## **Course Outline**



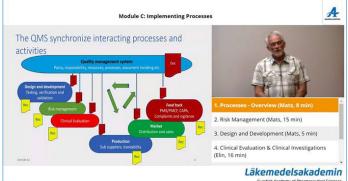
#### Module A: Introduction to the online course (15 min)

- 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)





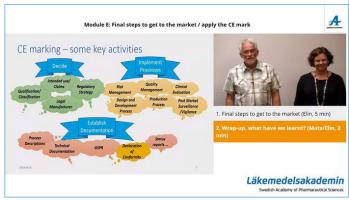
### Module C: Implementing Processes (65 min)

- 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 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)