COMBINATION PRODUCTS
DEVICE SPECIALISTS®

Training Process Auditor for Pharma

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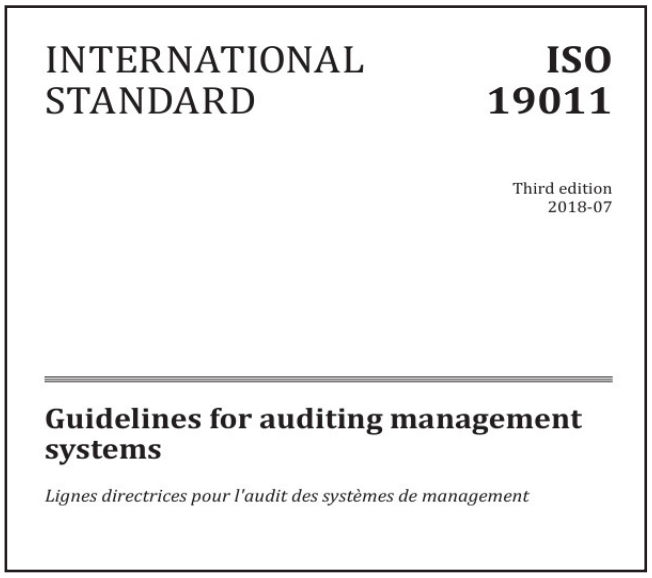
The professional Quality System process auditor training for: Pharma cGMP (EU/US), ISO 13485, GDP This training meets ISO 19011:2018 requirements.

Be the best & save money

CPDS has developed a coherent series of trainings and services to meet the diverse needs of the Pharma combination product manufacturers and their suppliers. The methods used are proven and mature (30 years experience). When followed and applied, Quality Management will become:

- Robust
- Efficient
- Mature
- Globally harmonized

ISO 19011:2018:


INTERNATIONAL STANDARD

ISO 19011

Third edition
2018-07

Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

CPDS adheres to the ISO 19011:2018 for nearly all requirements. However, these requirements are mapped and tailored to the CPDS methodology of process auditing. Examples are provided based on the CPDS's innovative approach to process management, particularly in the context of 21 CFR Part 4 and the new QMSR (ISO 13485:2016).

This document focuses on internal audits (first party) and audits conducted by organizations on their external providers and other external interested parties (second party). Additionally, it can serve as a valuable resource for external audits conducted for purposes beyond third-party management system certification.
ISO 19011 is designed to cater a wide range of users, including auditors, organizations implementing management systems and organizations required to conduct management system audits for contractual or regulatory purposes. Additionally, users of this document can apply its guidance to develop their own audit-related requirements.

Process Auditor training

Our training program is meticulously structured and thorough, ensuring precision and clarity at every step.
Process approach audits ensure that an organization's processes are well-defined, measurable, value-adding, efficient, controlled and aligned with business objectives. At CPDS, we have developed a comprehensive process audit model that systematically evaluates these aspects, as well as compliance with ISO 13485 and Pharma cGMP requirements.

Process approach audits:

- Lifecycle Performance: Evaluate a process's performance throughout its entire lifecycle, from input to processing, output, and continuous improvement.
- Detect Inefficiencies: Identify inefficiencies or non-conformances within the process itself, rather than isolating individual non-conformances in the process outputs.
- Defined and Measurable Activities: Ensure that process activities are clearly defined, measurable, value-adding, efficient, controlled, and documented. They should also deliver outputs that align with business objectives.

This methodology excels in evaluating compliance and effectiveness, surpassing other methods. Each process is thoroughly examined in relation to nearly all other QMS requirements.
To illustrate, within a single process you might examine:

- The document describing the process
- Inclusion in an internal audit or management review
- Training records.
- Complete recorded output
- The latest process risk assessment update
- Verification or validation reports
- Application of statistical methods corresponding data
- Inclusion in the management review agenda
- Part of the internal auditing schedule

Auditing a few processes using this methodology will provide valuable insights into the design and performance of the Quality Management System.

What you will learn & program:

Part A

Theory (ISO 19011) illustrated with examples and self-practicing
1 Scope
2 Normative references
3 Terms and definitions
4 Principles of auditing
5 Managing an audit program
6 Conducting an audit
7 Competence and evaluation of auditors

Examination: Achieve 80% correctness to receive a certificate.

Part B

Within 3 months following the successful completion of the theory exam, you will conduct 2 process audits at the company that initiated the training. You must submit all elements learned during the theory training to CPDS, including the final report and follow-up. After CPDS review, you will receive the CPDS Process Auditor Certificate.
During your practical audits, you will be paired with a colleague process auditor trainee as your "buddy." This buddy will provide immediate support and feedback, and you will reciprocate.
Throughout your practical audit period, you and your buddy can reach out to CPDS with any questions you cannot resolve on your own. (Buddies will be established during Part A).

Target Trainees

- Ideally, trainees should have several years work experience in Pharma or Device GMP. An affinity for quality management systems is a plus, but prior audit experience is not required
- Internal auditors looking to expand their capabilities to process auditing
- It is recommend to be familiar with ISO 13485:2016 and ISO 19011:2018

Custom

This training can be tailored to your specific needs and preferences at no additional costs, including the option to incorporate GDP.
Contact us to discuss the possibilities.

Availability and Costs:

This training includes both onsite sessions and off-site support/review. Our training fee is based on a set module rate plus expenses, with flexible attendance for the number of employees per module. Contact us for availability and pricing details.

Languages:

The training material is available in English.
The training can be delivered in:

- English
- German
- Dutch

Duration:

This training consists of 2 modules:
Module A: Theory (with practice) and theory exam. (2 days onsite, certificate awarded if 80% correct)
Module B: Practical Audits performing 2 process audits at the company, monitored by a trainee buddy. Supported, reviewed and certified off-site.

Benefits for the hosting Company:

Our inhouse training for pharma process auditors offers several advantages:

- State-of-the-Art Audit Methodology: The company can adopt cutting-edge audit practices
- Qualified Auditors: After completing the training and qualification, auditors will be ready for internal and external audits (e.g., suppliers)
- Comprehensive Practical Training: Under our supervision, the practical part of our training will generate 2 complete process audits per auditee.
- External Audit Readiness: When applied broadly and professionally, the company will be well-prepared for any external audit

Process auditing training: preceding CPDS modules:

1. Initial introduction meeting (2 days):
   An in-depth session to understand your company's current status and specific needs. This forms the basis for designing the future state based on well-informed decisions.
2. Gap assessment:
   This comprehensive assessment will result in a broad review of the Pharma cGMP QMS and the creation of the necessary "process interaction map".
3. CPDS innovative approach to process management:
   Learn about CPDS's new methodology for managing processes effectively.

Trainer: Pharma process auditor

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