A pre-conference session to the 21st APIC/CEFIC European Conference on Active Pharmaceutical Ingredients

ECA Academy
Your GMP/GDP Information Source

Speakers

Alejandro Sureda Salvadó
Farmhispania, Spain

Francois Vandeweyer
Janssen Pharmaceutica, Belgium

Highlights

- Practical assistance on how current requirements of ICH Q7 can be met and interpreted in the context of the principles laid down in the Guidelines ICH Q8 – ICH Q11

ICH Q7 How to do

Hot Topics from the revised APIC guidance

23 October 2018
Budapest, Hungary

APIC 25 years of promoting patient safety
active pharmaceutical ingredients committee

Objectives

This pre-Conference Session provides an interpretation of the GMP principles for the manufacture of APIs based on APIC's revised ICH Q7 How to do 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.

This pre-conference session ideally complements the following 21st 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 revised its **ICH Q7 How to do document** which intends to support industry with the implementation of the ICH Q7 principles. The new **ICH Q7 Q&A** How to document which was developed quite recently as a stand alone document to provide a detailed interpretation of the requirements of the ICH Q7 Q&As is now integrated in the revised **ICH Q7 How to do** Guide.

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 and control, technical and regulatory affairs departments. We are also addressing interested parties from the pharmaceutical industry and GMP inspectorates.

Programme

- The revised ICH Q7 How to do Document – an overview
  - Intention of the Htd Document
  - Content
  - Some highlights from the Htd Document
  - Advantages to Industry of the Htd 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.

- The ICH Q7 Q&A How to do Document; key aspects and highlights

APIC „ICH Q7 Q&A How to do" Document
2 Quality Management
Does ICH Q7 expect that sampling be performed by the quality unit?
No. ICH Q7 does not prescribe specifically who should perform the sampling … However, the quality unit has responsibility for reviewing and approving sampling plans … and procedures. …

Delegated sampling responsibilities should be proceduralised and evaluated by the QU for example during an internal audit. [Interpretation by APIC]

- Worked examples from therevised ICH How to do Document and the ICH Q7 Q & A Document

- Workshop:
  Hot topics out of the revised ICH Q7 How to do Document and the ICH Q7 Q&A How to do Document

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 re-calls/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

Alejandro Sureda Salvadó, Farmhispania, Spain
Organic chemist with 18-years experience in the API manufacturing in different positions (Production, Analitycal Development Technician, Quality Control Manager and Quality Assurance Manager) in Farmhispania, S.A., Menadiona, Kern Pharma and Farmhispania Group. In his current position as Industrial Quality Manager and GMP Compliance Auditor he is responsible for Auditing of suppliers (Key Raw Materials, Registered Starting Materials, Intermediates, Contracted Services), GMP Training, Data Integrity upgrade, Validation and Qualification activities and supporting the Industrial Area (Production, Engineering, Maintenance, EHS) on CAPAs and Change Control.

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 increading 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:
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.api-conference.org

Date
Tuesday, 23 October 2018, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)

Venue
Corinthia Hotel Budapest
Erzsébet körút 43-49
Budapest H-1073
HUNGARY

Phone +36 1 479 4000
Fax +36 1 479 4333
E-mail budapest@corinthia.com

Fee
EUR 990.- per delegate plus VAT.

A special fee of 790,- Euro is granted to participants who also register for the 21st 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
Fax +49 (0) 62 21/84 44 34
E-mail info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Gerhard Becker (Operations Director) at
+49 (0) 6221/84 44 65, or at
becker@concept-heidelberg.de
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 Budapest.
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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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34
69007 Heidelberg
Germany

☐ **Pre-Conference Session "ICH Q7 How to do – Hot Topics from the revised APIC guidance",** 23 October 2018, Budapest, Hungary

☐ **I also register for the 21st APIC/CEFIC European Conference on Active Pharmaceutical Ingredients**, 24-26 October 2018, Budapest, Hungary

I want to take part in
☐ **GMP Part** (24-25 October 2018)
☐ **Regulatory Affairs Part** (25-26 October 2018)
☐ **All three conference days** (24-26 October 2018)

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

Parallel Sessions - Part I
☐ Session 1: APIC's experience with supporting documentation for API filings in Emerging Countries
☐ Session 2: Risk based use of audits in the life cycle approach of a regulatory starting material
☐ Session 3: Statistical approach to process validation

Parallel Sessions - Part II
☐ Session 4: ICH Q3D consequences for APIs
☐ Session 5: Drug substance control strategy
☐ Session 6: Fraud in the supply chains

☐ 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

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City Zip Code Country

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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.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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