# M27 GCP Refresh

1st November 2023

**The day will start at 08:45 with registration and coffee for a prompt start at 09:15. We aim to finish by 17:30.**

# ICR Training

M27 GCP Refresh

10 CPD POINTS

1st November 2023

M27

Venue - Online Course,

Course Outline

Course Information

## The Course

Welcome to the GCP Refresh course! In the ever-evolving landscape of clinical research, staying updated is not just a mark of excellence but a legal imperative. This course is specifically tailored for clinical researchers who, having already been trained in Good Clinical Practice (GCP), understand the importance of continual learning. With regulations constantly evolving, especially in regions such as the EU and UK, it's crucial to stay abreast of best practices, GCP updates, and practical nuances associated with compliance. Over the duration of this course, we will delve into these updates and revisions, ensuring that you remain at the forefront of clinical research compliance and best practices. This GCP Refresh course helps to ensure you are equipped with the latest knowledge and insights to continue making impactful contributions to clinical research. ICH GCP is applicable to clinical trials of drugs (medicinal products). Different standards apply to drug non-interventional studies (ISPE GPP) and medical devices (ISO 14155:2020).
Delegates need Basic knowledge of clinical research and previous training in ICH GCP before attending
Please email office@icr-global.org for enquiries

## Learning Objectives

- Revisit the background and history (context) of the ICH and the GCP guidelines.
- Re-affirm the main principles and requirements of ICH GCP and understand how these relate to EU and UK clinical trials regulations.
- Recognize the significance of informed consent and its process.
- Grasp the pivotal role of the investigator's brochure, trial protocol, and record-keeping in ensuring participant safety and upholding data credibility in GCP.
- Receive practical insights on how to navigate the common challenges and pitfalls in GCP compliance.
- Gain up-to-date knowledge on the evolving GCP guidelines.
- Be able to navigate your research responsibilities with increased confidence and efficiency, knowing you're aligned with the most current standards.


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## Who would benefit

All Clinical research professionals, including Clinical Research Associates (CRAs), investigators, study coordinators, quality assurance professionals, regulatory affairs specialists, and anyone involved in the design, conduct, oversight, or review of clinical trials.

## Course Fees

| | |
|---|---|
| **Guest** | **£555.00** |
| **ICR Member** | **£450.00** |
| **ICR Member Academic** | **£350.00** |

Your Trainer

# Stuart McCully

Stuart is a pharmacologist who brings over 20 years of hands-on experience in clinical research and Good Clinical Practice (GCP). His background spans various roles within the pharmaceutical sector, where he has had the opportunity to engage in many aspects of clinical research and regulation.

**Notable Experiences**

- **NIHRand NHS Scotland** Stuart has had the privilege of contributing to GCPtraining programs for the UK's National Institute for Health Research (NIHR) and serving as a GCP trainer for NHS Scotland. These experiencehave furthered his understanding of the importance of compliance and quality in clinical research.
- **Quality Management**: Stuart has experience managing quality management systems for a variety of clinical studies, from Phase I to Phase IV, as well asnon-interventional studies. His work in this area focuses on supporting team members and maintaining study integrity.
- **Regulatory Engagements**: Stuart has been involved in coordinating responses to Quality Assurance (QA) audits and Competent Authority Inspections.Additionally, he has participated in the preparation and follow-up for MHRA GCP Inspections, always with the aim of learning and continuous improvement.

**Real-World Evidence and Regulatory Guidance**

- **Regulatory Advice**: Stuart has offered guidance on diverse study types, including non-interventional studies, low interventional clinical trials, and pragmatic clinical trials. His approach aims to facilitate easier navigation through regulatory landscapes for research teams.
- **Gap Analyses**: Stuart has contributed to the identification and analysis of GCP and NIS process gaps, with the intention of enhancing research quality and compliance.
- **Educational Support**: Stuart has developed and shared GCP training materials toorganizations, reflecting his belief in the importance of ongoing education and best practices in the field.

Pre-Course Questionnaire - To be completed by all delegates

# Pre-Course Questionnaire - To be completed by all delegates

Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Course Title: M27 GCP Refresh

Date: 01 November 2023

**Name:** .....

**Company / Hospital:** .....

**Position / Job Title:** .....

**How much experience of clinical trials do you have? (Years)**

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**What are you hoping to get out of the day?**

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**State one issue/problem you would like discussed at the meeting**

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**Dietary Requirements**

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* The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free - however it may not be possible to cover all requests for dietary preferences.

Training Location


**Address:** Online Course,

This course/forum will run online via Zoom

## Local Taxi Companies

N/A

## Accommodation

The ICR does not specifically recommend any accommodation - however the following are within easy travelling distance of the training venue

There are also a number of travel websites which may allow you to identify local accommodation and special offers - e.g. expedia

# The Small Print

As a matter of policy we do not issue electronic copies of the slides used.

All ICR materials are copyrighted.

All delegates receive a delegate book.

Payment must be received in advance of a training course commencing. The ICR has the right to refuse entry for non-payment. Payment by invoice must be settled within 14 days from the date of invoice.

We understand that occasionally circumstances may change and that you will be unable to attend your chosen course. Notification of cancellation must be made in writing. If you cancel **more than 14 days prior to the event**, we will refund the course less £50 to cover administration costs. If you cancel within 14 days, no refund will be payable, but we will allow you to transfer to another course of your choice.

We will accept a change of delegate at any time without you incurring a penalty. The Institute of Clinical Research reserves the right to cancel any course that is under-subscribed but will give you 7 days notice in writing and will refund your course fees without any liability for any consequential or indirect loss.

At anytime, you may transfer to the same course within 12 months, or to another course of your choice within 6 months; a £25 administration fee will be charged for such transfers.

We may also need to change the venue but will give you 7 days notice in writing of the new location.

Programmes as published are correct, however due to circumstances beyond our control, trainers, speakers and/or the programme may need to be altered occasionally.

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Registration Form

Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

# Registration Form

## Please photocopy this form for further registrations

**Course Title:** M27 GCP Refresh **Course Date:** 01 November 2023

**Membership No.:** ..... **Title(Dr,Mr,Mrs,etc):** ..... **First Name:** .....

**Surname:** ..... **Job Title:** .....

**Company Name:** .....

**Email Address:** .....

*Confirmation of booking will be sent by email, unless you request here that it is sent by post* ☐

### Correspondence Address

**Address:** .....

**Postcode:** ..... **Country:** ..... **Telephone Number:** .....

### Special Dietary Requirements

.....

### Declaration

I agree to the terms and conditions of booking **Signature:** .....

### Method of Payment

Please not that your place will only be confirmed when payment has been received (please tick as required)

**I wish to pay the fee of** .....

☐ I enclose a cheque payable to "The Institute of Clinical Research"

**OR**

☐ I wish to pay by

☐ VISA ☐ MASTERCARD ☐ DELTA ☐ EUROCARD

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

**Start Date** ☐☐ ☐☐ **Expiry Date** ☐☐ ☐☐

**Name (as it appears on the card)** .....

**Signature of card holder** .....

**OR**

☐ Please invoice my company using Purchase Order Number ☐☐☐☐☐☐☐☐ Invoices can only be raised when a PO no. is provided

### Correspondence Address

**Address:** .....

**Postcode:** ..... **Country:** .....