E-LEARNING

FORUM

GDP – Basic Training

Basic training to understand the requirements of GDP in today‘s pharmaceutical industry

TOPICS

- Defining GDP
- From regulations to implementation: quality management
- Key roles in the GDP environment
- GDP in practice: storage, incoming goods, picking and transport
- Qualification and validation
- Complaints, returns, suspicion of counterfeit drugs, drug recalls
- Life cycle supplier management
- GDP audits

BENEFITS

- Become proficient in all essential aspects of GDP in just 3.5 hours
- Integrated multiple-choice tests to check effectiveness and issue a certificate of completion
- Ideal for documentation to be provided during inspections and audits
- Special discounts for multiple participants from the same company

MORE INFORMATION: WWW.FORUM-INSTITUT.COM/ONLINE-TRAINING

E-learning: GDP – Basic Training

Aims and objectives

The EU ‘Guidelines on Good Distribution Practice of medicinal products for human use’ stipulate that all employees involved in wholesale activities must be trained in the requirements of Good Distribution Practice (GDP). They should possess the necessary competences and experience before commencing their duties.

This e-learning course provides you with the fundamental principles of GDP of medicinal products for human use. Our experienced speaker will guide you through the current regulatory framework and its implementation step by step, explaining key definitions, tasks and responsibilities.

All essential concepts are presented clearly and comprehensibly, illustrated through practical examples and interactive tools. Learning assessments after each module allow you to track your progress at any time and present it during audits and inspections.

Are you the responsible person for pharmaceutical wholesale in your company? With our e-learning course designed for participants without any prior technical knowledge, you can train your (new) employees at any time in a compact and efficient manner.

Who should attend?

Are you starting your role in GDP at a pharmaceutical company, a transport or storage service provider, or a wholesaler? Or are you working in another department that has touchpoints with GDP? This e-learning course offers a quick and effective way to learn the essentials of Good Distribution Practice and also serves as a refresher.

Content

The ‚GDP – Basic Training‘ e-learning programme comprises seven modules that include videos, examples and interactive tools in which the expert shares his expertise with you. You can also download and print the corresponding presentation documents. Some modules comprise additional documents (links, guideline texts, etc.), which help you practise and apply your newly gained knowledge.

Once you have completed the seven modules and passed a final multiple-choice test, you will be awarded a certificate, which you can print out directly. The e-learning programme should be completed within three months. Try our e-learning programme for free and familiarise yourself with our learning environment.

Your speaker

Dr Stefan Lakonig

Haecon GmbH

Dr Stefan Lakonig is an experienced GxP auditor and consultant with extensive international expertise in Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and quality management systems for the pharmaceutical industry. As the former Deputy Head of Quality Assurance at a German active pharmaceutical ingredient manufacturer, he gained expertise in quality assurance. He currently serves as a lead GMP and GDP auditor for third-party audits at Haecon GmbH.

His assignments have taken him across Europe, Turkey, China, India, Myanmar, Korea and Israel. He draws on a wealth of experience gained from successfully conducting more than 300 audits.

Basic training to understand the requirements of GDP

Module 1:
Basics: What is GDP?

- Defining GDP
- GDP for active ingredients and pharmaceuticals
- Supply chain integrity
- The regulatory environment in Europe
- Boundaries between GMP and GDP

Module 2:
Key roles in GDP: Who does what?

- Wholesale representative
- GDP responsible person
- Qualified person
- Differences and intersections

Module 3:
GDP – from regulations to implementation

- Quality management principles
- Quality management in GDP
- Components of a quality management system in GDP

Module 4:
GDP in practice

- Pharmaceutical storage: premises, environment and risk management
- Incoming goods: verification, condition check and storage requirements
- Picking process: from order receipt to dispatch
- Ensuring safe transport: temperature control, route planning, documentation and more
- Transport management systems

Module 5:
Qualification and validation

- Risk management for GDP
- Key elements of storage facilities
- Temperature mapping studies: how to install a GDP-compliant monitoring system
- Qualification of equipment (trailers)
- Verification of transport routes

Module 6:
Special situations

- Managing complaints: recording, investigating and resolving issues
- Returns: six steps to assess the quality of returned goods
- Suspicion of counterfeit drugs: things to do
- Reasons for drug recalls and how to set up the process

Module 7:
Life cycle supplier management

- Qualification of suppliers
- Contracts and written agreements
- Types of audits: on-site, remote and third-party audits
- Typical audit focal points
- Common errors and deficiencies

GDP – Basic Training

HOW TO REGISTER

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We also offer corporate rates!

REGISTRATION

Yes, I want to join the

☐ GDP – Basic Training

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

E-Mail (required for your login details)

Position

Company

Street address

Postal Code/City/Country

Tel. No.

Date, Signature

Fee

Your personal single account costs €490 (plus VAT) for a period of three months, during which you can access and complete the modules as often as you like. At the end, you will receive a personalised official certificate.
Attractive conditions are available for multiple users or cross-departmental accounts. Please feel free to contact us.

How does it work?

Book an e-learning course by phone, email or on our website. You will receive an email with the details to access our learning platform. Log in to our learning platform. Complete the learning modules at your own pace.

FREE demo

Demo versions of our e-learning programmes are available free of charge

CANCELLATION POLICY

Our general terms and conditions (as of 01 June 2024) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

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