ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Raphael Bar
BR Consulting, Israel

Dr Thomas Fürst
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Stability Studies to Support Shipping/ Distribution of Pharmaceuticals and Biopharmaceuticals

Live Online Training on 26 October 2021

Highlights

- Stability programs and stress testing – a regulatory overview
- Mean Kinetic Temperature and world climatic zones
- Stress studies of pharmaceuticals
- Studies at different temperatures and conditions
- Storage label statements in the EU and the US
- Investigation of excursions from storage label conditions

- 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 Stress Testing – Regulatory View (GMP and GDP)

- Long-term and accelerated storage conditions of new drug substances and products (EU, USA)
- Stability storage programs for generic drugs (EU, USA)
- GDP Guides (EU, WHO, USP Chapter <1079>)

§ *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

- 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

Storage Label Statements (EU and USA)

- Linking storage instructions to formal stability studies
- Labeling statements for various pharmaceuticals (EMA guideline)
- USP controlled temperatures

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

Q&A Session III

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

Speakers

Dr Raphael Bar
BR Consulting, Israel

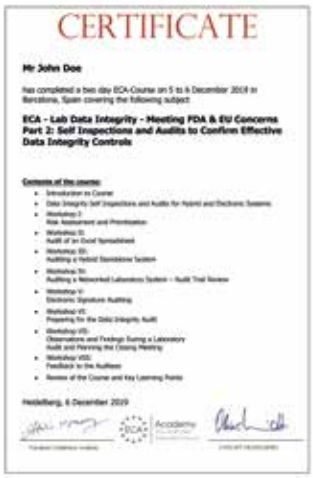
Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and the analytical QC laboratory at Pharmos. He served in the Scientific Advisory Board of global PDA (USA) and is presently a board member of Israel PDA Chapter as well as a member of the organizing committee of the Israel Society 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.


CERTIFICATE

Mr John Doe

has completed a two day ECA-Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

ECA - Lab Data Integrity - Meeting FDA & EU Concerns Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Contents of the course:

- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop I: Risk Assessment and Prioritization
- Workshop II: Audit of an Excel Spreadsheet
- Workshop III: Auditing a Hybrid Standalone System
- Workshop IV: Auditing a Networked Laboratory System – Audit Trail Review
- Workshop V: Electronic Signature Auditing
- Workshop VI: Preparing for the Data Integrity Audit
- Workshop VII: Observations and Findings During a Laboratory Audit and Planning the Closing Meeting
- Workshop VIII: Feedback to the Auditees
- Review of the Course and Key Learning Points

Heidelberg, 6 December 2019

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Reservation Form (Please complete in full)

Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals
Live Online Training on 26 October 2021

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)

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
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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 January 2012).
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

Tuesday, 26 October 2021, 09.00 – 17.00 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 445,-
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

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

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