



With interactive workshops

Risk Management in Sterile Manufacturing

13-14 May 2014, Copenhagen, Denmark

SPEAKERS:

Dr Daniel Kockelkorn
F. Hoffmann-La Roche

Dr Sandra Schinzel
F. Hoffmann-La Roche

Dr Ingrid Walther
Pharma Consulting Walther

LEARNING OBJECTIVES:

- Principles of risk management in sterile manufacturing
- Risk management tools and how to use them
- Microbiological and non-microbiological risks
- Risk management during qualification and validation



Risk Management in Sterile Manufacturing

13-14 May 2014, Copenhagen, Denmark

Learning Goals

Why you should attend this course:

- You get to know the methods of risk analysis and learn how to apply them to the specific questions of sterile manufacturing,
- You can distinguish between critical and uncritical risks and accordingly define measures for controlling these risks,
- In workshops, you analyse sterile processes, assess possible risks and suggest suitable countermeasures.

Background

The manufacture of sterile medicinal products is a risk-prone process. Whereas the product safety of terminally sterilised products can usually be ensured by validating the sterilisation process, aseptic manufacture makes great demands on process safety. As early as 2001, the FDA had defined the „Risk-based Approach“ for future inspections; involving high risk in the sense of the authority's definition and therefore being automatically in the focus of inspections is „aseptic processing“.

Even in advance, one has to study the question whether each process step poses a contamination risk, and if so, which one. Good risk management consists in identifying and assessing risks in time and taking measures in the production process in order to control or – if possible – eliminate these risks.

Everyday routine confronts us with a multitude of potential risks. Which of them are critical, which ones rather uncritical? How can risk assessment be done and which rationales play a role in this decision?

The speakers provide you with practice-oriented approaches to assessing, controlling and reducing risks in „sterile processes“ and to get safely through inspections.

Target Group

The event is directed at all those working in the field of sterile manufacturing who have to implement risk-based approaches in planning and assessing their company's production.

Programme

Introduction:

Risk management in sterile manufacturing

- ICH Q 9
 - Risk analysis
 - Risk control
 - Risk communication
- End to End approach
- Continuous improvement triggered by risk management

Risk management tools - Overview

- Fault tree analysis
- Fishbone diagram
- FMEA
- HACCP

Interactive Workshop:

Exercises FMEA (Sterile Filling Process)

Attendees will execute a process related FMEA on the base of a sterile filling process.



Interactive Workshop:

Exercise HACCP (Cleanroom Qualification)

Attendees will execute a HACCP risk assessment as a starting point for the cleanroom qualification. They will apply an easy to use documentation approach with office tools.

Root Cause Analysis (in sterile manufacturing)

- The RCA process
- Methods of Root Cause Analyses
 - Five times “Why”
 - Barrier analysis
- Fields of application
- Specific challenges in sterile manufacturing

Example:

Microbiological Risk Management (equipment)

The sample devices for active air samplers in Isolators are solid installed and cannot be exchanged during operations. This example deals with a risk based approach how to increase the reliability of this devices.

Interactive Workshop: Microbiological risk management

End to end Approach in Sterile Filling

- Description of a process using process maps
- Applying risk analysis systematically end to end
- Case studies

Interactive Workshop: End to End Approach in Sterile Filling

Non-microbiological Risks in Sterile Manufacturing

- Packaging Material Quality
- Product mix-ups
- Particles
- Degradation products
- Cross-contamination

Trending / Microbiological Deviations / Failure Investigations and CAPA

- Why is trending important?
- What are the possibilities?
- How to handle deviations and how to invest them
- The pain of finding a useful CAPA

Social Event

On 13 May 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.



Speakers



Dr Daniel Kockelkorn

F. Hoffmann-La Roche AG, Basel, Switzerland

Daniel Kockelkorn studied biology at the university Freiburg and Madrid. He did his doctorate in microbiology and biochemistry and worked as a postdoctoral fellow in Freiburg. From 4/2010 to 9/2011 he worked

as a deputy line Manager for liquid vials at F. Hoffmann-La Roche AG in Basel. Since 10/2011 he is working as laboratory head for environmental monitoring of the new Roche parenteralia production site in Kaiseraugst.



Dr Sandra Schinzel

F. Hoffmann-La Roche AG, Basel, Switzerland

Sandra Schinzel obtained a chemistry diploma from the University of Würzburg and a chemical engineer diploma from CPE Lyon in France. She joined F. Hoffmann-La Roche in 2010 as an operational excellence

project manager in Parenterals Production Kaiseraugst, Switzerland. In this brand-new and strategically important production facility of Roche, she is responsible for executing risk assessment and deploying various optimization projects. Sandra Schinzel is a LeanSixSigma green belt.



Dr Ingrid Walther

Pharma Consulting Walther, Friedrichsdorf, Germany

Dr Walther joined Fresenius AG in 1986.

She was employed in various positions and has long years of experience in the fields of research and development, quality assurance/quality control and the management of strategic projects. In 1997 she assumed a position as head of the Business Unit Validation and GMP Compliance at Pharmaplan GmbH, a daughter company of Fresenius. In a subsequent position at Pharmaplan, she became responsible for consulting projects and became COO. In 2007, she re-joined Fresenius, heading the business unit iv Drugs & Oncology. Since July 2009 she runs her own business as consultant.

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Reservation Form (Please complete in full)

☐ Risk Management in Sterile Manufacturing, 13-14 May 2014, Copenhagen, Denmark

☐ Environmental Monitoring, 15-16 May 2014, Copenhagen, Denmark

☐ Mr.

☐ Ms.

Title, first name, surname

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Department

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

D-69007 Heidelberg
GERMANY

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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 %
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Date

Tuesday, 13 May 2014, 09.00 h – 17.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 14 May 2014, 08.30 h – 16.00 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00, Fax +45 33 96 55 00

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
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.

Save up to € 390 and book the course “Environmental Monitoring” on 15-16 May 2014 simultaneously:
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EU GMP Inspectorates € 1,495.- per delegate plus VAT
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Accommodation

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Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

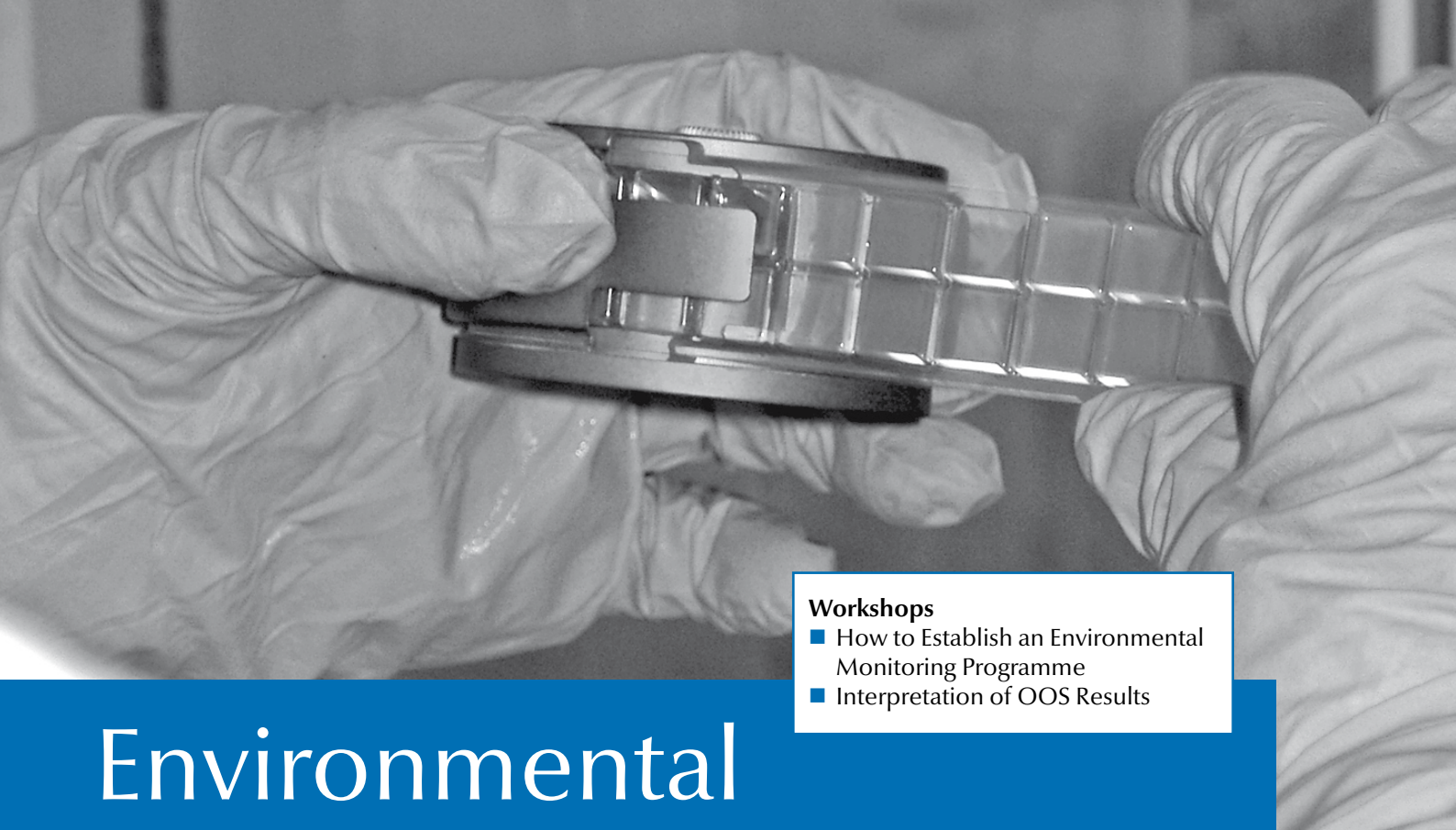
Conference language

The official conference language will be English.

Organisation and Contact

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For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at
+49-62 21 / 84 44 22 or per e-mail at bach@concept-heidelberg.de.



Workshops

- How to Establish an Environmental Monitoring Programme
- Interpretation of OOS Results

Environmental Monitoring

Compliant and Reasonable

15-16 May 2014, Copenhagen, Denmark

SPEAKERS:

Colin Booth

Oxoid, UK

Christopher Randell

De La Rue plc, UK

Dr Björn Wiese

Zimmer GmbH, Switzerland

PROGRAMME:

- Environmental Monitoring. Why do we do it – what does it tell us?
- Relevant Guidelines
- Non-viable (particulate) Air Monitoring
- Environmental Monitoring for Non-Steriles
- Clean Rooms - RABS - Isolator: Points to consider
- Case Study: The Trending Tool for Environmental Monitoring Data at Cilag
- Surface / Personnel / Air Monitoring
- Deviation Management for Environmental Monitoring
- Microbiological Methods
- Investigations / Documentation / Trending



Environmental Monitoring

15-16 May 2014, Copenhagen, Denmark

Objectives

Environmental monitoring is one of the systems that decide about the product quality in the manufacture of sterile medicinal products. Both European and American GMP regulations place special focus on this topic.

The USP 1116 and especially the FDA's "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice" deal in detail with environmental monitoring.

However, many of the requirements laid down in these documents seem to be excessive for everyday practice on the one hand and leave great scope for interpretation on the other hand.

In practice, environmental monitoring programmes sometimes develop into time-consuming, cost- and personnel-intensive measures. Therefore, it is the aim of this course to provide the participants with pragmatic recommendations for the creation and implementation of environmental monitoring programmes.

Within the framework of this course, the participants are confronted with current hot topics, like:

- Alert / action levels
- Relationship to batch release
- Locations and frequency
- Identification of isolates
- Sampling procedures

and get to know solutions for their own company practice.

Target Group

This Education Course is directed at staff from Production, Quality Assurance and Quality Control who is responsible for the planning and implementation of environmental monitoring programmes.

Moderator

Colin Booth

Social Event

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Programme

Environmental Monitoring.

Why do we do it – what does it tell us

Colin Booth

Relevant Guidelines

- EU-GMP Guide Annex 1
 - USP <1116>
 - FDA Aseptic Processing Guide
 - ISO 14644 and ISO13824
 - An overview about the most important guidances
- We are confronted with a wealth of environmental monitoring guidelines, which means that we are sometimes faced with conflicting specifications and classifications. Which one(s) should I follow? The objective of this session is to review the key points of the guidelines and to apply a common sense approach to their application to your facility and processes.*

Dr Björn Wiese

Non-viable (particulate) Air Monitoring

- The grading of areas for manufacture of sterile medicinal products in the EU
- How to claim classification of areas to current standards
- How to ensure continuing compliance with the classification
- Selection of sampling locations for qualification and routine
- Particle monitoring, how and how often
- Handling the data

This session addresses non-viable (particulate) monitoring in the context of the manufacture of sterile medicinal products. It highlights the current regulations and standards in Europe and the USA, explains why these requirements have been put in place, and describes how to comply with them.

Dr Björn Wiese

Viable Air Monitoring

- Regulatory Standards
- Settle Plates
 - Validation
 - Drying Issues
 - Where to place them?
- Active Air Sampling
 - Equipment options / comparison
 - Validation
 - Where to place them?

Viable air monitoring gives a snapshot in time of the microbiological status of a clean room. Current debates centre on the value of settle plates vs. active air monitoring. In this presentation we will evaluate both types in detail and establish when best and how to use them as part of your environmental monitoring programme.

Colin Booth



Workshop

How to Establish an Environmental Monitoring Programme

- Identifying weaknesses in contamination control systems
- Identifying locations which will provide “early warning” signals of loss of control
- Preparing useful environmental monitoring SOPs
- Keeping manageable records

Most personnel in the pharmaceutical industry inherit environmental monitoring programmes from the past and rarely get the opportunity to establish a programme for the regulatory requirements and first principles. This session gives participants hands-on experience of working with the regulations and standards versus simplified but “real-life” situations. It is intended to encourage participants to leave with a new outlook on what is being done in their own facilities with a view to improving compliance and adding value.

Colin Booth

Surface / Personnel Monitoring

- Surface:
 - How?
 - Surface sampling techniques
 - Limitations
 - Validation?
- Personnel:
 - When and how?
 - Results and specifications
 - How to deal with shedders/pathogen carriers.

Surface sampling techniques give a qualitative indication of surface cleanliness, their limitations should be understood before the results can be meaningfully interpreted. The question of validating recovery has often been raised but it is a question of trying to validate the impossible. Personnel are without doubt the major source of contamination in a clean room environment and are therefore the major hazard to aseptic process. Personnel monitoring is obviously of value in assessing contamination risks. The questions in personnel monitoring are basically when and how? There is the potential that the monitoring interventions do more harm than good and the results generated are valueless for risk assessment purposes but are very useful for pressurising QA personnel. The intention in this session is how to achieve results of real value from your surface and personnel monitoring programme.

Christopher Randell

Case Study:

Trending of Environmental Monitoring Data

- What is a trend?
- How can I use electronic systems to track and trend EM data?
- How to get meaningful information from trending
- Alert and action level setting
- Using trending as tool for pro-active environmental control measures

This case study will focus on the benefits you can achieve by effective trending of EM data. It will demonstrate the importance of getting the complete picture. Actual examples will show how you can succeed in identifying the root cause of microbiological contaminations.

Dr Björn Wiese

Microbiological Methods

- Microbiological media, growth requirements
- Identification of isolates
- Validating your methods
- Using rapid identification techniques
- Recovery problems
- Identification to the level of DNA, what value does it bring

Taking microbiological environmental samples is just the first step in your monitoring programme, you now have to grow, isolate and identify the microorganisms that you have collected. This session deals with all the aspects of this process and how to get reliable, consistent results.

Colin Booth



Clean Rooms – RABS – Isolator: Points to consider in Environmental Monitoring

- Comparison of the technical concepts
- Validation of microbiological media for the isolator
- Selection of sampling points
- Transfer of microbiological media
- Interpretation of the results and handling of excursions

The requirements on the manufacture of sterile products increase. RABS (Restricted Access Barrier Systems) and isolators represent the state of the art. Which consequences arise for environmental monitoring?

Björn Wiese

Environmental Monitoring for Non-Steriles

- Why monitor non-sterile areas
- Risk vs impact
- Overview of regulatory position
- Case study

In this session we will discuss the reasons behind environmental monitoring in a non-sterile area. Is it worth doing? Should you do this? Cover potential benefits against the cost, discuss regulatory view-point, and provide a case study.

Christopher Randell

Deviation Management for Environmental Monitoring

- Steps to be taken in case of excursions
- When is an excursion a deviation?
- Comprehensive root cause analysis
- The nasty "re-occurrence"
- Finding of appropriate actions

FDA and other inspectorates frequently observe deficiencies in deviation handling of Environmental and Utility Monitoring. It is crucial to have a well documented, comprehensive process. Finding a clear root cause for microbiological excursions is often not easy and effective measures against re-occurrence are also difficult to define. This session will discuss tools, concepts and examples for compliant deviation management.

Dr Björn Wiese

Workshop

Interpretation of OOS Results

- What is an OOS in environmental monitoring?
- OOS in relation to trends
- How to investigate
- Follow-up and corrective actions
- Consequences for batch release

Real life case studies are used to get an insight in how to investigate and handle OOS results in environmental monitoring. After an introduction on the principles, participants have to develop an investigation plan, define corrective actions on the presented cases, and assess the product impact. The workshop is very practical and requires the active participation of the participants.

Christopher Randell

Investigations / Documentation

- The information content of "variables" data versus quantitative limits
- Published and practical limits
- The information content of qualitative data
- Communicating with technical management and higher management

The final session of the programme addresses the translation of data from environmental monitoring into information which may be of practical use, add value to the company's operations and ensure compliance.

Colin Booth

Speakers

Colin Booth, Oxoid, UK



Colin was the manager of Pharmaceutical Microbiology for Glaxo Wellcome Research and Development based in the UK where he was responsible for all the microbiology associated with the development of all Glaxo Wellcome new products. In 2002 he joined Oxoid Limited where he is now Vice President Science and Technology. He is a member of PDA, a group dedicated to building interfaces with regulatory colleagues across Europe.

Dr Björn Wiese, Zimmer GmbH, Winterthur, Switzerland



From 1996 to 2000 Björn Wiese worked as project manager in R&D of Danisco Ingredients, Niebüll, Germany, and developed start up cultures. Since November 2000, he had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany. From 2005 - 2010 Björn worked at the pharmaceutical production site of Cilag in Schaffhausen, Switzerland. 2011 he joined Zimmer GmbH as Associate Director Sterilisation Technology and Analytical Testing.

Christopher Randell, De La Rue plc, UK



Chris has been working in the pharmaceutical and medical device industry for over 24 years, he has vast experience in both sterile and non-sterile pharmaceutical manufacturing environments as a microbiologist and as a quality assurance manager at Wyeth/Pfizer. Currently he is QC Laboratory Manager for De La Rue plc.

Conference Exhibition

The European Compliance Academy offers you the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490,-.

You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link „Conferences“ on the homepage.

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+49 (0)62 21 / 84 44 41, or by e-mail at
mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation

etc.: Ms Marion Weidemaier (Organisation Manager) at
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weidemaier@concept-heidelberg.de

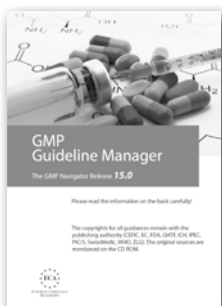
What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

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During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

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This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

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- ECA Sterile Production Manager
- ECA Biotech Manager
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On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

Easy Registration



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e-mail:
info@concept-heidelberg.de



Internet:
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+ 49 6221 84 44 34

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☐ Risk Management in Sterile Manufacturing, 13-14 May 2014, Copenhagen, Denmark

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number Purchase Order No. if applicable

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Venue

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