



SPEAKERS

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MODERATOR

RICHARD M. BONNER Chairman ECA

Annex 15 Conference

What could come with the revision of Annex 15?

19-20 November 2014, Berlin, Germany

HIGHLIGHTS:

- Annex 15 draft: What's new? What's really new?
- New requirements regarding organisation and planning for qualification and validation
- Validation documentation what comes?
- Qualification: Does the 7 step-qualification come?
- EU Process Validation parallels and differences with FDA Guidance
- Cleaning validation in the new Annex 15 draft - how to implement the PDE concept?



Annex 15 Conference

19-20 November 2014, Berlin, Germany

Objectives

The draft revision of Annex 15 was published in February 2014. After a short comment period the final revision document should be adopted by the EU in October 2014 The conference will give an overview about the new aspects of the draft regarding:

- Organisation and Planning for Qualification and Validation
- Validation Documentation
- Oualification
- Process Validation
- Cleaning Validation

An EU GMP inspector gives an overview about the new requirements from his point of view. Also the differences to the FDA Process Validation Guidance will be discussed. A tutorial workshop will end up the conference.

Background

Since 2001 the Annex 15 has been state of the art for Validation Master Plan, Qualification, Validation, Cleaning Validation and Change Control within the EU. In the meantime ICH Q 8-11 has been published. The FDA has implemented most of these ICH guidelines and introduced a Validation Process Life Cycle in its Process Validation Guidance from 2011. The EMA has published a revision of its Note for Guidance on Process Validation to implement this new aspects too. This is also the reason why the Annex 15 has to be revised. The first thoughts have been provided in a concept paper. Now the draft is available and shows the new direction.

Target Audience

Everyone who may be influenced by the Annex 15 revision.

Moderator

Richard M. Bonner, Chairman ECA

Programme

Overview of the new Annex 15 draft view of an EU GMP-inspector

- History of validation guidelines in the EU
- The Annex 15 revision
- The EMA Process Validation revision
- What's really new?

Organisation and Planning for Qualification and Validation

- Integration of outsourced data in a validation
- What is an "appropriate validation oversight"?
- New requirements in the Validation Master Plan
- Requirements regarding the qualification of suppliers
- Requirements regarding Risk Management

Validation Documentation

- Good Documentation Practice what does that mean for validation?
- How to support knowledge management
- Content of validation protocols and reports
- Conditional approvals a challenge

Qualification - Annex 15 draft vs FDA Process Validation Guidance

- The new first step(s) URS/FDS
- How to use FAT and SAT?
- Combinations of qualification stages IOQ/OPQ
- Interface PQ/Process Validation
- Is the requirement to qualify utilities really new?
- How to handle the qualification of established equipment (in-use) in the future?
- What's about alternatives (ASTM E 2500)?
- Are there differences to the FDA Process Validation Guidance?

Process Validation in the new Annex 15 draft - in the light of modern life cycle thinking

- The Process Validation Life Cycle
- Modern vs. traditional approach
- What is a hybrid approach?
- How is bracketing possible?
- Are the three magic runs still applicable?
- Clarification of the terms continuous process verification, continued process verification, ongoing process verification
- Is the Annex 15 draft in line with the FDA Process Validation Guidance?

Cleaning validation in the new Annex 15 draft - how to implement the PDE concept?

- Grouping of equipment a new possibility?
- How to validate manual cleaning operations`
- The new acceptance criteria: PDE how to implement?
- Choice of worst case products taking account of toxicity PDE values and solubility
- How to determine the cleaning validation batches?
- Cleaning verification what's that?

Speakers



KLAUS EICHMÜLLER, Regional Council Darmstadt, GMP Inspectorate, Germany After working in the pharmaceutical industry Klaus Eichmüller joined the District Government of Upper Bavaria in Munich. Since 1996 he is working in the field of GMP Inspections of manufacturer of medicinal products and importers. He was Deputy Head of the Central Authority for Supervision of Medicinal Products in Bavaria as long as it existed and is now Head of the Inspectorate for Drug

Products, APIs, Blood Products and Tissues in Hesse since March 2014



GERT MOELGAARD, NNE Pharmaplan, Denmark

Gert Moelgaard is Vice President for Strategic Development in NNE Pharmaplan. He has been working in the pharmaceutical industry for more than 25 years and has experience from a number of major projects within pharmaceutical manufacturing, automation systems and validation projects. He has made international contributions in international conferences on automation, process

validation, PAT and manufacturing excellence and has contributed to several courses, books and technical guidelines, including FDA's internal training course for investigators on process validation.



PETER MUNGENAST, Merck KGaA, Germany

He studied Biology and Chemistry at the University in Karlsruhe. Then he worked in different functions for Merck KGaA. Since 1996 in the Quality Assurance department responsible for cleaning validation, training and different projects.



DR THOMAS SCHNEPPE, Bayer Pharma AG, Germany

More than 20 years experience in the pharmaceutical industry. Since 2006 Bayer Pharma; Head of Mgmt. Training at Bayer Health Care - Product Supply - Compliance - Integrated Quality Mgmt.



DR INGRID WALTHER, Pharma Consulting Walther, 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 sub-

sequent 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.

Social Event



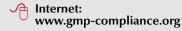
On 19 November 2014, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration









Date

Wednesday, 19 November 2014, 10.00 - 18.15 h (Registration and coffee 09.30 - 10.00 h) Thursday, 20 November 2014, 08.30 - 12.00 h

Steigenberger Hotel Berlin Los-Angeles-Platz 1 10789 Berlin, Germany Phone +49 (0)30 212 7 - 0 +49 (0)30 212 7-117 Fax

Fees (per delegate plus VAT)

ECA Members: € 1,390 APIC Members: € 1,490 EU GMP Inspectorates: € 795 Non-ECA Members: € 1,590

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all days and all refreshments.

VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation to receive the specially negotiated 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 and Contact

CONCEPT HEIDELBERG P.O. Box 10 17 64 D-69007 Heidelberg, Germany Phone +49 (0) 62 21/84 44-0 Fax +49 (0) 62 21/84 44 34 E-mail: 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.:

Susanne Ludwig (Organisation Manager) at +49-62 21/84 44 44, or per e-mail at ludwig@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:	Reservation Form (Please complete in full)	♣ +49 6221 84 44 34
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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 %

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