EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

We facilitate Clinical Research professionals to excel in their job for the benefit of patients.

FOUNDATIONAL ICH-GOOD CLINICAL PRACTICE (GCP) E6 (R2) TRAINING

Trainers : Dr. Marleen Verbeeck

eLearning

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Trainer(s)

ECCRT Virtual Campus

Enter the ECCRT Virtual Campus and get more about your course!

- Read general news from your trainer
- Post in forums to discuss course-related topics
- Find additional documentation on the course topic
- Download your training certificate

How to enter the Virtual Campus:

Refer to the instructions and credentials received by email. Should you have questions during or after the course, contact your dedicated helpline at campus@eccrt.com.

Important Note:

Your access to the Virtual Campus will expire 3 months after your enrolment date.

Contact details

European Centre for Clinical Research Training (ECCRT)

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info@eccrt.com
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1. Agenda

Course Credit: **7 hours**
Cumulated Videos Duration: **3h15** (excl. quizzes and workshops)
Final Grading Test: 60 minutes (35 questions).

Programme	Duration
Good Clinical Practice: Why?	09:00 min + 1 quiz
Chapter 1: Definitions	07:00 min + 1 workshop + 1 quiz
Chapter 2: The Principles of ICH GCP	02:00 min + 1 workshop + 1 quiz
Chapter 3: The IRB/IEC	06:00 min + 2 workshops
Chapter 4: The Investigator	45:00 min + 2 quizzes + 1 workshop
Chapter 5: The Sponsor (Monitoring)	47:00 min + 1 workshop + 3 quizzes
Chapter 6: The Clinical Trial Protocol & Amendments	30:00 min + 1 quiz
Chapter 7: The Investigator's Brochure	06:00 min + 1 quiz
Chapter 8: The essential documents	25:00 min + 1 workshop + 1 quiz
GCP-QUIZ	1 quiz
Common Non-Compliances	07:00 min + 2 workshops
The new ICH-GCP	08:00 min

2. Trainer

Dr. Marleen Verbeeck

Dr. Marleen Verbeeck is a clinical research professional since 1995. After her academic career in scientific research she gained solid grounding in clinical research, first as a clinical research associate, later as a medical writer and trainer. Since 2004 she works at the European Centre for Clinical Research Training (ECCRT) and trains staff from multinationals and small businesses of the pharmaceutical and medical device industry, of universities, as well as non-profit research organisations across Europe, the United States of America and the Middle East. She is author of scientific papers, clinical trial study protocols and final study reports (Phase I to IV). Her experience in medical areas include gastroenterology, central nervous system, rheumatology, oncology and immunotherapy.

Marleen enjoys developing, lecturing, evaluating and testing comprehension of courses and expands her vast educational classroom expertise by exploring new learning techniques.

As a trainer her expertise is “trial legislation and clinical operations”, such as:

- Good Clinical Practice (Refresher)
- Legal Requirements in Clinical Research in Pharmaceutical and Medical Devices industry in Belgium/ in Europe/ and in the USA
- Preparing for Audits/ Inspections
- Standard Operating Procedures and Operational Challenges
- Clinical Research Trainings for Administrators/Assistants
- Clinical Research Trainings for Clinical Trial Monitors (juniors and seniors)
- Clinical Research Trainings for Investigational Site Team
- Clinical Research Trainings for Investigators

She is providing classroom and virtual teaching of academics and company staff, located globally, but also tailor-made sessions adapted to the specific needs of client and/or company.