

CONTROL

SERVICE

AUDIT

REPORT

METHODS

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QUALITY

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CONTRO

HIGHLIGHTED TRAINING

REMOTE AUDITS:

New opportunities
for GMP/GDP assessment
from exceptional circumstances

June, 19 | 2023
ONLINE

Learning objectives

1. To understand similarities and differences between remote and on-site auditing techniques and assess applicability criteria of the former
2. To underline the importance of risk-based planning and feasibility evaluation steps
3. To review methodology to get an effective audit planning step
4. To identify key moment during audit conduct
5. To achieve familiarity with audit closing meeting: Communication of exit notes and/or audit findings

Speaker



Stefano Scorsini

Solid experience with more than 30 years in GMP Pharmaceutical Operations covering different roles (Head of Manufacturing Departments, Production Manager, Manufacturing site Director), completed by the fact of being appointed first Italian Technical Director (1992-2000) and then EU and MHRA Qualified Person in different Pharmaceutical Companies. Dr Scorsini had consolidated a remarkable experience in different areas as : Management of Quality System elements with associated routine tasks (Changes, Complaints, Deviations / Investigations, Risk assessment, APQRs), GMP/GDP auditing processes (Lead Auditor since 2014), entire flow of GMP pharmaceutical operations, project management of technology transfers, management of selection, installations and qualification - validation of production equipment and associated utilities, URS definition and start-up of ERP systems.

Purpose

The Covid 19 pandemic has prompted companies to review approaches and ways of working; one of the aspects touched upon is an alternative approach on audits management which has a potentiality to be used even in the routine basis as equivalent to the established methodology (on-site audit).

This course aims to improve the knowledge of remote auditing technique with evaluation of relevant pros and cons vs. on-site one, presenting challenges but mostly good opportunities of a possible use of a combination of the two modalities for GMP/GDP qualification and routine audits.

The delegate will become more familiar with efforts to be put and tools to be used in every process step of remote GMP/GDP auditing process, with the objective of achieving a complete and effective overview getting the expected interchange with on-site ones.

He will get additional awareness on the meaningful importance of a risk-based approach both for auditing process preliminary planning stages as well as for decisions on reauditing timelines. The course will provide also additional guidance and applicable suggestions, based on experienced situations presented as unreferenced case studies.

Who should attend?

This Training Course is of particular interest for: Quality Unit Specialists and Managers, Qualified Persons and any other cross-functional Team Member (e.g. Manufacturing, Engineering, Purchasing Departments) dealing with first level (self-inspection), API Manufacturers, Vendor and Outsourced GMP-Services Providers audits

Program

9.30

1. Overview of guidance documents

- Definition and scope
- Actual and potential future applicability

2. Peculiarities of remote audit

- Communication
- Systems access
- Documents sharing
- Document review
- GMP operations overview

3. Remote audit vs. on-site audit

- Plant tour
- Communication and inter-personal relation
- Time management

10.45

4. Remote Audit Step 1: Audit planning and feasibility

- Audit plan:
- Priorities
- Risk/criticality assessment
- Early contact with Auditee
- Feasibility questionnaire and “negotiation of practical items”

5. Remote Audit Step 2: Audit agenda

- Audit announcement
- Resources requirements
- Inclusion of practical items and potential challenges in agenda
- Who’s in charge of practical items?

12.00

6. Remote Audit Step 3: Conducting Remote Audit

- Opening meeting
- Audit execution
- Wrap-up meeting
- Closing meeting

7. Remote Audit Step 4: Audit report

- GMP/GDP non-compliance: Findings rating and classification
- Audit report conclusions

12.30

8. Workshop - Final session

Discussion on case studies presented during previous sessions

- Q&A



TERMS OF PAYMENT

Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Firenze, IBAN IT81P0503402801000000007431, Bic/SWIFT BAPPIT21N25 made payable to Pharma Education Center S.r.L., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling. Attendance to the event will be allowed upon payment received. Invoice of payment will be issued after the second half of the month after the course.

For further information and/or further assistance please contact (+39) 0550465181 or email: amministrazione@pharmaeducationcenter.it

COURSE/EVENT CANCELLATION

If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refund the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

CANCELLATION TERMS

In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

PARTICIPANT REPLACEMENT

It is possible to replace a participant attendance without additional cost, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement request within 5 days before the starting date of the course/event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

HOW TO REGISTER

Please, fill the form on the web site <https://www.pharmaeducationcenter.it/>

ENTRY FEE

450 €

400 € until May 19, 2023

Discounts are not cumulative

VAT not included

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