PAOFarmacie

Netherlands Centre for Post Academic Education in Pharmacy

Module2: Drug development from quality by design to clinical studies:

an integrated course for the pharmaceutical industry and hospital pharmacy

PROGRAM
17 - 19 June 2019
Hotel Bergse Bossen, Driebergen, the Netherlands

Monday, 17 June 2019

Themes*: Drug substance, Medicinal chemistry, pharmaceutical formulations, large scale production, Quality by Design, Hospital pharmacy*

09.30: Welcome and Introduction
Ineke Jonker-Hoogerkamp and Jan-Jaap Scherpbier
09.45: Introduction of the case study: antidepressant BODL2000
-The profile of BODL2000; R&D steps and R&D data
-Registration of BODL2000; role of RA department
-The quality of the registration dossier for BODL2000
Ineke Jonker-Hoogerkamp
10.45: The importance of Quality
-Quality from a regulatory and GMP perspective
-Legislation
-ICH and regional guidelines
Jan-Jaap Scherpbierp
11.00: Break
11.15: Medicinal chemistry: quality in lead finding and lead optimization
Jac Wijkmans
12.15: Lunch
13.15: Quality requirements from process chemistry to large scale roduction
Jac Wijkmans
14.15: Pharmaceutical formulations
-The development of drug products
-Quality management and cGMP in pharmaceutical development
-Small scale production
-From small scale to large scale
Erik Frijlink
15.45: Break
16.00: From R&D to production
-Quality by Design
-PAT and PCT in industry and hospital pharmacy
Erik Frijlink
17.30: Break
18.00: Drug development in Dutch hospital pharmacies
Katja van Rij
19.00: Dinner

Tuesday, 18 Juni 2019

Themes: *Regulatory requirements, GMP for clinical suppliest, Quality by Design applied, Nonclinical development, Pharmacology, Toxicology*

08.30: The Quality part of the registration dossier
-The Common Technical Document (CTD)
-Development and manufacture of Drug substance and Drug Product
-Clinical Trial Applications; quality requirements during development
Jan-Jaap Scherpbier
09.30: The Total Quality Management obtained by Quality by Design
-Real life examples in industry
Wim Oostra

10.30: Break
10.45: GMP for Clinical Supplies
TBD
11.45: GMP Case
TBD, Jan-Jaap Scherpbier
12.30: Lunch
13.30: Introduction GLP and Nonclinical RA
Ineke Jonker-Hoogerkamp
13.45: Pharmacokinetics and pharmacodynamics (PK/PD) in industrial practice
Peter Vis
15.15: Break
15.30: Toxicology
Eric de Waal
17.00: Break
17.30: Case study BODL2000: GLP and nonclinical development program:
-Deficiencies for registration in the BODL2000 nonclinical program
Ineke Jonker-Hoogerkamp and Eric de Waal
19.00: Group presentations
Wrap up of the case study
Ineke Jonker-Hoogerkamp and Eric de Waal
19.30: Dinner

Netherlands Centre for Post-Academic Education in Pharmacy
www.paofarmacie.nl T + 31(0)30-30 40 100
info@paofarmacie.nl F + 31(0)30 30 40 109

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Wednesday, 19 June 2019
Themes: *GLP applied, Clinical development, GCP applied, Inspectorate perspective*

08.30: Introduction to GLP
Chris Mitchell
09.15: Case study BODL2000: GLP and nonclinical development program:
-Action steps preparation and execution of a GLP compliant study
-GLP in a multi-site study
Chris Mitchell and Ineke Jonker-Hoogerkamp
10.00: Group presentations
Wrap up of the casestudy
Chris Mitchell and Ineke Jonker-Hoogerkamp
10.15: Break
11.00: Clinical development Phase I
-Principles, clinical study documents, requirements for a Phase I
-Clinic, clinical pharmacology, types of Phase I studies
Leo de Leede
12.00: Lunch
13.30: Clinical development Phase II and III (continued)
-Regulation of clinical trials in historical context
-Practical and methodological aspects of clinical trials
-Clinical development strategy, label as driver
Tjeerd Korver
14.30: Perspective from Dutch Inspectorate
Mieke van der Meulen
15.15: Break
15.30: Case study BODL2000: GCP and clinical development program
-Possible deficiencies in the clinical program
-Outline for a clinical trial
-Possible deficiencies in the informed consent
-Audit report
Eveline Krijger and Lisette Vromans
16.30: Group presentations
Wrap up of the case study
Eveline Krijger and Lisette Vromans
17.00: Evaluation of the course and learned lessons
Jan-Jaap Scherpbier and Ineke Jonker-Hoogerkamp
17.15: Close

Drug development from quality by design to clinical studies
Faculty

COURSE LEADER

Dr. A.(Ineke) Jonker-Hoogerkamp
Eagle Pharma Consult, the Netherlands

Drs. J.J. (Jan-Jaap) Scherpbier
Sonsbeek Pharma Consultancy BV and Garden State Pharmatech, the Netherlands

LECTURERS

Prof.dr. H.W. (Erik) Frijlink
Groningen University Institute for Drug Exploration (GUIDE), Dept. of Pharmaceutical Technology and Biopharmacy, the Netherlands

T. (Tjeerd) Korver, PhD
ReproVision Consultanty in Clinical Development, Oss, the Netherlands

Ir. E.M. (Eveline) Krijger
Kite Pharma Inc., Amsterdam, the Netherlands

Dr. L.G.J. (Leo) de Leede
Exelion Bio-Pharmaceutical Consultancy BV, Waddinxveen, the Netherlands

Drs. M. (Mieke) van der Meulen
Health and Youth Care Inspectorate (IGJ), Utrecht, the Netherlands

C. (Chris) Mitchell, BSc
Charles River Laboratories, Den Bosch, the Netherlands

Dr. W. (Wim) Oostra
Abbot Healthcare Products BV, Weesp, the Netherlands

Drs. P. (Peter) Vis
LAP&P Consultants, Leiden, the Netherlands

Ing. E.W.M. Vromans
Zwiers Regulatory Consultancy BV, Oss, the Netherlands

Dr. E.J. (Eric) de Waal
JanssenPharmaceutica N.V., Beerse, Belgium

Dr. J. (Jac) Wijkmans
Griffin Discoveries, Amsterdam, the Netherlands

GENERAL INFORMATION

See last page for information on registration, dates and costs is available on the website of **www.paofarmacie.nl**
Select course ***Quality Management***
For more information contact Hans Noordhuis, email address **h.noordhuis@paofarmacie.nl**

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