CTC Resourcing Solutions

Overview of the New EU Clinical Trial Regulation

1-Day Course

Overview

The new EU Clinical Trial Regulation (536/2014) will replace the European Clinical Trials Directive (2001/20/EC). It was originally due to come into effect in 2016, however implementation has been delayed until the new portal and clinical trial database have been completed and audited. Key aims of the new regulation are to harmonise procedures for carrying out clinical trials across the EU and to simplify the clinical trial approval dossier by submitting clinical trial information through a single point of entry.

This course is ideal for anyone requiring an overview of the EU Clinical Trial Regulation and changes for EU trials.

Course Objectives

- Gain a comprehensive overview of the EU Clinical Trial Regulation and changes for trials in the EU
- Review how the new regulation differs from the previous directive
- Discuss the implementation of the Clinical Trial Regulation Delegated Acts and other implementation documents
- Understand the new clinical trial authorisation process for regulatory approval and ethical approval

Key Topics

- Background to the EU Clinical Research Regulation (Eu. No 536/2014)
- Understand the framework of clinical trial regulations in Europe
- Changes in the new EU Clinical Trial Regulation
- Overview of the major new requirements of the clinical trial regulation including:
    - *Risk-based evaluations, Non-EU sponsors, Transparency, Informed consent, Trials in emergency situations, Serious breaches in GCP*
- Clinical trial regulatory authorisation and ethical approval
- Investigational medicinal product/auxiliary product guideline
- Pharmacovigilance and adverse event reporting – key safety requirement
- Considerations for regulatory inspection

Who should attend?

Anyone requiring an **understanding** and **update** on the new EU Clinical Trial Regulation 536/2014. It is relevant for those working in **clinical research**, **clinical operations**, **clinical project management**, **regulatory affairs**, **pharmacovigilance**, **quality assurance** (GCP auditors), **vendor/CRO** professionals, **study sites** and other **professionals** in pharmaceutical and biotechnology organisations **conducting trials** with drugs, biologics or combination products.

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 the **EU Clinical Trial Regulation**

Course Leader

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 in the pharmaceutical industry, having 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. Laura is an international expert on regulatory requirements in clinical research and was Chair of the Institute of Clinical Research GCP Forum for six years. She writes regularly on clinical research regulatory requirements. She is author of several articles on the new EU Clinical Trial Regulation and has written a chapter on GCP in International Pharmaceutical Product Registration.

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 asmp

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Date to be confirmed

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 fees for CTC employees
Special rates available for PhD Students, please contact training@ctcresourcing.com

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
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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*: _____