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Quality Compliance Manager

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Company: West Pharmaceutical Services

Location: Israel

Category: other-general

At West, we're a dedicated team that is connected by a purpose to improve patient lives that has been at the center of our Company for more than a century. Our story began when Herman O. West solved the problem of supplying penicillin in mass quantities to the US Government during World War 2. Through our work to deliver thousands of life-saving and life-enhancing injectable medicines to millions of patients daily, West's indelible mark on the healthcare industry has just begun. A name started our story. How will yours help write our future?

There's no better place to join an inclusive community of professionals with opportunities for lifelong learning, growth and development. Supported by benefit programs, we empower the physical, mental, emotional and financial health of our team members and their families.

We believe in giving back to help those in need in the communities where we live and work. And are equally committed to creating a healthier environment and planet through our sustainability efforts.

In this role, the Quality Compliance Engineering Manager leads a team of Quality Specialists who are responsible for the feedback system in the QMS- customer complaints handling, complaints trending, RMA and returned goods, issuing corrections and corrective actions related to complaints and Quality reports. The Quality Compliance Engineering Manager also leads the site's external audit program, preparedness, and execution by any third party, customer, applicable regulatory authorities (including Notified Body), while working within a multi-functional team environment for medical devices. As a part of the preparedness for external audits, the Quality Compliance Engineering Manager ensures that all applicable

activities done by all company employees meet applicable quality standards, consistent with internal procedures and acceptance criteria, while meeting applicable regulatory requirements. The Quality Compliance Engineering Manager also leads the supplier quality management system, audits, Quality agreements, SCAR, etc.

The Quality Compliance Engineering Manager will be a strong advocate for quality, supporting the site's abilities to meet all applicable and current versions of the Quality and Regulatory requirements, such as EN ISO/ISO 13485, Medical Device Regulation (MDR) 2017/745 and MDD 93/42/EEC, MDSAP, ISO 14971.

The Quality Compliance Engineering Manager supports continuance improvement of the QMS, site procedures alignment with applicable Regulatory requirements, alignment with the Enterprise Quality System and provides guidance and support to all duties associated with the auditing and documentation of compliance related items against GMP and ISO standards for West and its subcontractors. The Quality Compliance Engineering Manager will lead a team executing the QMS related transactions in relevant GMP systems (MasterControl,SAP, Share Point) and other relevant quality functions, as applicable.

Essential Duties and Responsibilities:

Exhibit a strong "quality first" mentality and ensure that QMS processes are held to the highest standard, Support the site's continuous quality improvement projects.

Lead QA Specialists/Engineers in the day-to-day activities- supervise and monitor over the employees' performance and tasks handling, training, and objectives according to the organizational goals.

Work cross-functionally with other team managers and project teams leaders to provide QA guidance and ensure success of projects and support other QA dept activities- second approval of batch release and graphics, CAPA/Corrections, quality agreements.

Lead Quality Management System compliance (EN ISO/ISO 13485 and MDSAP) and Quality System activities related to regulatory requirements (such as MDR 2017/745, MDSAP, etc.).

Lead QA Specialists/Engineers who are responsible for customer complaints handling-investigation, root cause analysis, Risk Based Approach, applicable corrections/corrective actions, Returned Material Authorization (RMA) and Returned Goods Authorization (RGA) handling.

Lead QA Specialists/Engineers who are- responsible for the site's complaints trending, support RA in identifying Adverse Events/Hazardous situations and provide inputs into the applicable product and process risk management (dFMEA/pFMEA).

Lead QA Specialists/Engineers who are- responsible for the site's supplier quality management, audits, Quality agreements, SCAR's, point of contact to customer/third party related matters/ inquiries/ questionnaires, Perform supplier/subcontractor and internal audits.

Lead the site's external audit program- verifying the readiness of all applicable personnel and processes, execute CDAs with the auditing party, perform preparations meetings with functional managers/team leaders/personnel. Execute External audits by any , while working within a multi-functional team environment for medical devices. Perform routine follow ups on External audits status, issue Corrections/Corrective actions and communicate responses to third party, customer, applicable regulatory authorities, and Notified Body.

Lead the site's quality system procedures maintenance by verifying their compliance to relevant regulatory requirements, and their alignment with applicable west Enterprise procedures.

Leading the site preparations of periodical management reviews.

Lead the risk management policy file maintenance activities.

Basic Qualifications:

B.Sc. - Chemistry/ Biology/ Eng. – an advantage

Minimum 8 years working in quality systems in the Medical Device industry

Relevant work history and/or experience may be considered in lieu of degree

Experience with customer interface and meeting customer expectations

Experience Risk Based Approach, Root Cause Analysis, Customer complaints, CAPA, Internal Audit

Experience with writing and reviewing Quality agreements- Advantage

Proven experience with ISO 13485, MDSAP and CE audits- Advantage

Excellent written and oral communication skills

Excellent critical reading and writing skills

Must have effective problem solving and interpersonal skills

Ability to work independently, multi-task and thrive in fast-paced environment

Problem solving including root cause failure analysis methods

Proficient in Windows OS, Microsoft Office Suite including Word, Excel, and Power Point

Able to be aware of all relevant SOPs as per Company policy as they are related to the position covered by this Job Description

Able to comply with the company's safety policy at all times

Preferred Knowledge, languages, Skills and Abilities:

Courses on topics related to quality system/regulatory requirements in the medical device

Proven knowledge with ISO 13485, MDSAP, and MDR 2017/745

English- high level in both verbal and written

Certified Quality Auditor

Adaptable to changes in the work environment, manage QA personnel in competing demands and deal with frequent change, delays or unexpected events.

Must be able to multi-task, work under time constraints, problem solve, and prioritize

Ability to make independent and sound judgments

Observe and interpret situations, analyze and provide guidance in different teams' problems solving

Effectively communicate and interface with various levels internally and lead the QA personnel for success.

Manage at least 2 Quality Specialists/engineers

Travel Requirements:

Must be able to travel up to ____10___ % of the time

Physical & Mental Requirements:

Very Heavy/ Heavy/ Medium/ Light/ Sedentary: Sedentary

List any mental requirements:communication, quick decision making, interpreting data, reading or writing, must be able to express or exchange ideas with employees; leadership skills, must be able to understand direction and adhere to established procedures

Delegation/s (Title):

Applicable qualified QA personnel/ QA Director

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