Sascha Weisshaar

MSc. International Product Management
University of Sciences Albstadt Sigmaringen

QA Expert with experience in regulatory affairs

ID1007

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Competences

- Project Management
- Executive Management, Strategy
- Quality Management Systems ISO 9001, ISO 13485, MDSAP
- Design Control and MDR transition
- Clean Room, Health and Hygiene and ETO-Sterilization
- Process- and sterilization validation
- Risk Management, FMEA
- Complaint Management
- Change Management
- Internal and supplier audits
- Management of Non-conformites, CAPA
- Communication with Authorities
- Post Market Surveillance
- Quality assurance sample testing, test plans
- Coordinate measurement systems (Multi sensor)
- NiTinol materials (shape memory alloy)

Software/Standards

- Medical Device Directive & Regulation..
- ISO 9001 - Quality Management
- ISO 13485 - Medical devices - Quality Management
- ISO 14971 - Medical devices - Risk management
- ISO 11135 - Sterilization of health-care products Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11607-1; -2 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems, Part 2: Validation requirements and processes
- ISO 14644 - Cleanrooms and ass. environments
- ISO 10993 - Biological evaluation of medical devices

Key results

10+ years maintenance and evolution of QMS from start-up to mid-size company and strategy change from contracted manufacturer to direct sales company.

Several successful sterilization validation projects with external customers

Successful ISO 13485: 2016 Implementation along with implementation of risk-based approach for key processes.

CE registration and international registration of various class IIa and IIb devices

Successful PLM certification audit class III cardiovascular medical devices

Successful company registration audit (GMP) of Brasil National competent authority

Personal Characteristics

Sascha has a wide range of Quality Management and Regulatory skills by his education and one and a half decades of hands-on and management experience. He knows how to develop, implement and follow up a company- and QMS-strategy by his experience as executive board member. He also understands the various needs of single departments, how cooperation in inter-departmental team structures works and how interfaces need to be be set up to meet stakeholders needs. His distinct customer orientation drives him to find pragmatic and cost-effective solutions.

In his free time Sascha is a passionate father and scuba diver. Following his diving passion, he is voluntarily active rescue diver and rescue and recreatinal diving instructor at German water rescue organization DLRG.

References

Medicologic A/S (2021 – present)

Senior Consultant QA Expert with RA experience

Ferring Pharmaceuticals A/S

QA support related to Medical Device & Combination Products

QMEDICS AG (Nov. 2020 - July 2021) Chief Operation Officer

Responsible for Production Department, Quality Affairs, Quality Management Representative.

QMEDICS AG (May 2019 – Oct. 2020) Chief Project Officer

Responsible for company internal key projects, implementation of customer projects and new technologies, Quality Affairs, Quality Management Representative

QMEDICS AG (Mar. 2010 – May 2019)

Head of Quality Affairs, Quality Management Representative
Responsible for Maintenance and continuous improvement of QMS, QA and QC-procedures, vascular implants and instruments.

Jakoubek Medizintechnik GmbH (Sept. 2005 - Feb. 2010)

Head of Quality Management, QM Representative
Responsible for Maintenance and continuous improvement of RA, QMS, QA and QC-procedures for minimally invasive surgical instruments and orthopedic implants.

Global QMS experience from
Johnson & Johnson divisions Ethicon
Olympus Winter & Ibe GmbH
Edwards Lifesciences
Ulrich Medical, Depuy Synthes and Karl Storz SE & Co