Course in English language

GDP 3

# GDP in Switzerland

## Specifics in the Distribution of Medicinal Products and APIs

Recorded Online Training

The revised Therapeutic Products Act (HMG 2): what you need to know

## Highlights

- Legal Bases for the Distribution of Medicinal Products
- Tasks and Responsibilities
- Distribution to, from and out of Switzerland
- Practical Aspects of Storage and Transportation
- Liability and Indemnification
- **Optimised as Live Online Event**
- **Live Discussion Session after each Presentation**

Supported by the European GDP Association

GDP ASSOCIATION

## Speakers

**Dr Ina Bach**
Dr. Bach

**Dr Johannes Fröhlich**
Akroswiss

**Dr Felix Kesselring**
Bratschi AG

**Dr Remo Studer**
Galexis

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## 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 Establ ishmentLicences(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.

Various transitional provisions for licenses issued under the old legislation are defined. However, for all new/renewed applications, the new legislation will apply in its entirety.

## Target Audience

This Live Online Training 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

Introduction

### Legal Bases for the Distribution of Medicinal Products

- Legal basis in Switzerland including EU regulations
- The Ordinance on Establishment Licences OEL (AMBV, OAMéd)
- The revised Therapeutic Products Act (HMG 2): relevant changes
- GMP/GDP Interface
- Working with contractors

### Tasks and Responsibilities

- Requirements and due diligence for the Responsible Person according Art. 9 and 13 of the Ordinance on Establishment Licences
- Storage and distribution: current expectations
- Cross-border Distribution: Requirements for Import and Export
- Requirements for specific products
- Qualification of suppliers and recipients
- Senior Management
- Responsible Person

### Liability

- Principles of liability
- Who is liable?
- Potential sanctions
- Examples from the real life, case law

## 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

## Practical Implementation in Switzerland

- The GDP Inspection: what do inspectorates expect and how to prepare
- Wholesaler vs. Pre-Wholesaler: interfaces and delimitation
- Transport at storage conditions: best practices
- Case Study: transport validation

GDP ASSOCIATION

**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 2.000 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 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

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.

Participants' comments:

*"Very good course"*
Igor Todorcevski, Alkaloidpharm SA

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

**Absender**

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**Anmeldung/Bitte vollständig ausfüllen**

GDP in Switzerland - Specifics in the Distribution of Medicinal Products and APIs (GDP 3)
Recorded Online Training from 01 September 2020

Titel, Name, Vorname

Abteilung

Firma

Telefon / Fax

E-Mail ( bitte angeben)

Allgemeine Geschäftsbedingungen
Bei einer Stornierung der Teilnahme an der Veranstaltung berechnen wir folgende Bearbeitungsgebühr:

- Bis 2 Wochen vor Veranstaltungsbeginn 10 % der Teilnehmergebühr.
- Bis 1 Woche vor Veranstaltungsbeginn 50 % der Teilnehmergebühr.
- Innerhalb 1 Woche vor Veranstaltungsbeginn 100 % der Teilnehmergebühr.

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## Recorded Online Training

With your registration confirmation for this recorded versions you will receive a link and the login. This login will be open for two days, in which you are free to watch the recorded version. Together with the link and login you will also receive the PDFs of all presentations.
Please note that you don't need to install any additional software - the recording can be watched in any browser.

## Fees (per delegate, plus VAT)

GDP Association Members € 990
(equates 1.051 CHF, dated May 2020)
Non-members € 1.190
(equates 1.263 CHF, dated May 2020)
Relevant for payment is the price in EURO. The conference fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org

## Certificate

Each participant will receive a certificate of participation at the end of the access period.

## Conference language

The official conference language will be English.

## Organisation

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