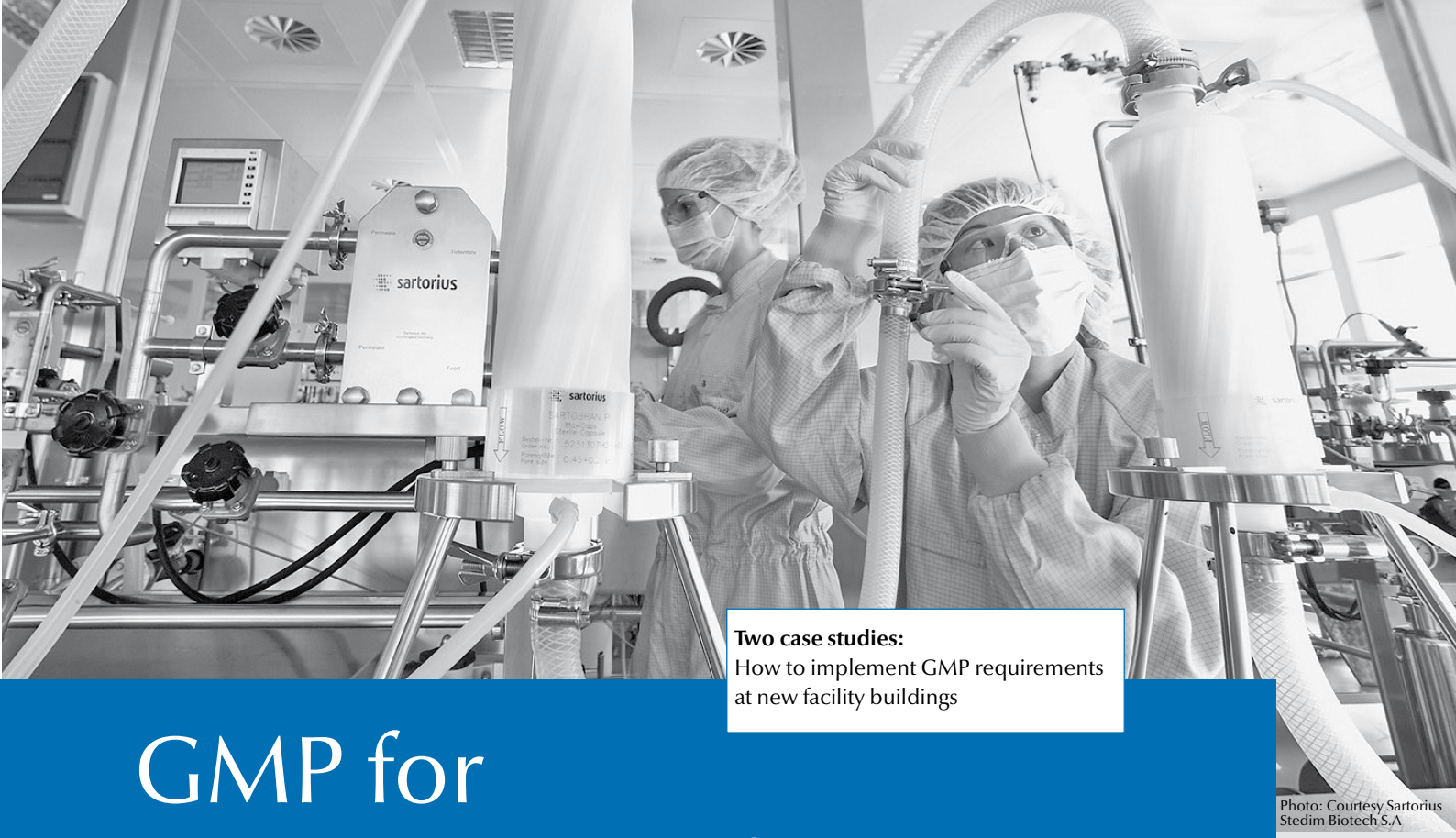


Two case studies:
How to implement GMP requirements at new facility buildings

Photo: Courtesy Sartorius Stedim Biotech S.A

GMP for Vaccine Manufacturers

Current Regulatory Requirements and Practical Implementation

25 – 27 April 2012, Berlin, Germany

SPEAKERS:

Dr Robert Eskes
Novartis Vaccines, Germany

Dr Heidi Mayer
Paul Ehrlich Institut, Germany

Dr Andreas Neubert
IDT Biologika, Germany

Dr Volker Öppling
Paul Ehrlich Institut, Germany

Dr Sjoerd Rijpkema
NIBSC, United Kingdom

Jolande Schoemaker
Schoemaker Consultancy, The Netherlands

Robert Schwarz
Baxter AG, Austria

Dr Jörg Weyermann
Novartis Vaccines, Germany

HIGHLIGHTS:

- Case Study: New building of a multipurpose vaccine production facility
- Case Study: New filling facility in direct cooperation with an existing bulk production
- Product and staff safety
- GMP issues for upstream and downstream processing
- Case study „Validation of a dry fog system for room disinfection“

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Biotech Manager“. Please find details at www.gmp-certification.eu

GMP for Vaccine Manufacturers

25 – 27 April 2012, Berlin, Germany

Objectives

The development and production of vaccines makes high demands on the manufacturing pharmaceutical industry. The special requirements on handling and safety with live organisms necessitate measures which exceed the requirements of classic pharmaceutical manufacturing.
Topics like, the enhanced risk of cross-contaminations, questions about individual safety of staff and the issues of cleaning and disinfection of rooms and equipment concern a vaccine manufacturer in a considerable scale. Specifically the demands of the necessary bio safety classes with negative pressure of rooms versus that of aseptic processing with positive pressure requires a well thought out design of vaccine facilities.
Also the safety of the environment and the waste disposal should be receiving proper attention already in the design phase. But the dedicated requirements on staff safety are although a challenge in vaccine manufacturing
This Course should give you the possibility to see the theoretical background as well as the practical implementation of GMP requirements in the vaccine production. A combination of theoretical requirements and practical case studies is the best way to learn this.
Speakers from regulatory bodies, consulting and practising experts will give you the chance to get to know the different views and participants will have ample opportunity to discuss with speakers and other participants about specific issues.

Background

"Vaccines are expected to be very safe" is one of the headlines in the presentation of the CBER "Vaccine safety team". At the same time, new vaccines are needed for diseases for which currently no vaccine is available, and production technologies need improvement to deal with the shortage of certain types of vaccines. This has led to the emergence of new technologies. One of the important questions from the authorities however is "How safe are the new technologies". The FDA has issued a draft guideline on new cell substrates for vaccine manufacturing to detail requirements in this area.

In the development of new technologies for the pharmaceutical and biopharmaceutical production of vaccines again the question of GMP compliance and safety is emphasised.

Furthermore, with the Quality Initiative for the 21st Century from the FDA new guidelines have been issued, which have an impact not just on the conventional pharmaceutical industry but also on vaccine manufacturers. Risk management and quality in design are essential in the implementation of new technologies and the introduction of new vaccines. Ensuring the expected safety is one of the greatest challenges of all vaccine producers.

Target Audience

The course is designed for personnel of pharmaceutical industries, their suppliers and regulatory bodies who

- are responsible for quality control and/or quality assurance in vaccine/biopharmaceutical production
- manage the vaccine production
- establish the operator protection
- audit vaccine manufacturers
- design or operate vaccine production sites

Moderator

Axel H Schroeder, Concept Heidelberg

Programme

GMP for Vaccines: What are the Issues?

- Differences between vaccines and conventional products
- Inactivated and live vaccines
- Control of vaccine strains and cell lines
- Risk of (cross-)contamination
- (Bio)safety issues

Jolande Schoemaker, Schoemaker Consultancy

The Peculiarities of Bacterial Vaccines

- Types of vaccines available
- Manufacturing of classical/modern bacteria
- Vaccine challenges in manufacturing (quality/regulatory issues) new products

Volker Öppling, Paul Ehrlich Institut

The Peculiarities of Viral Vaccines

- From viral seeds to finished products
- Requirements for raw and starting materials
- Efficient process and product control
- Setting specifications adequately
- Appropriate tests and assays for product release
- Stability testing
- Viral safety aspects
- TSE compliance
- How to deal with OOS results?
- Requirements for early and late clinical trial phases

Heidi Mayer, Paul Ehrlich Institut

Containment, Biological Safety and Product Protection

- Containment, product safety versus environmental safety
- Primary containment and additional measures
- Negative pressure areas in aseptic manufacturing
- Decontamination of facilities
- Personnel as critical component in containment

Jolande Schoemaker, Schoemaker Consultancy

Case Study: New Building of a Multipurpose Vaccine Production Facility

- Practical issues with flow of material, personnel and waste material
- Clean room qualification
- Segregation of cell preparation, virus production and downstream processing
- Change over procedures for manufacturing campaigns

Andreas Neubert, IDT Biologika

Case Study: Decontamination of Rooms

- Different gassing systems
- Qualification of a dry fog system
- Validation of a dry fog detergent

Robert Schwarz, Baxter AG

Issues of Staff Safety

- Requirements and Guidelines
- Differences Vaccines Products and Plasma Products
- Use of S3 Coveralls
- Environmental Health and Safety challenges
- Examples from Daily Business

Axel H. Schroeder, Concept Heidelberg

Decontamination, Virus Inactivation and Virus Removal Techniques

- Decontamination of surfaces
- Validation of decontamination procedures
- Virus inactivation: principles and methods
- Virus removal methods
- GMP issues on virus inactivation and virus removal techniques

Robert Eskes, Novartis Vaccines and Diagnostics

cGMP Issues for Upstream Processing

- General GMP concerns for upstream processing
- Raw materials and media preparation
- Cell culture
- Virus culture
- Inactivation of microorganisms

Jörg Weyermann, Novartis Vaccines and Diagnostics

GMP Manufacturing of Recombinant Viral Vaccines for Clinical Trials

- Regulatory expectations for vaccine batches for phase 1/2/3 clinical trials
- Development vs. validation
- Regulatory expectations for the implementation of analytical methods – qualification and validation
- Contract manufacturing of IMPDs

Andreas Neubert, IDT Biologika

cGMP Issues for Downstream Processing

- General GMP concerns for downstream processing
- (Ultra)filtration techniques
- (Ultra)centrifugation techniques
- Sterile filtration and aseptic processing

Jörg Weyermann, Novartis Vaccines and Diagnostics

Cell Banks and Virus Seeds

- Principles of cell banks and virus seeds
- Risks of primary isolates
- Regulatory requirements, FDA and EMEA guidances
- Manufacturing and storage
- How to test and control cell lines and virus seeds

Jolande Schoemaker, Schoemaker Consultancy

Biological Assays

- Design of an in vivo potency assay for a bacterial vaccine
  - Role of biological standards
  - Statistical analysis
- Can in vitro assays act as replacements for in vivo potency assays (3Rs)?
- Use global expression analysis (the theomics technology) to identifying relevant biological markers
- Safety assays

Sjoerd Rijpkema, NIBSC

Case Study: Planning and Realization of a new filling facility in direct cooperation with existing bulk production

- Requirements of design
- Issues of construction
- Qualification challenges

Andreas Neubert, IDT

Social Event

On 25 April, 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 Robert Eskes,
Novartis Vaccines and Diagnostics GmbH, Marburg, Germany
Robert Eskes is Quality Assurance head for Rabies and FSME bulk production at Novartis Vaccines and Diagnostics GmbH. Until September 2011 he was in Manufacturing Science and technologies leading the manufacturing support and tech transfer of Rabies and FSME also at Novartis Vaccines and Diagnostics GmbH. Before that he was Validation manager at CSL-Behring GmbH.

Dr Heidi Mayer,
Paul-Ehrlich-Institut, Germany
Heidi Meyer is a biologist and holds a Ph.D. in virology. After her university career she worked from 1993 to 2002 in the virology laboratories of IMMUNO AG/Baxter AG, Vienna, Austria on various aspects of the development, preclinical testing and production of cell culture derived viral vaccines as well as on virus safety aspects. In 2002 she joined the Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines of Germany. In her current position she is responsible for all regulatory and scientific issues related to vaccine authorisation and official batch release. Since 2002 she acts as an expert for human vaccines, biologicals and biotechnological products to EMA and is frequently involved as WHO temporary advisor for the prequalification of vaccines.

Dr Andreas Neubert,
IDT Biologika, Germany
Andreas Neubert completed his study of veterinary medicine with graduation. He has been working for several years in different positions at IDT and is currently head of production there.

Dr Volker Öppling,
Paul Ehrlich Institut, Germany
After studying Veterinary Medicine and a PhD on characterisation of a protective antigen of the virus causing infectious bursitis disease in chicken, he was appointed specialist of Veterinary Microbiology in 1993.1990-2007 Scientist in section responsible for human bacterial (especially polysaccharide-based) and fungal vaccines in the department "Human Bacterial Vaccines" at the Paul-Ehrlich-Institut. Main responsibilities for: assessment of marketing authorisation applications (quality, pre-clinic and clinic), batch release, assessment of clinical trial applications, provision of regulatory and scientific advise, managing of regulatory affairs issues. Nomination for head of section in 1998. 2007 Nomination for head of section "Microbiological Vaccines" (all bacterial, fungal and parasitic vaccines). Main responsibilities for: assessment of marketing authorisation applications (quality, pre-clinic and clinic), batch release, assessment of clinical trial applications, provision of regulatory and scientific advise, managing of regulatory affairs issues.

Dr Sjoerd Rijpkema,
NIBSC, United Kingdom
Dr Sjoerd RIJPKEMA, obtained an MSc in Microbiology and Immunology from the University of Nijmegen (The Netherlands). From 1985 to 1997, he was employed at the National Institute of Public Health and the Environment (RIVM), where he used models to study the protective mechanism of experimental cholera vaccines and he developed various assays to diagnose Lyme borreliosis and to study the transmission of the disease's agent Borrelia burgdorferi sensu lato. He obtained his PhD at the Faculty of Veterinary Science, University of Utrecht in 1995. In 1997, he was appointed as study director for anthrax, typhoid and cholera vaccines at the National Institute for Biological Standards and Control (United Kingdom). Initially, he studied the pathogenesis of Helicobacter pylori and developed models to study experimental Helicobacter vaccines. Since 2002 his research has focussed on assay development and the role of anthrax toxins in disease and immunity. He produced three international standard preparations for the WHO.

Jolande Schoemaker,
Schoemaker Consultancy, The Netherlands
Jolande is currently located in The Netherlands and works as a consultant to the pharmaceutical industry. Previous to her current role she was the Director Quality Affairs at Crucell. Jolande gained a wide field of experience in many aspects of the pharmaceutical and biotechnology industry, including formulation of drugs, manufacturing of sterile pharmaceutical products, hospital care and clinical trials, regulatory affairs, quality control and quality assurance. Furthermore, she was involved in many regulatory inspections, including some conducted by the US FDA, the Canadian and the British Inspectorate.

Robert Schwarz,
Baxter AG, Austria
After his apprenticeship as medical/technical analyst Robert Schwarz joined at IMCL / Labor Hernals, Vienna. From 2001 to 2005 he was employed as the coordinator of environmental monitoring at Baxter, Vienna. Since 2005 he is their validation specialist for equipment qualification. He is responsible for the validation of the room disinfection systems.

Dr Jörg Weyermann,
Novartis Vaccines and Diagnostics GmbH, Germany
Jörg Weyermann is head Head Quality Assurance at Novartis Vaccines and Diagnostics GmbH. Until 2009 he was the Head Quality Operations for Sandoz Industrial Products GmbH. Before that he was Head Quality Control at Sandoz.

About CONCEPT HEIDELBERG

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.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.
The ECA will provide 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.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

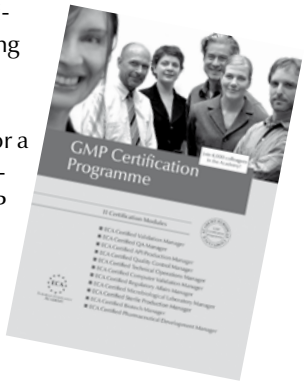
How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **www.gmp-compliance.org.**

GMP Certification Programme

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

- ECA Validation Manager
- ECA QA Manager
- ECA API Production Manager
- ECA Quality Control Manager
- ECA Technical Operations Manager
- ECA Computer Validation Manager
- ECA Regulatory Affairs Manager
- ECA Microbiological Laboratory Manager
- ECA Sterile Production Manager
- ECA Biotech Manager
- ECA Pharmaceutical Development Manager

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.



Lufthansa is Mobility Partner for all ECA Events

Lufthansa
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As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

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

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

GMP for Vaccine Manufacturers
25 – 27 April 2012, 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: 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

Wednesday, 25 April 2012, 09.30 h – 17.30 h lectures
(Registration and coffee 09.00 h – 9.30 h)
Thursday, 26 April 2012, 09.00 h – 17.30 h lectures
Friday, 27 April 2012, 09.00 h – 13.00 h lectures

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Tel 030 2127 0
Fax 030 2127 117

Fees

ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on the first day 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 for your room reservation or be sure to mention "ECA" to receive the specially negotiated rate (single room € 125,- per night, incl. brekfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 24 March 2012. 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 and Contact

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