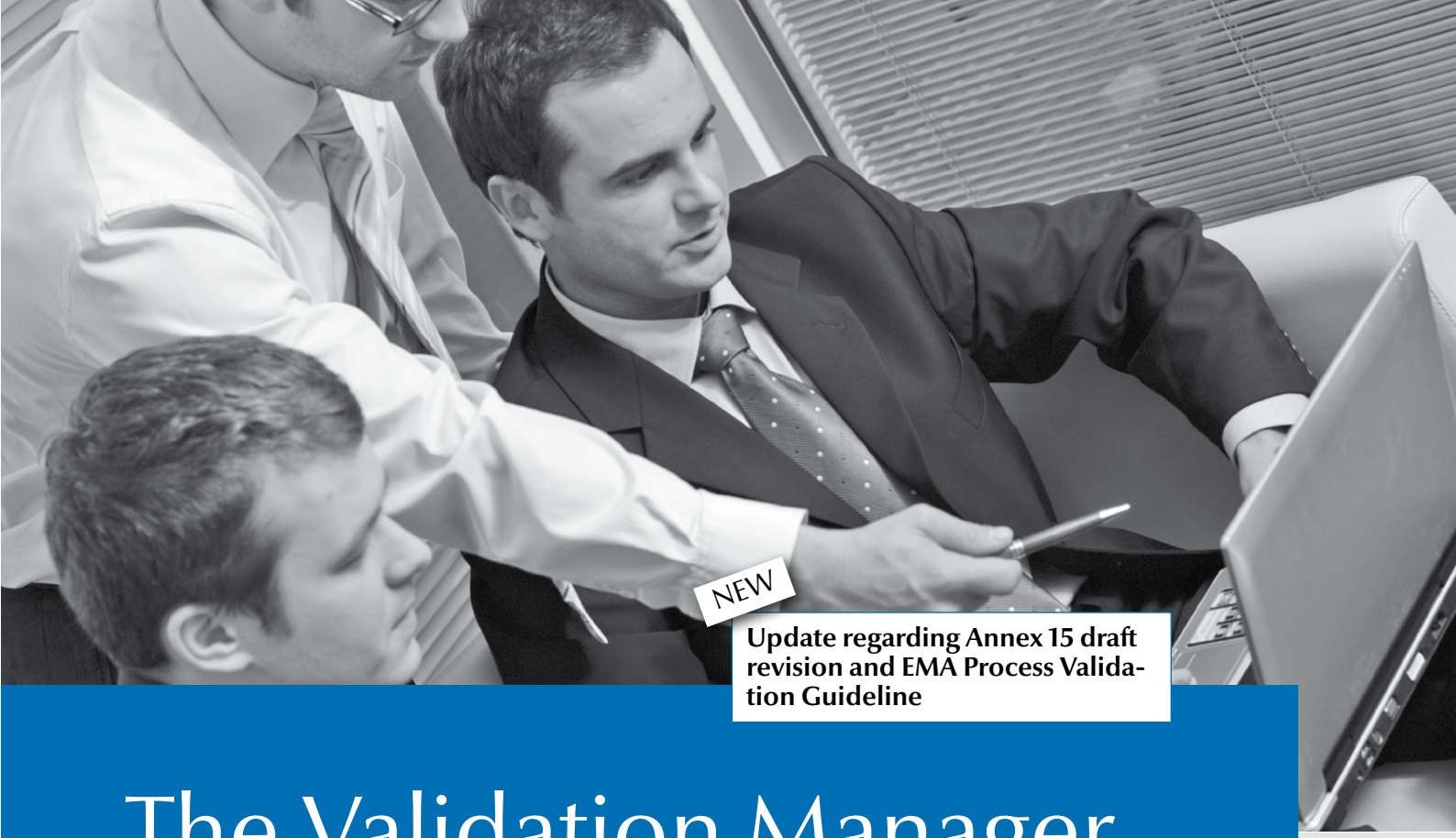

NEW

Update regarding Annex 15 draft revision and EMA Process Validation Guideline

The Validation Manager

Overview of the cGMP requirements on the whole range of validation/qualification

5 - 7 November 2014, Barcelona, Spain

SPEAKERS:

Lynn Bryan
Ballygan Consulting, UK

Dr Norbert Skuballa
Biologische Arzneimittel Heel, Germany

Dr Wolfgang Schumacher
Hoffmann-La Roche, Switzerland

All participants receive
„GMP Inspectors Guide Validation/ Qualification Aide Memoire"
and practical examples on CD ROM

PROGRAMME:

- Regulatory Requirements
- Risk Assessment
- Validation Master Plan
- Qualification
- Validation
- Computer Validation
- Cleaning Validation
- Qualification/Validation in API Manufacturing
- Change Control
- Case Study Qualification
- Case Study Validation

ECA ACADEMY

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

The Validation Manager

5 - 7 November 2014, Barcelona, Spain

Learning Objectives

For years, the topic validation/qualification has been among the top deviations in FDA's warning letter statistics. This is true both of pharmaceutical manufacturers and of the API industry. Other frequent citations refer to the related topics cleaning validation and change control. What is also checked during inspections – and mentioned in warning letters – is computer validation. In order to give you an overview of the cGMP requirements and an **update regarding the new draft of Annex 15** on the whole range of validation / qualification, we have designed the practice-oriented 3-day GMP Education Course "Validation Manager" for you. In many pharmaceutical and API enterprises, the Validation Manager has become an established function.

One focus will be on the **new FDA Guidance on Process Validation**. What are differences, what are similarities to European validation guidelines?

Parallel workshops on risk analysis and detailed case studies on qualification and validation help to consolidate the theory and demonstrate the practical implementation.

Target Audience

The addressees of the event are qualified staff charged with or responsible for validation activities such as commissioners for validation, heads of quality assurance, department heads, etc. It also addresses members of validation teams (e.g. engineers, chemists, pharmacists, microbiologists) as well as representatives of the plant engineering industry and consultants.
Note: The number of participants is limited to 40 persons.

Social Event

The European Compliance Academy cordially invites the conference participants to join them and the speakers for a social event on Wednesday evening. During an informal dinner you will have the opportunity to meet and discuss the hot topics of the day with your colleagues.

NEW

The participants receive the "GMP Inspectors Guide Validation/Qualification Aide Memoire"

Validation/Qualification Aide Memoire (GMP Inspectors Guide) developed by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) – English translation. This 52 page document covers the whole spectrum of validation and qualification (including Cleaning Validation, Validation of Analytical Procedures and Change Control). The Aide Memoire is really helpful as a tool to prepare for an Authority's GMP Inspection.

Programme

Overview

Regulatory Requirements on Qualification / Validation Aspects - From history to PAT

- EU GMP guideline and annexes
- Revision of Annex 15 – what is new?
- PIC/S guidelines
- Systematics of plant qualification and process validation
- New approaches to validation
- The new FDA Draft Guidance on Process Validation

Industrial View

Risk Assessment

- Why is risk assessment necessary?
- ICH Q9
- Risk assessment techniques
- Case study

Validation Master Plan

- Target
- Format
- Content
- Differences between PIC/S and Annex 15
- New requirements regarding Annex 15 revision
- Validation Master Plan and Lost Guide

Qualification

- Why do we do this - history
- Update Draft Annex 15 requirements
- DQ, IQ, OQ, PQ – how the stages of validation fit together
- How to handle qualification logistics?
- Re-qualification
- Qualification of equipment in use

Case Study Qualification

The case study describes how a purified water system can be qualified according cGMP.

Case Study Validation

The case study describes a process validation study of a tabletting process.

Validation

- The validation life cycle
- Prospective vs concurrent validation
- Is retrospective validation still allowed ?
- Are 3 runs still valid ?
- What does Hybrid Approach mean?
- Revalidation vs. Continued Process Verification and Ongoing Process Verification
- Pitfalls

Computer Validation
- Organisation of computer validation
- Classification (GAMP® 5)
- Risk analysis
- Change control
- Legacy systems

Cleaning Validation
- Validation protocol
- Risk assessment
- Sampling
- Which limits are acceptable?
- The new PDE approach in Annex 15 revision
- Case study

Qualification/Validation in the Field of API Manufacturing
- Guidelines focused on qualification/validation aspects for API production
- GMP requirements for qualification/validation in the field of API manufacturing
  - Differences to drug manufacturing
  - Retrospective qualification
  - Revalidation
  - Pitfalls

Change Management
- Technical change management
- Regulatory change management
- Change management documentation
- Update Draft Annex 15 requirements

Workshops: We offer four parallel workshops.
You can take part in one of the workshops.

Workshop 1: Organisation of Validation
An interactive workshop to find out and discuss how validation activities can be implemented in an existing QM System and how to write a Validation Master Plan

Workshop 2: Risk Assessment Qualification
In the workshop you look at risk assessment associated with qualification activities in a typical production environment. You will assess a new filling line as per the ISPE baseline guide to create an impact assessment plan. This plan will then be translated into requirements for validation and the resultant tests associated with the validation steps of DQ through to OQ.

Workshop 3: Risk Assessment Process Validation
An interactive workshop to find out and discuss GMP-relevant aspects of the validation of tabletting.

Workshop 4: Risk Assessment Cleaning Validation
An interactive workshop to find out and discuss GMP-relevant aspects of the validation of cleaning with the focus on calculating of acceptance criteria.

Speakers

Lynn Bryan
BSc. (University of Liverpool), P.G.C.E (University of Reading)
Lynn has had Qualified Person status within the industry for 10 years and has her own QA/Validation consultancy business. Previously Lynn was the Quality Manager at a radiopharmaceutical manufacturer, the Technical Manager at a veterinary manufacturer and a validation manager at a pharmaceutical company manufacturing blood products and vaccines in sterile liquid and freeze dried form. Lynn also worked as the production support manager responsible for calibration, validation and new product introduction at a contract aerosol manufacturing company. The company produced MDI's, DPI's, pump spray and aerosol products to the US and Europe. Lynn has been presenting on training courses on validation, training approach, GMP and water/steam systems for over 15 years.

Dr Norbert Skuballa
Biologische Arzneimittel Heel, Germany
Norbert Skuballa is head of the Pharmaceutical Compliance Management function at Heel and responsible for development and coordination of all compliance related GxP and regulatory affairs processes. He has been working in the pharmaceutical industry since 1991, mainly for Schering (now Bayer Pharmaceuticals) in Research, Production and Quality Management.

Dr Wolfgang Schumacher
Hoffmann-La Roche, Switzerland
Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he is in the Quality Unit of information technology, the quality assurance of global applications and the qualification of the IT infrastructure. He is a member of the ECA Advisory Board.

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)

+ 49 6221 84 44 34

The Validation Manager, 5 - 7 November 2014, Barcelona, Spain

Please choose **ONE** workshop:

- ☐ Workshop 1: Organisation of Validation
- ☐ Workshop 2: Risk Assessment Qualification
- ☐ Workshop 3: Risk Assessment Process Validation (Tabletting)
- ☐ Workshop 4: Cleaning Validation (Please bring a calculator)

☐ 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)

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)! (As of January 2012)

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

Date

Wednesday, 5 November 2014, 09.30 h - 18.00 h
(Registration and coffee 09.00-09.30 h)
Thursday, 6 November 2014, 8.30 h - 17.30 h
Friday, 7 November 2014, 8.30 h - 13.15 h

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 (93) 503 53 00
Fax +34 (93) 490 60 45

Fees

ECA Members: € 1,790,- per delegate + VAT.
APIC Members € 1,890.- per delegate plus VAT
Non-ECA Members: € 1,990,- per delegate + VAT.
EU GMP Inspectorates € 995,- per delegate + VAT.
Including: Conference documentation, lunch and social event on the first day, lunch on the second day, all refreshments.

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 to receive the specially negotiated room rate for the duration of your stay. Reservation should be made directly with the hotel. 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:
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.:
Ms Nicole Bach (Organisation Manager) at
+49-622 1/ 84 44 22, or per e-mail at
bach@concept-heidelberg.de.

wa/vers1/03122014