



BSI Training Academy & Qserve Transition MDD to MDR - Workshop

Save the Date: 04 th - 05 th of June 2018

Location: Universität Basel / Kollegienhaus
Petersplatz 1, CH-45051

Pricing: 1 Day 750 €
2 Days 950 €

Agenda - Day 1 - BSI Training Academy

- Organizational, Introduction
- Check device is with the scope of the MDR/ Determine risk class of device
- Identify applicable safety and performance requirements
- Apply conformity assessment procedure | Complete declaration of conformity | Affix CE mark
- Post-market surveillance and updates
- Transitional arrangements laid down in the Regulation



Dr. Marco Rost
BSI Germany - Training

Transition MDD to MDR – Workshop

Agenda - Day 2 - Qserve

- Changes to the structure and administration of the regulation
- Important changes to the requirements for conformity assessment
- Main effects on the QMS in connection with the o.G. Steps, including:
 - Frequency, scope and execution of audits
 - Electronic data management and public access to data
- Clinical Data with Case Study
- Labelling and UDI
- Economic Operators - Upstream and Downstream
- Proposal how to implement a MDR project
- Organizational, End of course, feedback



Stefan Menzl - PHD
Qserve Group EU
Principal Consultant

Please give us a **call** or contact us per **e-mail** !

Oliver Schaer
Phone: +49 (0) 69 2222 89 265
Email: Oliver.Schaer@bsigroup.com

