



## K13 GCP for Experts

6th May 2021



**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.**



## The Course

This course provides an in-depth look at the regulatory systems currently in operation in the EU and their impact, together with UK legislation, on the conduct of clinical research. Starting with a refresher on the history of medicinal product regulations and the need for ethics, the course explains in more detail the practical applications of GCP and outlines recent major developments in GCP.

Delegates will receive a complimentary copy of the ICH GCP guidelines and a workbook.

## Learning Objectives

- Outline recent major developments in Good Clinical Practice
  - Discuss the purpose and impact of EU regulations on the conduct of clinical research
  - Outline the proposed Clinical Trial Regulation
  - Summarise other current issues that affect clinical trials
- e.g. risk based monitoring

- The need for ethics & regulation
- Roles & responsibilities in Clinical research
- EU Clinical Trials directive
- Changes in ICH GCP
- Risk Management
- UK legislation
- The EU Regulation proposals
- Substantial amendments
- IMPs & NIMPs
- Informed consent
- GMP Annex 13
- Inspections

## Who would benefit

Experienced clinical researchers with prior knowledge of GCP who wish explore the wider application and gain a more in-depth understanding of the regulatory aspects of clinical research.

## Course Fees

Guest	£550.00
ICR Member	£450.00
ICR Member Academic	£350.00

## Jeannette Dixon

Jeannette has held GCP quality-focused positions since 2008 at various pharmaceutical companies, and started her own consultancy business in 2017. Prior to transitioning to GCP/GCLP work, she held positions in pharmaceutical training management, project management in Phase I-IV projects, worked as CRA and in academic research laboratories.

Jeannette led quality teams and has extensive experience in Quality Management System (QMS) development, managing audits, CAPAs, risk management and inspection readiness activities as well as in hosting regulatory agency inspections.

Her educational background is a BSc in Medical Sciences, a BSc in Pharmacology, and a Master in Quality Management.

She enjoys travelling, cycling, swimming and painting, and hopes to be able to see a few more deserts in the world...



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

Please complete and sent to [training@icr-global.org](mailto:training@icr-global.org) or fax to +44 01628 501 709

Course Title: K13 GCP for Experts

Date: 06 May 2021

Name: .....

Company / Hospital: .....

Position / Job Title: .....

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

.....  
.....  
.....

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.



**Address:** The Institute of Clinical Research Training Suite, Suite 1, Cedar Court Grove Business Park White Waltham, Berkshire, SL6 3LW

The ICR's training suite is situated near the charming village of White Waltham. Located just off the A404, with connections by road or rail.

The Institute of Clinical Research Training Suite

Suite 1, Cedar Court

Grove Business Park

White Waltham

Maidenhead

SL6 3LW

**By Car:** Join the A404 either via at J5 of the M40, or J8/9 of the M4. Follow the A404 until you reach J9A signposted to Maidenhead/Reading. Turn right at the first roundabout, then continue on that road, going straight across any subsequent roundabouts. Take the second right past the airfield. If you reach the village, you've gone too far.

Once inside Grove Park, turn left at the first mini roundabout, then right at the T junction. Turn right at the red brick building, and we are in the one furthest from the road. Park in the large car park on your right. Please contact the Secretariat using the buzzer by the door - type in 12 and then press the small bell.

**By Train:** The nearest station is Maidenhead, located on the Paddington - Reading line. We recommend getting a taxi from the station, as bus routes are sporadic. It should take roughly 15 minutes.

## Local Taxi Companies

Dot to Dot + 44 01628 200 999

Golden Executive + 44 1628 622955

Imperial +44 1628 771777

## Accommodation

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

Hotel or Bed & Breakfast Name	Contact number	Website	Approximate Distance to The Institute of Clinical Research
Premier Inn Maidenhead	08715 279520	<a href="http://www.premierinn.com">http://www.premierinn.com</a>	4 miles 14 minutes
Taplow House Hotel	01628 670056	<a href="https://taplowhousehotel.com">https://taplowhousehotel.com</a>	6 miles 16 miles
Bel & The Dragon	01628 521263	<a href="https://belandthedragon-cookham.co.uk/">https://belandthedragon-cookham.co.uk/</a>	7 miles 18 minutes
CIM Moor Hall	+44 1628 427500	<a href="https://moorhall.cim.co.uk/">https://moorhall.cim.co.uk/</a>	7 miles 18 minutes

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.

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

Please complete and sent to [training@icr-global.org](mailto:training@icr-global.org) or fax to +44 01628 501 709

## Registration Form

Please photocopy this form for further registrations

**Course Title:** K13 GCP for Experts **Course Date:** 06 May 2021

**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 note 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:** .....