Pharmaceutical Contract Management Group

Kindly sponsored by:

Worldwide Clinical Trials

PCMG Workshop: An Inspector Calls

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

16th April 2024
etc Venues, 50-52 Chancery Lane, London, WC2A 1HL

AGENDA

09:00 **Registration opens**

Refreshments will be served, and we encourage you to network with your industry peers during this time.

09:30 **Introduction to the workshop**

Before the day begins, we want to hear your experiences.
***Lan Bandara** - Franchise Sourcing Lead, argenx*
***Emmet Browne** - VP, Commercial, EU, Worldwide Clinical Trials*

09:40 **Setting the Scene: Current and future inspection requirements related to Outsourcing tasks and responsibilities**

'Start with the end in mind' – Study lifecycle and landscape, and vendor oversight for successful inspection outcomes!
This session will cover:

- *Recent changes in clinical trial delivery and inspection conduct*
- *The current regulations that drive inspections*
- *Inspections overview including:*
  - *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*

Speaker:
***Rosemarie Corrigan** – EVP Global Quality, Worldwide Clinical Trials*

10:40 **Refreshments and Networking Break**

An opportunity to discuss learnings from the workshop and network with colleagues from across the industry.

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

We'll hear the reality of inspection readiness from the outsourcing community.
This session will cover:

- ***Inspection Readiness – Who? What? Where? When? How?***
  - *Inspection process, boundaries and integration between Outsourcing and Operations inspection responsibilities*
  - *Interview preparation: Mock inspections, SOPs and 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.*
  - *Storyboarding: What and When*
- ***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.*

Speakers:
***Rebecca Elton** – Senior Clinical Vendor Manager, Leo Pharma*
***Clare Riddle** – Director, Audit & Inspection, Worldwide Clinical Trials*
***Jenny Martin** – Director, Regulatory Intelligence Compliance, Worldwide Clinical Trials*
***Richard Scaife** – Director, PCMG & Former Biotech Outsourcing VP*

12:30 Lunch and Networking Break
An opportunity to discuss learnings from the workshop and network with colleagues from across the industry.

13:30 Practical Workshop
Attendees will be given case study challenges and split into groups to work through scenarios based on real-life inspection situations to develop readiness actions and predicted outcomes.
Led by the PCMG and Worldwide Clinical Trials workshop experts

14:30 Refreshments and Networking Break
An opportunity to discuss learnings from the workshop and network with colleagues from across the industry.

15:00 The inspection experience
This session will cover:
- *Hints and tips to address inspection observations*
- *The Inspector's perspective (from a former MHRA-inspector)*
- *The do's and don'ts of inspections*
- ***The inspection checklist for outsourcing management:** Collectively constructing a pre-inspection assessment tool.*

15:45 Workshop summary, conclusion and follow-up actions

16:00 Workshop closes

As a not-for-profit association, PCMG is grateful to Worldwide Clinical Trials for operational support and financial sponsorship that makes this workshop possible for PCMG attendees from Pharma and Biotech companies. Please note only the sponsoring supplier will be present at the workshop in the capacity of expert support and guidance for the workshop content and conduct.

Speakers

Lan Bandara	*Franchise Sourcing Lead, argenx*
Emmet Browne	*VP, Commercial, EU, Worldwide Clinical Trials*
Rosemarie Corrigan	*EVP Global Quality, Worldwide Clinical Trials*
Rebecca Elton	*Senior Clinical Vendor Manager, Leo Pharma*
Jenny Martin	*Director, Regulatory Intelligence Compliance, Worldwide Clinical Trials*
Claire Riddle	*Director, Audit & Inspection, Worldwide Clinical Trials*
Richard Scaife	*Director, PCMG & Former Biotech Outsourcing VP*