



GDP in Switzerland

Specifics in the Distribution of Medicinal Products and APIs



Live Online Training on 01 September 2020



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

Speakers



Dr Ina Bach
Dr. Bach



Dr Johannes Fröhlich
Akroswiss



Dr Felix Kesselring
Bratschi AG



Dr Remo Studer
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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



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.

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

09.00 – 09.10 h
Introduction

09.10 – 10.00 h
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

10.00 – 10.20 h
Break

10.20 – 11.40 h
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

11.40 – 12.30 h
Liability

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

12.30 – 13.30 h
Break



13.30 – 15.30 h 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

15.30 – 15.50 h Break

15.50 – 17.15 h 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

17.15 – 17.30 h Final Discussion



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 free 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

Anmeldung/Bitte vollständig ausfüllen

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

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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.

Selbstverständlich akzeptieren wir ohne zusätzliche Kosten einen Ersatzteilnehmer. Der Veranstalter behält sich Themen- sowie Referentenänderungen vor. Muss die Veranstaltung seitens des Veranstalters aus organisatorischen oder sonstigen Gründen abgesagt werden, wird die Teilnehmergebühr in voller Höhe erstattet.

Zahlungsbedingungen: Zahlbar ohne Abzug innerhalb von 10 Tagen nach Erhalt der Rechnung.

Bitte beachten Sie: Dies ist eine verbindliche Anmeldung. Stornierungen bedürfen der Schriftform. Die Stornogebühren richten sich nach dem Eingang der Stornierung. Im Falle des Nicht-Erscheins auf der Veranstaltung ohne vorherige schriftliche Information werden die vollen Seminargebühren fällig. Die Teilnahmeberechtigung erfolgt nach Eingang der Zahlung. Der Zahlungseingang wird nicht bestätigt. (Stand Januar 2012)

Es gilt deutsches Recht. Gerichtsstand ist Heidelberg.

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Date of the Live Online Training
Tuesday, 01 September 2020, 9.00 – 17.30 h

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.

At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.gdp-navigator.de or www.gmp-navigator.com

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at any time at <https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars>.

Organisation

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