Pharmakon

Process Validation

Gain control over your Process validation

Learn how to ensure product quality throughout its lifecycle. This course provides in-depth knowledge of process validation, applying advanced tools, and understanding regulatory requirements from the EMA and FDA.

The course starts with an introduction to modern process validation and emphasizes its importance. You will learn about Quality Risk Management and Process Design using Quality by Design principles. We focus on establishing process understanding and using Design of Experiments (DoE) and Process Analytical Technology (PAT) for process design. You will understand how DoE is used to identify critical process parameters and design a robust process space.

The course also introduces science- and risk-based facility and equipment qualification. We provide an example of how Novo Nordisk implemented their process validation lifecycle with a focus on facility design and qualification. Discussions on regulatory observations, traditional, continuous, and hybrid validation methods give you insights into best practices. We cover process validation readiness, evaluation, and presentation of validation results, focusing on Ongoing Process Verification for both new and existing products.

An expert from Lundbeck will share practical experiences about their OPV program. Statistical tools for process validation and monitoring will be reviewed, and you will learn how to use these tools to ensure that the process remains in control. Finally, we look ahead to the future of process validation with fully automated processes.

Upon completing this course, you will be able to apply a science- and risk-based approach to process validation, develop and implement control strategies, and ensure that your processes comply with regulatory requirements. This course combines theory, practical case studies, and experience sharing to equip you with the necessary tools for effective process validation.

The course language is English.

At this course you will meet:

Line Lundsberg, Managing Consultant, NNE
Andreas Houmann, QMS Specialist, Novo Nordisk A/S
Michael Lauridsen, Senior Specialist, Lundbeck A/S

Course facts

FORMAT
3 days

RATING
4,2 out of 5

PRICE THIS YEAR
22.200 DKK excl. VAT, overnatning inkluderet

Sign-up dates

Hillerød

18. nov. — **20. nov.**
2025

Do you have questions about this course?

Kontakt
Kursuskoordinator
Andreas Goldschadt
+45 48 20 62 63
ag@pharmakon.dk

Target group

This course is designed for production managers, quality assurance professionals, process engineers, regulatory specialists, and others involved in the development, manufacturing, and control of pharmaceutical products.

It is also relevant for those working in process optimization, quality assurance, and regulatory compliance. If you want to update your knowledge on modern process validation, implement advanced tools, and ensure compliance with international standards, this course is ideal for you.

Your benefits

• Gain in-depth knowledge of modern process validation techniques and standards, enabling you to ensure high product quality
• Get introduced to Design of Experiments and statistical tools to identify and control critical process parameters
• Obtain insights into both EU and FDA requirements, preparing you to ensure compliance with international standards.

Your company's benefits

• Your employee will help improve regulatory compliance and reduce the risk of supply issues and production errors
• Your employee will be able to implement an effective process validation methodology, ensuring the company’s products are robust and consistently meet quality requirements
• Your employee will be introduced to advanced statistical tools and quality management methods, potentially leading to more efficient production and long-term savings.