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# Biocompatibility and EO sterilization for medical devices

30.05.2023 01.00 PM (CET)

live webinar

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## Biocompatibility and EO sterilization for medical devices
## 30.05.2023 13:00 CET

The live **webinar** focuses on the latest aspects of **biocompatibility** and **ethylene oxide sterilization** (EO/EtO) requirements. It is suitable for people responsible for the quality, regulatory, R&D, vigilance, clinical evaluation, and management of medical device manufacturers.

The live webinar is for all, who want to find **state-of-the-art approaches and requirements**, and most important: **how to handle them**!

The **biocompatibility** part which takes **2h**, will answer the following questions:

- What are the requirements of **MDR**, **ISO 10993**, **Notified Bodies** and **Competent Authorities**?
- Biological Evaluation Plan (**BEP**), Biological Evaluation Report/Biological Risk Assessment (**BER/BRA**) – how to waive some testing using it?
- **How to prepare samples** for testing? **How many samples** are needed? How do I need to be prepared?
- What is the role of **ISO 17025** and **GLP**?
- **Which tests are needed** for my medical device?
- ISO 10993-18 chemical characterization (**extractables & leachables**) – how to handle that?
- How to plan **extraction strategy** and **solvent selection**?
- What is the role of Analytical Evaluation Threshold (**AET**) calculation and analytical **uncertainty factor**?
- **Toxicological evaluation** ISO 10993-17 – is it always necessary?
- **How long** does biocompatibility testing take?
- Which changes in medical devices require additional testing?
- **A new standard revision** - do I need to test my product again?
- What are the biocompatibility testing requirements in **various countries**?

The **EO sterilization** part which takes **1h**, will answer the following questions:

- What basic knowledge of microbiology **is necessary** for you?

- What are the **advantages** and **disadvantages** of EO sterilization?
- What is the flow of a **typical EO** sterilization process?
- What is the influence of **critical parameters** on the effectiveness of EO sterilization process
- How **to validate** EO sterilization process?
- How to **calculate D-value**?
- How to create appropriate **PCD**s?
- How to determine **half-cycle dwell time**?
- How to determine **residuals level**?
- What **challenges** can you expect during EO process validation?

**Dr. Damian Matak**

- Ph.D. in medical sciences, M.Sc. and Eng. in biotechnology, postgraduate degrees in management, clinical trials, evidence-based toxicology
- Member of Polish Society of Toxicology, I Local Ethical Committee
- Expert of OECD Group in immunotoxicology, Foundation for Polish Science, National Centre for Research and Development, Medical Research Agency
- Author or co-author of >15 scientific articles and book chapters
- Recipient of >10 scientific awards
- Inventor of III-class medical devices, experienced in the certification process
- CEO of ISO 17025-accredited, and GLP-certified laboratories specialized in comprehensive medical device testing: chemistry, biocompatibility, microbiology & sterility, reprocessing validation, packaging validation, and aging

**Dr. Lukasz Szymański**

- Ph.D. in medical sciences
- 35 publications in scientific journals with an impact factor
- Principal investigator or co-investigator in >10 scientific projects
- Head, principal investigator, or co-investigator in >10 R&D projects
- Evidence-based Toxicology, Johns Hopkins University
- Polish Society of Toxicology member
- Principle GLP Investigator
- OECD Expert Group member in immunotoxicology
- Certified Internal Auditor ISO 19011
- Notified Body Technical Expert

**Dr. Andrzej Decewicz**

- Medical degree, Specialty – gynecology, obstetrics, cytology, ultrasonography
- 10+ Years of medical practice
- 30+ Years of medical industry practice including sterilization and validation
- Experienced in clinical evaluation and risk management
- Experienced in the validation of EO sterilization process
- Experienced in the design and development of medical devices
- Inventor of 14 patented medical devices or improvements
- CEO of medical devices manufacturer

## Live webinar price: 100 € (the price does not include VAT tax)