



# 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

For our webinars, we 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 plugin. 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.

## 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?

For questions regarding content please contact:

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For questions regarding organisational aspects please contact:

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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](http://www.gmp-compliance.org).

Please tick:

- Single Participation**
- Group Participation**
  - 3-10 Persons
  - 11-20 Persons
  - more than 20 Persons

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

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### 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 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. 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!)