



PCMG (in-person) Workshop: AN INSPECTOR CALLS

Ensuring Pharma/Biotech outsourcing managers are fully prepared to plan and execute measures to successfully complete GXP regulatory inspections.

16 April 2024. ETC Venues, 50-52 Chancery Lane London WC2A 1 HL

AGENDA

09:00 Workshop Registration, Refreshments & Networking

09:30 Introduction and workshop objectives: PCMG and Worldwide Clinical Trials

Speakers: Lan Bandara Franchise Sourcing Lead, Argenix,
Emmet Browne VP, Commercial, EU, Worldwide Clinical Trials

09.40 Setting the scene. Current and future inspection requirements related to Outsourcing tasks and responsibilities.

Speaker: Rosmarie Corrigan, EVP Global Quality, Worldwide Clinical Trials

- **'Start with the end in mind'** – Study lifecycle and landscape, and vendor oversight for successful inspection outcomes!
 - Recent changes in clinical trial delivery and inspection conduct
 - The current regulations that drive inspections
 - Inspections overview
 - Types of inspections
 - Different approaches to preparation
 - Key observations and hot topics
 - The inspection process.
 - The Inspector's expectations regarding vendor oversight including Qualification and Oversight

10:40 Refreshment & networking break

11:00 The inspection framework and key tools for successful outcomes

Speakers: Rebecca Elton, Senior Clinical Vendor Manager, Leo Pharma

Worldwide Clinical Trials (TBC) including former MHRA GCP Inspector

Richard Scaife, Former Biotech Outsourcing VP & PCMG Director

- **PCMG member survey:**
The reality of inspection readiness from the outsourcing community – good, bad, and inspirational?
- **Inspection Readiness – Who? What? Where? When? How?**
 - Boundaries and integration between Outsourcing and Operations inspection responsibilities
 - Interview preparation: Mock Inspections, SOPs, Vendors,
 - Documentation – Which outsourcing-related files are needed and where should they be TMF or not TMF? That is the question.
 - Interview preparation: Communicating with the inspector.
 - Framing the response: Storyboarding
- **Inspection Readiness: Short case studies and lessons learned.**
 - How storyboarding can demonstrate compliance in a complex outsourcing situation
 - Small is beautiful but challenging, the Inspection perspective for a smaller company
 - Topic TBC

12:30 Lunch & networking break

13:30 Practical Workshop led by the PCMG and WCT workshop experts

- Case study challenges in groups to work through scenarios based on real-life inspection situations to develop readiness actions and predicted outcomes.
 - Scenario 1 TBC
 - Scenario 2 TBC

14:30 Refreshment & networking break

15:00 Inspections Outcomes

- Common inspection observations and how to address them
- The Inspector's perspective (from a former MHRA-inspector)
- Do's and don'ts of inspections
- **The inspection checklist for outsourcing management:** Collectively constructing a pre-inspection assessment tool.

15:45 Summary, conclusions, and follow-up actions.

16.00 Workshop close

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