



GDP in Switzerland

Specifics in the Distribution of Medicinal Products and APIs

03 September 2019, Bern



Speakers



Dr. Ina Bach
Dr. Bach AG,
form. RHI



Ursula Eggenberger Stöckli
Bratschi Wiederkehr & Buob
AG, Lawyers



Dr. Johannes Fröhlich
Akroswiss



Dr. Remo Studer
Galexis AG

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

Highlights

- EU Regulations and their Implementation in Switzerland
- Tasks and Responsibilities
- Distribution to, from and out of Switzerland
- Practical Aspects of Storage and Transportation
- Liability and Indemnification

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European GDP Association



Programme

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**)

Now, 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.

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

EU Regulations and their Implementation in Switzerland

- 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

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

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
- 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 (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

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.



Ursula Eggenberger Stöckli
Rechtsanwältin und Apothekerin
Bratschi Wiederkehr & Buob

Ursula Eggenberger Stöckli studied Pharmacy and was working for 10 years in the pharmaceutical industry. After that she studied law and became a lawyer. As a lawyer she is specialised in pharma and life science law.



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 and the 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.



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

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) 03 September 2019, Bern

| | | |
|---|-----------|------------------------|
| CONCEPT HEIDELBERG Postfach 10 17 64 Fax 06221/84 44 34 | Abteilung | Titel, Name, Vorname |
| D-69007 Heidelberg | Firma | Telefon / Fax |
| | | E-Mail (bitte angeben) |

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

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.

Date

Tuesday, 03 September 2019, 9.00h – 17.30h
(Registration and coffee 8.30h – 9.00h)

Venue

Hotel Ambassador & Spa
Seftigenstrasse 99
3007 Bern, Switzerland
Telefon +41 (0)31 370 99 99
Fax +41 (0)31 371 41 17
E-Mail ambassador@fhotels.ch

Fees

GDP Association Members € 990 (equates 1.133 CHF
(dated November 2018)

Non-members 1.190 € (equates 1.363 CHF
(dated November 2018)

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 or www.gmp-navigator.com

Conference language

The official conference language will be English.

Organisation

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:

Mr Wolfgang Schmitt (Director Operations) at +49-62 21/84 44 39, or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:

Ms Nicole Bach (Organisation Manager) at +49-62 21/84 44 22, or per e-mail at bach@concept-heidelberg.de.