CTC Resourcing Solutions

ICH GCP REFRESHER INCLUDING INSPECTIONS, CURRENT ISSUES AND HOT TOPICS

Date 2020 to be confirmed

1-Day Course

Who should attend?

This course is designed for those with experience in clinical research seeking to update and refresh their knowledge on the ICH-GCP Guideline, including E6 R2 and for those requiring guidance and advice on how to prepare for GCP inspections. It is aimed at **Clinical Research Assistants/Coordinators, Clinical Trial/Project Managers, Clinical Research Physicians, Study Data Managers, Monitors, those working in Clinical Quality and Compliance,** and will also be of interest to those in related functions (**Clinical Science, Drug Supply, Drug Safety, Regulatory**).

Course Objectives

The course offers a thorough update of the current understanding and interpretation of Good Clinical Practice including the changes to ICH-GCP, current issues and hot topics as well as practical guidance/advice on how to ensure readiness for Health Authority inspections, both of Sponsor and Investigator sites. With this course you will:

- Refresh knowledge of ICH-GCP, particularly from the Sponsor perspective including changes to E6 R2
- Learn practical steps in preparing for Sponsor and Investigator site inspections
- Become familiar and discuss current "hot topics" in the Clinical Development environment
- Participate in interactive workshop exercises to improve course retention

Course Leader

Ms. Alison E. Roberts has been involved in ICH-GCP, Clinical Research and Clinical Quality Assurance training for almost twenty years. She gained a BSc in Pharmacology from the University of Bath (UK) and has worked in the pharmaceutical industry since 1979, initially in Clinical Research operations and since 1991, in Clinical Quality Assurance. For the past fifteen years she has been working as an independent Clinical Quality Assurance Auditor, Trainer and Consultant.

Topics

- Overview of the history of GCP and the implementation of ICH-GCP
- Review of key elements of ICH-GCP (including E6R2), particularly related to Investigator / Sponsor responsibilities
- Inspection-Readiness: how to prepare for Sponsor / Site inspections
- Current "hot topics" in the area of Clinical Research, including: e-source documents, remote and risk-based monitoring

Learning Methodology

Interactive sessions with a mix of lecture, workshop exercises and Q&A.

Continuing Education

This course is accredited by the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM).

SwAPP Swiss Association of Pharmaceutical Professionals sgpm ashmp

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Date to be confirmed / 1-Day Course

REGISTRATION FORM

First Name*: _____

Last Name*:

Company*: _____

Job Title*: _____

Billing Address*: _____

_____

_____

Telephone*: _____

Email Address*: _____

Background: _____

Experience: _____

_____

Are you a CTC employee? ☐ yes ☐ no

Are you a SwAPP member? ☐ yes ☐ no
Are you a SBA member? ☐ yes ☐ no

What do you expect to get from this course?

_____

_____

Do you require help in finding hotel accommodation?
☐ yes ☐ no

Do you wish to receive regular training updates? ☐ yes ☐ no

I agree to the terms and conditions ☐ yes

REGISTRATION INFORMATION

Date:
To be confirmed

Time:
09:00 – 17:00 hrs

Venue:
CTC AG, Münchensteinerstr. 41, CH-4052 Basel

Directions:
Tram 15, tram stop «Grosspeterstrasse»

Registration Fee: CHF 950.00 + 7.7% VAT
15 % reduction for members of SwAPP and SBA
Special registration fees for CTC employees

Registration fees include: Course documentation, refreshments, lunch and a course participation certificate.

Payment: After registration you will receive confirmation and an invoice with instructions on how to complete the bank transfer. Full prepayment is needed prior to the course.

Cancellation Policy:
- Cancellations received **more than 14 days before** course: **100% refund** less bank charges & cancellation fee of CHF 50.00
- Cancellations received **7-14 days before** the course: **50% refund**
- Cancellations received **7 days before** the course: **no refund**

In case of no show, no refund will be made.

Please note that CTC reserves the right to cancel this course or to make minor alterations to the content and timing of the programme or to the identity of the speakers. In the unlikely event of cancellation, delegates will be offered a full refund. CTC will not, however, be held responsible for any related expense incurred by the participant.

Transfer Policy
Subject to agreement from CTC Clinical Trial Consulting AG (CTC) prior to the event, the registration may be transferred to another person from the same company or organization at no extra charge. Updated registration information will be required.

Photography and Video Policy
By attending this training, you give permission for pictures, images etc. of you, captured during the training through video, photo, and/or digital devices, to be used by CTC in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

Privacy Policy
At CTC, we're committed to protecting and respecting your privacy. To view our privacy policy, go to www.ctcresourcing.com/en/about-us/privacy-policy/

REGISTRATION:

- **Email:** training@ctcresourcing.com
- **Internet:** www.ctcresourcing.com
- **Fax:** +41 61 695 88 67

If you have NOT received an official confirmation 7 days after registering, please call CTC at +41 61 695 88 66 or send an email to training@ctcresourcing.com. THANK YOU!

☐ **These dates do not suite me - Please provide me with new training dates once available:**

First Name*: _____ **Last Name*:** _____

Email Address*: _____