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GMP: KnowHow Pharma Logistics (GDP)

A knowledge portal for the practical and up-to-date implementation of GDP-compliant storage and transport.

What are the features of the GMP:KnowHow Pharma Logistics (GDP)?

The online knowledge portal GMP:KnowHow Pharma Logistics (GDP) offers comprehensive logistics knowledge for everyone involved in the supply chain of medicinal products and medical devices. It provides practical guidance on implementing the EU GDP guidelines and other relevant regulations. Editable sample documents such as SOPs and various quality documents are also available.

Background

The supply chain for medicinal products and medical devices is international and involves numerous actors. The understanding of GDP varies greatly depending on the country and industry. Different guidelines and laws apply and the interfaces to GMP must be considered.

To ensure patient safety, the supply chain of medicinal products and medical devices is subject to strict regulation and monitoring. In Europe, the EU GDP guidelines are the leading document.

Content

- Quality Management
- Personnel
- Facilities and Equipment
- Documentation
- Operation
- Complaints and Returns
- Outsourced Activities
- Self-inspection
- Transport

Sample Documents

- Quality Agreement for GMP/GDP-compliant Logistics Services
- Quality Manual
- SOPs
- Job Descriptions
- GDP Questionnaire
- Site Master File with Organisational Chart
- Best Practice the Peither Logistik GmbH

All documents can be edited individually.

Cited Regulations

- EU GDP guidelines (2013/C 343/01 and 2015/C 95/01)
- EU GMP Guide Parts I III and Annexes
- Swiss TPA, MPLO
- PIC/S (PE 011-1, PI 047-1 Annex)
- WHO (GSDP u. GTDP)
- DIN EN ISO 9001:2015, 13485:2016

The Author

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Simone Ferrante was previously Head of Quality Control and Responsible Person for the entire Grieshaber Group. Furthermore, she is a long-time author and GDP expert for the GMP-Verlag Peither AG.

Advantages for Users

- Knowledge and experience of a long-standing GDP expert.
- Regular updating and expanding of the knowledge portal

- Editable sample documents for easy creation of SOPs, job descriptions and other qualityrelevant documents.
- Topic-specific direct comparison of practical knowledge and regulatory principles.

Target Group

Employees in the supply chain of pharmaceuticals and medical devices, e.g. pharmaceutical companies, medical device manufacturers, wholesalers, and logistics service providers.

Technical Requirements

E-mail address, internet connection, PC, tablet or smartphone.

Licences and Prices

Type of Licence	Language	Duration	Price in €*
Named User Licence Online access for one person	<u>English</u>	3 months	460,-
	<u>English</u>	12 months	610,-
Business Package Online access for up to 5 persons per package	<u>English</u>	12 months	1.830,-

^{*} Prices excl. legal VAT.

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