IPI Academy

MANAGEMENT forum



Presented by
Management Forum

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

12-13 April 27
+ 14-15 October 27

Optimising oversight for inspection compliance.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

With the implementation of ICH GCP E6(R3), regulators are placing increased emphasis on sponsor oversight of outsourced activities, risk-based management and demonstrable control of service providers. Sponsors must now be able to evidence proportionate oversight and informed decision-making throughout the clinical lifecycle.

Additionally, as regulatory inspectors continue to identify deficiencies in vendor oversight by sponsor organisations, the pharmaceutical industry must place even greater emphasis on implementing 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

12-13 April 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17688*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 15 Feb**
14-15 October 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17689*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 19 Aug**

How to book

Online:
ipi.academy/2179

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

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% 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 the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

This was a comprehensive webinar training that met my expectations: highly illustrated with examples, interactive, enabling experience sharing with other attendees. All parts were complete and great speaker. I really appreciated the introduction of tools and templates that are helpful.

katia Hay
Clinical trial coordinator
Adocia
Jun 23 2025

★★★★☆

It was very useful to have specific ideas, tools, websites and portals introduced as to what should be done for CRO oversight.

Kenji Tada
Unit Manager, Clinical Operation Unit
JCR Pharmaceuticals Co
Feb 6 2025

★★★★★

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

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.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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