

Senior Quality Systems Manager - Medtech - EMEA

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Company: Michael Page

Location: Brussels

Category: computer-and-mathematical

As the Successful Sr Quality System Manager - Medtech - you will have the following responsibilities:

Support the International organization to ensure an adequate and effective quality management system, supports the quality policy and sustains a quality

Lead and manage Quality Systems activities including audit readiness.

Lead and manage specifically the Document Management, Record Management, Training Management, CAPA, QNC, Field Action, and Supplier Quality Management quality systems in the region.

Provide strategic and tactical vision and consultation toward the quality system development and implementation.

Provide strategic and executive support to ensure alignment within the International Organization.

Manage communications with the organization's Certification Body regarding all quality systems related activities and issues, including planning and responding to audits.

Develop objectives and key performance indicators and tenaciously pursue

Maintain state of the art knowledge in the quality related fields

Leads the implementation, maintenance and training for relevant quality systems and

tools, compliant to internal and external requirements, to meet business needs.

Respond to customer needs in an accurate and timely fashion

Provide leadership for quality system development, and ongoing process improvements.

Initiate, develop and implement new quality concepts, tools and strategies to improve business systems, practices, and assure business objectives are met.

Communicate project strategy and status to superiors and peers in a way that is timely, concise, accurate and responsive.

Work in close cooperation with the Regulatory team.

As the Successful Sr Quality System Manager - Medtech - you will have the following requirements:

At least a Bachelor's degree in a science, business, engineering, or related

At least 10 years of related experience in the medical device or pharmaceutical industry managing quality systems.

Analytical & detail oriented, team player.

Excellent communication, problem solving and management skills are required.

Proven Experience with CAPA, Change Management, Supplier Quality Assurance, and Risk Management is required.

Position requires strong knowledge of MDD 93/42/EEC / MDR 2017/745, ISO 9001, and ISO 13485 requirements

Ideally knowledge also on FDA, cGMP

Experience in MS Office and Teams

Excellent verbal and written English communication

Experience with managing CE-marking and EU Regulatory Affairs

As the Successful Sr Quality System Manager - Medtech - you will have:

A complete and attractive salary package in line with your experience (Base salary, Bonus, Company Car, Net allowances, Insurances, etc.)

The chance to join a market leader with high people value

Join a company that values and offers multiple career opportunity locally & globally

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