



Speakers



David Abraham
Quality Resource Solutions



Dr Zvonimir Majic
IATA Senior consultant for
Healthcare, Croatia

Pharma Supply Chain: GDP Requirements and Certification for Logistics Vendors



Live Online Training on 02 October 2025, 09:30 - 16:45 h



Highlights

- Mastering Supply Chain Risks
- Quality and Risk Management Systems
- Standards and Guidance in Supply Chain (GDP meets ISO; Certification and Selection of Logistics Suppliers)
- GDP Provisions for Transport, Handling and Storage of Time- and Temperature-sensitive Pharma Products in Supply Chain
- Practical Examples and Exercises
- Questions and Answers Session

Objectives

It is of key importance that medicinal products are not only made to a high quality in accordance with **Good Manufacturing Practice (GMP)**, but that the quality and integrity of these products are maintained through the entire supply chain to the patient. This is where **Good Distribution Practice (GDP)** comes into play.

During this Live Online Training, well-experienced speakers will share their expert knowledge about all relevant aspects regarding the **GDP requirements for logistic vendors**. You will learn how these requirements evolve and how they can be implemented efficiently to bring and keep your organization in compliance with the GDP regulations. Furthermore, different **certification options** for logistic vendors will be discussed. **Practical examples and exercises** (including polling questions) and a **Q&A session** ensure interaction and that all questions are answered.

Background

Medicinal products are subject to **special regulations for storage and transport**. Good Distribution Practice (GDP) is the part of quality assurance that ensures that the quality of medicinal products is maintained at all stages of the supply chain.

The EU GDP-Guidelines are intended to ensure **control of the distribution chain** and consequently maintain the quality and integrity of medicinal products. Each manufacturer of a medicinal product needs to control and supervise the supply chain (wholesaler, transport and distribution companies etc.) of the finished products.

In the supply chain, many logistic activities are **outsourced to service providers**, e.g. logistic vendors. Transport companies do not need to hold a wholesale distribution authorisation to transport medicinal products. However, they should follow the parts of the GDP guideline relevant to their activities. Therefore transport companies need to follow GDP but will not receive a GDP certificate.

An **independent assessment of compliance** against international GDP requirements could be an effective way for logistic vendors to establish that their Quality Management Systems (QMS) align with the GDP requirement.

'**ISO**' is an abbreviation for the International Organization for Standardization, an independent, non-governmental international organization. There are a variety of ISO standards that transport and logistic companies can implement. Achieving an ISO certification means implementing a management system that improves the processes and procedures. Before signing a contract, a standard question may be about the type of certificates the company holds. In this way, quality standards can help to gain a competitive advantage in the transport and logistics sector. **ISO 9001** is a generic quality management system providing a good framework for any organisation. However, the EU GDP expectations are not clearly detailed in this standard. It is therefore recommended that companies using the ISO framework **incorporate the specific GDP requirements** to ensure a **compliant and workable QMS** is available for the company.

Target Audience

This Live Online Training is aimed at all personnel of logistic vendors, but also to management and quality personnel from pharmaceutical companies, wholesalers, distributors and service providers involved in the distribution of medicinal products.

Moderator

Dr Markus Funk

Programme

Mastering Supply Chain Risks

- Understanding supply chain impacts
- Threats, vulnerabilities and impacts
- The role of Due Diligence
- Management of supply chain security measures (TSM)



EU GDP-Guidelines (Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use)

Chapter 1

[...] Wholesale distributors must maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities.

[...]

The quality system should be fully documented and its effectiveness monitored. All quality-system-related activities should be defined and documented. A quality manual or equivalent documentation approach should be established.

[...]

The quality system should extend to the control and review of any outsourced activities related to the procurement, holding, supply or export of medicinal products. These processes should incorporate quality risk management and include: (i) assessing the suitability and competence of the contract acceptor to carry out the activity and checking authorisation status

[...]



Stay informed with the GMP Newsletters from ECA

The ECA offers various free of charge GMP newsletters for which you can subscribe to according to your needs.

To subscribe, simply scan the QR code on the right or visit www.gmp-compliance.org/gmp-newsletter



Quality and Risk Management Systems

- QRMS procedures – customer focus and compliance requirements
- Risk management – risk assessment of lanes, cross dock operations, transport mode and shipping systems (active, passive), transport vehicles and containers
- Quality agreements and SLA requirements
- Supplier management
- Audits
- KPIs and performance management

Standards and Guidance in Supply Chain

- Supply Chain Standards
- GDP meets ISO
- Certification and selection of logistics suppliers
- Building mitigation into your QMS

GDP Provisions for Transport, Handling and Storage of Time- and Temperature-sensitive Pharma Products in Supply Chain

- Specific provisions and requirements for air, ocean and road transport
- Specific requirements for in-transit storage premises and cross docks
- Certification requirements and industry best practices
- Continuous monitoring and improvement programs for logistics
- Monitoring technologies and requirements

Practical Examples / Exercises

(Dr Zvonimir Majic and David Abraham)

- Applying supply chain learnings



Questions and Answers Session

(Dr Zvonimir Majic and David Abraham)

- Participants are invited to ask questions



David Abraham
Quality Resource Solutions Ltd

David is Quality Director of QRS-Associates, with over 20 years' experience within Pharmaceutical and Healthcare arena designing, developing, implementing, maintaining and improving business processes and Pharmaceutical Quality Management Systems in line with the application of both GMP and GDP. His work continues to see his engagement with manufacturers, wholesalers, logistics as well as supply chain and training organisations providing resource, awareness, training and consulting in GDP, Quality Management and the application of GxP in addition to continuing to provide representation and input into a number of Technical committees at a national, European and International level.



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.

Agenda

09:30 - 09:45 h Welcome and Introduction

09:45 - 10:45 h **Presentation 1**

10:45 - 11:00 h Break

11:00 - 12:00 h **Presentation 2**

12:00 - 12:15 h Break

12:15 - 13:15 h **Presentation 3**

13:15 - 14:00 h Lunch

14:00 - 15:00 h **Presentation 4**

15:00 - 15:15 h Break

15:15 - 16:00 h **Practical Examples / Exercises**

16:00 - 16:45 h **Q&A Session**

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)



Pharma Supply Chain: GDP Requirements and Certification for Logistics Vendors
Live Online Training on 02 October 2025, 09:30 - 16:45 h

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)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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 4 weeks prior to the conference 10 %
 - Cancellation until 3 weeks prior to the conference 25 %
 - Cancellation until 2 weeks prior to the conference 50 %
 - Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. 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 cancel-

lation 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) (As of July 2022).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.



Date of the Live Online Training

Thursday, 02 October 2025, 09:30 - 16:45 h
All times mentioned are 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 1,190.-
Regular Fee EUR 1,290.-
APIC Members EUR 1,240.-
GDP Association Members 1,190.-
EU GMP Inspectorates EUR 645.-
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or **search and register directly at www.gmp-compliance.org under the number 21763**. To avoid incorrect information, please give us the exact address and full name of the participant.

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 | D-69007 Heidelberg
Phone: +49 (0) 6221/84 44 0
Fax: +49 (0) 6221/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content:

Dr Markus Funk (Director Operations) at
+49 (0) 6221/84 44 40, or per e-mail at
funk@concept-heidelberg.de

For questions regarding organisation please contact:

Ms Nicole Bach (Organisation Manager) at
+49 (0) 6221/84 44 22, or per e-mail at
nicole.bach@concept-heidelberg.de