ECA Certified Validation Manager Course*

**NEW:** Optional Internet-based examination "Certified Medical Devices Validation Manager"

# Medical Devices Validation Manager

## EU and FDA Aspects

18 - 19 January 2012, Heidelberg, Germany

SPEAKERS:

Martin Loch
*Boehringer Ingelheim microParts GmbH*

Dr Thomas Manz
*Qiagen GmbH*

Dr Heinrich Prinz
*Apceth GmbH & Co. KG*

HIGHLIGHTS:

Workshops about

- Validation Master Plan
- Qualification
- Validation

All participants will receive a practical example of a **validation protocol** as well as the **Medical Device Warning Letter Navigator on CD**

ECA
EUROPEAN COMPLIANCE ACADEMY

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

# Medical Devices Validation Manager

18 - 19 January 2012, Heidelberg, Germany

## Objectives

It is the aim of this ECA course to show how the regulatory requirements concerning activities in the medical device industry can be implemented in a practice-oriented way.

Three parallel workshops on the topics validation master plan, qualification and validation protocol form the core of this event. The outcome of these workshops are sample documents, which you can adapt to your needs and use in your company. Each parallel workshop is held twice, so that you have the opportunity to take part in two of them.

Already during the presentations, practical examples help to specifically demonstrate the implementation with regard to equipment qualification and process validation.

In addition, an introductory lecture explains the qualification and validation requirements of the relevant regulations. Moreover, the topics risk management and computer validation are covered in a separate presentation.

## Background

According to EU law, a functioning QM system is a prerequisite for placing medical devices on the market. In the USA, the cGMP rules for medical devices are in force (Quality System Regulations, 21 CFR 820).
Usually, the basis for a QM system can consist in certification under EN ISO 9001, alternatively it is also possible to choose EN ISO 13485.

The European guideline requires a reproducible process to ensure the manufacture of a quality product for the market. Together with the two standards mentioned above, there is the need to have a QA system on site to show that a qualification and a validation system is in place. Currently, the **notified bodies** insist increasingly on the implementation of these requirements. In the USA, the validation of medical devices has been a standard since the 80s. The Quality System Regulations also dedicate a paragraph of its own, 21 CFR 820.75, to this subject. Finally, validation ranks 3rd in the FDA warning letters statistics for fiscal year 2010. State of the art is also the GHTF Process Validation Guideline.

## Target Group

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

## Programme

### Validation/Qualification/Calibration in Directives, Guidelines, Laws and Standards

- Validation aspects in EN ISO 9001 and 13485
- 21 CFR 820.75
- Harmonised standards regarding validation and qualification
- GHTF guideline on process validation

### Risk Management as Basis for Qualification and Validation

- Requirements of the EN ISO 14971
- Helpful points regarding ICH Q9
- Practical examples
- Proposals for a risk matrix

### Qualification of Equipment which is used for the Manufacture and Testing of Medical Devices

- What has to be qualified?
- DQ, IQ, OQ, PQ
- Differences to Design Validation
- Qualification protocol and plan
- How to handle qualification deviations
- Case study

### Process Validation

- What has to be validated?
- Risk-based validation requirements
- Validation protocol and plan
- How to handle validation deviations
- Case study

### Computer Validation in the Medical Device Field

- Regulatory background
- Life Cycle approach in Computer Validation
- V-Modell according GAMP (with examples)
- GMP-compliant operation of computerised systems
- 21 CFR Part 11 requirements and how to deal with
- Validation documentation

## 3 Parallel Workshops

- **Organisation of Validation**
  - Implementation of validation activities in an existing quality management handbook
  - How to write a Validation Master Plan
- **Qualification of Equipment which is Used for the Production of Medical Devices**
  - Writing qualification protocols
- **Process Validation**
  - Writing a process validation protocol in comparison with a practical example

**Please choose two workshops on the registration form.**

## Speakers

### Martin Loch

*Boehringer Ingelheim microParts GmbH, Germany*

Martin Loch studied mechanical engineering with an emphasis on precision engineering at the University of Applied Sciences Gießen-Friedberg. From 1992 till 1999 he worked as an engineer in product development and quality management in the ophthalmic optics industry. In 1999 he started to work for Boehringer Ingelheim microParts GmbH as validation engineer and project leader for several process validation and software validation projects. Since 2005 he is the head of the quality assurance unit of Boehringer Ingelheim microParts GmbH.

### Dr Thomas Manz

*Qiagen GmbH, Germany*

Dr Manz studied Organic and Polymer Chemistry at University Duesseldorf, Germany. He did his Ph.D. in chemistry in the area of development of polymer based HPLC materials for chiral separation of Enantiomers. After that Mr. Manz joined a small start up Biotech Company and worked in Research & Development as well as Manufacturing and Quality Control. In 1995 Mr Manz joined QIAGEN GmbH and helds the position of Vice President Global Quality Assurance. He is responsible for seven manufacturing sites in the USA, Europe and Asia, and he is Head of a Global Total Quality System according to EN ISO 9001 and ISO 13485 as well as according to 21 CFR 820 and Japanese MHLW Ministerial Ordinance No 169. He is member of the Quality Systems workgroup of the German Diagnostics Manufacturer Association (VDGH).

### 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

## 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
- EC Medical Device-Directives and MedDevDocuments
- A user interface that offers a full-text search
- All Medical Device associated FDA Warning Letters of the last 8 years.

## Internet Examination - "Certified Medical Devices Validation Manager"

Participants who attended the course have the possibility to take an Internet-based examination to become a „Certified Medical Devices Validation Manager ". Please find more information about the examination and the registration at www.gmp-compliance.org, button "Certification Programme". Or you call Mr S. Pommeranz: +49 (0)6221 - 84 44 47

## Social Event

On 18 January 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.

## Special offer with Lufthansa - up to 20% discounted travel for all ECA Events Attendees

Lufthansa Mobility Partner

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:

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Medical Devices Validation Manager, 18 - 19 January 2012, Heidelberg, Germany

Please choose two workshops:
☐ Organisation of Validation
☐ Qualification of equipment which is used for the production of medical devices
☐ Process Validation
☐ I would like to take the Internet Examination after the course (€ 190 plus VAT).

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

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

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

**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, 18 January 2012, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Thursday, 19 January 2012, 08.30 – 13.00 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 € 1,290.- per delegate plus VAT
APIC Members € 1,390.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,490.- per delegate plus VAT
EU GMP Inspectorates € 745.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner and lunch 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 (€ 139,- per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 20 December 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 and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
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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