GCP CERTIFICATE

Interactive Training in Applied GCP for Investigators & Site Personnel

The EU Clinical Trial Directive and Its Implications on Your Clinical Research Practice

23 February 2018 – UZ Leuven (campus Gasthuisberg), Belgium

Mevr. Linde Buntinx, Kindergeneeskunde

Attended the above training course and successfully passed the related final test.

Venue: Leuven, Belgium
Date: 23/02/2018
Provider: European Forum for Good Clinical Practice, Brussels, Belgium
Duration: 5:00 hours

Modules:

- Good Clinical (Research) Practice in European legislation
- Belgian legislation for clinical trials
- Set-up of a clinical trial at the investigative site
- GCP compliance in document management
- Optimising the informed consent process
- Critical elements of conducting clinical trials
- Reliable safety management at the site
- ICH-GCP E6 (R2)

Learning Outcomes: Understand the GCP principles and the underlying ethical principles; Understand the elements of Belgian clinical trial legislation; Understand the ethical review process by ethics committees; Know elements and needs for preparation of a clinical trial at the site; Appreciate the need and elements of a patient-centric informed consent process; Understand the elements of IMP management; Discuss critical elements in clinical trial execution at the site; Understand the principles of reliable document management; Understand adverse event terminology, assessment principles and reporting obligations

Expert: Ingrid Klingmann, MD, PhD, FFPM, FBCPM
EFGCP Consultant & Trainer
EFGCP Chairman

Brussels, 20th March 2018

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