COURSE IN ENGLISH LANGUAGE

The QP in Switzerland

Role, Accountability and Liability of the Responsible Person

22/23 May 2024 | Bern, Switzerland

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

Speakers

Dr Ina Bach
Dr Bach, form. RHI

Dr Karin Hofstetter
BioAtrium

Dr Felix Kesselring
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Dr Ulrich Kissel
European QP Association

Dr Carsten Meininghaus
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Jette Petersen
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QP ASSOCIATION

Supported by the European QP Association

CONCEPT HEIDELBERG

Pharmaceutical Quality
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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.**

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.

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

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.

Membership is open to all registered EU QPs but also to RPs from Switzerland and is free of charge.

Learn more at www.qp-association.eu

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.

Dr Karin Hofstetter
BioAtrium AG

Dr Karin Hofstetter is Senior Manager QMS & Compliance. Before that she was, amongst others, Senior Manager Quality Release and Head Quality Release in various Suisse pharmaceutical companies.

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 Felix Kesselring
Bratschi AG Attorneys at Law

Dr Felix Kesselring is a lawyer and advises Swiss and international companies in the health, pharmaceutical, medical device and biotechnology industries. He was also Seconded Legal Counsel at an internationally active Swiss pharmaceutical company.

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.

Jette Petersen
Roche

Jette Petersen is Quality Assurance Specialist IMP. Before that she was, amongst others, QP at Fisher Clinical Services.

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Reservation Form (Please complete in full)

The QP in Switzerland | 22/23 May 2024, 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)

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General terms and conditions

If you cannot attend the conference you have two options:
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- 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 %.

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date

Wednesday, 22 May 2024, 9.30h – 17.30h
(Registration and coffee 9.00h – 9.30)
Thursday, 23 May 2024, 9.00h – 16.15h

Venue

Hotel Ambassador & Spa
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Fees (per delegate, plus VAT)

QP Association Members € 1,590 (equates 1,550 CHF, dated July 2023)
Non-members 1,690€ (equates 1,650 CHF, dated July 2023)
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.

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.gmp-compliance.org.

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.

Conference language

The official conference language will be English.

Organisation and Contact

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