10 CIEC years

INVITATION / ONLINE TRAINING

Interactive Training in Applied GCP for Investigators & Site Personnel

Performance of clinical trials according to Good Clinical Practice (GCP) principles has been introduced as a European regulatory requirement by the Clinical Trial Directive 2001/20/EC. Strict adherence to this standard ensures patient protection and reliable data. It is the basis for acceptance of publications and for patients' access to new treatments. This standard has implications for all stakeholders and processes in clinical trials. However, despite overall commitment and best intentions to apply to these requirements, monitoring, audits and inspections regularly find deficiencies of different levels of severity.

In this interactive workshop current experience and requirements of GCP-conform set-up and performance of clinical trials will be presented, their practical implications and examples discussed and pragmatic solutions for your daily practice elaborated.

1.00pm	Welcome and Introduction
1.10pm	Good Clinical (Research) Practice in European legislation
2.10pm	Questions & Answers
2.20pm	*Break*
2.35pm	Set-up of a clinical trial at the investigative site
3.00pm	Discussion
3.10pm	Optimising the informed consent process
3.35pm	Discussion
3.40pm	*Break*
3.50pm	GCP compliance in document management
4.25pm	Discussion
4.30pm	*Break*
4.45pm	Critical elements of conducting clinical trials
5.30pm	Discussion
5.35pm	*Break*
5.45pm	Reliable safety management at the site
6.00pm	Final Test
7.00pm	End of the Training

TRAINER

Ingrid Klingmann

MD, PhD, FFPM, FBCPM
Expert in Drug Development Planning and Site Management Support, Pharmaplex bv, Brussels, Belgium & Chairman of the Board of European Forum for Good Clinical Practice (EFGCP)

DATE & TIME

15th of March 2021
From 13:00 till 19:00

ONLINE WEBINAR

INFORMATION & REGISTRATION
Registration: **gcptraining.lih.lu**

› Training will be held in English

CONTACT
tania.zamboni@lih.lu

Organized by **Clinical and Epidemiological Investigation Center**
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