



Presented by
Management Forum

Managing Service Providers including CRO and CMOs oversight to comply with ICH GCP R3

24-25 June 2024
+ 17-18 October 2024

Optimising oversight for
inspection compliance



Format:
Live online



CPD:
12 hours for your
records



Certificate of
completion

Course overview

With regulatory inspectors increasingly finding issues with vendor oversight by sponsor organisations, it is becoming even more important for the pharmaceutical industry to employ efficient and accurate strategies for managing outsourced activities. A company's ability to identify and select the right CRO/ vendor for the right project and manage them efficiently and effectively will help to ensure compliance with the regulator's expectations.

On this course you will learn how to prepare a request for proposal (RFP), evaluate and select the right CRO and establish procedures for vendor oversight for R&D projects you need to outsource. You will also cover the techniques for successfully managing CROs/ vendors and the shared responsibilities required by the sponsor and the service provider. Managing CRO performance issues will also be discussed.

The course is equally useful to CROs/other vendors and consultants to understand how to work effectively with sponsor organisations.

Benefits of attending:

- **Understand** how to effectively manage CROs/vendors used in the pharma industry
- **Build** an understanding of your responsibilities as the sponsor and identify the right level of management and oversight
- **Discuss** how to put in place a robust CRO/vendor selection process
- **Discover** tools and processes to manage CROs and other vendors
- **Measure** CRO performance including metrics and key performance indicators (KPIs)

Who should attend

This event is designed for personnel involved in CRO/vendor management and oversight in the pharmaceutical, biotechnology, animal health and medical device industries including those working in clinical research, regulatory affairs, pharmacovigilance, manufacturing, clinical outsourcing, contracts, quality, clinical operations, vendor management and global QA/compliance. It will also be relevant for outsourcing, purchasing, finance and contract management staff who participate in the RFP process who will find this course a valuable introduction or refresher course focusing on best practice.

This course will also help CRO/vendor personnel to work more successfully with pharmaceutical, biotechnology and medical device companies through gaining a much clearer understanding of their needs when outsourcing.

Programme

Day 1

Background to the CRO industry and meeting regulatory expectations

- Outsourcing today for the biopharma industry
- Different models of outsourcing
- Challenges of working with CROs/Vendors and solutions
- Core components of Vendor Governance
- The potential benefits and drivers of outsourcing
- Outsourcing Trends

Oversight of CROs/Vendors and meeting regulatory inspectors' expectations

- Understanding Oversight
- Key elements of Vendor Oversight
- Examples of Vendor Oversight documents
- Examine EU and FDA expectations for outsourcing in the pharma and biopharma industry

Building an effective relationship

- Factors critical for a successful relationship
- Building trust

Vendor/CRO selection – an overview of selection and bidding processes

- Identifying Vendors/ CROs
- Preparing the RFP
- Evaluating responses to the RFP
- Pre-qualification of vendors and vendor audits
- Writing the RFP
- Contracts with Vendors/CROs
- Bid defence meetings

Day 2

Vendor/CRO selection – an overview of selection and bidding processes - continued

Managing vendor/CRO project set-up

- How to set the stage so the CRO focuses on quality
- Effective Kick-off meetings
- Training CROs
- Which SOPs should CROs use?
- Risk assessment
- Tools and techniques for managing CRO performance
- Understand the KPIs/ dashboards
- Communications with CROs

Ongoing oversight and management

- Tracking and measuring CRO progress and performance
- Ongoing training and integrating new CRO staff
- Maintaining effective communication with your CRO
- Report processes to manage CROs/vendors
- Progress and update meetings/TCs with CROs
- Meetings with CROs
- Update reports
- Auditing CROs
- Escalation
- Troubleshooting problems with CROs – common problems and possible solutions

End of project oversight: reviewing CROs during and at the end of the project

- Review meetings
- Feedback and learnings for using in the future
- Evaluation of suppliers

Presenter



Laura Brown

Dr Laura Brown is an independent pharmaceutical QA and training consultant and the Senior Lecturer for the MSc in Clinical Research, School of Pharmacy, University of Cardiff. Laura is an expert in outsourcing pharmaceutical research projects including CRO selection, management and oversight audit and management. She has more than 20 years' experience in the pharmaceutical industry in a number of senior roles and has worked for several companies, including GSK, Hoechst Marion Roussel and Phoenix International in outsourcing pharmaceutical projects. She has worked in several vendor selection and management roles which have included reviewing quality and performance of CROs and has advised companies on how to implement quality systems for CRO selection and management.

Course dates

24-25 June 2024

Live online

09:30-17:00 **UK (London)** (UTC+01)

Course code 13783

GBP **1,299**

EUR **1,869**

USD **2,129**

17-18 October 2024

Live online

09:30-17:00 **UK (London)** (UTC+01)

Course code 13941

GBP **1,099** ~~1,299~~

EUR **1,589** ~~1,869~~

USD **1,817** ~~2,129~~

Until 12 Sep

How to book



Online:

ipi.academy/2179

Alternatively contact us to book, or if you have any queries:



Email:

info@ipi.academy



Phone:

[+44 \(0\)20 7749 4749](tel:+442077494749)

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note

IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions

The rest of our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews



Content was great. Speaker was wonderful!



Elsje Du Preez

Manager Vendor Management & Administration
Hillevax GmbH
Apr 18 2024



The speaker demonstrated a deep knowledge of all themes presented during the course. Sessions were well organized and enough time was dedicated to each of them.



Vincenzo Velleca

Global Safety Operations
Zambon SpA
Oct 19 2023



Dr Laura Brown is an excellent speaker with deep expertise in clinical trials research regulatory requirements and expectations!



Virginia Suarez

Executive Director, Clinical Quality
MEI Pharma
Jul 11 2022



Understanding RFP and RFI were achieved. KPI session was very helpful and I learnt about oversight plan which I never knew about. Laura was very good, provided great content of the subject matter and discussions included were good and relevant.



Stephanie Yearwood

Senior Vendor Management Coordinator
IQVIA
Apr 11 2022

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

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IPI Academy

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