Qualified Person Education Course
Module B

Mastering the QP Role in daily Practice

02/03 June 2022, Copenhagen, Denmark

With an optional pre-course Session:
"Interpersonal and Soft Skills for the QP"
on 01 June 2022

Speakers:

Georg Göstl
Qualified Person, Takeda, Austria

Arnoud Herremans
Y47 Consultancy,
The Netherlands

Dr Ulrich Kissel
European QP Association

Sue Mann
Sue Mann Consultancy, U.K.

Jens-Uwe Rengers
JeRo Consulting, Switzerland

Ewa Rybak
Polpharma Biologics, Poland

Dr Ulrich Kissel

Dear Colleagues,

The European Qualified Person Association (EQPA) has developed two Education Course Modules for new, trainee and practising Qualified Persons to address general compulsory and regulatory issues. This **Module B** has been compiled by the EQPA Board of Directors to show and discuss how to master the QP role in practice including its interfaces and necessary interactions.
Module A provides a comprehensive overview on the special tasks and responsibilities of a QP.
Further impacts of the latest developments, specific tasks and detailed discussions will be part of the annual QP Forum of the European Qualified Person Association.

Best regards,

Ulrich Kissel
Chairman of the European Qualified Person Association

Objectives

Broaden your knowledge of the Qualified Person's duties and see and discuss which responsibilities and tasks are parts of a QP's daily life – besides batch certification. With fulfilling these tasks, the QP has a lot of interfaces and interactions. How this can be managed will be a topic in Module B and its pre-course session on soft skills.

Background

Over the last years the role and responsibilities of the Qualified Person have been increasing considerably. As a key person in the company, the QP has to consider many issues and has to take up the challenges within its areas of responsibilities. Additionally, as laid out in Article 49 of the European Directive 2001/83/EC, the QP needs to be highly qualified and experienced. EQPA's education course modules will help the QP to be well prepared and to be on top of current developments in GMP and regulatory requirements.

Target Audience

New and practicing Qualified Persons who are looking for ongoing training and want to improve their effectiveness and liaison with other functions.

Moderator

Wolfgang Schmitt
On behalf of EQPA

Programme QP Education Course Module B on 02/03 June 2022

QP Interfaces

- Which roles are essential for a QP to work efficiently and effectively (e.g. Head of Production, Head of Quality Control, QPPV, QA)
- Identifying the best working practice for QPs working with colleagues in supportive roles
- Links with regulatory authorities and inspectors

Import – Export – Product Flow

- Applicable legislation: a view on Annex 16 and Annex 21
- Different Mutual Recognition Agreements (MRAs)
- What's expected with regard to Supplier Qualification, Supply Chain Overview, Re-Testing and PQ

Interpretation of Data (with a Focus on Batch Documentation and the PQR)

- Which key figures are relevant for the QP?
- Data verification: determining the acceptability of data
- When is a system or process deemed to be robust?
- Necessary key figures: always easy to understand?
- When is a trend a trend? And what to do with OOT (out of trend)?

Workshop: Interpretation of Data

- Learn how to interpret data and understand the consequences of appropriate and inappropriate performance parameters
- Evaluate with other delegates the content and lay-out of given examples and discuss it with the speakers

Human Error

- What is behind "Human Error"?
- What the QP needs to know about it
- Is Human error avoidable?
- Human error and Data Integrity issues

How to ensure that a Batch is in Compliance with the Requirements of its Marketing Authorisation (MA)

- Structure of the MA – which are the relevant parts for the QP?
- How to keep the QP Declaration up to date?
- How can the QP ensure compliance?
- Involvement in Change Control processes
- Challenges for the QP
- Possible Work Flows

Quality Risk Management for the QP

The term "quality risk management" is used throughout Annex 16. But how could the QP use this tool? In this session you will get some practical advice!

About the European QP Association

The European Qualified Person (QP) Association was founded in July 2006 by the European Compliance Academy's (ECA) Advisory Board Members. With this unique association the ECA wants to provide QPs in Europe with a platform allowing them to exchange their experience, discuss the latest regulatory requirements, to identify and address difficulties and challenges and to support a harmonised European approach.
All details at www.qp-association.eu.

QP Involvement in Investigations and CAPA

- QP role in deviation process
  - Product deviation
  - Process deviation
  - Reoccurring deviations
- QP role in handling of product deviations
- Does QP need to be involved in all deviations?
- QP final decision regarding product deviation and batch certification
- QP involvement in product complaints
- Tools for performing investigations
- The importance of CAPA in the deviation process
- Workshop with examples

Thinking outside the Box: Certification of Plasma Products

New classes of medicines such as ATMPs, Blood and Plasma Products are creating special challenges for the QPs certifying these products. This session aims to provide insight into the challenges when certifying plasma products. Discuss these challenges and see what delegates from different areas can learn from each other.

Speakers QP Education Course

Georg Göstl
Takeda, Austria
Qualified Person
Georg Göstl is Chair of the Austrian QP Association aqpa and member of the EQPA Board of Directors.

Dr Ulrich Kissel
European QP Association (EQPA)
Chairman of the Board of Directors
Ulrich Kissel 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.

Sue Mann
Sue Mann Consultancy, U.K.
Managing Director
Sue Mann is a Qualified Person and a QP Assessor in the U.K. working on behalf of the MHRA, representing the Royal Pharmaceutical Society. She was Vice President of International Quality Assurance at Shire Pharmaceuticals before founding her company in 2009.

Jens-Uwe Rengers
JeRo Consulting GmbH, Switzerland
CEO and Managing Consultant
Prior to the funding of his consultancy business, Jens-Uwe Renger acted as General Manager at Akorn AG. Before that he was Director Quality and QP and held different other roles at Byk Gulden (now Takeda), Cytos Biotechnology AG and Siegfried Ltd.

Ewa Rybak
Polpharma Biologics, Poland
Qualified Person
Ewa Rybak is Quality Compliance Expert, Qualified Person at Polpharma Biologics and an Academic Lecturer for Quality Management at Warsaw University of Technology.

Pre-course Session: : Interpersonal and Soft Skills for the QP on 01 June 2022

Objectives and Background

The QP job requires interaction with others. It is so much more than sitting at the desk certifying batches. A QP is not expected to have all the necessary qualifications and experience from day one. But a QP needs to learn and grow in the role. Education and knowledge are important for fulfilling the tasks and responsibilities. Besides that, experience and soft skills are important when it comes to interacting with colleagues, management, other departments and authorities. Soft skills help the QP to function in teams and organisations as a whole.

Target Audience

New colleagues becoming QPs, but also experienced QPs looking for continuous training and enhancement of their soft skills.

Programme

- Communication, Negotiation and Conflict Management
- Leadership and motivation in line and in the matrix
  - Enforcing decisions on a larger scale
  - Reasonably represent your own opinion
  - Teamwork
- Problem solving
- Pressure and time management
- Self-Motivation

Speakers Pre-Course Session

Arnoud Herremans
Y47 Consultancy, The Netherlands
Founder and CEO
Arnoud Herremans is psychologist by training and holds a PhD in Neuroscience. He is experienced in pharmaceutical industry as researcher and manager.

Sue Mann
Sue Mann Consultancy, U.K.
Managing Director
Sue Mann is a Qualified Person and a QP Assessor in the U.K. working on behalf of the MHRA, representing the Royal Pharmaceutical Society. She was Vice President of International Quality Assurance at Shire Pharmaceuticals before founding her company in 2009.

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69007 Heidelberg
Germany

Reservation Form (Please complete in full)

☐ **Qualified Person Education Course – Understand the Implications of becoming a QP - Module B**
02/03 June 2022, Copenhagen, Denmark

☐ **Pre-course Session: Interpersonal and Soft Skills for the QP** | 01 June 2022, Copenhagen, Denmark

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number and your PO Number

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Dates
Pre-course Session: Interpersonal and Soft Skills for the QP
Wednesday, 01 June 2022, 13.00 – 17.30 h
(Registration and business lunch 12.00 – 13.00 h)

QP Education Course – Module B
Thursday, 02 June 2022, 9.00 – 18.00h
(Registration and coffee 8.30 – 9.00)
Friday, 03 June 2022, 8.30 – 15.00 h

Venue for both events
Radisson Blu Scandinavia Hotel
Amager Boulevard 70 | 2300 | Copenhagen S | Denmark
Phone: +45 (0) 33/ 96 50 00 | Fax: +49 (0) 33/ 96 55 00
On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on site event, it will be conducted live online. In this case, you will be informed in due time.

Fees (per delegate plus VAT)
Pre-course Session: Interpersonal and Soft Skills for the QP
QP Association Members € 690
ECA Members € 690
Non-ECA Members € 790
EU GMP Inspectorates € 395

QP Education Course
QP Association Members € 1,490
ECA Members € 1,490
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

Save money when booking both events
If you book the QP Education Course TOGETHER WITH the Pre-course Session, the fee will be as follows (per delegate plus VAT):
QP Association Members € 1,990
ECA Members € 1,990
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145

The conference fee is payable in advance after receipt of invoice and lunch on both days and all refreshments. VAT is reclaimable.

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.

Conference language
The official conference language will be English.

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

Accommodation
CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Organisation / Contact
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