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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)

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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
[...]

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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**

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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

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City | ZIP Code | Country

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Date of the Live Online Training
Thursday, 02 October 2025, 09:30 – 16:45 h
All times mentioned are CEST.

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Fees (per delegate, plus VAT)
ECA Members EUR 990,-
Regular Fee EUR 1.190,-
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GDP Association Members 990,-
EU GMP Inspectorates EUR 595,-
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.

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