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## Speakers

Dr Raphael Bar
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# Stability Studies to Support Shipping/ Distribution of Pharmaceuticals and Biopharmaceuticals

Live Online Training on 08 September 2022


## Highlights

- Stability programs and storage statements
- Mean Kinetic Temperature and world climatic zones
- Stress studies of pharmaceuticals
- Studies at different temperatures and conditions
- Investigation of excursions from storage label conditions
- Evaluation of the impact of temperature excursion

- Optimised as Online Event
- With 3 Q&A Sessions

## Objective

This Live Online Training will give an overview of tools that a Qualified Person (QP), Quality Assurance personnel or a Product Manager/ Manufacturer should have in order to evaluate the impact of excursions from the storage label instructions on the disposition of distributed shipments of pharmaceutical/biopharmaceutical products.

## Background

The formal stability studies of pharmaceuticals and biopharmaceuticals are a well established discipline and they are regularly conducted at precisely monitored conditions of temperature (within 2 °C) and of humidity (within 5% RH) under cGMP. However, the inevitable processes of shipping and distributing medicines from the manufacturer to wholesaler to warehouses to the end user via air, ship or car exposes often the shipments to temperatures and humidity different from the label storage conditions. For instance, how would you handle a shipment that was exposed to a varying temperature up to 61°C in the airport for an accumulated duration of several days? How would you evaluate the quality of a refrigerated injectable that was exposed to near zero or freezing temperatures for a few hours? Would you release or reject such a shipment which may cost hundreds of thousands of dollars?

Shipping/Distribution of a medicine is considered a "mobile storage". However, a temperature excursion outside the label instructions may also be considered a 'trauma" inflicted on the medicine and this may impact the quality of the newly arrived shipments. But, the big question remains: how would that 'trauma" affect the quality at the end of the declared shelf life of any pharmaceutical and of a biopharmaceutical in particular? Will the long-term impact lead to a "hidden OOS"?
This Live Online Training will address these aspects.

## Target Audience

This Live Online Training will be of significant value to

- Qualified Persons
- Quality Assurance personnel
- Pharmacists
- Project coordinators/product managers
- Stability testing personnel
- Stability program logistics personnel
- R&D personnel involved in product development

## Moderator

Dr Markus Funk

## Programme

### Overview of Stability Programs and Storage Statements

- Stability studies and development phases
- Long-term and accelerated storage conditions of new drug substances and products (EU, USA)
- Stability storage programs for generic drugs (EU, USA)
- Specific storage statements (EU, WHO, USP)
- Labeling statements for various pharmaceuticals

§ *ICH Q1A(R2) - Stability Testing of new Drug Substances and Products:*
*"[...]Data from the accelerated storage condition and, if appropriate, from the intermediate storage condition can be used to evaluate the effect of short term excursions outside the label storage conditions (such as might occur during shipping). [...]"*

### Mean Kinetic Temperature (MKT) and World Climatic Zones

- Mean Kinetic Temperature (MKT) and relative humidity
- Interpretation of MKT
- MKT from temperature loggers

§ *USP <1079>- Good Storage and Distribution Practices for Drug Products:*
*"Mean Kinetic Temperature (MKT): The single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures."g shipping). [...]"*

### Q&A Session I

### Stress Studies of Pharmaceuticals

- Degradation reactions
- Stressing factors and conditions
- Stress studies in the pharmaceutical industry

§ *ICH Q5C - Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products:*
*"[...] Studies under stress conditions may be useful in determining whether accidental exposures to conditions other than those proposed (e.g., during transportation) are deleterious to the product and also for evaluating which specific test parameters may be the best indicators of product stability. Studies of the exposure of the drug substance or drug product to extreme conditions may help to reveal patterns of degradation; if so, such changes should be monitored under proposed storage conditions. [...]"*

## Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals

- Stress testing vs Forced Degradations
- Studies at elevated extreme temperatures
- Studies at low extreme conditions
- When, how and what?
- Thermal Cyclic studies
- What attributes to test

## Q&A Session II

## Investigation of Excursions from Storage Label Conditions

- "Time-out-of-Storage" and stability budget" concept
- Handling an excursion
- What stability data are required to investigate temperature excursions
- Responsibilities of manufacturer, distributor and QP

## Evaluation of the Impact of Temperature Excursions

- Estimation of the impact by the excursion temperature on the quality attribute
- Estimation of the quality attribute at the end of shelf-life/retest date

## Q&A Session III

Three Q&A sessions ensure interaction and that your questions are answered.

### Dr Raphael Bar
BR Consulting, Israel

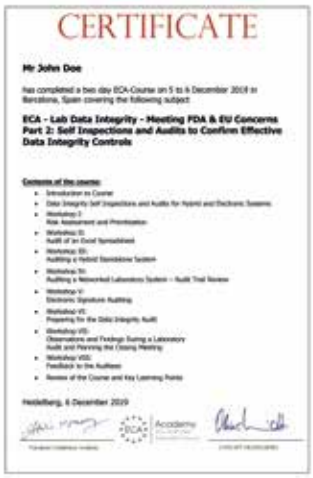
Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and the analytical QC laboratory at Pharmos. He served in the Scientific Advisory Board of global PDA (USA) and is presently a board member of Israel PDA Chapter as well as a member of the organizing committee of the Israel Society for Analytical Chemistry. For the lasts ten years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.

### Dr Thomas Fürst
Boehringer Ingelheim, Germany

Dr Fürst joined Schering in 1997 working in a production facility for oral dosage forms. In 2007 he joined Boehringer Ingelheim as a CMC expert. From 2013 – 2018 he was head of development of Consumer Healthcare at Boehringer (from 2017 SANOFI). Since 2018 Dr Fürst is again with Boehringer as head of laboratory of the development department.

## Your Benefit:
## Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.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# Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals
# Live Online Training on 08 September 2022

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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## Date of the Live Online Training
Thursday, 08 September 2022, 09.00 – 17.15 h CEST

## Technical Requirements
For our Live Online Training Courses and Webinars use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

## Fees (per delegate, plus VAT)
ECA Members EUR 790,-
APIC Members EUR 890,-
Non-ECA Members EUR 990,-
EU GMP Inspectorates EUR 495,-
The fee is payable in advance after receipt of invoice.

## Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

## Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

## Conference language
The official conference language will be English.

## Ordering Recordings
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## Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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