COURSE OUTLINE, "Medical Device Sterilization" (#5504)

1. Before the course: The course literature is distributed as e-book (or printed if you prefer so) 3 weeks before the training. To get the most out of the training is highly recommended that you read this book and get well familiarized with the content. The amount of preparation needed depends on your previous experience with the various sterilization methods.

2. During the course: The course includes exercises during daytime, but also two exercises done as homework (Tuesday and Thursday evening).

3. After the course, you can choose to undergo an examination to verify your knowledge. The exam consists of eight questions that shall be answered with free text (there are no alternatives to choose from). It is an open exam, so you can make use of the e-book, the training material and any other information while preparing the answers, but please note that it is an individual test, meaning that no co-operation with other attendees should occur when preparing and submitting the answers.

=> Agenda: see next page.

Course content

Day 1 (08.30-17.00)

- Introduction, overview of standards for sterilization
- Sterilization of Medical Devices - Requirements for development, validation and routine control of a sterilization process. (ISO 14937:2009)
- Sterilization standards and their relationship with ISO 13485:2016
- Microbiology - Introduction
- Bioburden. Microbiological methods - Part 1. Determination of population of microorganisms (ISO 11737-1:2018)
- Use of Biological Indicators (ISO 11138-1:2017)

Day 2 (08.30-16.45, plus an individual exercise in the evening)

- Microbial inactivation kinetics – Requirements for terminally sterilized device to be designated "STERILE" (EN 556-1)
- "Test of sterility vs test for sterility" 11737-2 vs EU Pharmacopeia
- Choice of sterilization method
- Radiation sterilization Part 1. Nature of ionising radiation and measurement of dose (11137-1, -3)
- Radiation sterilization Part 2. Dosimetry
- Radiation sterilization Part 3. Establishing the sterilization dose (ISO 11137-2)

Day 3 (08.30-16.45)

- Radiation sterilization Part 4. Installation Qualification, Performance Qualification and Routine Control
- Packaging for terminally sterilized medical devices – Requirements on materials, sterile barrier system and packaging systems (ISO 11607-1:2019)
- Cleanrooms and associated controlled environments (ISO 14644, Part 1–5)

Day 4 (08.30-16.45, plus time for individual exercise in the evening)

- Ethylene oxide – Validation and routine control of the sterilization process (ISO 11135:2014)
- Moist heat – Validation and routine control of the sterilization process (ISO 17665-1:2006)
- Dry heat — Validation and routine control of the sterilization process (ISO 20857:2013)
- Start-up – individual exercise

Day 5 (08.30-12.30)

- Aseptic processing. Part 1: General requirements ISO 13408-1 (to some extent, Part 2-5 and EN 556)
- Exercise on aseptic processing
- Summary – closing remarks and information about the exam.