

Dr. Ralph Hermann

Senior Consultant



Expertise

- Implementation and operation of an EO- Sterilization Chamber / EO sterilization processes
- Implementation and development of validation strategies and validation master plans in accordance with normative specifications (ISO 11135, ISO 11137, ISO 11607, ISO 19227)
- Performing sterilization, cleaning and packaging validations (ISO 11137, ISO 11135, ISO 19227, ISO 11607)
- DGQ/EOQ Auditor. Preparation and implementation of authorities audits (FDA, ANVISA, PMDA, Regional council), Internal, supplier and Notified Body Audits acc.13485 > 100
- Advice on the approval of new medical devices
- Conducting training courses, auditor training for notified bodies
- Implementation and Qualification of Cleanrooms (ISO 7), Cleanroom monitoring, new machines, Biological Lab (security level "2"), Water treatment (Highly purified water)
- Generating of risk analyses in accordance with ISO 14971 risk management
- Supervision and support of computer software validations (including Label- Software) in accordance with GAMP5
- Until 2024 Member of the standards committee "Sterile supply"
- Participation in the ethylene oxide interest group
- Review and assessment of international standards

Personal details

Date of Birth

13th January 1969

Family status

Married, 3 Children

Nationality

German

Qualification

Academic studies

Dr. rer. nat. (Dipl. Biol.)

Skills

Hands-on, Competence in EO handling / TRGS 513, EOQ Auditor, Management, 13485 QM- Systems

Languages

German

Native Speaker

English

Business fluent

Contact

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75210 Keltern

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Work experience

Since March 2025

H27 Consulting Service GmbH

Senior Consultant Validation and Sterilization

March 2022 –
February 2024

Eurofins Inpac Medizintechnik GmbH

Managing Director

June 2010 –
February 2022

Inpac Medizintechnik GmbH

Managing Director, Head of sterilization

July 2003 –
June 2010

Inpac Medizintechnik GmbH

Founder of inpac Medizintechnik GmbH /
Quality Manager, Head of validation

March 2001-
June 2003

LIPAC GmbH / Medical Service GmbH

Quality Manager / QMB

March 2000-
March 2001

University of Karlsruhe (TU)

Post doc. position