COURSE IN ENGLISH LANGUAGE

The QP in Switzerland

Role, Accountability and Liability of the Responsible Person

Live Online Training on 03/04 June 2020

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 AG, form. RHI

Ursula Eggenberger Stöckli
Bratschi Wiederkehr & Buob AG Lawyers

Karin Hofstetter
CSL Behring AG

Dr Ulrich Kissel
European QP Association

Dr Tillmann Lindenblatt
Fisher Clinical Services

Dr Carsten Meininghaus
DSM

QP ASSOCIATION

Supported by the European QP Association

CONCEPT HEIDELBERG

Pharmaceutical Quality
Training. Conferences. Services.

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.**

In 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

Wednesday, 03 June 2020

09.30 – 09.40 Introduction

09.40 – 10.30
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)

10.30 – 10.50 Coffee Break

10.50 – 12.00
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

12.00 – 12.15 Time for discussion

12.15 – 13.20 Lunch break

13.20 - 15.20
Examples: Certification and Batch Release

- To certify or not, that's the question
- Decision making process

15.20 – 15.40 Coffee Break

15.40 – 16.20
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

16.20 – 17.20
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

17.20 – 17.30 Time for discussion

Thursday, 04 June 2020

09.00 – 09.50
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

09.50 – 10.40
The API Supply Chain

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

10.40 – 11.00 Coffee Break

11.00 – 12.00
The Responsible Person's daily Work: what the RP need to know about:

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

12.00 – 12.45
Liability

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

12.45 – 13.00 Time for discussion

13.00 – 14.00 Lunch break

14.00 - 15.30
Examples: Quality Control and Laboratory

- What the RP needs to know
- Responsibilities
- OOS, OOE und OOT
- Fault analysis
- Statistics

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.

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The QP in Switzerland
Live Online Training on 03/04 June 2020

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Date Live Online Training

Wednesday, 03 June 2020, 9-30 h – 17.30 h
Thursday, 04 June 2020, 9.00 h – 15.30 h

Technical Requirements

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Presentation/Certificate

The presentation will be made available to you prior to the Online Training as a PDF file. After the Online Training, we will automatically send you a certificate of participation.

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. VAT is reclaimable.

Registration

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

Important
Deadline is 12 noon on 02 June 2020

Conference language

The official conference language will be English.

Organisation and Contact

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