United States Jobs Expertini®

Sr Quality Manager

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Company: Thermo Fisher Scientific

Location: Miami

Category: other-general

The is a leadership position responsible for implementing and improving Site Quality Management System and Quality Assurance structure to cover various internal functions, build scale, and most relevantly, better serve our customers.

What will you do?

Support and provide expertise to the Quality Management System (QMS) and Quality department to optimally meet or exceed goals and targets.

Collaborate with the various functions to ensure the quality management system is comprehensive, incorporates standard processes, and is consistent with the strategic plan.

Product Development responsibilities including design controls, risk management, document control and record management, and supplier management.

Manufacturing responsibilities including master record, training, process controls, labeling, change control, and CAPA.

Responsible for monitoring and measurement including validations, calibrations, customer feedback and complaints, internal audits.

Responsible for all site quality metrics and reporting for monthly and quarterly business reviews – , Product Complaint rates, Cost of Poor Quality, CAPA, etc.

Support and provide quality expertise to the business process transfer activities – , process implementation/validation.

Hire and retain a diverse, highly qualified staff and provides ongoing performance feedback. Set goals which align to department plans and lead the execution of goals through coaching and mentoring.

Ensure continuous improvement through the Practical Process Improvement (PPI)

Install and maintain a quality culture – Right First Time.

How will you get here?

Education:

Minimum required education: Bachelor's Degree: Life Sciences, Engineering or related science/engineering degree preferred

Experience:

10+ years of professional quality experience required

5+ years of people leadership experience in quality operations environment

Quality site leadership experienced preferred

Proven understanding and experience with ISO 9001 and ISO 13485 standards

Experienced knowledge and implement the following: Design and Process FMEA's (Failure Mode Effects Analysis), CAPA (Corrective and Preventive Actions) process, NPI (New Product Introduction) process – Design Transfer, V&V, Complaints Handling process and Change Control process

Experience working and providing customer support, investigations, and relationship management

Experience supporting organizational change efforts

Knowledge, Skills, and Abilities:

Understanding of the Life Sciences and IVD/Medical Devices industries and required compliance regulations for Cell Culture and Supplement products and processes preferred.

Ability to travel domestically and internationally – up to 10%

Validated communication and customer leadership skills

Validated people leadership skills

Demonstrates personal awareness and desire for continual learning and personal development

Hands-on and committed - Normally receives little instruction on day-to-day work, general instructions on new assignments.

Must possess the presentation skills and integrity to project a professional image, both internally and externally

Strong interpersonal, verbal and written communications skills are important.

Our Mission is to enable our customers to make the world healthier, cleaner and safer. Watch as our colleagues explain 5 reasons to work with us. As one global team of 100,000 colleagues, we share a common set of values - Integrity, Intensity, Innovation and Involvement - working together to accelerate research, solve complex scientific challenges, drive technological innovation and support patients in need. #StartYourStory at Thermo Fisher Scientific, where diverse experiences, backgrounds and perspectives are valued.

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