ECA Academy
Your GMP/GDP Information Source

Speaker

Dr Ulrich Kissel
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GMP meets Pharmacovigilance

Live Online Training on 29 October 2024

GMP / GVP Interfaces and Challenges

Highlights

- QP / QPPV Interfaces and Responsibilities
- GVP Inspections & Audits
- How to handle Complaints & Recalls
- Real World Data & Signal Management
- How to implement Safety Variations
- Risk Minimization Measures

Objectives

In this live online training, you will learn from experienced experts what you need to consider as a Qualified Person for Pharmacovigilance (QPPV). You will receive information on similarities and demarcations with other roles, like Qualified Persons (QPs), Information Officers and the German graduated plan officer ("Stufenplanbeauftragter").

Background

The systematic recording, collection and evaluation of reports on adverse drug reactions as well as quality defects and falsifications are the main tasks of the QPPV in the context of drug safety. The establishment and maintenance of a pharmacovigilance system (PVS), reviewing the PVS with the help of audits, as well as the preparation, monitoring and follow-up of authority inspections are also part of the QPPV tasks. QPPVs also have an important function in the event of complaints and recalls. This include direct contact with the authorities in connection with processing quality defects, including analysing the causes, the description of corrective and preventive measures, as well as the preparation of regularly updated safety reports (PSURs) and the implementation of safety variations.

Target Audience

This course is designed for:

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Qualified Persons (QPs),
- Sponsors of clinical trials,
- Individuals involved in GVP inspections & audits, complaint handling, and signal & data management.

Programme

Complaints & Recalls: GMP Requirements

- Do we know the definitions of complaint and recall?
- EU GMP Part I chapter 8
- Difference within EU GMP cocnerning IMPs and ATMPs
- News from the Compilations of Union Procedures
- Recall as a risk mitigating measure
- Mock Recall
- Examples

The QP Involvement and Perspective on Pharmacovigilance

- The QP and the QPPV - similar roles?
- Technical complaints and safety signals
- Who decides? Expectations.
- Spectrum of national legal differences within EU
- Examples and experience sharing

Interfaces & Demarcations - The QPPV Perspective

Responsible persons according to GMP, GDP and GVP

- Tasks and obligations of the QPPV, QP and GDP responsible person
- Interfaces between QPPV, QP and GDP responsible person during daily practice
- Examples from daily business
- Special case in Germany – "Stufenplanbeauftragter"

Q&A Session 1

GVP Inspections & Audits

- Expectations for GMP/GVP interfaces in audits and inspections
- Typical findings in GMP/GVP collaboration/interface
- Relevant contracts in the interfacial daily business QP/QPPV
- Inspection readiness do's and don'ts

Real-World Data and Signal Management

- Data sources in the post-authorization phase, solicited versus unstructured data
- Study designs in real-world settings
- Understanding and analyzing large datasets, signal algorithms versus manual assessment
- Assessing the impact of safety findings on the benefit risk profile

Safety Variations and Risk Minimization Measures

- When the alarm bell rings: a safety signal is verified, what to do next?
- Internal process requirements and external reporting obligations
- Prioritization of safety variations
- Is a labeling update sufficient to prevent further onset of adverse reactions? What is the role of additional risk minimization measures?

Q&A Session 2

Your Benefit

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

The EU GMP Guide requires:
„... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“.

This is why you receive an acknowledged participant certificate, which lists the contents of the live online training in detail and with which you document your training.

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

Speakers

Dr Ulrich Kissel, European QP Association, KisselPharmaConsulting, Germany

Ulrich is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to 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.

Julia Pfaff, Merz Therapeutics, Germany

Julia is Director Head of Pharmacovigilance, EU and UK QPPV. She holds a Master of Science in Nutritional Science, specialized in biochemistry and molecular biology from Justus-Liebig University in Gießen. She has more than 14 years' experience in Pharmacovigilance and Drug Safety from small and mid-size pharma companies as well as big pharma, in the field of specialty pharmaceutical products and for generics. Since 2016, she acts as QPPV and "Stufenplanbeauftragte".

Dr Bianca Scholz, ScholzPharma Consulting, Germany

Bianca has been Managing Director of Scholz Consulting since 2008 and advises clients in the areas of GVP, GCP, GLP, GDP and GMP with a focus on quality management, audit and inspection. She is DGQ/EQO certified auditor, specialised pharmacist for drug information / and carries out numerous audits in the field of pharmacovigilance (including inspection preparations/"inspection readiness").

Dr Heinz Weidenthaler, Bavarian Nordic, Germany

Heinz is a Global Principal Safety Physician and EU-QPPV for Bavarian Nordic's vaccines. He joined Bavarian Nordic in 2013, initially as Director Pharmacovigilance. From Jan-2019 to late 2022 he served as VP Clinical Strategy, a role in clinical research supporting the FDA licensure of a poxvirus vaccine and the clinical development of RSV and COVID-19 vaccine candidates from Phase 1 into Phase 3. Since 2023 he has been working on the post-authorization benefit risk profile of the Imvanex/Jynneos smallpox and mpox vaccine, and as EU-QPPV for the licensed vaccine portfolio of Bavarian Nordic.

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GERMANY

Reservation Form (Please complete in full)

GMP meets Pharmacovigilance
Live Online Training on 29 October 2024

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- 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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. 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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 29 October 2024, 09.00 h – 17.00 h CET

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members EUR 1090,-
APIC Members EUR 1140,-
Non-ECA Members EUR 1190,-
EU GMP Inspectorates EUR 595,-
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21356.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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