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Speakers

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Stability Studies to Support Shipping/ Distribution of Pharmaceuticals and Biopharmaceuticals

14/15 October 2020 | Hamburg, Germany

Highlights

- Stability programs and stress testing – a regulatory overview
- Stress studies and degradation rates of pharmaceuticals
- Qualification of shipment and temperature monitoring
- World climatic zones and Mean Kinetic Temperature
- Storage label statements in the EU and the US
- Shipping of Vaccines
- Studies at different temperatures and conditions
- Investigation and evaluation of excursions and responsibility issues

Workshops on
• Evaluation of a Temperature Excursion
• Design of stability studies for a refrigerated protein solution

Objective

This Education Course will give a comprehensive 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 2oC) 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^{0}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 course will address these aspects. Finally, a workshop will demonstrate how the evaluation of an example of a temperature excursion may be approached.

Target Audience

This Education Course 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 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>)
- PDA Technical reports on GDP

Stress studies of pharmaceuticals

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

Degradation rates of pharmaceuticals

- Arrhenius kinetics
- Estimating degradation rate in a given temperature

Mean Kinetic Temperature (MKT) and World climatic zones

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

Overview of qualification of shipment of pharmaceuticals and Temperature Monitoring

- The four Qs: DQ, IQ, OQ and PQ
- Field studies and in controlled rooms

Workshop
Evaluation of a Temperature Excursion in a shipped refrigerated drug product.

Storage label statements (EU and USA)

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

Shipping of Vaccines

- Various shipping conditions for vaccines
- Impact of temperature excursions on vaccines
- Vaccine vial monitor (VVM)

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

Workshop

Design of stability studies to support shipping and distribution of a refrigerated protein solution of a biopharmaceutical product.

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 a Temperature Excursion

- Estimation of degradation rates at the excursion temperature
- Estimation of degradation at the expected long-term shelf-life
- Estimation of a maximal "Time-out-of-Storage" of a drug

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 Torsten Sokoliess
Boehringer Ingelheim, Germany

Torsten Sokoliess is CMC expert for NCE development projects at Boehringer Ingelheim Pharma GmbH & Co. KG (BI). His current position involves the assessment and guidance regarding scientific CMC aspects of development projects taking into account regulatory requirements for the development and registration of NCE projects. In addition, he is assigned as Qualified Person for Investigational Medicinal Products.

Social Event

In the evening of the first day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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GERMANY

Reservation Form (Please complete in full)

Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals
14/15 October 2020, Hamburg, Germany

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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Date
Wednesday, 14 October 2020, 09.00 h - 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 15 October 2020, 9.00 – 16.00

Venue
Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany
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Fees (per delegate, plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
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 event. 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.gmp-compliance.org.

Conference language
The official conference language will be English.

Certificate of Participation
Shortly after the event, you will receive your certificate of participation by email.

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