GDP 3

GDP in Switzerland

Specifics in the Distribution of Medicinal Products and APIs

12 September 2024, Basel

ON SITE

CERTIFICATE

SPEAKERS

Dr Ina Bach
Dr Bach

Dr Johannes Fröhlich
Akroswiss

Dr Felix Kesselring
Bratschi

Dr Remo Studer
Galexis

- Legal Bases for the Distribution of Medicinal Products
- Tasks and Responsibilities, Liability
- Practical Implementation in Switzerland
- Distribution to, from and out of Switzerland
- Practical Aspects of Storage and Transportation
- Case Study: Validation of Transport Routes, Qualification of Transport Vehicles

Course in Englisch language

Supported by the European GDP Association

CONCEPT HEIDELBERG
EUROPE'S LARGEST GMP/GDP ACADEMY

OBJECTIVES

- Learn and discuss how to manage your distribution activities GDP-compliant.
- Exchange opinions and convey possible solutions to problems addressed in case studies.
- Benefit from the speakers' experience in industry, authority and legal advice.

Since 1 July 2015, the EU GDP guidelines do also apply for Switzerland (final implementation on January 1st 2016). This was realised through an adaptation of Annex 2 of Ordinance on EstablishmentLicences(Arzneimittel-Bewilligungsverordnung - **AMBV** or Ordonnance sur les autorisations dans le domaine des médicaments - **OAMéd**).

On 1 January 2019, the revised **Therapeutic Products Act (HMG 2)** and the majority of the revised implementing ordinances **(Therapeutic Products Ordinance Package IV)** came into force - with some interesting changes.

Holders of an operating license for wholesale activities are obliged to designate a **Responsible Person ("Fachtechnisch Verantwortliche Person, FvP)".**

The requirements for a Responsible Person are described in the Ordinance on Establishment Licences.

TARGET AUDIENCE

This course has been designed for employees, specialists and managers from storage, transportation and distribution as well as their colleagues from quality control, quality assurance and production, which are involved in the various processes of drug logistics.

PROGRAMME

Legal Bases for the Distribution of Medicinal Products

- Swiss Law and European Law
  - Act on Therapeutic Products
  - Ordinance on Establishment Licences
  - European Guidelines on Good Distribution Practice of Medicinal Products for Human Use (GDP)
  - European GDP Guidelines for Active Substances
- Outsourced activities
- Written contract for outsourced activities

Tasks and Responsibilities

- General considerations on GDP in Switzerland
- Legal basis
- Revision of the Therapeutic Products Act (HMG) and its effects
- Authorization types
- GDP Requirements
- Quality in the supply chain
- Technically Responsible Person (FvP) - General
- FvP - Delegation

THE EUROPEAN GDP ASSOCIATION

GDP ASSOCIATION

The European GDP Association aims to support Pharmaceutical Industry, Authorities and Logistic Providers with regard to the implementation of Good Distribution Practice.

It represents all stakeholders e.g. from Pharmaceutical Industry, Authorities and Logistic Providers and supports all members and stakeholders by providing them information and support in the implementation of GDP.

The Association is a not for profit organisation under the umbrella of the ECA Foundation. Membership is fee to all individuals involved in Good Distribution Practice (currently more than 4.300 members).

www.good-distribution-practice-group.org

Liability

- Responsibility and liability: terms
- Different kinds of responsibilities
  - Administrative responsibility
  - Civil responsibility
  - Criminal responsibility
- Protection of the Responsible Person
- The Responsible Person in case law

Practical Implementation in Switzerland

- The GDP inspection: preparation and implementation
- Wholesale vs. pre-wholesale: demarcation and similarities
- Transport in accordance with storage conditions: best practices
- Case study: validation of transport routes, qualification of transport vehicles

INTERACTIVE SESSION

Storage and Transport: Practical Aspects

a) Warehouse
- Requirements
- Qualification
- Mapping
- Hygiene
- Documentation

b) Transport
- Transport qualification/ validation
- Transport at ambient conditions: expectations and control
- Deviation management
- Cool and cold chain
- Risk Analysis
- Training

SPEAKERS

Dr Ina Bach
Dr. Ina Bach AG

General Manager of Dr. Bach AG in St. Gallen. Dr Bach was a GMP- and GDP-Inspector at the RHI (Regionales Heilmittelinspektorat der Nordwestschweiz) and point of contact for foreign inspections by FDA, ANVISA and EMA.

Dr Johannes Fröhlich
Akroswiss AG

Pharmacist and General Manager at Akroswiss AG. Also consultant in the area of GDP and Responsible Person (RP) Lecturer at the pharmaceutical institute of the ETH-Zürich.

Dr Felix Kesselring, LL.M. (LSE)
Bratschi AG

LL.M. in Public Law from the London School of Economics and Political Science (LSE) and a doctorate (Dr. iur.) from the University of Basel. Felix Kesselring has been working as a lawyer since 2009. Lecturer at the ETH-Zürich.

Dr Remo Studer
Galexis AG

Head of Quality Management and Responsible Person at Galexis AG, a wholesaler and part of Galenica.

PARTICIPANTS' COMMENTS

"Very good course"
Igor Todorcevski, Alkaloidpharm SA

"Very useful presentations! Thank you!"
Dr Thorsten Dedecke, Fresenius Medical Care (Schweiz)

BOOK NOW

Date
Thursday, 12 September 2024
9.00 h – 17.30 h
(Registration and coffee 8.30 h – 9.00 h)

Venue
Essential by Dorint Basel City

Schönaustrasse 10
4058 Basel, Switzerland
Phone: + 41 61 695 70 00
E-mail: info.basel@dorint.com

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive an information form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference Language
The official conference language will be English.

Fees

€ 1.090,-
GDP Assocation Members

€ .1290,-
Non-Members

(equates 1.228 CHF, dated September 2023)
Relevant for payment is the price in Euro.
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments.
VAT is reclaimable.

Organisation

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Do you have questions?

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Presentations/Certificate
The presentations of this GDP Course will be available for download and your print-out one week before the conference.

Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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REGISTRATION

Seminar Number 21328

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