



Programme

Programme GUIDE Course "Good Research Practices: GCP and GLP"

Monday March 12, 2018

- Subject **New Drug Development; Good Research Practices: Good Clinical Practices: Introduction**
- Organization GUIDE
Graduate School for Drug Exploration University of Groningen
- Responsible teacher Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.
Professor em. Quality Management in Drug Research and Manufacturing
University of Groningen
PharmAdvices
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- Web: www.pharmadvices.com
- Building/Room University of Groningen
Medische Wetenschappen, Farmacie, Tandheelkunde en
Bewegingswetenschappen
Antonius Deusinglaan 1
Building: 3215
Room : 0149
NL - 9713 AV GRONINGEN
- 09:00 - 10:00 Welcome
Introduction of the participants
Introduction on the Course Leader
Introduction on the Course
- 10:00 - 10:15 Introduction on New Drug Development (Part I)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 10:15 - 10:30 Break
- 10:30 - 11:50 Introduction on New Drug Development (Part II)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)

- 11:50 - 12:35 Marketing Authorization Procedures
(L. Vromans, MA)
- 12:35 - 13:05 Video - Big pharma and 21st Century drug development
(Prof. Dr. Chas Bountra)
- 13:05 - 14:00 Lunch
- 14:00 - 15:00 Good Research Practices: GCP (Part I)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 15:00 - 15:15 Introduction on the Case Studies
- 15:15 - end Preparation of Case Studies (Home work)

Tuesday March 13, 2018

Subject **Good Clinical Practices: Theory**

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- 09:00 - 09:05 Video – White Board – Clinical Trials 101
- 09:05 - 10:00 Good Research Practices: GCP (Part II)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 10:00 - 10:15 Break
- 10:15 - 10:45 Video – The Belmont Report: Basic Ethical Principles and their Application
(U.S. Department of Health & Human Services); Office for Human Research
Protections)
- 10:45 - 12:00 Good Clinical Practices: the European Directive and Regulation (Part I)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 12:00 - 12:15 Break
- 12:15 - 12:45 Good Clinical Practices: the European Directive and Regulation (Part II)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 12:45 - 13:45 Medical Research with Human Subjects in The Netherlands; The Role of
Medical Research Ethics Committees
(Prof. Dr. G.H. Koëter, Former Chairman of CCMO, Centrale Commissie
Mensgebonden Onderzoek)
- 13:45 - end Preparation of Case Studies (Home work)

Wednesday March 14, 2018

Subject **Good Clinical Practices: Theory**

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09:00 - 10:00 Responsibilities of the Sponsor during Clinical Drug Research
(R. van Olden, M.D.; Horizon Pharma)

10:00 - 10:15 Break

10:15 - 11:15 The Responsibility of the Investigator for a Safe Conduct of Clinical
Trials (Part I)
(Th. van Iersel, M.D., PRA International B.V.)

11:15 - 12:15 The Responsibility of the Investigator for a Safe Conduct of Clinical
Trials (Part II)
(Th. van Iersel, M.D., PRA International B.V.)

12:15 - end Preparation of Case Studies (Home work)

Thursday March 15, 2018

Subject **Good Clinical Practices: Practice**

09:00 - 14:00 Excursion including Workshop; Clinical Research Centre of QPS
Netherlands B.V., Groningen
L.J. Zielstraweg 2
University Medical Center
NL-9713 GX GRONINGEN
Contact person: Dr. W. Tamminga
Phone: +31 50 3048000

14:00 - end Preparation of Case Studies (Home work)

Friday March 16, 2018

Subject **Good Research Practices and Quality Management: Theory**

Building/Room University of Groningen
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Bewegingswetenschappen
Antonius Deusinglaan 1
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- 09:00 - 10:15 Quality Management in Drug Research
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 10:15 - 10:30 Break
- 10:30 - 11:00 Standard Operating Procedures (SOP's)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 11:00 - 11:30 Document Management and Archiving
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 11:30 - 12:00 Practical Approaches to Implement GxP's
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 12:00 - 12:45 Lunch
- 12:45 - 13:45 Quality Assurance Audits by Sponsors
(Henk W. Visscher, M. Ph. Sc., M. M. Sc.,
Associate Director Clinical Quality Assurance, Astellas Pharma Europe B.V.)
- 13:45 - end Preparation of Case Studies (Home work)

Monday March 19, 2018

Subject Good Clinical Practices: Compliance

- Building/Room** University of Groningen
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- 09:00 - 10:00 Computer System Validation in Clinical Research
(Jean-Paul Eycken, M.Sc., M.B.A.
Director FormaliS SA, Diekirch, G-D Luxembourg)
- 10:00 - 10:15 Break
- 10:15 - 11:30 How to Mislead Inspectors during an Inspection?
(Jean-Paul Eycken, M.S.c., M.B.A.
Director, FormaliS SA, Diekirch, G-D Luxembourg)
- 11:15 - 11:30 Break
- 11:30 - 12:45 Compliance with Good Clinical Practices: Inspections in The Netherlands,
Europe and Third Countries
(W.R. Verweij, Ph.D.,
Dutch Health Care Inspectorate
Senior Inspector Clinical Trials; Ministry of Health, Welfare and Sport)
- 12:45 - 13:30 Lunch
- 13:30 - 14:30 Misconduct in Biomedical Research
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R.Ph.)
- 14:30 - 14:45 Video – Research Integrity (Ben Goldacre, M.D.)
- 14:45 - end Preparation of Case Studies (Home work)

Tuesday March 20, 2018

Subject **Good Laboratory Practices: Theory and Compliance**

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- 09:00 - 10:00 Good Research Practices: GLP (Part I)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R. Ph.)
- 10:00 - 10:15 Break
- 10:15 - 11:00 Good Research Practices: GLP (Part II)
(Prof. JanHasker G. Jonkman, Ph.D., F.C.P., F.R.Q.A., R. Ph.)
- 11:00 - 11:30 Video GLP
- 11:30 - 11:45 Break
- 11:45 - 13:15 Good Laboratory Practice
(Th. Helder, M. Sc., Former Head of the GLP Monitoring Program in The Netherlands)
- 13:15 - end Preparation of Case Studies (Home work)

Wednesday March 21, 2018

Subject **Good Laboratory Practices: Theory and Practice**

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- 09:00 - 10:00 Performing a Bioanalytical Study (Part I)
(M. Kranenborg, Ph.D., QPS Netherlands B.V.)
- 10:00 - 10:15 Break
- 10:15 - 10:45 Performing a Bioanalytical Study (Part II)
(M. Kranenborg, Ph.D., QPS Netherlands B.V.)
- 11:00 - 13:30 Excursion to the Bioanalytical Laboratories of QPS Netherlands B.V.,
Groningen
Prof. Rankestraat 42
NL-9713 GZ GRONINGEN
Contact person: Dr. M. Kranenborg
Phone: +31 50 3048003
- 13:30 - end Preparation of Case Studies (Home work)

Thursday March 22, 2018

Subject Case Studies

(Presentations by the participants on the course; Discussion)

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09:00 - 10:00 Case Study 1

10:00 - 10:15 Break

10:15 - 11:15 Case Study 2

11:15 - 11:30 Break

11:30 - 12:30 Case Study 3

Friday March 23, 2018

Subject Case Studies

(Presentations by the participants on the course; Discussion)

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09:00 - 10:00 Case Study 4

10:00 - 10:15 Break

10:15 - 11:15 Case Study 5

11:15 - 11:30 Break

11:30 - 12:30 Case Study 6

12:30 - 13:00 Final Discussion; Filling out Evaluation Forms

13:00 End of course