

Course Outline

Module A: Introduction to the online course

Content and structure

- A. Introduction to the course
 - 1. Presenters and structure
 - 2. Introduction
- B. Early Decisions and Strategies
 - 1. Make up your mind!
 - 2. Define your device
 - 3. Manufacturer's obligations
 - 4. Regulatory strategy
- C. Implementing Processes
 - 1. Processes – Overview
 - 2. Risk Management
 - 3. Design and development
 - 4. Clinical Evaluation and Clinical Investigations
 - 5. Production
 - 6. Post Market Processes
- D. Establish Documentation
- E. Final steps to get to the market/apply the CE mark

+ Reading materials

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Module A: Introduction to the online course (15 min)

1. Presenters and Structure (Elin & Mats, 7 min)
2. Introduction (Elin, 8 min)

Module B: Early Decisions and Strategies (44 min)

1. Make up your mind (Mats, 4 min)
2. Define your device (Elin, 17 min)
3. Manufacturer's obligations (Mats, 10 min)
4. Regulatory strategy (Mats, 13 min)

Module B: Early Decisions and Strategies

Who determines the device classification?

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Module C: Implementing Processes

The QMS synchronize interacting processes and activities

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Module C: Implementing Processes (65 min)

1. Processes – Overview (Mats, 9 min)
2. Risk Management (Mats, 16 min)
3. Design and Development (Mats, 5 min)
4. Clinical Evaluation & Clinical Investigation (Elin, 16 min)
5. Production and Manufacturing (Mats, 8 min)
6. Post Market Processes (Elin, 11 min)

Module D: Establish documentation (13 min)

1. Establish documentation (Elin, 13 min)

Module D: Establish documentation

Technical documentation
Design and manufacturing

Design and manufacturing information including e.g.

- specifications,
- manufacturing processes with their validation and monitoring,
- final product testing,
- details on manufacturing sites including sub-contractors and suppliers.

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Module E: Final steps to get to the market / apply the CE mark

CE marking – some key activities

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Module E: Final steps to get to the market / apply the CE mark (8 min)

1. Final steps to get to the market (Elin, 6 min)
2. Wrap-up, what have we learnt? (Mats & Elin, 2 min)