ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Ina Bach
Dr Bach

Dr Johannes Fröhlich
Akroswiss

Dr Felix Kesselring
Bratschi

Dr Matthias Schwebe
Roche Pharma

Supported by the
European GDP Association

GDP ASSOCIATION

GDP in Switzerland

Specifics in the Distribution of Medicinal Products and APIs

09 September 2025 | Basel, Switzerland

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

Objective

- 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

- 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

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

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

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

Speakers

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 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.

Dr Matthias Schwebe
Roche Pharma

Dr Matthias Schwebe is Head of Quality Management at Roche Pharma Schweiz in Basel. Prior to this, he was Head of Quality Assurance and member of the management team at Alloga AG.

PARTICIPANTS' COMMENTS

"Very good course"
Igor Todorcevski, Alkaloidpharm SA

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

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GDP in Switzerland 09 September 2025, Basel, Switzerland

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 %,
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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 January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date
Tuesday, 09 September 2025, 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
Email info.basel@dorint.com

Fees (per delegate, plus VAT)
ECA Members € 1,090
(equates 1,024 CHF, dated January 2025)
European GDP Association Members € 1,090
(equates 1,024 CHF, dated January 2025)
APIC Members € 1,190
(equates 1,118 CHF, dated January 2025)
Non-ECA Members € 1,290
(equates 1,212 CHF, dated January 2025)
EU GMP/GDP Inspectorates € 645
(equates 606 CHF, dated January 2025)
Relevant for payment is the price in Euro.
The conference fee is payable in advance after receipt of invoice and includes lunch and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG 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 – or search and register directly at www.gmp-compliance.org under the number 21964.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. 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.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44 0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Markus Funk (Operations Director) at
+49(0)62 21/84 44 40 or at funk@concept-heidelberg.de

For questions regarding organisation please contact:
Ms Nicole Bach (Organisation Manager) at
+49(0)62 21/84 44 22 or at nicole.bach@concept-heidelberg.de