EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

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

ICH-GCP E6 (R2) REFRESHER + COMPLEMENTARY ICH-GCP REFRESHER FOR REGULATORY STAFF

Trainers: Dr. Marleen Verbeeck
Ms. Nelle Stocquart

eLearning

Table of Content

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- 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

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1. Agenda

Course Credit: **5 hours**
Cumulated Videos Duration: **1h40** (excl. quizzes and workshops)
Final Grading Test: 60 minutes (25 questions).

PART I - ICH-GCP E6 (R2) REFRESHER	**Duration**
Introduction	04:00 min
ICH-Good Clinical Practice E6 (R2) 2016	
GCP Chapter 1: Definitions	01:00 min + 1 quiz
GCP Chapter 2: Principles	01:00 min + 1 quiz
GCP Chapter 3: IRB/IEC	02:00min + 1 workshop
GCP Chapter 4: Investigator	06:00 min + 1 quiz
GCP Chapter 5: Sponsor	12:00 min + 2 quizzes
GCP Chapter 6: Clinical Trial Protocol	03:00 min
GCP Chapter 7: Investigator's Brochure	01:00 min
GCP Chapter 8: Essential Documents	04:00 min
GCP Common Audit Findings	
At investigator site	16:00 min + 3 real case scenarios
At Sponsor	19:00 min + 1 quiz + 1 workshop
Conclusion	01:00 min

PART II – COMPLEMENTARY ICH-GCP REFRESHER FOR REGULATORY STAFF	Duration
Introduction to regulatory Requirements	02:00 min + 1 quiz
Definitions & Principles	05:00 min + 1 quiz + 1 workshop
IRB/IEC Responsibilities	01:00 min + 1 workshop
Investigator's Responsibilities	1 quiz
Sponsor's Responsibilities	10:00 min + 3 quizzes
Essential Documents, Protocol & Investigator's Brochure	7:00 min + 1 real case scenario + 1 quiz + 1 workshop
Quality	01:00 + 1 workshop

2. Trainers

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.

Ms. Nelle Stocquart

Nelle obtained a master in Chemistry in 1997 at ULB. She then worked in variety of companies and institutions as researcher until 2002.
Her first experience in clinical trials was in 2003 when she became an IVRS project manager at S-Clinica, a Belgian CRO. Her wish was finally to be on the field and she became CRA at PAREXEL where she got involved in may international phases II & II from early study stage till closure. She then evolved as project manager in pharmaceutical companies and CRO where she managed local and international studies from phase I to phase IV.

Nelle has experience in managing international phase I, II and III studies in oncology but also rare diseases, cardiology and immunology. Training, coaching, education and continuous professional development have always been the common pillars in her educational path and professional career.