



GMP Webinar

Expiry Dating for Chemicals, Reagents, Solutions, and Solvents: Requirements and Practical Implementation

Date:

Wednesday, 29 April 2015, 14.00 – 15.30 h CEST

Speaker:

Dr Joachim Ermer

Head of QC Services Chemistry Frankfurt, Sanofi, Germany



ECA has entrusted
CONCEPT HEIDELBERG with the
organisation of this webinar.

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Expiry Dating for Chemicals, Reagents, Solutions, and Solvents

Background

According to cGMP regulations, analytical procedures must be designed to assure that pharmaceuticals conform to appropriate standards of identity, strength, quality, and purity (21 CFR 211.160). This includes that components of these procedures such as reagents, solvents, mobile phases, and standard solutions are sufficiently controlled to maintain the required quality for an accurate testing. Therefore, appropriate instructions for preparation and storage must be established, as well as an expiry date (EU GMP Guide Part 1 Chapter 6: Quality Control and FDA Q&As on Current Good Manufacturing Practices).

Educational Objectives

This webinar will provide recommendations how to establish expiry dates of reagents and solutions used in analytical procedures. Approaches range from literature-based information to specific stability studies, according to the risk of the respective component for the accuracy of the test procedure.

Practical aspects:

- What are the documentation and labelling requirements?
- Which approaches are suitable to establish an expiry date?
- How can a risk-evaluation be performed to justify an appropriate expiry date establishment?
- Practical examples for a scientifically sound stability evaluation of solutions used in quantification.

Target Audience

The webinar targets executives and staff in quality control laboratories and quality assurance, who want to get an overview on GMP requirements with respect to expiry dating of chemicals, reagents, solutions, and solvents, as well as their efficient practical implementation.

Speaker



Dr Joachim Ermer is Head of Quality Control Services Chemistry Frankfurt (Sanofi, Germany), and Global Reference Standards Coordinator of Sanofi. He studied biochemistry at University of Halle and has about 25 years' experience in pharmaceutical analytics including development products, global responsibilities as Director of Analytical Processes and Technology, and Head of Quality Control. He is member of the USP Expert Panel on Validation and Verification and of the EFPIA Quality by Design working group.

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Fees (plus VAT)

Single participation: € 149.- for ECA Members
Single participation: € 199.- for non-ECA Members (This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/eca_about.html.)

Group Participation (fee per person):

3-10 Persons € 169,15
11-20 Persons € 149,25
more than 20 Persons € 129,35

Technical Requirements

To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers.

Your Internet browser must have following features to use the GMP Webinar system:

1. Adobe Flash-Player must be installed.
2. Javascript must be allowed.
3. Port 1935 must be released.

Registration

By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Do you have any questions?

For questions regarding content:

Dr Günter Brendelberger, phone +49 62 21 - 84 44 40,
E-Mail: brendelberger@concept-heidelberg.de,

For questions regarding technical aspects:

Mr Matthias Zimmermann, phone +49 62 21 - 84 44 59,
zimmermann@concept-heidelberg.de.

**Registration for the GMP-Webinar:
Expiry Dating for Chemicals, Reagents, Solutions, and Solvents
on Wednesday, 29 April 2015, 14.00 – 15.30 h CEST
Speaker: Dr Joachim Ermer**

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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 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.

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