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GDP Webinar
Cold Chain Management and its Validation

Date:
Wednesday, 19 August 2020, 14.00 -15.30 h CEST

Speaker:
Dr Zvonimir Majic, Teva Pharmaceutical Industries

ECA has entrusted
CONCEPT HEIDELBERG with the
organisation of this webinar.

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Background
Growing regulatory expectations regarding pharmaceutical storage, transport and cold chain management are forcing the pharmaceutical industry to challenge their current practices.
For temperature sensitive products, different regulations apply. For example, the EU-GDP Guidelines (2013/C 343/01) state that "qualified equipment (e.g. thermal packaging, temperature-controlled containers or temperature-controlled vehicles) should be used to ensure correct transport conditions are maintained between the manufacturer, wholesale distributor and customer." According to USP General Chapter 1079 "vehicles designated to provide appropriate temperature range for the product being shipped should be used." More regulatory documents around the globe are emphasizing need of having qualified shipping systems in place. Besides the logistics service providers, packaging (active or passive), transport modes and lanes and vehicles require risk assessment and qualifications. This webinar will provide insights on how to ensure compliance in this important GDP aspect.

Educational Objectives
The aim of this webinar is to give participants a comprehensive yet compact overview of cold chain management and its validation. The following topics are addressed:
- Regulatory requirement
- Qualification vs. validation
- Cold chain management system components
- Qualification of logistic service providers
- Qualification of temperature-controlled shipping system for pharmaceutical products
- Transport equipment qualification
- Risk evaluation, quality control and monitoring

Target Audience
This webinar addresses itself to all managers, supervisors and other staff members who are involved in pharmaceutical cold chain management. Those are e.g. employees from the following industries:
- Pharmaceutical manufacturers (e.g. logistics and QA)
- Drug wholesaler
- Logistics companies
- External warehouses
- Further service providers in the distribution of pharmaceuticals

Speaker

Dr Zvonimir Majic
Teva Pharmaceutical Industries Ltd., Croatia
Dr Zvonimir Majic is Director Global Quality Logistics. He has Ph.D. in Transportation and Logistics and is certified Quality and Risk Manager (EOQ - European Organization for Quality), Process Design Manager and a Lead Auditor for ISO and EU OPS norm. He is a member of the European steering committee of PDA's SCIG and IATA CEIV consultant.

Fees (plus VAT)
Single participation: € 199,- for ECA Members
Single participation: € 249,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at
https://www.gmp-compliance.org/about-the-academy).

Participation of a Group
You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):
3-10 Persons € 211,65
11-20 Persons € 186,75
more than 20 Persons € 161,85

Registration
By mail, fax, e-mail or online on the Internet at
https://www.gmp-compliance.org/. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Technical Requirements
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Presentation/Certificate
The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact
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Do you have any questions?
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Registration for the GMP-Webinar: "Cold Chain Management and its Validation" on Wednesday, 19 August 2020, 14.00 -15.30 h CEST
Speaker: Dr Zvonimir Majic
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
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  ☐ 3-10 Persons
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  ☐ more than 20 Persons

Important: Deadline for registration is 12 noon on 18 August 2020

Title, First Name, Last Name

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2. If you have to cancel entirely we must charge the following processing fees:
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