ICH Q7 How to do - Document

Hot Topics from the revised APIC guidance

A pre-conference session of the 25th APIC/CEFIC Global GMP & Regulatory API Conference

25 October 2022
Amsterdam, The Netherlands
or live online

Send us your questions and real life scenarios/ challenges related to the ICH Q7 requirements!

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

APIC 30 YEARS ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE a sector group of cefic

In cooperation with ECA Academy Your GMP/GDP Information Source

Overview

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. During interactive sessions you will get to know

- Which aspects of ICH Q7 have to be re-considered
- What are the practical consequences of the ICH Q7 How to do 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 25th APIC/CEFIC Global GMP & Regulatory API Conference.

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.

Annually, APIC has revised its **ICH Q7 How to do document**, which intends to support industry with the implementation of the ICH Q7 principles. More than 12 chapters has been adjusted and updated in the last 4 years and provide answers to the questions raised by the API industry.

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 revised ICH Q7 How to do Document – an overview

- Intention of the How to do Document
- Content
- Some highlights from the How to do Document
- Advantages to Industry of the How to do Document

APIC's ICH Q7 How to do Document 10.2 Distribution procedures
… For 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 How to do Document – key aspects and highlights

- Understand specific changes in chapters like:
  - Material management
  - Brokers, traders and distributers
  - Production and in process controls
  - Storage and distribution
  - Contract Manufacturers and contract labs
- Benefit from APIC's Task Force members' experiences
- Good opportunity to discuss unclarities

APIC's ICH Q7 How to do Document
Chapter 17: Agents, Brokers, Traders, Distributors, Repackers and Relabellers
…Current expectation are that if the API or intermediate is re-packed or re-labelled the trader etc. should perform a documented risk assessment and determine which sections of Q7 are applicable to their activities. Section 13, Change Control and an appropriate Quality system are always applicable to all operators and their operations…

Real life cases and how to use the ICH Q7 How to do Document in implementing GMP compliant systems – Part I and II

- General insight on the use of the How to Do Document in implementing GMP requirements
- Examples of industry combined with best practices in last updated chapters
- Explain benefits of the use of the How to Do Document in real life cases

Take advantage of the **experiences** of our speakers and send us your questions and real life scenarios/challenges related to the ICH Q7 requirements prior to the pre-conference session. Your questions and examples are welcome and will be answered as comprehensively as possible by the experts during the Q&A sessions and exchange sessions.

The next revision of the ICH Q7 How to do Document – how to support

- Exchange "How to Do" hurdles and "learn" from attendees and APIC representatives
- Contribute in updating the next "How to Do" edition

Speakers

Francois Vandeweyer
VDWcGMP Consultancy, Belgium

Mr Vandeweyer 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. Starting from 1995 he joined the QA department. Several Senior Manager responsibilities. 2005 Sr Manager GMP Compliance Chemical Operations Belgium (sites Geel – Olen – Beerse). 2009 Director Global Compliance EMEA/AP for Johnson & Johnson. Since May 2019 he is a freelance consultant.

Alejandro Sureda Salvadó
Farmhispania Group, Spain

Organic chemist with more than 22-years experience in the API manufacturing in different positions (Production, Analytical 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 Deviation investigations, CAPAs and Change Control.

Important Information
The presentations will be made available to you prior to the pre-conference session as PDF files. After the event, you will automatically receive your certificate of participation.

Date pre-conference session
Tuesday, 25 October 2022, 09.30 - 17.45 h
(Registration and coffee 09.00 - 09.30 h – for taking part onsite in Amsterdam only)
All times mentioned are CEST.

Venue – for taking part onsite in Amsterdam only
Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11
1019 BR Amsterdam
The Netherlands
Phone: +31 (0) 20 519 1200
hotel.amsterdam@movenpick.com

Technical Requirements
We use Webex Events for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fee
EUR 990.- per delegate plus VAT.

A special fee of 890,- Euro is granted to participants who also register for the 25th APIC/CEFIC Global GMP & Regulatory API Conference.

The registration fee is payable in advance after receipt of invoice. VAT is reclaimable.

Accommodation – for taking part onsite in Amsterdam only
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. 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.
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Germany

☐ **ICH Q7 How to do – Hot Topics from the revised APIC Guidance,** 25 October 2022 in Amsterdam or live online

☐ **I also register for the 25th Global GMP & Regulatory API Conference,** 26-27 October 2022 in Amsterdam or live online

Please choose 5 out of 10 parallel sessions (one choice in Session A, B, C, D and one in Session E):
Parallel Session A
☐ Session 1: Risk based approach during supplier qualification and management
☐ Session 2: Practical experience with the Brazilian CADIFA
Parallel Session B
☐ Session 3: How to assure successful investigations and CAPA's
☐ Session 4: Information sharing between the API manufacturer and the Drug Product manufacturer
Parallel Session C
☐ Session 5: Regulatory hurdles and opportunities
☐ Session 6: Auditing manufacturers of regulatory starting materials
Parallel Session D
☐ Session 7: Latest developments in nitrosamines – what have we learnt from the EMA's call for review?
☐ Session 8: Challenges with API registration in China
Parallel Session E
☐ Session 9: ICH Q12 implementation in practice
☐ Session 10: Cloud Computing in the API industry

I will
☐ **participate on-site in Amsterdam.**
☐ **participate live online.**
☐ **decide later.**

☐ Mr ☐ Ms Title _____

First name, surname

Company o APIC Member o ECA Member o 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.
German law shall apply. Court of jurisdiction is Heidelberg.

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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