MANAGEMENT forum

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GCP and Clinical Research Update - Hot Inspection Topics

10 Mar 2022, Live webinar
+ 2 more dates - see back page for full schedule

This course provides recent updates on the EU Clinical Trial Regulation, other EU, MHRA and FDA requirements, consideration for managing Covid-19 for studies in the future and technology developments

Programme at a glance:

- Brief review of regulatory authority inspections findings
- Hot inspection topics, including EMA, MHRA and FDA findings
- EU Clinical Trial Regulation (536/2014) update
- Requirements of the EMA TMF from EMA GCP Inspectors Working Group
- Data Integrity guidance
- ICH update
- Awareness update from other EU, MHRA and FDA
- Digitalisation and technology advances and GCP
- Conclusion and final Q&A

Full programme inside

★★★★★ *"[Laura] is a good presenter, she has world of knowledge. She was also able to get open discussion with the participant which made the course more interesting."*

Angelo Jacala, Director, Clinical QA, MEI Pharma

★★★★★ *"Very good and worthwhile attending."*

Christopher Rollinson, Research Governance Manager, University Hospitals Plymouth NHS Trust

★★★★★ *"It was understandable and fullfiled my expectations. I received many useful links and publications, which I can search for. The content was good but a bit too much information in a short timeslot."*

Ines Kovacikova, Lead CRA, Octapharma Pharmazeutika Produktionsges.m.b.H.

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Course overview

Clinical research is a constantly evolving field and the regulatory requirements are frequently being updated. In order to stay ahead and maintain your GCP knowledge, it is important to receive regular training.

This must-attend course provides a review of recent changes to relevant legislation and guidance and will look at how these developments have been implemented. Topics covered will include the latest update of the EU Clinical Trial Regulation, the final EMA TMF guideline and the further renovation of ICH GCP R2. The programme will also examine inspection findings and common failings in these new areas and how these should be addressed.

This is a highly interactive course suitable for those who need to refresh their knowledge and to demonstrate recent and up-to-date training to regulatory inspectors.

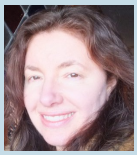
Benefits of attending:

- **Discuss** recent developments in GCP and clinical trial legislation and guidance in the EU, UK and FDA considerations including Covid 19 for future studies
- **Review** the requirements of the TMF
- **Identify** common audit and inspection findings to help prepare for inspection
- **Understand** the EU Clinical Trial Regulation implementation
- **Be updated** on the ICH including ICH GCP R3 renovation
- **Clarify** requirements for data integrity
- **Technology** advances and GCP

Who should attend

The course is of particular relevance for those working in clinical research, regulatory affairs and pharmacovigilance, QA, Audit, CROs, academic trialists and regulatory inspectors. It will also be of interest to those departments who liaise/support clinical trial personnel and all other professionals who want to know more about updates in GCP regulations and guidelines covering clinical trials.

Expert trainer



Laura Brown

Dr Laura Brown is an independent QA and training consultant and director of the MSc in Clinical Research, School of Pharmacy, University of Cardiff. Laura has many years' experience of managing GCP inspections in the pharmaceutical industry and has worked for several leading companies including GSK, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International. She has worked as a clinical research manager, audit director and head of a training department. She is an international expert on GCP and clinical trial requirements and was chair of the Institute of Clinical Research GCP Forum for six years. Laura writes regularly on clinical research regulatory requirements and has written a chapter in International Pharmaceutical Product Registration and several articles on the EU Clinical Trial Regulation, Brexit, and ICH GCP R2.

Brief review of regulatory authority inspections findings

Hot inspection topics, including EMA, MHRA and FDA findings

EU Clinical Trial Regulation (536/2014) update

- Electronic EU clinical trial authorisation and the new CTIS
- Update on implementation
- Review of the key changes

Requirements of the EMA TMF from EMA GCP Inspectors Working Group

- TMF structure, content, security, control, managing correspondence and emails, scanning and certified copies, maintaining the TMF and storage, e-TMFs, archiving and retention
- The TMF plan – recommended format for compliance

Data Integrity guidance

- What inspectors look for in this
- MHRA integrity guidance

ICH update

- New European Commission Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products (ATMPs)
- ICH E8
- ICH GCP E6 R3 update

Awareness update from other EU, MHRA and FDA

EU

- EU Guidance on trials during Covid - pandemic-proof' studies moving forward
- EMA guidance on validation & qualification of computerised systems
- ENpr-EMA Guideline: Assent / Informed Consent Guidance for Paediatric Clinical Trials

MHRA

- Brexit and running clinical trials in the UK

FDA

- Guidance for Industry, Investigators, and Institutional Review Boards: FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic
- FDA methods to obtain informed consent during Covid
- FDA Guidance on Enhancing the Diversity of clinical trial populations

Digitalisation and technology advances and GCP

- Technology innovations and drug development
- Electronic informed consent
- Apps, medical devices and mobile technologies in clinical trials
- Artificial intelligence
- Virtual clinical trials

Conclusion and final Q&A

GCP and Clinical Research Update - Hot Inspection Topics

Schedule and prices

Three ways to book:

Online
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Email
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Ref	Date	Location	Price	Early booking price	Until*
11585	**10 Mar 2022**	Live webinar	GBP **599** + VAT = 718.80 EUR **859** + VAT = 1,030.80 USD **970** + VAT = 1,164.00	GBP **499** + VAT = 598.80 EUR **719** + VAT = 862.80 USD **814** + VAT = 976.80	3 Feb 22
11379	**16 Jun 2022**	Venue TBC	GBP **699** + VAT = 838.80 EUR **979** + VAT = 1,174.80 USD **1,090** + VAT = 1,308.00	GBP **599** + VAT = 718.80 EUR **839** + VAT = 1,006.80 USD **934** + VAT = 1,120.80	12 May 22
11700	**22 Sep 2022**	Live webinar	GBP **599** + VAT = 718.80 EUR **859** + VAT = 1,030.80 USD **970** + VAT = 1,164.00	GBP **499** + VAT = 598.80 EUR **719** + VAT = 862.80 USD **814** + VAT = 976.80	18 Aug 22

Your choice of date & location

We can present this course on an in-house basis, tailored to your requirements, at your location and/or online. Contact us at inhouse@management-forum.co.uk or see inside the brochure for more details of how this can be a more cost-effective approach.

Multiple booking discounts

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

The 'Small Print'

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

Falconbury Ltd 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, Falconbury will refund the registration fee and disclaim any further liability.

TERMS AND CONDITIONS

The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit management-forum.co.uk/content/terms-and-conditions