



The QP in Switzerland

Role, Accountability and Liability of the Responsible Person

03/04 June 2020, Bern, Switzerland



Speakers



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Highlights

- EU Regulations and their Implementation in Switzerland
- Revision of the Therapeutic Products Act and Amendments to Ordinances
- Tasks and Responsibilities in the Supply Chain
- Investigational Medicinal Products
- Liability and Indemnification

Objectives

- Learn and discuss the special tasks and responsibilities of the Responsible Person (RP) in Switzerland (Qualified Person/ QP according EU legislation).
- Exchange opinions and convey possible solutions to problems addressed in case studies and workshops.
- Benefit from the speakers' experience in industry, authority and legal advice.

Background

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. This means that the GMP requirements of Directive 2001/83 / EC (in particular Article 46. to 52 for the QP) also apply in Switzerland.

The requirements for a Responsible Person ("**Fachtechnisch Verantwortliche Person**" in the German speaking part) are described in art. 5, art. 10, art. 14 and art. 15 of the Ordinance on Establishment Licences. With its signature, the RP confirms that a batch meets the specifications and has been manufactured in a GMP-compliant system. This system-related statement is considerably more comprehensive than a batch-related confirmation, which aims solely to comply with the specifications. **Therefore the duties and responsibilities can be rather extensive.**

Now, on 1 January 2019, the revised Therapeutic Products Act (HMG 2) and amendments to the ordinances (Therapeutic Products Ordinance Package IV) came into force - with some interesting alterations.

Target Audience

Responsible Persons/ RPs for batch certification and release and Executives and Managers who want to get an overview on the duties and responsibilities of the RP.

The European Qualified Person Association

The European Qualified Person Association was founded by the members of the Advisory Board of the European Compliance Academy (ECA) in 2006. It is the only association of its kind and serves Qualified Persons as a platform for the exchange of experiences and allows members to discuss the latest developments and challenges.

Meanwhile, the European Qualified Person Association counts more than 2.700 members and has experienced a correspondingly large international recognition. Membership is open to all registered EU QPs but also to RPs from Switzerland and is free of charge.

Learn more: <http://www.qp-association.eu/>

Programme

EU Regulations and their Implementation in Switzerland

- Directive 2001/83/EG and the Qualified Person
- Mutual Recognition Agreement
- Ordinance on Establishment Licences OEL (AMBV, OAMéd)

Role and Tasks of the Responsible Person

- The role in the company and the organisation chart
- Batch certification and release
- Cross-boarder activities
- Personal duties and responsibilities
- Delegation
- Deputies
- Internal delimitation of responsibilities
- Contract RPs

Outsourcing: What the RP should know about assuring Product Quality

- Compliance with the registration
- Compliance with GMP
- Audits and supplier qualification
- Necessary batch documentation
- Product Quality Review (PQR)
- Delimitation of Responsibilities in the supply chain
- Quality (Technical) Agreement

Workshop

- Certification and Batch Release: to certify or not, that's the question!
- Decision making based on real examples

The Supply Chain

- Requirements in Switzerland and the EU
- Responsibilities of the RP
- Questions, challenges and solutions

The GMP/GDP Interface

- Consequences of the Therapeutic Products Act and amendments to Ordinances
- Storage and transport
- Import and export: particularities
- Cool and cold chain issues
- Supply chain traceability

The Responsible Person's daily Work: what the RP need to know about:

- Communication and collaboration with the authorities
- Risk Management
- KPIs
- Management Review

What the Responsible Person needs to know about Investigational Medicinal Products (IMPs)

- The new EU Clinical Trial Regulation and the consequences for Switzerland
- IMP supply to the EU
- IMP transfer in Switzerland
- Labelling
- Named Patient Import

Liability

- Principles of liability
- When will the RP be liable?
- Potential sanctions
- Examples from the real life, case law



Workshop Quality Control and Laboratory: what the RP needs to know

- Responsibilities
- OOS, OOE und OOT
- Fault analysis
- Statistics
- Decision making based on real examples

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. After that she was Senior Compliance Auditor in a Global Auditing Group of a global pharmaceutical company in Switzerland. Besides this experience, Ina Bach was also working as Responsible Person.



Ursula Eggenberger Stöckli, Attorney at Law and Pharmacist, Bratschi Wiederkehr & Buob AG

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.



Karin Hofstetter, CSL Behring

Karin Hofstetter is Senior Manager Quality Release at CSL Behring. Amongst others, she was also working as QA Expert at Novartis and Head Quality Release at Crucell.



Dr Ulrich Kissel, European QP Association, KisselPharmaConsulting

Dr Ulrich Kissel is Qualified Person and Member of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP for the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche



Dr Tillmann Lindenblatt, Fisher Clinical Services GmbH

Dr Tillmann Lindenblatt is Director QA/ Responsible Person at Fisher Clinical Services in Allschwil(CH) and Weil am Rhein (D) (both NCEs and NBEs). Before that he held several RP and Head of Quality Control positions at other companies.



Dr Carsten Meininghaus, DSM

Dr Carsten Meininghaus is Head of Compliance Quality . Before that he was Director Quality Compliance and Responsible Person at Crucell Switzerland AG and Head of Quality Control Biopharma and Responsible Person at Lonza AG.

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

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

D-69007 Heidelberg

Reservation Form (Please complete in full)

The QP in Switzerland, 03/04 June 2020, Bern, Switzerland

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number (if applicable)

Street/P.O. Box

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.

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Cancellation

- until 2 weeks prior to the conference: 10 %

- until 1 week prior to the conference: 50 %

- within 1 week prior to the conference: 100 %

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German law shall apply. Court of jurisdiction is Heidelberg.

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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)

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Date

Wednesday, 03 June 2020, 9-30 h – 17.30 h

(Registration and coffee 9.00 h – 9.30 h)

Thursday, 04 June 2020, 9.00 h – 15.30 h

Venue

Hotel Ambassador & Spa

Seftigenstrasse 99

3007 Bern, Switzerland

Phone +41 (0)31 370 99 99

Email ambassador@fhotels.ch

Fees (per delegate plus VAT)

QP Association Members € 1.390

(equates 1.550 CHF, dated July 2019)

Non-members € 1.490

(equates 1.660 CHF, dated July 2019)

Relevant for payment is the price in Euro.

The conference fee is payable in advance after receipt of invoice and includes conference documentation (download), lunch on both days and all refreshments. VAT is reclaimable.



Important Information!

The presentations of the course will be available for download and your print-out one week before and after the conference.

Note: there will be no print-outs available during the course.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive an information 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 message. Or you register online at www.gmp-compliance.org

Conference language

The official conference language will be English.

Organisation and Contact

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