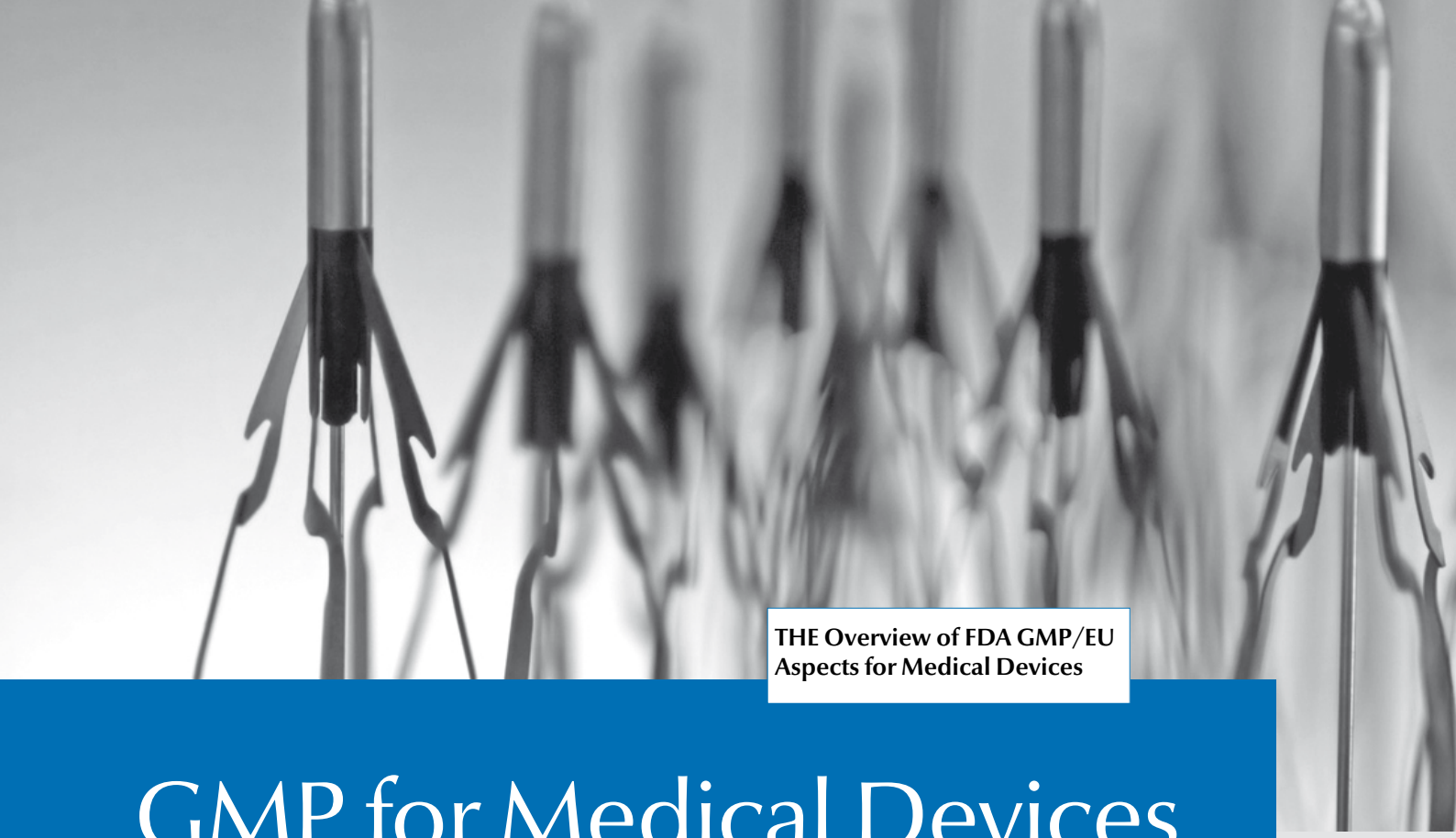

THE Overview of FDA GMP/EU Aspects for Medical Devices

GMP for Medical Devices

EU versus USA

18-19 September 2012, Heidelberg, Germany

SPEAKERS:

Dr Gerhard Bauer
Chemgineering Business Design GmbH

Harald Rentschler
mdc, medical devices certification GmbH

Dr Heinrich Prinz
Apceth GmbH & Co. KG

HIGHLIGHTS:

- Regulatory Requirements
- Certification Procedures
- Technical Documentation
- Design Controls
- Validation /Qualification
- Regulatory Audits
- CAPA and Complaint Handling

Two add-ons for free:
- FDA Medical Device Warning Letter Navigator on CD-ROM
- Validation of Processes for Production and Service Provision (including Software) - Essential Requirements

ECA
EUROPEAN COMPLIANCE ACADEMY

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

GMP for Medical Devices

18-19 September 2012, Heidelberg, Germany

Objectives

The aim of the course is to identify similarities and differences between the regulations of the FDA and the European regulations for Medical Devices. The focus will be on

- Certification Procedures
- Technical Documentation vs Device History File and Device Master Record
- Design Controls
- Validation / Qualification
- Regulatory Audits
- CAPA and Complaint Handling

A Notified Bodies representative will start the course by explaining the regulatory requirements.

In the further presentations particular attention will be paid to findings made during FDA inspections.

3 Parallel workshops – concentrating on technical documentation, preparing a FDA inspection and audit findings – will provide practical orientation.

Background

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 represent the state-of-the-art in the area of 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 5 deviations.

Target Audience

This event has been especially designed for the manufacturers who are subject to the **medical device legislation** and want to become familiar with the **practice-oriented implementation** of the legal requirements in the USA and in Europe.

Programme

Regulatory Requirements
- European Directives
- FDA
- Standards
- Notified Bodies

Differences between EU and FDA Requirements
- European Requirements
- FDA Requirements
- Differences and common interests

CE and ISO Certification
- Requirements of the EC/EU Directives
- Use of Standards
- ISO 13485 as a basic norm
- Implementing a system
- Certification Procedures

Technical Documentation vs. DHF/DMR
- Content of Technical Documentation
- Technical Documentation as a linking document between production and quality control
- Change Management – Retests
- Content of the DHF
- Relation to the DMR
- Link to Technical Documentation
- Audit and inspection findings

Design Controls
- Introduction of regulatory requirements
- Common aspects/differences regarding the requirements of the ISO 13485 and 21 CFR 820
- How to implement Design Controls in the whole life cycle process
- Modern concepts of development of products
- Audit and inspection findings

Qualification and Validation
- Regulatory requirements (FDA, Standards, GHTF)
- Risk assessments
- Qualification
- Validation
- Audit and inspection findings

Audits
- Preparing for an Audit
- Performance of an Audit
- Nuts and bolts of an Audit
- The Audit report

CAPA/Complaint Handling
- Regulatory requirements (EU, FDA, Standards, GHTF)
- Common aspects/differences regarding the requirements of the ISO 13485 and 21 CFR 820
- CAPA – the motor for continuous improvement
- Monitoring as a subsystem
- Interface complaint handling /CAPA System
- Audit and inspection findings

3 Parallel Workshops

- Documentation
  - How to structure a technical documentation
- FDA Inspection
  - How to prepare an FDA inspection
- Audit findings
  - Assessment of audit findings – how to react?

Speakers

Dr Gerhard Bauer
Chemgineering Business Design GmbH
Dr Bauer has more than 20 years of professional experience in the Life Science Industry. He has experience as project manager, Head of Controlling, Head of Procurement, external and internal consulting (GMP Compliance), Audits of pharmaceuticals, medical devices, and API manufacturers in the EU, Asia, and the US. Since 2004 he is Head of the Business Unit Consulting of the Chemgineering Group.

Harald Rentschler
mdc medical device certification GmbH
Mr Rentschler is a Biomedical Engineer and since more than 17 years performing conformity assessment activities for medical devices. He is General Manager of mdc medical device certification GmbH, a Notified Body with broad experience in the field of medical devices and in-vitro diagnostic devices. Mr. Rentschler is a member of national and international working groups in the field of medical devices and quality system certification.

Dr Heinrich Prinz
Apceth GmbH & Co. KG, Germany
Dr Prinz worked with Boehringer Mannheim before he joined Biotest where he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division. Since 2003 he works as a freelance consultant and part of his time he is the Senior Supervisor 'Production and Quality Assurance' at Apceth, a biotech company.

Moderator

Dr Heinrich Prinz, Apceth GmbH & Co. KG

Social Event

On 18 September 2012, 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.

Two add-ons for free

FDA Medical Device Warning Letter Navigator on CD-ROM
All participants will receive the Medical Device Warning Letter Navigator. This CD contains:

- The Medical Device-associated FDA and GHTF Guidelines in full text
- EU Medical Device Directives and MedDev Documents
- A user interface that offers a full-text search
- All Medical Device associated FDA Warning Letters of the last 8 years.

You will also receive the document **„Validation of Processes for Production and Service Provision (including Software) - Essential Requirements"** developed by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) – English translation. This 8 page document aims at reaching a common understanding of validation of processes, including validation of software among notified bodies, manufacturers and the competent authorities, and at defining uniform requirements on the validation of processes to be met by the manufacturers and on the auditing of these processes by notified bodies or certification authorities.


ZLG

Essential Requirements 3.9 B 18

Validation of Processes for Production and Service Provision (including Software)

1 Introduction

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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)

GMP for Medical Devices, 18-19 September 2012, Heidelberg, Germany

Please choose two workshops:
☐ Workshop 1 Technical Documentation
☐ Workshop 2 Audit findings
☐ Workshop 3 Preparing an FDA audit

☐ 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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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)! (As of January 2012)

Date

Tuesday, 18 September 2012, 10.00 – 18.00 h
(Registration and coffee 09.30 – 10.00 h)
Wednesday, 19 September 2012, 08.30 – 16.30 h

Venue

Crowne Plaza Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone +49 (0)6221 – 9170
Fax +49 (0)6221 – 21 00 7

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
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.

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 € 139,- per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 20 August 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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Phone ++49-62 21/84 44-0
Fax ++49-62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Mr Sven Pommeranz (Operations Director) at +49-62 21/84 44 47, or per e-mail at pommeranz@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

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