Post-Conference Session

Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals

1 December 2017, Vienna, Austria

Speaker:

DR RAPHAEL BAR
BR Consulting, Israel

Highlights:

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

With Workshop on **Evaluation of a Temperature Excursion in a shipped drug product**

This post-Conference Session ideally complements the ECA education courses
"Setting Specifications" (28-29 November 2017 in Vienna, Austria)
and
"Stability Testing of Drug Substances and Drug Products"
(29-30 November 2017 in Vienna, Austria).

This course is recognised for the ECA GMP Certification Programme „Certified QC Manager".
Please find details at www.gmp-certification.eu

Post Conference Session "Stability Studies to Support Shipping/ Distribution of Pharmaceuticals and Biopharmaceuticals"

1 December 2017, Vienna, Austria

Objectives

This session 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 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 course will address these aspects. Finally, a workshop will demonstrate how the evaluation of an example of a temperature excursion may be approached

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)
- Stress testing vs Forced Degradations
- Stressing factors
- GDP Guides (EU, WHO, USP Chapter <1079>)
- "Time-out-of-Storage" and "stability budget" concept

Overview of qualification of shipment of pharmaceuticals and Temperature Monitoring

- The four Qs: DQ, IQ, OQ and PQ
- Temperature monitoring in a shipment

World climatic zones and Mean Kinetic Temperature (MKT)

- Mean Kinetic Temperature (MKT) and relative humidity
- Interpretation of MKT
- MKT from temperature loggers
- Global climatic zones by ICH and WHO

Storage label statements (EU and USA)

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

Programme

Stability studies to support shipping/distribution of pharmaceuticals and biopharmaceuticals

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

Workshop
Evaluation of a Temperature Excursion in shipped refrigerated drug product

Investigation of excursions from storage label conditions

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

Evaluation of Temperature Excursions

- 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

Speaker

DR RAPHAEL BAR, BR CONSULTING, ISRAEL
Raphael Bar is presently a pharmaceutical consultant for the Pharma and bio-Pharma industries. He is consulting various companies and provides development and analytical support to investigational, generic, new drugs as well as combination device-drug products and CMC project management. With a doctorate in Chemistry (1984), Dr. Bar joined (1995) Teva Pharmaceuticals and headed for three years the Analytical R&D Laboratory. He was involved in preparation of ANDA files. He then joined Pharmos where he managed the quality control and R&D laboratory till 2007.
As Senior Director of Analytical Development he was actively involved in preparation of CMC packages for clinical trial studies. From 2009 until June 2015, he was a member of the scientific advisory board of global PDA (USA).

This post-Conference Session ideally complements the ECA education courses "Setting Specifications" (28-29 November 2017 in Vienna, Austria) and "Stability Testing of Drug Substances and Drug Products" (29-30 November 2017 in Vienna, Austria).

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Friday, 1 December 2017, 08.30 h - 16.00 h
(Registration and coffee 08.00 h - 08.30 h)

Venue
Austria Trend Hotel Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
Fax +43/1/891 109 050
email Park.royal.palace@austria-trend.at

Fees (per delegate plus VAT)
ECA Members € 690
APIC Members € 790
Non-ECA Members € 890
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice and includes conference documentation, all refreshments. VAT is reclaimable.

Would you like to save money?
If you book the post-Conference Session "Stability Studies to Support Shipping/Distribution of Pharmaceuticals and Biopharmaceuticals" AND in addition the conference

- Stability Testing in Drug Substances and Drug Products (29-30 November 2017) AND the conference
- Setting Specifications (28-29 November 2017)

the fees reduce as follows:

Stability Testing for Drug Substances and Drug Products AND post-Conference Session
ECA Members € 1,980
APIC Members € 2,180
Non-ECA Members € 2,380
EU GMP Inspectorates € 1,190

Setting Specifications and Acceptance Criteria AND Stability Testing for Drug Substances and Drug Products AND post-Conference Session
ECA Members € 2,970
APIC Members € 3,270
Non-ECA Members € 3,570
EU GMP Inspectorates € 1,785

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

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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69007 Heidelberg, Germany
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will help you with any questions as regards content.

Mr Niklaus Thiel
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the responsible Organisation Manager,
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❑ Post-Conference Session **Stability studies to support shipping/distribution of Pharmaceuticals and Biopharmaceuticals,** 1 December 2017, Vienna, Austria

❑ **Setting Specifications,** 28-29 November 2017, Vienna, Austria
❑ **Stability Testing for Drug Substances and Drug Products,** 29-30 November 2017, Vienna, Austria

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If you cannot attend the conference you have two options:
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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 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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.

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