DEUTSCHE
GESELLSCHAFT
FÜR
REGULATORY AFFAIRS

3rd School
Clinical Documentation

Introduction to the current and upcoming regulatory framework for clinical trials

November 2nd and 3rd, 2020

Virtual Event

Moderation: Dr. Ingrid Klingmann, Pharmaplex, Brussels

Speakers:

- Prof. Dr. Thomas Bieber, University Hospital Bonn, Bonn
- Dr. Martin Coenen, University Hospital Bonn, Bonn
- Dr. Ingrid Klingmann, Pharmaplex, Brussels
- PD Dr. Thomas Sudhop, Federal Institute for Drugs and Medical Devices, Bonn
- Prof. Dr. Bob Wilffert, University of Groningen

Program November 2nd, 2020

9.00 a.m. **I. Introduction to the Clinical Drug Development Process Leading to the Label**
Dr. Ingrid Klingmann

9.45 a.m. Bio break

9.55 a.m. **II. Basics of Clinical Trials Phase I to IV**
Dr. Ingrid Klingmann

10.40 a.m Coffee break

11.00 a.m. **III. Informed Consent Process and Data Protection**
Prof. *Dr. Bob Wilffert*

11.40 a.m. Bio break

11.50 a.m. **IV. Ethical Review Process for Clinical Trials in Europe**
Prof. *Dr. Bob Wilffert*

12.30 p.m. Lunch

1.30 p.m. **V. Good Clinical Practice**
Dr. Martin Coenen

2.15 p.m. Bio break

2.25 p.m. **VI. Management of Trial Documents: from Essential Documents to Trial Master File**
Dr. Martin Coenen

3.30 p.m. Coffee break

4.00 p.m. **VII. Quality Management in Clinical Trials**
Dr. Ingrid Klingmann

4.45 p.m. Bio breack

4.55 p.m. VIII. Audits and Inspections
Dr. Ingrid Klingmann

5.30 p.m. End of Day 1

Program November 3rd, 2020

9.00 a.m. **IX. Safety Data Collection and Assessment**
PD Dr. Thomas Sudhop

9.40 a.m. Bio break

9.50 a.m. **X. Safety Reporting in Clinical Trials**
PD Dr. Thomas Sudhop

10.30 a.m. Coffee break

11.00 a.m. **XI. Current Clinical Trial Legislation: Directive 2001/20/EC and Commission Directive 2005/28/EC**
Dr. Ingrid Klingmann

12.00 p.m. Bio break

12.10 p.m. **XII. Clinical Trial Authorisation and Reporting**
PD Dr. Thomas Sudhop

13.15 a.m. Lunch

2.15 p.m. **XIII. Upcoming Clinical Trial Legislation: Regulation 536/2014**
Dr. Ingrid Klingmann

2.45 p.m. Bio break

2.55 p.m. **XIV. Coordinated Assessment Procedures: from VHP to Pilot Projects**
PD Dr. Thomas Sudhop

3.30 p.m. Coffee break

4.00 p.m. **XV. Clinical Development Strategies**
Prof. Dr. Thomas Bieber

5.30 p.m. End

(There maybe changes to the program)

Information and organisational references

Date:
Monday, November 2nd, 2020
Start: 9.00 a.m.
Tuesday, November 3rd, 2020
End: ca. 5.30 p.m.

Venue:
The workshop is an online workshop via Zoom. You will receive the login data by mail one week before the event.

Participation fees:
For DGRA members and M.D.R.A. students: 390 €, for non-members: 540 €

Cancellation conditions:
Cancellation will incur a handling fee of 50€.
In case of short-term cancellation (2 weeks before) 50 % of the registration fee will be charged.
One week before the event the full fee has to be paid,
unless a substitute participant (DGRA member) is named.

In case of cancellation by the organizer, already paid fees will be refunded in full.

Workshop language:
German

Registration:
Please use the form at
https://dgra.de/deutsch/fortbildung/?nav=fortbildung

Registration of non-members please by mail to info@dgra.de

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