pharmakon

Validation of IT Systems

Understand and apply the current standards for IT validation

Learn how to manage the validation of IT systems and ensure data integrity and compliance. The course gives you the tools you need to understand the requirements, apply best practices, and strategically plan and execute IT validation.

Validation of IT systems refers to a process in which you examine and confirm that a given IT system meets specified requirements, functions as intended, and performs as expected.

The course provides you with an overview of current requirements and best practices for validation of IT systems. We review GAMP® 5, EudraLex Vol. 4 Annex 11, and 21 CFR Part 11 with a focus on validation, data integrity, and compliance. In addition, we discuss different validation approaches and how to strategically plan the validation using risk assessment and the validation master plan. In addition to legislation, we focus on the more operational part of validation. You will get tips on how to prepare IT systems specifications, carry out the validation, and ensure traceability between requirements and testing.

After the course, you will be ready to carry out a full IT system validation, apply your knowledge of legislation and the V-model as a validation strategy, and understand what is required to plan, execute and/or approve an IT validation. The course is a combination of presentations and workshops, where the topics are explored in greater depth.

The course language is English.
If all participants are Danish-speaking, the course will be conducted in Danish with English slides.

On this course, you will meet:
Marjun Jepsen, Validation Specialist, QV-Compliance A/S

Course facts

FORMAT
2 days

RATING
4,15 out of 5

PRICE THIS YEAR
18.100 DKK excl. VAT, overnight stay included

Sign-up dates

Hillerød
7. okt. – **8. okt.**
2027

Do you have questions about this course?

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

Target group

Employees in the life science (Pharma and Medical Devices) as well as suppliers involved in validation of IT systems.
For example:

- Technical employees who will perform the validation
- Project managers who will plan the validation
- Suppliers who will design and develop IT systems
- QA staff who will approve protocols, test plans, and reports

Your benefits

- you understand the current regulatory requirements for IT validation
- you can plan and carry out a validation of IT systems
- you can demonstrate, both internally and to the regulatory authorities, that the IT system is in compliance

Your company's benefits

- your employee knows the process for IT validation and participates actively
- your employee takes responsibility for a full validation of IT systems
- your employee ensures that your IT systems are in compliance

Course agenda

The course is a 2-day course with overnight accommodation.

Day 1: 09.00 - 21.00

- GAMP® 5 and 21 CFR Part 11/Annex 11
- Risk management
- Assessment of suppliers
- Handling of incidents, changes and configurations
- Validation master plan and validation plan
- Specifications
- Design and Software Review
- System and Data Flow

Day 2: 09.00 - 15.30

- Test documentation
- Data Migration
- Business continuity plan and disaster recovery plan
- Traceability and maintenance throughout the lifecycle
- Planning the decommissioning of the IT system
- Cloud solutions
- Artificial intelligence

The course is a combination of presentations and workshops, where the topics are explored in greater depth.

Sign up online at
www.pharmakon.dk