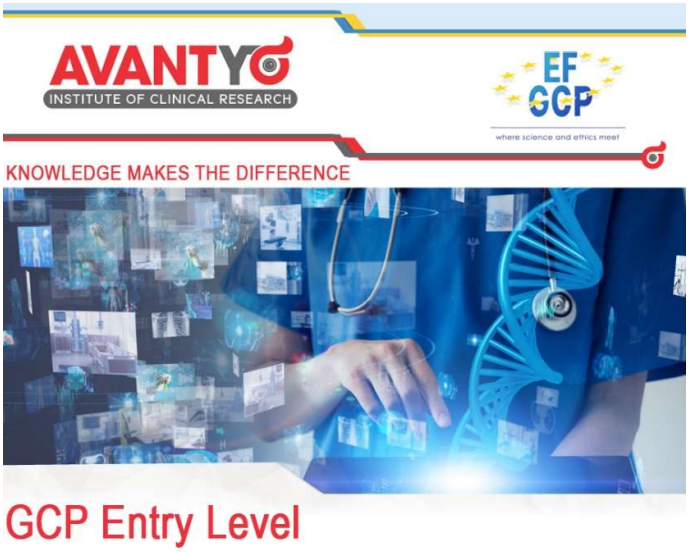
GCP Entry Level



19 & 20 April, 2021

SCOPE OF TRAINING:

This course presents the approach to clinical trial planning and execution as defined by the ICH Good Clinical Practice (GCP) standard and is a comprehensive training solution for all individuals that need to acquire GCP knowledge.

INTRODUCTION

The two-days training contains practice-oriented presentations and real-world group exercises that will allow you to enjoy the learning process and easily understand the fundamentals of GCP.

Attending a GCP course like ours is an essential requirement for any professional working in clinical trials from academia, professional clinical sites, Clinical Research Organizations (CROs), Sponsors, members of Ethics Committees or Competent Authorities, researchers or other research or medical staff.

Applying the GCP principles provides assurance that the rights, safety and well-being of research subjects are protected and that the results of the study are credible.

Successful attendance of our GCP online training as demonstrated in a final multiple-choice test will provide you with the internationally recognized “EFGCP GCP Certificate of Completion”. The course is recognized by TransCelerate Minimum Criteria of GCP Training Courses.

TRAINING DETAILS:

Date/Time: April 19 & 20, 2021
Location: Online
Language: English
Online registration: open until: April 15, 17:00 (EET)
Trainer: Ingrid Klingmann, MD, PhD, FFPM, FBCPM- Chairman of European Forum for Good Clinical Practice (EFGCP), EFGCP Consultant & Trainer
Host: Cristina Florescu Moraid, MD, MSc, EuSpLM, MRQA -CEO AVANTYO Institute of Clinical Research
Participation fee: 1125.00 lei / 225 euro (no VAT refund)
Discounts: 5% for over 3 participants and 10% for over 5 participants from the same institution. For assistance please contact us at diana.lupu@avantyo.com, 0726 840 456.

SPEAKER:

INGRID KLINGMANN, MD, PHD, FFPM, FBCPMPHARMAPLEX bv, EFGCP, PharmaTrain Federation

Ingrid Klingmann, MD, PhD, European Forum for Good Clinical Practice (EFGCP), Pharmaplex bv, Brussels, has 30 years of practical experience with planning and performance of clinical trials from a sponsor and investigator perspective in the pharmaceutical industry, CRO and academic institution. Through her activities in multi-stakeholder not-for-profit organisations

like EFGCP, she gained broad experience in ethical, quality and regulatory challenges in clinical research and possible approaches to solutions.

- Physician, specialized in General Medicine, Clinical Pharmacology and Pharmaceutical Medicine with over 30 years of experience in different senior medical, operational and managerial functions in the pharmaceutical industry, CROs and clinical trial sites with focus on clinical trial design and management, ethical and regulatory aspects.
- Since January 2003 she has her pharmaceutical development and site management support consulting company.
- Dr Klingmann is Chairman of the Board of the European Forum for Good Clinical Practice (EFGCP). On behalf of EFGCP she was and is involved in different FP7- and IMI-funded projects (ICREL, PatientPartner, PharmaTrain, EUPATI, Combacte-NET, PARADIGM and ConCEPTION) and with her company in the FP7-funded paediatric LENA project. Her broad professional background as a physician with experience in patient care, clinical development, site management and patient engagement enables Dr Klingmann to bridge the gaps between the interests and skills of all different stakeholders in medicines development to develop new patient-relevant treatments more efficiently.
- Dr Klingmann is also President of PharmaTrain Federation, the not-for-profit organisation focussing on global standardisation and improvement of post-graduate training in medicines development sciences. She also teaches on different clinical research and regulatory affairs topics in diploma and master courses at the University of Bonn, Germany, University of Basel, Switzerland, and the Université Libre de Bruxelles, Belgium.

AGENDA:

DAY 1

08:30 - 09:00

- Registration open

09:00 - 09:15

- Welcome and Introduction

09:15 - 09:45

- Understanding the medicines development process

09:45 - 10:45

- Introduction to Good Clinical Practice including risk management;

10:45 - 11:00 - Break

11:00 - 11:15

- GCP in European legislation;

11:15 - 11:50

- Understand a protocol;

11:50 - 12:30

- Exercise 1 in Break-out Groups:

  Identification of critical data and processes in your protocol

12:30 - 12:45

- Result presentation and joint discussion

12:45 - 13:45 - Lunch

13:45 - 15:00

- Preparation of a clinical trial from the sponsor and investigator perspectives

15:00 - 15:20 - Break

15:20 - 16:00

- The Informed Consent process

16:00 - 16:30

- Safety data collection and reporting

16:30 - 16:50 - Break

16:50 - 17:30

- Exercise 2 in Break-out Groups:

  Planning a study day at a trial site

17:30

- End of Day 1

DAY 2

09:00 - 09:30

- Exercise 2 Result presentation and joint discussion

09:30 - 10:15

- Quality assurance in clinical trials

10:15 - 10:45

- Ethical review of clinical trials

10:45 - Break

11:05 - 11:50

- Study documentation

11:50 - 12:30

- Exercise 3:

  Managing study documentation

12:30 - 13:30 - Lunch

13:30 - 14:45

- Critically important trial management aspects

14:45 - 15:45

- Exercise 4:

  How to build and manage your team for your study

15:45 - 16:10

- Exercise 4 Result presentation and joint discussion

16:10 - 16:30 - Break

16:30 - 17:30

- Final multiple choice test

17:30 - End or Training

Note:

Online event | The ZOOM details and instructions will be sent a few days in advance, as well as the support material of the course and a protocol synopsis that has to be read upfront to the training not to lose time during the exercise session.

During the online meeting, the participants' names will be disclosed as they will be split into small groups for an exercise session.

Discounts and assistance | Please contact us: info@avantyo.com, diana.lupu@avantyo.com, 0726 840 456.

Not sure how to book? Click here for instructions in Romanian.

Newsletter

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Waiting list

If you would like to be placed on a waiting list for the next course or you need something else, please let us know at info@avantyo.com. Do not forget to mention your specific education needs in clinical trials

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