A pre-conference session to the
19th APIC/CEFIC European Conference
on Active Pharmaceutical Ingredients

APIC Active Pharmaceutical Ingredients Committee

ECA ACADEMY

Speakers

Anthoney Storey
Pfizer, United Kingdom

Francois Vandeweyer
Janssen Pharmaceutica, Belgium

The ICH Q7 Questions & Answers Document

– an Update on GMP for APIs

22 November 2016,
Barcelona, Spain

Highlights

- Key aspects of the ICH Q7 Q&A document in the context of the principles laid down in the Guide-lines ICH Q8 – ICH Q11

At this session APIC will launch an ICH Q7 Q&A How to do document

All participants will receive a copy

Objectives

This pre-Conference Session provides an interpretation of the GMP principles for the manufacture of APIs against the backdrop of the ICH Q7 Questions and Answers Document.

You will get to know:

- Which aspects of ICH Q7 have to be re-considered
- What are the practical consequences of the ICH Q7 Q&A document
- What has to be taken into account when preparing for a GMP inspection

Furthermore you will have the opportunity to reach clarification on ambiguous issues by bringing your questions concerning ICH Q7 up for discussion.

Create your own Workshop:
You will be asked to choose 5 Questions/Answers out of the Q&A document you would like to be discussed during the workshop session.
For this purpose you will receive a questionnaire after having registered for this pre-Conference Session.

Those Questions/Answers of the Q&A Document chosen by the participants as being of main interest will be discussed during the afternoon workshop session.

This pre-conference session ideally complements the following 19th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients.

Background

Since its successful implementation in the regulatory framework by most authorities around the world experience has been gained with the ICH Q7 Guideline on „Good Manufacturing Practice for Active Pharmaceutical Ingredients". Meanwhile it turned out that ambiguities related to the interpretation of some sections in ICH Q7 may lead to misconceptions. Furthermore, the principles outlined in the ICH Guidelines Q8 – Q11, in particular the life cycle approach and some technical issues related to API manufacturing procedures, need also to be considered in order to achieve a comprehensive implementation of GMP for APIs.

The ICH Q7 Questions & Answers Document which reached Step 4 of the ICH process in June 2015 intends to remove these ambiguities and to contribute as well to harmonization of GMP inspections of both small molecules and biotech APIs.

APIC has developed an **ICH Q7 Q&A How to document** based on the official ICH Q7 Q&As. This document intends to support industry with the implementation of the ICH Q7 principles. The comments elaborated by APIC referring to each question/answer of the ICH Q7 Q&A document provide a detailed interpretation of the requirements of the ICH Q7 Q&As.

Target Audience

This pre-conference session is designed for all persons involved in the manufacture of APIs especially for persons from production, quality control, quality assurance, technical and regulatory affairs departments. We are also addressing interested parties from the pharmaceutical industry and GMP inspectorates.

Programme

The ICH Q7 Questions and Answers Document – an overview

- Intention of the Q&A Document
- Content
- Some highlights from the Q&A Document
- Advantages to Industry of the Q&A document

APIC „ICH Q7 How to do" Document
10.2 Distribution procedures
… For intercontinental API shipments a system should be in place to assure packaging and supply chain integrity. If needed, special controls should be in place to assure shipments meet the defined requirements. …

Interpretation of the ICH Q7 Guide: APIC's „How to do Document"
- Information on APIC
- Purpose of the "How to do" Document
- Content and highlights
- Interrelationship to the ICH Q7 Q&A document

APIC „ICH Q7 How to do" Document
12.1 Validation Policy
…A risk assessment should be performed to map out critical parameter attributes prior to validation. (for example ICH Q8 and Q11) These parameters need careful consideration as they will form the basis for assessing the system to be validated. …

Worked examples from the ICH Q7 Q & A Document

Workshop

Important Questions/Answers out of the ICH Q7 Q&A Document
- The Q&As of main interest chosen by the participants of the pre-Conference Session will be discussed –

APIC „ICH Q7 How to do" Document
15 Complaints and Recalls
…The API manufacturer should have a procedure describing the process and responsibilities re-lated to recalls/product (API) traceability, and should be able to document that batches can be traced and reconciled. Key personnel involved should be identified. Likewise, the responsibility for notifying customers and local authorities, if applicable, should be addressed. …

Speakers

Anthony Storey, Pfizer, United Kingdom
Tony Storey is currently located in Sandwich, UK. Tony is responsible for quality management of contract manufacturers. Prior to this Tony worked as an API QA manager at a Pfizer site with overall quality responsibility of the API plants at the facility. Tony is currently vice president of APIC (Active Pharmaceutical Ingredients Committee) and was previously chair of the APIC Quality Working Group.

Francois Vandeweyer, Janssen Pharmaceutica, Belgium
Graduated in 1979 as Bachelor in Chemistry. He joined Janssen Pharmaceutica (part of Johnson & Johnson) in 1981 in chemical development. Until 1995 increasing responsibilities within the organisation mainly in the Quality Control Unit (Manager QC Lab 1994). Starting from 1995 he joined the QA department. Several Senior Manager responsibilities (sGMP Auditor – Release – Quality Systems). 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMEA/AP for Johnson & Johnson.

Easy Registration

Reservation Form:
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P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.api-conference.org

Date
Tuesday, 22 November 2016, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)

Venue
Crowne Plaza
Barcelona – Fira Center
Av. Rius i Taulet, 1-3
E-08004 Barcelona
Phone: +34 93 426 22 23
Fax: +34 93 425 50 47

Fee
EUR 890.- per delegate plus VAT.

A special fee of 690,- Euro is granted to participants who also register for the 19th APIC/CEFIC European Conference on APIs.

The conference fee is payable in advance after receipt of invoice and includes lunch 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 link when you have registered for the event. Please use this link 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.api-conference.org.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted CONCEPT HEIDELBERG with the organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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For questions regarding content:
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For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at + 49 (0)6221/84 44 18, or at grimm@concept-heidelberg.de

Important Information!
You will receive a USB memo stick when you register in Barcelona.
Note: there will be **no print-outs** available during the conference.

If the bill-to-address deviates from the specification to the right, please fill out here:

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☐ **Pre-Conference Session "The ICH Q7 Questions & Answers Document – an Update on GMP for APIs"**
22 November 2016, Barcelona, Spain

☐ **I also register for the 19th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients**, 23-25 November 2016, Barcelona, Spain

I want to take part in
☐ **GMP Part** (23-24 November 2016)
☐ **Regulatory Affairs Part** (24-25 November 2016)
☐ **All three conference days** (23-25 November 2016)

Please choose 2 out of 6 parallel sessions (one choice in Session I and one in Session II)

Parallel Sessions I
☐ Session 1: Quality expectation of starting materials
☐ Session 2: GMP requirements on API facility design
☐ Session 3: Regulatory Hurdles and Opportunities

Parallel Sessions II
☐ Session 4: ICH Q3D - the role and responsibilities of API manufacturers
☐ Session 5: GDUFA practical experiences
☐ Session 6: Data integrity - Industry perspective

☐ Mr ☐ Ms Title _____

First name, surname

Company ☐ APIC Member ☐ ECA Member ☐ Inspectorate

Department

Important: 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 of Business
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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**

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