occasionally lift and move up to 25 pounds to waist height unaccompanied
- Regularly sit for duration of shift in a normal office environment
- Occasionally required to stoop, climb, or balance
- Coordinated use of hands and fingers to grasp, feel objects, transfer small items from one hand to another, fine manipulation, and bilateral reach with arms
- Use of close vision, depth perception and ability to adjust focus

Desired Education/Experience:

- Two/Four year Engineering/Technical degree preferred
- 5 years previous related experience and/or training required
- Experience with ISO standards, required
- Experience with Auditing, report writing, technical writing, document proofing, basic understanding of various types of equipment, both manufacturing and measurement preferred
- Presentation, training, and measurement experience preferred
- RAPS and ASQ certifications a plus

If you are interested in joining our team as a Quality Systems Specialist, please send your resume to hr@microbiologics.com.