



# GDP in Switzerland

Specifics in the Distribution of Medicinal Products and APIs

12 September 2024, Basel



## Speakers



**Dr Ina Bach**  
Dr Bach



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## Highlights

- 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

Supported by the  
European GDP Association



## 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.

## Background

Quality requirements for medicines do not end after production and packaging. Medicines and APIs are often shipped over long distances and different climate zones and stored in various warehouses. Once the WHO has taken the lead with its guidelines „Good Storage Practices for Pharmaceuticals“ (2003) and „Good Distribution Practices for Pharmaceutical Products“ (2010), more and more compliance with good storage, transportation and distribution practice was emphasised worldwide. Another milestone were the EU-GDP guidelines from 2013 with a lot of intensified demands.

For quite a while it was rather unclear how these guidelines are applicable in the non-EU country Switzerland. Under the Agreement of 21 June 1999 between the Swiss Confederation and the European Community (**Mutual Recognition Agreement, MRA**), Switzerland obliged to comply with the EU-GMP regulation. However, GDP was not covered.

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 Establishment Licences (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

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- 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

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- 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

### Liability

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- 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

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- 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





## Storage and Transport: Practical Aspects (Interactive Session)

### 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



**Dr Ina Bach**  
Dr. Bach AG

Dr Ina Bach is 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

Dr Johannes M. Fröhlich is Pharmacist and General Manager at Akroswiss AG. He also works as a consultant in the area of GDP an das Responsible Person (RP). He holds a lectureship at the pharmaceutical institute of the ETH-Zürich.



**Dr Remo Studer**  
Galexis AG

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



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

Dr Felix Kesselring studied at the universities of Zurich and Strasbourg. He received an 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. He holds a lectureship at the ETH-Zürich.



### The European 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](http://www.good-distribution-practice-group.org)



### Participants' comments:

*"Very good course"*

Igor Todorcevski, Alkaloidpharm SA

*"Very useful presentations! Thank you!"*

Dr Thorsten Dedecke, Fresenius Medical Care (Schweiz)



### 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](http://www.gmp-compliance.org/gmp-newsletter)



Absender

Anmeldung/Bitte vollständig ausfüllen

## GDP in Switzerland - Specifics in the Distribution of Medicinal Products and APIs (GDP 3) 12 September 2024, Basel

Titel, Name, Vorname

Abteilung

Firma

Telefon / Fax

E-Mail (bitte angeben)

CONCEPT HEIDELBERG  
Postfach 10 17 64  
Fax 06221/84 44 34

D-69007 Heidelberg

### 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 %
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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.

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### 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](mailto:info.basel@dorint.com)

### Fees

GDP Association Members € 1.090  
(equates 1.038 CHF, dated September 2023)  
Non-members 1.290 €  
(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.



### Important Information!

The presentations of this GDP Course will be available for download and your print-out one week before the conference. **Note: there will be no print-outs available during the conference.**

### Accommodation

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.

### Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gdp-navigator.de](http://www.gdp-navigator.de) or [www.gmp-navigator.com](http://www.gmp-navigator.com)

### Conference language

The official conference language will be English.

### Organisation

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