The QP in Switzerland

Role, Accountability and Liability of the Responsible Person

04/05 March 2026, Bern, Switzerland

ON SITE

CERTIFICATE

SPEAKERS

Dr Ina Bach
Dr Bach, form. RHI

Dr Karin Hofstetter
BioAtrium

Dr Felix Kesselring
Bratschi Rechtsanwälte

Dr Ulrich Kissel
European QP Association

Dr Carsten Meininghaus
dsm-firmenich

Jette Petersen
Roche

- 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

Course in Englisch language

Supported by the European QP Association

CONCEPT HEIDELBERG
EUROPE'S LARGEST GMP/GDP ACADEMY

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.

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.

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: 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

INTERACTIVE SESSION

Certification and Batch Release: to certify or not, that's the question!

Decision making based on real examples

The API 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

PARTICIPANTS' COMMENTS

"Very informative and appreciated the Q&As. Case studies generated much good discussion."
Tim Tratthen, Moderna

The Responsible Person's daily Work: what the RP needs 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

INTERACTIVE SESSION

Quality Control and Laboratory: what the RP needs to know

- Responsibilities
- OOS, OOE und OOT
- Fault analysis
- Statistics

IMPORTANT INFORMATION!

The presentations of the course will be available for download and your print-out 1 week before and after the conference.
Note: there will be no print-outs available during the course.

SPEAKERS

Dr Ina Bach

Dr. Bach AG
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, Senior Compliance Auditor in a Global Auditing Group of a global pharmaceutical company in Switzerland. Besides, she 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 Felix Kesselring

Bratschi AG Attorneys at Law
Lawyer and advisor for 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 Ulrich Kissel

European QP Association,
KisselPharmaConsulting
Qualified Person and Member of the Board of Directors of the European Qualified Person Association (EQPA). GMP consultant and contract QP for the Pharmaceutical Industry. Previous to his current role, leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Dr Carsten Meininghaus

dsm-firmenich
Responsible Person (FvP). Before that, 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.

BOOK NOW

Date
04/05 March 2026

Wednesday, 04 March 2026, 9.30h – 17.30h
(Registration and coffee 9.00h – 9.30h)
Thursday, 05 March 2026, 8.30h – 16.00h

Venue
Hotel Ambassador & Spa

Seftigenstrasse 99
3007 Bern
Switzerland
Tel.: +41 (0)31 370 99 99
Fax: +41 (0)31 371 41 17
E-Mail: ambassador@fhotels.ch

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.

Conference Language

The official conference language will be English.

Fees

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.

€ 1.790,-
QP Assocation Members
(equates 1.667 CHF, dated July 2025)

€ .1990,-
Non-Members
(equates 1.853 CHF, dated July 2025)

Organisation

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Phone: +49 (0)6221 8444-0
Fax : +49 (0)6221 8444-34
E-Mail: info@concept-heidelberg.de
www.gmp-navigator.com

Do you have questions?

Regarding content, please contact:
Mr Wolfgang Schmitt (Operations Director)
Phone: +49 (0)6221 8444-39
E-Mail: w.schmitt@concept-heidelberg.de

Regarding organisation, please contact:
Ms Nicole Bach (Organisation Manager),
Phone:+49 (0)6221 8444-22
E-Mail: nicole.bach@concept-heidelberg.de

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site.

After the event, you will automatically receive your certificate of participation.

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REGISTRATION

Seminar Number 22104

By e-mail or online at www.gmp-compliance.org. Search and register directly under the number 22104. To avoid incorrect information, please give us the exact address and full name of the participant.