



- Interactive Workshops
- Discussion of failures from the participants' own daily practice

Failure Investigations and CAPA in Sterile Manufacturing

How to do it GMP-compliant?

27-28 September 2011, Heidelberg, Germany

Speakers:

Dr Manfred Berchtold
*Novartis Pharma Stein AG,
Switzerland*

Dr Klaus Haberer
*Compliance Advice and Services
in Microbiology, Germany*

Dr Bettina Lauer
*Vetter Pharma Fertigung GmbH & Co. KG,
Germany*

Programme:

- Deviation Management as an Integral Part of Quality Management - Regulatory Requirements
- Definitions
- Failures in Sterile Manufacturing - Types of Failure - How are Failures Recognized?
- How to Deal with Failures / Deviations?
- Risk Management in Failure Investigation
- Case Studies
- Workshops

Failure Investigations and CAPA in Sterile Manufacturing

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Learning Objectives

- You learn to systematically find deviations and failures in the manufacture of sterile medicinal products, to evaluate them and to handle them in a GMP-compliant way.
- Case studies are used to demonstrate the evaluation and handling of real-life deviations and failures found in daily routine.
- In workshops, you discuss and work out autonomous solution strategies for failures occurred in sterile manufacture.
- You can discuss failures and deviations from your own daily practice with speakers and colleagues.

Background

In sterile manufacture and in the microbiological laboratory, a large number of failures and deviations can occur. The GMP requirements expect that failures and deviations are recognised and dealt with in a systematic way. In this process, the impact on the product has to be assessed, and measures have to be taken to remedy these deficiencies and to avoid them in the future.

In daily routine, it is often difficult to identify the failure causes unambiguously and to take systematic avoidance measures.

This course will familiarise you with the regulatory requirements and introduce you to the essentials of failure handling. The emphasis is on the independent handling of failures and deviations in your everyday work. In case studies, successful strategies from practice are presented to you, in workshops you independently work out solution approaches to failures and deviations typically occurring in a sterile manufacturing site under different scenarios.

Target Group

The event is directed at all those working in the field of sterile manufacturing, e.g. people from

- Production
- QA
- QC
- Qualification / Validation

who have to manage failures and deviations.

Programme

Welcome / Introduction

- What delegates expect from the course

Deviation Management as an integral Part of Quality Management - Regulatory Requirements

- EU GMP Annex I
- FDA Aseptic Guide
- FDA Guidance for Industry 'Quality Systems Approach to Pharmaceutical cGMP Regulations'
- ISO 9000 series
- ICH Q10

Definitions

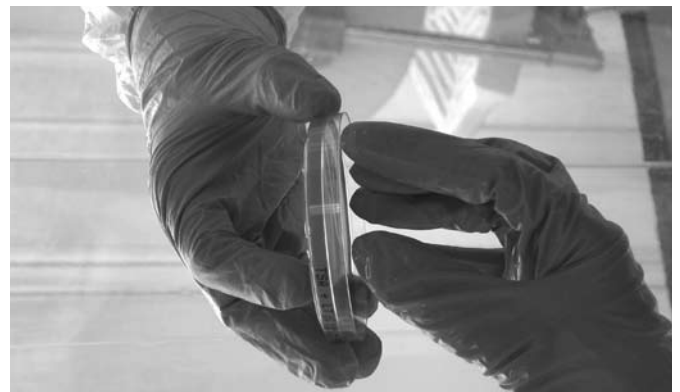
- Deviation
- OOS, OOE, OOL, OOT
- Alert/Action Level; Target Value
- MDD (Microbial Data Deviation)
- Failure Investigation
- CAPA

Failures in sterile manufacturing: Types of failures / How are failures recognized?

- Contamination routes
 - Product stream
 - Penetration of barriers
 - Environmental protection failure
 - Handling errors
 - Failures in removal of microorganisms
- Failure recognition
 - Monitoring excursions
 - Failure of IPC or release tests
 - Adverse events on the market
 - Media fills
 - Audits /inspections

How to deal with failures / deviations?

- Principles
- Detection
- Evaluation / Risk analysis
- Investigations
- Corrective actions
- Preventive actions



Picture: Heipha Dr. Müller GmbH

Real Life Case Studies

In different case studies, the speakers present actual cases of deviations/failures from daily practice to you. They explain the approaches to each of these examples and show you the measures that have been taken.

- Description of the Case
- Detection of the failure
- Preliminary risk analysis
- Discussion of the content of investigations
- Results of the investigations
- Risk analysis
- Discussion of corrective measures
- Discussion of preventive measures
- Outcome of the real case

Cases presented, e.g.:

- Repeated isolation of spore formers in the grade A environment
- 164 Positive units in a media fill
- Cases of positive sterility tests
- Unusual microorganisms in environmental monitoring
- Contamination in an isolator

Apart from this, you have the opportunity to discuss failures and deviations found in your own company with the speakers and your fellow participants. Please send a brief description of the failure/deviation to mangel@concept-heidelberg.de.

Risk Management in Failure Investigation

- Interpretation of the results
- Risk recognition
- Available Tools
- Suitable and non-suitable tools
- Application of tools

Workshops

The participants independently work on different cases from practice and discuss the chosen solution with the colleagues and speakers. Participants can also contribute their own examples to the workshops and talk about them with their colleagues.

Workshops among other things on:

- Failures in a Media Fill
- Failures in environmental monitoring
- Failures in sterility tests
- Bioburden failure
- Cleanroom behaviour
- Isolator glove integrity

Speakers

Dr Manfred Berchtold

Novartis Pharma Stein AG, Stein, Schweiz



Manfred Berchtold studied biology and did a doctorate in microbiology at the University of Ulm, Germany. After that, he was a lecturer and researcher at the Institute of Microbiology and Vinology of the University of Mainz. Since 2001, he has been working in QA/Microbiology (sterile forms) at Novartis Pharma in Stein, Switzerland. Currently, he is a team leader and among other things responsible for media fills, environmental monitoring, product releases, deviation handling and rapid microbiology.

Dr Klaus Haberer

Compliance Advice and Services in Microbiology GmbH, Cologne, Germany



Klaus Haberer studied Biology and Biochemistry at the Universities of Tübingen and Cologne. From 1983 to 1986, Head of Microbiological Quality Control at Hoffmann-La Roche AG, Grenzach, Germany. From 1986 to 1999 Head of Microbiological Quality Control and later Director Microbiology Global Quality Operations at Hoechst Marion Roussel AG in Frankfurt, Germany. Beginning from 1999: Managing Director of Compliance Advice and Services in Microbiology GmbH at Cologne, Germany, his own consulting company with microbiological laboratory service. Dr. Haberer is working as an expert in a number of international committees, e.g. of European Pharmacopoeia, ISO, and PDA.

Dr. Bettina Lauer

Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany



During her time at Vetter Pharma-Fertigung GmbH & Co. KG she worked as lab manager of different laboratories focusing on environmental monitoring, testing of utilities and product testing. At present Dr. Bettina Lauer is deputy head of Microbiology and works as a senior expert in Microbiology responsible for customer audits and authority's inspections As Black Belt she is involved in process optimization projects using the tools of Six Sigma

Social Event

On 27 September 2011, 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.




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

 + 49 6221 84 44 34

Reservation Form (Please complete in full)

Failure Investigations and CAPA in Sterile Manufacturing
27-28 September 2011, Heidelberg, Germany

Mr. Ms.

Title, first name, surname

Company

Department

Please indicate your company's VAT ID Number

P.O. Number if applicable

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

If the bill-to-address deviates from the specifications on the right, please fill out here:

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: Cancellation
 - until 2 weeks prior to the conference 10 %
 - until 1 weeks 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.

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).

Date

Tuesday, 27 September 2011, 10.00 h – 18.00 h
(Registration and coffee 09.30 h – 10.00 h)
Wednesday, 28 September 2011, 08.30 h – 16.00 h

Venue

Crowne Plaza Hotel Heidelberg
Kurfürstenanlage 1
69115 Heidelberg
Germany
Phone +49 6221 917 - 0
Fax +49 6221 21007

Fees

ECA Members: € 1,490,- per delegate + VAT.
APIC Members € 1,590,- per delegate plus VAT (does not include ECA membership)
Non-ECA Members: € 1,690,- per delegate + VAT.
EU GMP Inspectorates: € 845,- per delegate + VAT.
Including: Conference documentation, lunch and dinner on the first day, lunch on the second day, all refreshments, Social event

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 for your room reservation or be sure to mention "VA 6921 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 29 August 2011. 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.

Conference Language

The official conference language will be English.

Organisation

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany,
Phone ++49-62 21/84 44-0
Fax ++49-62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:

Dr. Andreas Mangel (Operations Director) at
+49-62 21/84 44 41, or per e-mail at
mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Nicole Bach (Organisation Manager) at
+49-62 21/84 44 22, or per e-mail at
bach@concept-heidelberg.de.