

RESPONSIBLE PERSON FOR GDP

1 DAY COURSE

PRACTICAL INFORMATION

This interactive course with workshops is designed to bring you up-to-date with the current regulatory expectations and GDP requirements. You will learn about the role of the Responsible Person and his/her responsibilities according to GDP requirements.

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|-------------------|---|
| Audience | Anyone who is becoming or is in function as RP, Deputy or QP, or is involved in QA/RA. Anyone interested in Good Distribution Practice requirements. |
| Time | 08u30 - 09u00 Registration & Coffee 09u00 - 17u00 Course (lunch included) |
| Location | Quastion Learning Center Leuvensesteenweg 643, 1930 Zaventem |
| Course fee | €899 per participant (exclusive 21% VAT) this includes: <ul style="list-style-type: none"> ✓ exclusive learning approach ✓ personal course documentation ✓ course certificate after participation ✓ breakfast, coffee & water ✓ networking |
| Payment | The course fee is payable after we confirm your registration. We would like to receive it before the course, on the account of Qplus Consult bvba: IBAN: BE82 0016 3318 6168 SWIFT/BIC: GEBA BE BB The reference will be a unique ordercode, which you will receive after we receive your filled-in signup form. |

[See the next page for the course program](#)

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PROGRAM

Implementation of the New EU GDP Guideline

- Well-known or new: a summary of the most important changes

GDP Compliance: How to Achieve It?

- Roadmap: what do I need?
- How to get started and to maintain a GDP-compliant status?
- The counterfeit and pharma supply chain

Quality Management System

- How to develop and implement an effective Quality Management System?

Roles and Responsibilities of the RP

- Qualification requirements to the RP
- Duties of the RP
- How to keep it all under control?
- What and how to delegate?
- How to report and control delegated activities?
- RP deputy: who can help me?

RP Quality Oversight: Principles & Practical Approach

- RP Quality Oversight: what to oversee and how to proceed?
- How to establish a Quality Oversight process

Batch Release for Sale: Requirements & Reality

- Batch release for sale: is this mandatory?
- Batch release for sale: to do or not to do?
- What does Final Batch Release mean for RP?
- RP vs. QP role in Final Batch Release
- Where your responsibility as RP GDP stops
- How to identify what to verify and control?

Returns: Time- & Risk-reducing Approach

- What are the requirements and how to implement?
- Time- & risk-reducing approach

GDP(/GMP) Inspections

- GDP inspection readiness
- Frequent findings
- Expectations with regards to the RP

Temperature-controlled Distribution

- Get known your distribution chain
- How to identify the weakest links and what to do?
- How to manage cold chain products: warehousing & transport
- How to manage 15-25°C products: warehousing & transport
- Temperature monitoring or control? – what is the best option for the product

How to Manage Outsourced GDP Activities & Audits

- What is a GDP activity?
- How to qualify & manage GDP outsourced activities?
- Approach a GDP Audit
- Reporting deficiencies : CAPA's or risk mitigation plan?
- Quality Agreements requirements & inspectorate expectations

Transport: a Grey-zone or Well-known Activity

- How to manage GDP-transport?
- Risk-based approach and where to pay attention to

Management Review & Monitoring in Practice

- How to identify the parameters for monitoring
- The Best Industry Practices for Management Review and Monitoring

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SIGN UP FORM

Please fill in the registration form, and send this as an attachment to quastion@qplusconsult.com. Our General Terms and Conditions and Privacy Policy are hereby accepted (see bottom of the page).

You will receive a confirmation of your registration as soon as we finish handling this form. We will also send you a request for payment, with the total amount due and your unique ordercode. The invoice will be issued after the payment is received.

Course date (please check a box)

12/9/2019

Company details

company name _____

VAT-number _____

address _____ postal code _____

city _____ country _____

e-mail address _____

if eligible for KMO-portefeuille, please check a box:

Small Enterprise

Medium-sized Enterprise

Participants (fill in a second form if you are more than six participants)

| | first name | last name | possible food restrictions |
|---|------------|-----------|----------------------------|
| 1 | _____ | _____ | _____ |
| 2 | _____ | _____ | _____ |
| 3 | _____ | _____ | _____ |
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| 5 | _____ | _____ | _____ |
| 6 | _____ | _____ | _____ |

General terms and conditions: If you cannot attend the event you have two options: 1. We are happy to welcome a substitute colleague at any time. 2. If you have to cancel entirely, we ask you to inform us via mail at quastion@qplusconsult.com. In this case we must charge the following processing fees: Cancellation - until 2 weeks prior to the course 10 %; - until 1 week prior to the course 50 %; - within 1 week prior to the course 100 %. Qplus consult reserves the right to change the materials, instructors, or speakers without notice or to cancel the course. If the course must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. Qplus consult will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. Full text of Terms and Conditions is published on our website www.quastioncourses.com.

Terms of payment: Payable without deductions before the date of the course.

Important: This is a binding registration and the course 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 course 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 course (receipt of payment will not be confirmed).

Privacy Policy: By registering for this course you accept this Privacy Policy: I accept the processing of my Personal Data. Qplus consult 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. Qplus consult will only send me information in relation with this order or other activities of Qplus consult. My personal data will not be disclosed to third parties. I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on the website www.quastioncourses.com. Full text of Privacy Policy is published on our website www.quastioncourses.com.