Qserve®

.....the practical approach

European MDR Compliance Modular Workshop-Training program 2017

"Will the new MDR affect your business?"

Overview of the 10 MDR modular Qserve workshops in 2017

"Invest in knowledge, train your staff"

Introduction

The new MDR will affect all Medical Device manufacturers. Scope & Plan, GAP assessment, Portfolio analysis, Global Impact Assessment are just some of the steps on the road to MDR implementation that must be addressed to ensure compliance.

The road to MDR compliance can be a daunting process, so Qserve has designed a monthly modular MDR workshop program to assist in determining the crucial steps needed for your organization.

Qserve's panel of guest speakers will provide the opportunity to interact, network and discuss your organizations' challenges, thus making these workshops unique.

The monthly workshops will present participating organizations the opportunity to prepare their subject matter experts. thus, employees will be trained on the implementation process in their specific area of expertise.

The implementation model featured in the workshops will be delivered via use of a "hypothetical" medical device manufacturer. Throughout the sessions, this model will be the key element to explain implementation of EU-MDR compliance, and will be applicable for small, mid-size, and multi-national manufacturers. Panel discussions will conclude each session.

Workshops will follow this format:

- Presentations by Industry leaders and Notified Bodies
- Lunch and interactive workshop training
- Panel discussion, followed by question and answer session with speakers

Fee for the 10 modular workshops

Flexible options for your company, team, or individual subject experts. (It's allowed to send different subject experts on a full or choice company pass).

Intro Pass:	€ 350 (only valid in January and February)
Day Pass:	€ 400
Choice Pass:	5 workshops € 1.750
Full Pass:	10 workshops € 3.000

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Workshop explanation:

The workshops will focus on the practical approach with a "hypothetical" medical device manufacturer. A key element in the workshop will be the "How to' questions. For example: How to understand critical impacts, how to persuade my management to prepare budget/resources, how to prepare the roadmap, etc.

The workshops are relevant for:

RA executives, managers and associates. QA managers. Clinical managers. Employees dealing with RA/QA issues. Subject matter experts, Design and Development Specialists, anyone involved with Product Development.

The clinical workshops are especially relevant for:

Clinical Specialists, Product Development & Product Managers, QA/ RA Managers. Employees dealing with RA/ QA issues. Subject matter experts.

Agenda

09:30 – 12:00	Subject presentations from Industry, Notified bodies and Qserve
12:45 – 15:30	Workshop "hypothetical" medical device manufacturer"
15:45 – 17:30	Panel discussion

Location for all workshops:

Novotel Amsterdam Schiphol Airport,
Taurusavenue 12,
2132 LS Hoofddorp, The Netherlands

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About Qserve

Our mission is to support all medical device manufacturers with a practical approach, translating existing regulations to understandable requirements. We serve to guide manufacturers in gaining a maintaining compliance for their safe and qualitative medical devices. Qserve's global team combines their regulatory knowledge and experience in the medical device industry, sharing more than 500 years' worth of combined expertise in the medical field. The combination of regulatory knowledge and device experience, together with our willingness to go the extra mile for our customers, is what makes us your global partner for Medical Device Regulatory Compliance.

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16 JAN 2017

Steps to implement EU-MDR Compliance program

Presenters:

Gert Bos (Qserve): Gert is the moderator of the training. Gert is leading the Qserve teams that implement the MDR at manufacturers. Qserve uses a structured approach and Gert will explain this approach.

Dr. Susana Wäsch (Geistlich): Susana will present "A view from the Industry". She already prepared the implementation plan 3 years ago, being one of the early adopters to the MDR. Their devices are class III, animal tissue, combination devices.

Philippe Soly (Philips): Philippe will present "How to implement a MDR roadmap in a multinational, with several QMS, several NoBo's, BU's and product classifications".

Inette Nieveen (Qserve): Inette will present her experiences with the implementation model.

Deliverables: Understand how to implement the MDR in a structural approach. How will the MDR impact your global registrations. How to perform a GAP assessment. How to perform a portfolio analysis. How to write a roadmap to implementation.

20 FEB 2017

Clinical Evaluation MEDDEV 2.7.1. Rev 4

Presenters:

Bassil Akra (TüV): Basil will present "How to analyze critical impacts for clinical evaluation. How to set up a clinical strategy plan. What is best Approach for PMCF? ".

Sabina Hoekstra (Philips): Sabina will present " How to set up a clinical program, MDR compliance in a multinational having a multitude of devices & technoligies."

Geeske van Oort (The eNose Company): Geeske will present " Experiences with MEDDEV 2.7.1. Rev. 4.

Anna Pietersma (Qserve): Anna will present "How to prepare data that is useful for the CER MDR".

Deliverables: How to analyse the critical impacts for clinical evaluation. How to set up a clinical strategy plan. What is best approach for PMCF.

20 MAR 2017

Pre-Market requirements

Presenters:

Eric Verstegen (Medela) : Eric will present "Experiences with Pre-Market requirements"

Sharmila Gardner (BSI): Sharmila will present "Classification, conformity assessment routes and unannounced audits".

Alexandra Maria Tautan (Qserve): Alexandra will present "How the stakeholder interaction is managed and how to prepare budget overview".

Stephanie Valk (Qserve): Stephanie will present her experiences with Pre-market requirements.

Deliverables: How to analyse the impacts on the new requirements for the operating model, like: UDI requirements, Supply chain, Economic operators.

20 APR 2017

QMS Alignment

Presenters:

Math van Sloun (Bracco Diagnostics): Math will present "How to deal with changes in Quality agreements, responsibility matrix and authorization".

Guido Ligthart (Dekra) Guido will present "How will the Notified Body audits change in the MDR".

Peter Reijntjes (Qserve): Peter will present "ISO13485, can you prepare one central system?"

Deliverables: QMS impact assessment including costs to implement the changes. How to analyse the impact on resources.

15 MAY 2017

Supply Chain

Presenters:

Eric Vollebregt (Axon lawyers): Eric will present "How to stay in control on liabilities, authorities, responsibilities in contracts".

Sophie Tabutin (BSI):

Rene Schings (Qserve): Rene will present "Traceability, UDI, Authorized Rep., Economic Operators, when to do audits, how to oversee the supply chain. More control within current resources".

Deliverables: Understand the business risks of supply chain management. How to analyse the impacts for supply chain.

26 JUN 2017

Technical file set up

Presenters:

Benjamin Hagendorn (Merz): Benjamin will present "How to comply with new requirements, how to use lifecycle management of your file to stay in compliance, from portfolio analyses, reflection how 'difficult' it is to update files".

Giovanni Di Rienzo (TüV Süd): Giovanni will present "Structure of a Technical file".

Inette Nieveen (Qserve): Inette will present "Effective use of existing documentation, which changes in QMS are needed to make sure your tech file is always up-to-date".

Deliverables: How to prepare a Master Impact Matrix for your technical files. How to prepare the product rationalization, remediate or retire?

18 SEP 2017

Clinical PMCF

Presenters:

Enrico Schuur (Medtronic): Enrico will present "The process to PMCF Flow of data, which to use in update of CER".

Bassil Akra (TüV): Bassil will present "Theory on a PMCF".

Anna Pietersma (Qserve): Anna will present "How from intended use, flow of data and which to use in update of CER".

Deliverables: How to prepare PMCF strategies. How to perform PMCF for devices that are in the market for many years. Will the MDR change the way Notified Bodies review clinical evaluations.

16 OCT 2017

Combination products

Presenters:

Sophie Tabutin (Bsi): Sophie will present "What is process for combination devices, how will it change in MDR and how will Notified Body react. Scrutiny process, drug agency, how will Notified Bodies help to align".

Janine Jamison (MHRA): Janine will present "Experiences as regulator, looking back and forward, how to make use of MDR".

Hen Baron (Qserve): Hen will present "Pre-consultation importance, Scientific consultation, what is the process for consultations?"

Deliverables: Understand the impacts of the MDR on combination devices. How to create the roadmap to implementation for combination devices.

23 NOV 2017

IVD

Presenters:

Gert Bos (Qserve): Gert is the moderator of the training. Gert helped to write the text for the MDR and is leading the Qserve teams that implement the MDR at manufacturers

Sue Spencer (UL/ EX Abbott): Sue will present "Re-classification, How will Notified Body handle all the resources needed."

Bénédicte Astier: Bénédicte will present "How to make GAP assessment for IVD Portfolio analyses."

Deliverables: How different is the roadmap to implementation for IVD. Understand how to prepare for the Notified Body review and audit.

11 DEC 2017

Wrap up & Notified Bodies

Presenters:

Gert Bos (Qserve): Impact on Global registration

Hans-Heiner Junker (TüV): Latest development, Common specifications, Transition timeline updates

Notified Body speaker (tbc): Latest development, Common specifications, Transition timeline updates

Deliverables: You have written your roadmap to implementation. Hear the Notified Body perspective and status with progress MDR/IVDR.

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