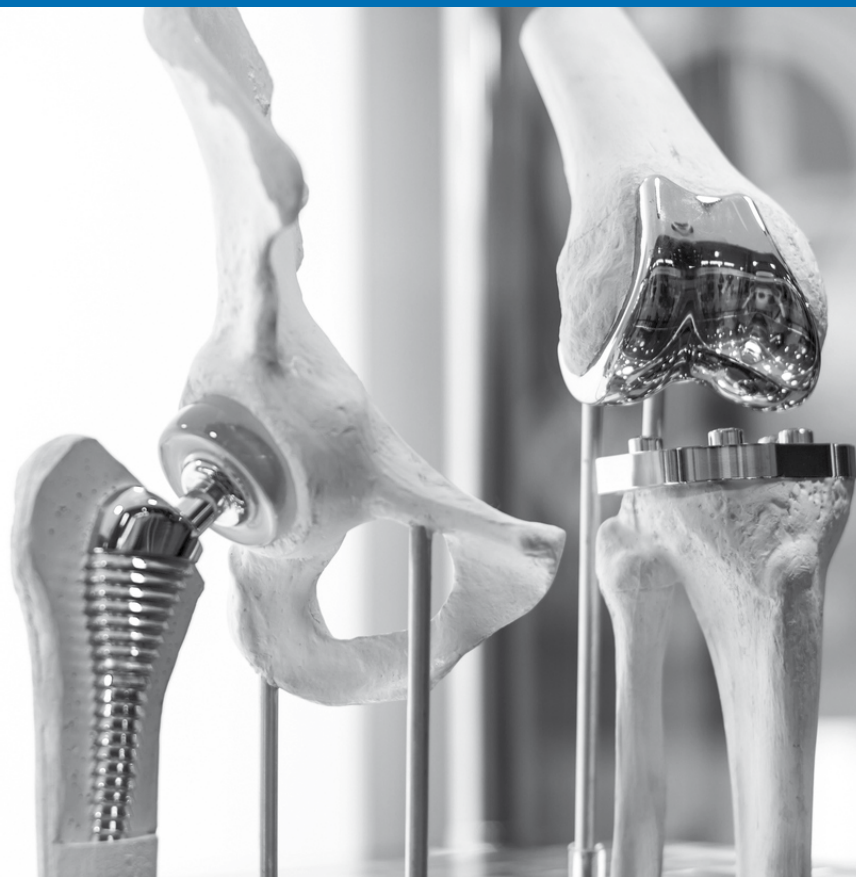


# Microbiological & Toxicological Quality and Safety of Medical Devices



## SPEAKERS:



**Dr Jörg Degen**  
*Eurofins*



**Lothar Fruth**  
*Toxicological Expert  
Services, Göttingen*



**Jan Havel**  
*TÜV Süd*



**Hana Hofman-  
Hüther**  
*Eurofins*



**Peter Huonker**  
*Zimmer Biomet*



**Walter Zwisler**  
*Zwisler Laboratorium*

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5-6 December 2017, Berlin, Germany

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## HIGHLIGHTS:

- Regulatory Requirements
- Sterilisation Methods
- Endotoxin Testing – incl. alternate Methods
- Bioburden and Identification
- Biocompatibility
- Toxicological Evaluation and Analysis



# Microbiological and Toxicological Quality and Safety of Medical Devices

5-6 December 2017, Berlin, Germany

## Objectives

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This course will provide you with information about the current regulatory requirements for microbiological and toxicological quality of Medical Devices. Well-versed speakers from Notified Body, Manufacturer and Quality Laboratory will share their experiences with implementation and validation of suitable test methods, common pitfalls, and the expectations of auditors and customers. They will share their knowledge in transfer the regulatory requirements in the daily business and how to manage the challenges in the fast developing field of Medical Devices.

## Background

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Since 1996, the requirements for the development, the manufacture and the distribution of Medical Devices in the USA have been laid down in the revised cGMP regulations for Medical Devices (21 CFR 820, QSR). In the USA, medical devices are regulated by the FDA's Center for Devices and Radiological Health (CDRH). Inspections are primarily performed by the FDA.

In Europe, three EU directives (90/385/EWG, 93/42/EWG and 98/79/EG) and one amending directives regulate the medical devices industry. GMP regulations - strictly speaking - are not notified. Instead, harmonised standards, especially ISO 13485, revised in 2016, represent the state-of-the-art in the EU. Inspections are primarily performed by Notified Bodies („New Approach for Product Regulations and Conformity Assessment“).

Statistical data about deficiencies of medical devices do only exist in the USA because of the Freedom of Information Act. For years now, CAPA/Complaint Handling, insufficient Design Controls, Management Responsibility, Process Controls and Process Validation and Quality Audits have been among the Top 10 deviations.

An additional focus of authorities and notified bodies is the microbiological and toxicological safety. This means the requirements for hygienic production, sterilisation appropriate to ISO 11137/11135 as well as a suitable method for bioburden sterility testing or endotoxin detection.

A new challenge relating to microbiological and sterilisation safety became the ISO 17664 and which Information must the MD Manufacturer provide now to the customer.

For toxicological and biocompatibility analysis, the ISO 10993 defines some requirements, but a current question will be: "How can I get the data I need" especially for the raw materials and intermediates whilst a medical grade is not really defined.

## Moderator

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Axel H Schroeder, Concept Heidelberg

## Target Audience

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This course is designed for all people from

- Medical Device Manufacturing
- Medical Device Quality Control
- Contract Laboratories
- Regulatory Authorities
- Notified Bodies

who are involved in quality and safety issues of medical devices.

## Programme

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### Regulatory Requirements on Medical Devices

- General requirements for Sterile Products and packaging
- Requirements for control of manufacturing and microbiological and biological safety
- General requirements on documentation for validation and biological safety

### Biological Safety of Medical Devices: general and agency expectations

- General biological safety requirements
- ISO10993
- MDR

### Short Introduction into Microbiology

- What are Microorganisms
- Behaviour of Microorganisms

### Microbiological Quality Control during Production of Medical Devices

- Essentials of ISO 11737-1 and USP <1229.3>-Sampling, Extraction, Testing, Validation, Limits
  - Regulatory Requirements concerning hygienic aspects
    - Environmental Control of Production Processes
    - Microbiological Quality Control Testing
    - Bioburden and Validation
    - Sterility including Suitability Testing
    - Endotoxins

### Consideration of different sterilization methods for medical devices, focusing on gamma radiation and ethylene oxide

- Methods of microbial inactivation and destruction
- Suitability of different methods for different materials
- Shelf-life testing

### Validation of Sterilisation appropriate to ISO 11137/11135 - New sterilization approach X-ray

- General introduction of ISO 11137 and some practical remarks
- General introduction of ISO 11135 and some practical remarks
- Different X Ray technologies and treatment approaches

## Current Requirements of ISO 17664 – Which Information must the MD Manufacturer provide for the processing of resterilizable medical devices

- Introduction
- The (Re-)Processing cycle of MDs
- Instruction for use – part (re-)processing: the need of a validated process

## Microbial Identification with MalDI: A comparison with other methods (cons/pros)

- General overview about current identification methods: DNA, biochemical, and phenotypical identification methods
- Technical introduction of MALDI-TOF
- Financial aspects and for whom it could be an interesting investment

## Endotoxin Testing - Studies on BET Recovery rates with different Methods and Materials

- Endotoxin test with LAL
- Recovery efficiency with ultrasonic bathes
- Recovery efficiency with different materials, like polymer, ceramic and metal
- Combined methods

## MAT and Medical Devices

- MAT overview
- Pyrogens in (MD-) Production
- MAT for MD

## Requirements on ISO 10993 - current updates

- General introduction of ISO 10993
- Update of ISO 10993-1
- ISO 10993-12: is the extraction procedure sufficient for all tests?

## Toxicological evaluation - Risk Assessment and TTC approach

- Prerequisites and elements of a successful risk assessment
- How to close typical data gaps
- TTC approach as a quick way out from the efforts of the traditional way in toxicology?
- Limitations of the TTC concept

## Biocompatibility as challenge for the communication in the supply chain - how do I get the data I need?

- Typical situations in the daily communication
- Recommendations for the definition of the minimum requirements for the data from the suppliers
- How to accelerate the process
- Data plausibility check: Trust or control?

## Cleanliness/Validation of washing machines/chemical and microbiological aspects

- Instruments: Basics about ISO 15883
- Implants: Chemical and biological cleaning validation and its aspects

## Speakers

### Joerg Degen, Eurofins BioPharma Product Testing Munich GmbH, Germany, Head of Microbiology

Joerg Degen studied Biology at the University of Wuerzburg. He obtained his PhD at the Fraunhofer Institute for Interfacial Engineering and Biotechnology (IGB)Stuttgart- In 2006 he joined BSL Bioservice as study director for microbiological testings for pharmaceuticals and medical devices. In his current position, he is the head of the Microbiology Laboratory at Eurofins BioPharma and Medical Device Testing.

### Lothar Fruth, Toxicological Expert Services, Germany

Lothar Fruth studied Pharmacy at the university of Regensburg and Hamburg. he received his degree as “Specialist Pharmacist for Toxicology and Ecology” in parallel to his career as specialist and consultant for risk assessments with respect to human health especially from complex matrices in different companies. He is lecturer for toxicology at the Chamber of Pharmacists in Lower Saxony as well as member of the examinations board for toxicologists. Due to his long practical experience in toxicological risk assessments he is also “Publicly Certified Expert for Toxicological Risk Assessments” (IHK Hannover). Medical devices are one of his favourites in risk and safety assessments due to their typically complex composition. Another field are packaging materials for medicinal products, where he is active in the assessment of extractables and leachables for example. Besides the traditional way in toxicological assessments he has expertise in QSAR modelling (like the TTC concept).

### Jan Havel, TÜV-SÜD Product Service, Medical and Health Services, Germany

Non-active medical devices – Team leader for experts in the field of validation of sterilization, reprocessing, sterile packaging processes and biocompatibility testing. Besides that he is an EN ISO 13485/ 9001 CMDCAS/MDD auditor and an active member of ASTM F0 for flexible barrier packaging.

### Dr Hana Hofman-Hüther, Head of Eurofins Professional Consulting Services Munich, Germany

Hana Hofman-Hüther has more than 15 years experience in toxicology and genotoxicity, in vitro bioassays, radiation protection, Apoptosis, DNA repair and cancer development as well as assay development. Her background includes extensive demonstrated expertise in the medical device industry in the areas of quality assurance & regulatory affairs with a specialty in biocompatibility/toxicity, toxicological risk assessments. She is a toxicologist and an active member at DIN /ISO, IVTIP, GUM, DGPT, EEMS, NETVAL. Mrs Hofman-Hüther holds a PhD in biology from the University of Goettingen.

### Peter Huonker, Zimmer Biomet, Switzerland

For about 9 years, Peter Huonker has been working at the medical device company Zimmer Biomet, where he is responsible for the microbiology laboratory, terminal sterilization, qualification and monitoring of cleanrooms and water systems. He studied Biology at the University of Zürich, where he received his degree as Master in Human Biology. In 2014, he gained an additional Master in Management, Economy and Engineering.

### Dr Walter Zwisler, Zwisler Laboratorium GmbH, Germany

Dr Walter Zwisler, CEO of `Zwisler Laboratorium GmbH, Konstanz studied Biology at the University of Konstanz and got his PhD at the University of Oldenburg. For more than ten years the testing of Medical Devices is in the focus of his Lab. Validation of reprocessing processes and the Invitro Pyrogen Testing (MAT) with thousands of tested samples (medical devices and pharmaceutical samples) are – beneath other microbiological tests – key services of the Lab.

## Easy Registration



Reservation Form:  
**CONCEPT HEIDELBERG**  
P.O. Box 10 17 64  
69007 Heidelberg  
Germany



Reservation Form:  
**+ 49 6221 84 44 34**



e-mail:  
**info@concept-heidelberg.de**



Internet:  
**www.gmp-compliance.org**



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Reservation Form (Please complete in full)

### Microbiological and Toxicological Quality and Safety of Medical Devices

5-6 December 2017, Berlin, Germany

Mr.  Ms.

Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**

**P.O. No if applicable**

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

**CONCEPT HEIDELBERG**  
P.O. Box 101764  
Fax +49 (0) 62 21/84 44 34

**D-69007 Heidelberg**  
**GERMANY**

#### General terms and conditions

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.

2. If you have to cancel entirely we must charge the following processing fees:

- until 2 weeks prior to the conference 10 %

- until 1 week prior to the conference 50 %

- within 1 week prior to the conference 100 %

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

**Terms of payment:** Payable without deductions within 10 days after receipt of invoice.

German law shall apply. Court of jurisdiction is Heidelberg.

**Important:** This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)

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#### Date

Tuesday, 05 December 2017, 09.00 – 17.30 h

(Registration and coffee 08.30 – 09.00 h)

Wednesday, 06 December 2017, 08.30 – 16.00 h

#### Venue

Steigenberger Hotel Berlin

Los-Angeles-Platz 1

10789 Berlin, Germany

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email [berlin@steigenberger.de](mailto:berlin@steigenberger.de)

#### Fees (per delegate plus VAT)

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

#### Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

#### Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

#### Social Event



In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

#### Conference Language

The official conference language will be English.

#### Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG

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