RADIATION STERILIZATION SEMINAR

Course content and acquired skills

2022

INTRODUCTION TO THE INDUSTRIAL USE OF IONIZING RADIATION

- A brief history
- Introduction into the variety of applications in different fields of technology
- Advantages and disadvantages of each radiation type for different requirements
- Regulatory base for medicinal products and medical devices

RADIATION STERILIZATION TECHNOLOGY BACKGROUND

- Ionization: definition and relevant aspects for radiation sterilization
- Photon interaction of radiation with matter: survey reaction mechanism
- The Compton Effect: kinematics and consequences for radiation processing
- Dose deposition in photon beams
- Electron interaction with matter: discussion for homogeneous and inhomogeneous materials, electron scattering and fringe effects
- Dose and dose rate
- Electron beam sources: low, medium and high energy accelerators principles and applications
- Electron energy and dose defining parameters in electron beam processing
- X-Ray sources: electron conversion and Bremsstrahlung mechanism
- Characteristics of X-Ray beams
- Gamma processing: physics and technical basics
- Characteristics of Gamma processing
- The energy limit for E-Beam and X-Ray irradiation

QUALIFICATION AND VALIDATION OF RADIATION STERILIZATION PROCESSES

- The ISO 11137 family of standards: latest revisions and their relevance for different steps in the radiation sterilization process
- Overview of Installation Qualification and with examples worked out in detail
- Overview of Operational Qualification: examples in E-Beam, X-Ray and Gamma processing
- Transfer of D^{ster} and $D^{max,acc}$: reference to TIR 104
- Performance Qualification: general principles, processing category
- Dosimetry grid and dosimeter placement: particularizing for E-Beam, X-Ray and Gamma
- PQ: guidance in 11137-3
- Process setting, process control guidance in TS 11137-4
- Worked out example of dose map interpretation and process setting
- Product release: discussion of concepts and examples provided in TS 11137-4
- Surface dose process parameter relationship and the Mediscan concept of machine dose
- Process control utilizing SPC techniques
- Parametric release: concept ad implementation with example
- Dosimetry: general principles and discussion of relevant ASTM standards
- Monte Carlo modelling as support for OQ and PQ with examples

DOSE MAPPING AND DOSIMETRY - HANDS ON TRAINING

DOSE MAPPING IN GAMMA

- Mapping exercise of real product (homogeneous vs. inhomogeneous mass distribution)
- Dosimeter location concept, discussion dosimeter placement for reproducible results
- Hands on dosimeter reading, dosimeter calibration techniques
- Dose map analysis: determination of min and max dose zones

DOSE MAPPING IN ELECTRON BEAM

- Mapping exercise of real product (homogeneous vs. inhomogeneous mass distribution)
- Dosimeter location concept, discussion dosimeter placement for reproducible results
- Product orientation: discuss differences in dose map
- Hands on dosimeter reading: dosimeter calibration techniques
- Dose map analysis: determination of min and max dose zones
- Demonstration of different dosimeter types, energy wedge

DOSE MAPPING IN X-RAY

- Dose map of real product (homogeneous vs. inhomogeneous mass distribution)
- Dosimeter location concept, discussion dosimeter placement for reproducible results
- E-Beam vs. X-Ray dose mapping concepts

DOSE SETTING

DOSE ESTABLISHMENT AND VERIFICATION

- Terms and definitions
- Product group vs. processing category
- Bioburden, sterility, SAL and D10 value
- Method 1, Method 2 and Method VDmax according to ISO 11137-2, introduction, choice, examples and pitfalls
- Dose audits

MAXIMUM ACCEPTABLE DOSE

- Effects of radiation on polymers and biopolymers
- Stability of organic compounds
- What to test and how to establish the maximum acceptable dose