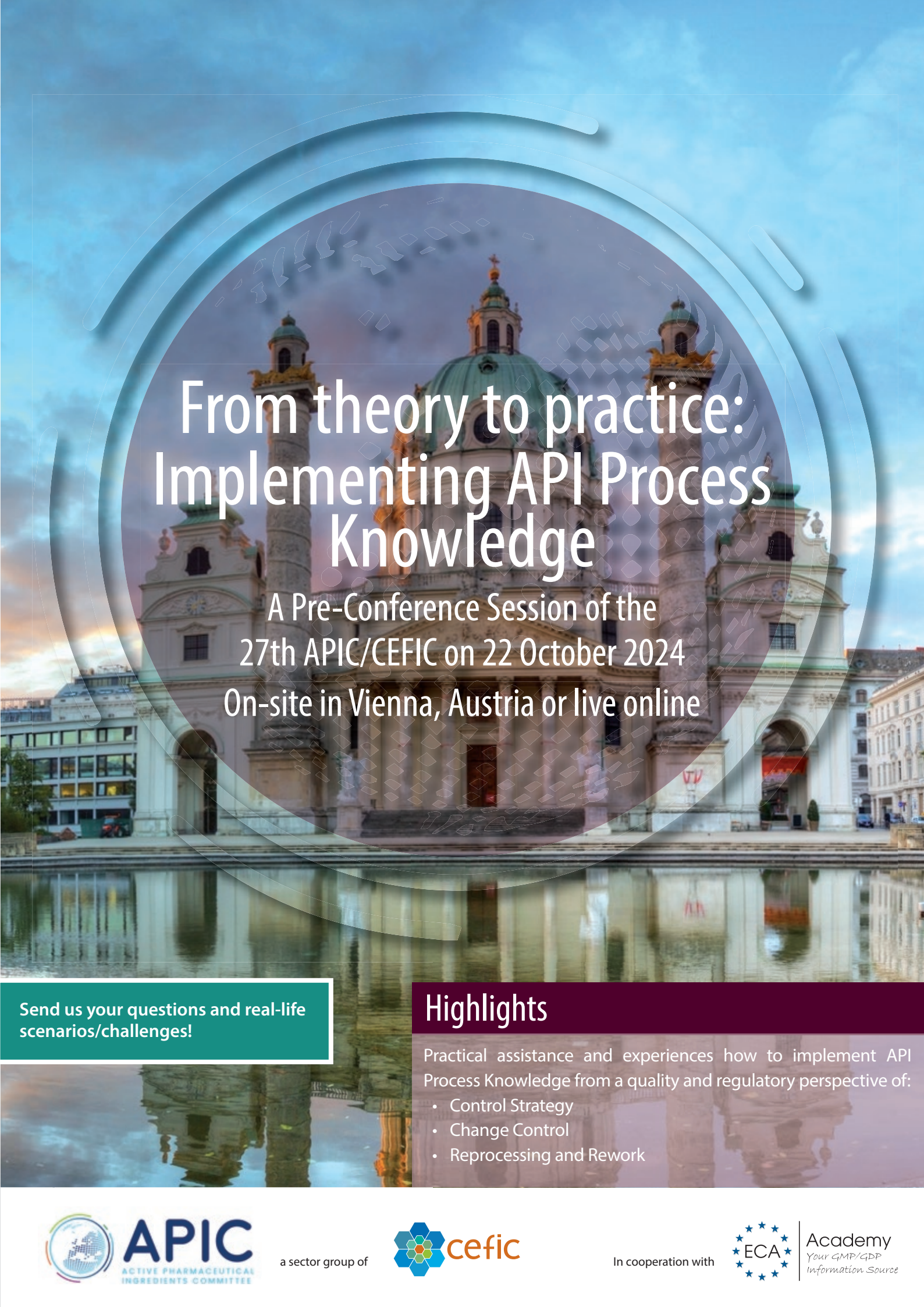

From theory to practice: Implementing API Process Knowledge

A Pre-Conference Session of the 27th APIC/CEFIC on 22 October 2024

On-site in Vienna, Austria or live online

Send us your questions and real-life scenarios/challenges!

Highlights

Practical assistance and experiences how to implement API Process Knowledge from a quality and regulatory perspective of:

- Control Strategy
- Change Control
- Reprocessing and Rework

APIC ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE

a sector group of cefic

In cooperation with ECA Academy Your GMP/GDP Information Source

Objectives

This Pre-Conference Session provides an overview of the regulatory and quality GMP requirements and approaches for implementing API Process Knowledge in the pharmaceutical industry. During interactive sessions you will get to know:

- Which GMP and regulatory aspects have to be considered for establishing an adequate Change Control Management?
- What do the guidelines tell us for reprocessing and reworking? And what are the practical consequences during the production of APIs?
- What has to be taken into account when implementing control strategies?

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

This Pre-Conference Session ideally complements the following 27th APIC/CEFIC Global GMP & Regulatory API Conference.

Background

The API world is changing rapidly. Nowadays, Process Knowledge is one of the most important topics in the API industry. Companies are struggling with the challenge how to implement and how to obtain Process Knowledge and ensure the quality of their products during their life cycles. On the one hand, for that matter the theoretical obligations need to be considered and well known, while on the other hand the practical implementation needs to be valuable and manageable in the daily API work.

Three hot topics out of the long list of options how to obtain and implement Process Knowledge in your company are selected and will be considered and explained during the Pre-Conference Session. Besides explaining the requirements of the guidelines of e.g. the ICH Q7 and ICH Q12 guideline for the respective themes, the speakers will share their approaches, experiences and best practices on these API related quality and regulatory topics.

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.

APIC Industry Best Practice documents

APIC developed a number of guidances on GMP and Regulatory Affairs, e.g. "Guidance on aspects of cleaning validation in active pharmaceutical ingredient plants" or "How to do – Interpretation of ICH Q7 document & « Review form »".

All APIC guidance documents are available for free download on the APIC/CEFIC website: https://apic.cefic.org/publications/

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.

Programme

Control Strategy from a Quality perspective

- Sound science & risk management all along the life cycle
- Quality trends
- Elements of a control strategy
- QRM as integral part of quality by design
- Areas of controls (hierarchy and practical examples)
- Impact on cost of quality

Control Strategy from a Regulatory perspective

- The control strategy in the regulatory files
- A complete story
- What to share with the customers

Take advantage of the experiences of our speakers and send us your questions and real-life scenarios/challenges 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.

Changes from a Quality perspective

- Different changes during product life cycle
- Scope and importance of a change control
- General change control requirements
- Detailed change control requirements for specific systems (i.e. materials, process, equipment, utilities, specs & methods) with practical examples
- Implementation requirements

Changes from a Regulatory perspective

- Change procedures in different regions
- Supply chain issues related to changes
- The impact of ICH Q12

Reprocessing and rework: options and obligations

- Definitions
- ICH Q7 section 14.2 and ICH Q7 Q&A section 14
- Q&A's on practical real-life examples

Speakers

Marieke van Dalen

MARA Consultancy, The Netherlands

Marieke van Dalen is a global API regulatory specialist leading her own small consultancy in the Netherlands. Marieke has 38 years of experience in the API industry, always in the regulatory field. Her latest position was with Aspen API in the Netherlands. She was for a long time a Board member of APIC (the European API organisation) and represented APIC often in meetings and symposia with health Authorities all around the world.

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.

Date Pre-Conference Session
Tuesday, 22 October 2024, 09.30 - 17.15 h
(Registration and coffee 09.00 - 09.30 h – for taking part onsite in Vienna only)

All times mentioned are CEST.

Venue – for taking part onsite in Vienna only
Austria Trend Parkhotel Schönbrunn
Hietzinger Hauptstr. 10-14
1130 Vienna, Austria
Phone: +43 (1) 878 04 0
parkhotel.schoenbrunn@austria-trend.at

Technical Requirements
We will stream the pre-conference and recommend using the latest version of Chrome, Firefox, Edge or Safari to participate. Technical instruction for the livestream will be provided shortly prior to the conference.

Fee
EUR 1090.- per delegate plus VAT.

A special fee of 990,- Euro is granted to participants who also register for the 27th 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 Vienna 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.
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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Ms Anne Günster (Operations Director) at
+49 (0) 6221/84 44 50, or at
guenster@concept-heidelberg.de

For questions regarding organisation etc.:
Ms Sarah Schmidt (Organisation Manager) at
+ 49 (0)6221/84 44 16, or at
s.schmidt@concept-heidelberg.de

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

☐ **From theory to practice: Implementing API Process Knowledge,** 22 October 2024 in Vienna or live online

☐ **I also register for the 27th Global GMP & Regulatory API Conference,** 23-24 October 2024 in Vienna 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: How does the EU pharmaceutical package impact the EU variation classification and
☐ procedural guidance's?
Session 2: Differences in the focus of inspections by non-EU authorities

Parallel Session B
☐ Session 3: Global DMF challenges
☐ Session 4: Prevention of (Cross-)Contamination in Non-Sterile API Manufacturing Processes

Parallel Session C
☐ Session 5: ICH M4Q(R2): designing the Common Technical Document for the future
☐ Session 6: New APIC Guidance on aspects of cleaning validation in API plants

Parallel Session D
☐ Session 7: Microbiological Quality Control of APIs
☐ Session 8: Recycled raw materials in API manufacturing process for a greater sustainability

Parallel Session E
☐ Session 9: API Registration in China: Recent Industry Experience
☐ Session 10: A new era in the assessment of Process-Equipment-Related Leachables (PERLs)

I will
☐ **participate on-site in Vienna.**
☐ **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 and conditions
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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG 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 HEIDELBERG 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. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.
Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

CF/RI/13032024