ECA Academy
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Speakers

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Stability Studies to Support Shipping/ Distribution of Pharmaceuticals and Biopharmaceuticals

Live Online Training on 17/18 June 2026

Highlights

- Stability Programs and Storage Statements
- Mean Kinetic Temperature (MKT) and World Climatic Zones
- Stress Studies of Pharmaceuticals
- Studies at different Temperatures and Conditions
- Investigation and Handling of Excursions from Storage Label Conditions
- Evaluation of the Impact of Temperature Excursion

NEW: Participants are invited to submit anonymized examples of shipping excursions in advance. Selected cases will be discussed during the seminar to address real-life situations.

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 training will address these aspects. In addition, the course also includes two case studies and a session with video presentations. Further, a set of Q&A sessions will follow the lectures. Thus, take advantage of this opportunity to pose your questions.

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

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)
- Labelling statements for various pharmaceuticals

Mean Kinetic Temperature (MKT) and World Climatic Zones/Uses and Misuses of MKT

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

§ *USP <1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products*
"Mean kinetic temperature (MKT) is a way to summarize the time history of a product's temperature exposure with a single "effective" or "virtual" temperature. It is defined as 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. [...]"

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

Cycling Studies: Case Study

Excursions During Shipping and Distributions

- "Time-out-of-Storage" and stability budget" concept
- Handling an excursion

Investigating Excursions During Shipping and Distributions

- What stability data are required to investigate temperature excursions
- Responsibilities of manufacturer, distributor and QP

Video Presentations

- Selected video examples
- Commentary and discussion by the speaker

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

Handling of Excursions: Case Studies – Including Real Cases Submitted by Participants

- Participants are invited to submit anonymized examples of real shipping excursions from their company in advance. Please send submissions to funk@concept-heidelberg.de
- Selected cases will be discussed during the final session to illustrate practical approaches to evaluating and handling temperature excursions.

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

Dr Raphael Bar
BR Consulting, Israel

Dr Bar headed the Analytical R&D Laboratory at Teva Pharmaceuticals and the QC Laboratory at Pharmos. He has been involved with the Pharma industry for the last 30 years. He served as a member of the Scientific Advisory Board of global PDA (USA). He is past president and now a member of the Israel PDA Chapter as well as a member of the organizing committee of Israel Society of Analytical Chemistry. For the last fifteen 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 has been head of laboratory of the development department at Boehringer.

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CERTIFICATE

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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Reservation Form (Please complete in full)

Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals
Live Online Training on 17/18 June 2026

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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If you cannot attend the conference you have two options:
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- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
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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.

Date of the Live Online Training
Wednesday, 17 June 2026 from 09.00 - 16.00 h
Thursday, 18 June 2026 from 09.00 - 16.00 h
All times mentioned are CEST.

Technical Requirements
We use Webex 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.

Fees (per delegate, plus VAT)
ECA Members EUR 1,890.-
APIC Members EUR 1,990.-
Non-ECA Members EUR 2,090.-
EU GMP Inspectorates EUR 1,045.-

The fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22564.

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.

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

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