Invitation to MDSAP Course

Mediteq is proud to host a course on the global Medical Device Single Audit Programme (MDSAP) in Gothenburg 29 - 30 January 2020. This is a highly interactive training for you with a working knowledge of quality management systems. After this course you will be prepared to host a MDSAP audit and support your organization to maintain compliance to ISO 13485 and country specific requirements for the MDSAP program.

Target audience are personnel from all levels within the organisation with responsibility for designing, implementing and maintaining a QMS, e.g. quality and regulatory managers, internal or external auditors, process owners or managers from functions such as R&D, production or procurement, or QMS consultants.

This two-day course is delivered in English by Irish Quality Centre (IQC) and Fergal King will be our trainer. He is a very experienced trainer in QMS and auditing for medical device industry and has worked with MDSAP since 2015 and MDSAP training since 2018. Fergal has more than 20 years of work in quality and regulatory for medical device industry.

Time:	January 29th and 30th 2020, from 9 to 16:30
Place:	Jonsereds Herrgård, Gothenburg area, Sweden
Price:	15 000 SEK (excl. VAT) with 10 % discount for Mediteq Forum Members

Sign up for your participation via the link → Sign Up Form

Welcome to contact us at utbildning@mediteq.se

Mediteq is a team of consultants who helps and guides you in the regulatory landscape of requirements for medical device development, market access and CE-marking. We always have clear goals, an open mindset and a long-term perspective in our deliverables.

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Course content

This is a highly interactive training with many team exercises and discussion on the following topics;

- ✓ Introduction to MDSAP including pros and cons
- ✓ MDSAP related key terms
- ✓ MDSAP Companion Document
- ✓ Compliance and auditing

- ✓ Identify, implement and revise internal procedures and other documents in relation to MDSAP requirements
- ✓ Identify all key players, including participating countries, regulatory bodies, and auditing organizations
- ✓ Country specific requirements under the MDSAP such as QMS, labelling and registration

- ✓ MDSAP application and Auditing Organization
- ✓ Plan and prepare for an MDSAP audit
- ✓ MDSAP audit differences to other certifications
- ✓ Understand the MDSAP non-conformance rating system
- ✓ The three steps audit approval process and re-certification timeframe

- ✓ MDSAP implications and other certifications
- ✓ Compare to EU and US medical device regulations

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