Dr. Bernhard Bauer
Medical Devices Consulting
Regulatory Affairs and Quality Management

Professional Background

PhD in Medical Physics (University of Heidelberg, German Cancer Research Center)

20 year experience as international consultant for medical devices and interim management

- MDR (EU Regulation 2017/745): Audits and approvals
- MDD (EU Directive 93/42/EEC): Audits and approvals
- FDA approvals and inspections
- Auditee for ISO and MDSAP audits, FDA inspections

Professional experience within the medical device industry

- Managing Director of a medical device company specializing in major equipment and software.
- 15 years executive management in industry leading international medical device manufacturers. Management experience in product and software development, product management, marketing, regulatory affairs and quality management.
- Developed cutting edge CT imaging software for stereotactic radiotherapy (PhD dissertation)

TÜV-Rheinland certified QA expert and auditor
Document review or creation in English or German

My Consulting Services

Assistance and support in the **transition to MDR** (EU Regulation 2017/745)

- Detailed gap analyses
- Coordination, preparation or review of complete or partial technical documentation
- Extension of the quality management system to meet MDR requirements
- Support in communication with the Notified Body

Assistance and support in **FDA market clearance** of Class II devices (510k)

- Coordination, preparation or review of product documentation
- 510k submission preparation
- Assistance in communication with the FDA

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Assistance and support in **postmarket surveillance** and vigilance (MDR Art 83 - 89)

- Planning for market surveillance
- Preparation of market surveillance and safety reports (PMS Report, PSUR)
- Support in reporting of incidents and safety corrective actions in the field (FSCA)

Preparation of **summary reports** according to Canadian regulations (CMDR Art 61)

Planning and execution of product design, process or software validation activities

- **risk management**
- **validations**

Definition and implementation of **quality management systems** that meets one or more of the following requirements: ISO 13485, MDR, MDSAP, 21 CFR 820 (USA)

Preparation for and support of **external audits** by certification bodies, Notified Body, or FDA inspections

Planning and execution of **internal audits**, and **supplier audits** for supplier qualification and surveillance

Effective **in-house training** on the above topics