

Ready for Inspection|company

Be Ready for Your Next Regulatory Inspection

Understand the requirements, roles and appropriate conduct before, during and after an inspection. Employees receive practical advice to help your company approach the inspector calmly, knowledgeably and professionally.

Om kurset

[Read about the benefits of a company course](#)

When the authorities come knocking, the entire organisation needs to know what to expect. Production may be asked to present batch documentation. QA may need to explain a deviation, or a specialist may be asked to provide details about a system, a process or a requirement in the marketing authorisation.

An inspection can take place at short notice and requires technical expertise, proper documentation and appropriate conduct. During the course, employees gain insight into what the authorities typically look for and how you can demonstrate that your company has control of its processes, responsibilities, quality and the requirements of the marketing authorisation.

You will work with the entire inspection process. We look at how the company can prepare, who has which roles, how an inspection is typically conducted and followed up. You will also learn about common pitfalls.

After the course, employees will be familiar with the regulatory requirements. You will understand how to contribute before, during and after the inspection, and how to act calmly, clearly and professionally when communicating with the inspector.

The course alternates between presentations, discussions, case studies and exercises. You will have the opportunity to relate the requirements to your own working environment and discuss specific situations that may arise when the authorities visit.

Målgruppe

The course is intended for employees in GxP companies who may have a role before, during or after a regulatory inspection. Employees do not

Tilmeld dig kurset

Kursus

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Format

Half-day in-company course

Vælg dato og tilmeld kursus

Hillerød 31. dec – 31. dec. 2040

need prior experience with inspections.

Dine fordele ved at vælge dette kursus

Dit udbytte

- You know what is required before, during and after a regulatory inspection.
- You can act calmly and professionally when the inspector asks questions.
- You become familiar with common pitfalls and learn how to avoid them.

Din virksomheds udbytte

- Employees know how to contribute to a successful inspection.
- Employees help reduce the risk of unnecessary observations and critical findings.
- Employees help strengthen the organisation through a shared understanding and clear expectations for conduct.

Kursusprogram

- Legislation and Purpose
- Planning and Preparation
- Conducting the Inspection
- Common Pitfalls
- Deviations/Observations
- Reporting and Follow-up