Turkey Jobs Expertini®

Quality Assurance Engineer

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Company: Maquet Cardiopulmonary Medikal Teknik Sa

Location: Antalya

Category: other-general

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Qualifications:

· Bachelor degree in Engineering and technical or Health/Life Sciences departments of universities.

· Min 2 years of experience in Quality Management Systems preferably in Medical Devices Industry

· Good command of English is compulsory, German knowledge would be an asset

· Knowledge of tools/ methodologies such as design control, risk management, root cause investigation methods, process validation, statistical process control (SPC), protocol/ report preparation.

· Knowledge of ISO 13485, European Medical Device Regulation and FDA 21 CFR 820 requirements, understanding the medical device regulatory environment and requirements

· Knowledge of ISO 11135, ISO 11137, ISO 11737-1, AAMI ST72 etc. related EO/Gama Sterilization, Bioburden, LAL and Envoiremental Monitoring System regulations

· Familiar with QMS processes like Technical File preparation, CAPA, Complaint management, document control, internal audit etc.

· Good knowledge of MS Office applications is required and SAP is an asset

· Statistical data analysis, documentation and report writing skills

· Internal auditor certification preferred

· 6 Sigma certification preferred

· Exceptional analytical, problem solving & root-cause analysis skills

· High level of attention to details and accuracy

· Excellent communication skills, ability to work in a team environment and lead a project team

· Ability to lead or work with multi- departmental project teams and resolve quality related issues in a timely and effective manner

· Be self-motivated, self-starter, be able to meet deadlines, be a good team player, be able to assist and support others

· Result oriented

· Be open-minded and willing to learn

· Ability to travel as required

Job Description :

For Quality Assurance Engineer position, more than one colleague will be hired and assigned to the appropriate main groups of Quality Management System listed below.

The person who hired will be responsible for one or several processes in assigned group.

Quality Assurance :

o Non-Conforming Product Management with using QDMS

o Product Release

o Control and approval of laboratory routine test results

o Rework Process

o HHE,FSCA, Hold processes

o Customer Complaint Handling Management with usign TrackWise

o Customer Complaints Reporting Process

Quality Assurance –QMS:

o Management of Corrective and Preventive Actions with usign TrackWise

o Internal audits with using QDMS

o Management of Document Control Process with using QDMS

o External audits

o QMS statistical analyzes

o KPIs / Quality Objectives

o Quality Management System Plans

o Implementation of Global Procedures

o Environmental Management System Compliance

o Quality Management System trainings with using LMS

o GMP Renewal Process

Design Quality:

o Computerized systems validation

o Control and approval of validation studies (Process, test method etc.)

o Control and approval of Receiving Inspection plans

o Control and approval of label designs/layout

o Control and approval of Technical File Content

o Monitoring and organization of Quality responsibilities in Change Management System

o Design quality assurance processes

o Control and approval of calibration forms

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