ECA
ACADEMY

SPEAKERS

KLAUS EICHMÜLLER
Regional Council Darmstadt, Germany

GERT MOELGAARD
NNE Pharmaplan, Denmark

PETER MUNGENAST
Merck KGaA, Germany

DR THOMAS SCHNEPPE
Bayer AG, Germany

DR INGRID WALTHER
Pharma Consulting Walther, Germany

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?

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

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
- Qualification
- 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 subsequent 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

Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

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

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.

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Annex 15 Conference
19-20 November 2014, Berlin, Germany

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