pharmakon

PQS compliance with new requirements

Stay ahead of new regulatory requirements

Learn a practical and reliable process for monitoring and implementing new requirements in your PQS. Discover how AI can reduce manual review and highlight exactly what impacts your quality system.

Course facts

FORMAT
1 day

PRICE THIS YEAR
5.900 DKK excl. VAT

A Pharmaceutical Quality System (PQS) is the structured framework that ensures your company consistently complies with GMP and maintains product quality throughout the product lifecycle.

Your PQS defines how you manage processes, documentation, risk, and continuous improvement.

Regulatory requirements change continuously.
If you do not detect and assess them in time, your PQS may no longer be compliant.

This course gives you a practical and reliable approach to PQS compliance.

You will work with a clear process for how to:
- Capture new external regulatory requirements
- Assess their relevance and impact on your quality system
- Decide what needs to change
- Implement updates in a structured way

You will see how others structure their work and where they experience the greatest challenges.
We guide you through a robust process that helps you avoid blind spots and reduce manual guesswork.

You will see how an AI-based tool can support your work by:

- Identify relevant regulatory requirements
- Map them to your quality documents
- Support impact assessment
- Provide overview of deadlines and compliance status

You work with practical examples and discussions throughout the day.

The course language is English.

At the course you will meet:

Anette Yan Marcussen, Senior Pharma Consultant, Marcussen Group ApS

Sign-up dates

Hillerød
9. nov.
2026

Do you have questions about this course?

Kontakt
Kursuskoordinator
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Target group

The course is for those working with new external requirements and updating the quality system.
Experienced specialists in the field, SMEs, Regulatory Quality and Intelligence professionals, process experts, and specialists.

Your benefits

- Gain a clearer structure for monitoring and implementing new regulatory requirements in your PQS
- Perform focused and practical impact assessments of new requirements
- Understand how structured processes and AI can reduce manual review and increase overview

Your company's benefits

- Strengthen PQS compliance through a more systematic approach to new regulatory requirements
- Achieve faster and more consistent assessment of regulatory impact, supported by AI-based requirement mapping
- Reduce the risk of overlooking critical compliance gaps

Course agenda

The course covers:

- How others keep their PQS aligned with new regulatory requirements
- A structured approach to capturing, assessing, and implementing new requirements
- Identification of high-risk and resource-intensive steps in the process
- How AI can detect relevant requirements, support impact assessment, and provide overview of affected documents and deadlines

You will work with practical examples, group discussions, and a walkthrough of a high-level process model.
We also discuss how to strengthen or redesign your current approach — with and without AI support.

Sign up online at
www.pharmakon.dk