CTC Resourcing Solutions

OVERVIEW OF THE NEW EU CLINICAL TRIAL REGULATION

27th October 2021

Overview

The new EU Clinical Trial Regulation (536/2014) will replace the European Clinical Trials Directive (2001/20/EC). 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. The go-live of the centralised clinical trial portal is scheduled for December 2021.

This course is ideal for anyone requiring an overview of the EU Clinical Trial Regulation and changes for EU trials. It will provide an essential understanding to help with compliance with the new Regulation and associated implementing acts and other texts for carrying out clinical trials in the EU.

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:
  TMF, Risk-based evaluations, Non-EU sponsors, Transparency, Informed consent, Trials in emergency situations, Serious breaches in GCP, Pharmacovigilance and adverse event reporting, and Investigational medicinal product
- The new centralised Portal for Clinical Trial Regulatory and Ethical Authorisation

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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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 Regulatory Affairs, TOPRA and Senior Lecturer, MSc 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 Director of Clinical Research, 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.

Learning Methodologies

Interactive sessions with a mix of lecture, group exercises and discussions.

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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?

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

I agree to the terms and conditions ☐ yes

REGISTRATION INFORMATION

Dates:
27th October 2021

Time:
09:00-17:00

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

Directions:
Tram 15, tram stop «Grosspeterstrasse»

Registration Fee: CHF 850.00 + 7.7% VAT
15 % reduction for members of SwAPP and SBA
Special fees for CTC employees
Group discounts available, 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 start date.

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
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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!