Abbreviated Curriculum Vitae

Peter Reijntjes Drs.

Principal Consultant

INTRODUCTION

Peter is an expert on Quality Management System requirements for more than 25 years of experience as consultant, lead auditor and trainer.

After an extensive career at KEMA Quality (nowadays known as DEKRA Certification) Peter joined the Qserve Group in 2007 to combine his quality system knowledge with the regulations in the medical device industry.

Peter uses a pragmatic and practical approach with a strong focus on strategic and operational compliance and excellence. He is well known for his trainings.

With his background as physicist Peter is mainly concerned with medical electrical devices. Peter is Principal consultant Quality and Regulatory Affairs and Head of Training within the Qserve Group. Peter holds a MSc degree in Physics of the Leiden University.

COMPETENCES

- Since the introduction of the EU MDR 2017/745 I am involved in and leading various projects to prepare and manage the transi- tion from EU MDD to EU MDR, including associated trainings;
- 25+ years of experience in development, maintenance and performance of In-company and in-house trainings, courses and workshops on several subjects: EU MDD, EU MDR, QMS, Risk Management, Technical Documentation (STED), Internal (lead) auditor, Vigilance, Regulatory pathways and many more.....
- Qualified trainer on all medical device related trainings for Notified Body;
- 12+ years of experience in design, documentation, implementa- tion, monitoring and maintenance of Quality Management;
- Systems at various companies in the medical device industry;
- 12+ years of experience in design and documentation of Design History Files and Technical Files of a range of devices for low-risk (Class I) to medium risk devices (Class IIb) for submission to Regulatory Authorities in EU, US and Canada; the devices range from wound care products to medical electrical equipment for use in the Healthcare Sector;
- Expert advice on the interpretation of the Medical Device Directives and other laws pertaining to in regard to items such as regulatory pathways, classification, including preparation of rationales;
- Expert advice on Risk Management;
- Interim Quality Assurance & Regulatory Affairs manager at various companies with medium risk medical devices;
- Project Planning & Management;
- Qualified Lead auditor ISO 13485 for Notified Body;
- Qualified Lead auditor CE certification, Annex V & Annex VI MDD 93\42\EEC for Notified Body;
- 20+ years of experience in design, documentation, implemen- tation, monitoring and maintenance of Quality Management systems at various companies in the profit and not for profit sectors: industry, trade, IT-software support, (nuclear) energy industry and medical industry, government and civil services, public services;
- Definition and implementation of quality improvement projectsand change management;
- Interim Quality Assurance manager at various companies.