



Speaker



Dr Zvonimir Majic
IATA Senior consultant for Healthcare,
Croatia

GDP Audits

How to Audit Logistics Service Providers



Live Online Training on 13 June 2024



Highlights

- Audit methodology for different transport modes
- How to audit
 - Road transport vendors
 - Forwarders on airfreight service
 - Forwarders on ocean freight service
- How to host and prepare for a Quality and Risk Management System and GDP audit
- Feedback summary for self-study scenarios
- Q&A sessions

All participants will exclusively receive the following documents:

- Audit check list for air, road and ocean
- Regulatory requirements for transport of time and temperature sensitive pharmaceutical products

Objectives

In this Live Online Training you will learn

- How to conduct GDP audits of road transport vendors, forwarders on airfreight service and forwarders on ocean freight service
- How to host and prepare for a Quality and Risk Management System and GDP audit

As a participant you will exclusively receive an audit checklist for air, road and ocean transport as well as a compilation of regulatory requirements for the transport of time and temperature sensitive pharmaceutical products. You will further receive two short self-study scenarios with some questions. Answers will be provided during the training.

Background

The EU GDP Guidelines highlight the need for appropriate controls for all partners and service providers in the distribution chain (like road transport vendors, forwarders on airfreight service and ocean freight service). Qualification of these partners, for example through audits, is a core element in implementing the GDP requirements.

Target Audience

This Live Online Training has been developed for logistics service providers and pharma manufacturers. It is directed at everybody involved in GDP audits.

Moderator Dr Markus Funk

Programme

Module 1: Auditing Forwarders, Logistics Service Providers and Transport Companies

- Part 1: Audit methodology for different transport modes (on site, paper audit, virtual audit considerations)
- Part 2: Audit of road transport vendors
- Part 3: Audit of forwarders on airfreight service
- Part 4: Audit of forwarders on ocean freight service

Module 2: Hosting and Preparation for a Quality and Risk Management System and GDP Audit

- Part 1: Compliance requirements for road transport vendors
- Part 2: Requirements for forwarders offering airfreight service
- Part 3: Requirements for forwarders offering ocean freight service

Feedback Summary for Self-Study Scenarios & Q&A Sessions

Speaker

Dr Zvonimir Majic | IATA Senior consultant for Healthcare, Croatia

Dr Zvonimir Majic is former Global Director for supply chain quality assurance and GDP in Teva Pharmaceutical Industries Ltd. He has a 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. Since 2010, he is an active member of Parenteral Drug Association, SC Interest Group steering committee in Europe, under which he has co-authored several Technical reports on GDP. He also published several articles of special products logistics and quality assurance in supply chain.



Date of the Live Online Training

Thursday, 13 June 2024, 09.00 – 17.30 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 990,-

APIC Members EUR 1.090,-

Non-ECA Members EUR 1.190,-

EU GMP Inspectorates EUR 595,-

The fee is payable in advance after receipt of invoice.

Registration

Please 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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

CONCEPT HEIDELBERG

P.O. Box 10 17 64

69007 Heidelberg, Germany

Phone +49(0)62 21/84 44-0

Fax +49(0)62 21/84 44 34

info@concept-heidelberg.de

www.concept-heidelberg.de

For questions regarding content please contact:

Dr Markus Funk (Operations Director) at

+49(0) 62 21/84 44 40, or at

funk@concept-heidelberg.de

For questions regarding organisation please contact:

Ms Nicole Bach (Organisation Manager) at

+49(0) 62 21/84 44 22 or at

bach@concept-heidelberg.de