PROGRAM

Day 1

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

9.30	**Welcome and introduction** *Ineke Jonker-Hoogerkamp and Jan-Jaap Scherpbier*
9.45	**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 Scherpbier*
11..00	Coffee 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 production** *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	*Coffee break*
16.00	**From R&D to production** - **Quality by Design** - **PAT and PCT in industry and hospital pharmacy** *Erik Frijlink*
17.30	**snack**
18.00	**Drug development in Dutch hospital pharmacies** *Katja van Rij*
19.00	Dinner

Day 2

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

8.30	**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*
9.30	**The Total Quality Management obtained by Quality by Design** - **Real life examples in industry** *Wim Oostra*
10.30	*Coffee 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	Coffee break
15.30	**Toxicology** *Eric de Waal*
17.00	*snack*
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

Day 3

Themes: GLP applied, Clinical development, GCP applied, Inspectorate perspective

8.30	**Introduction to GLP** *Chris Mitchell*
9.15	**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 case study** *Chris Mitchell and Ineke Jonker-Hoogerkamp*
10.15	*Coffee break*
10.30	**Introduction clinical development and GCP** *Eveline Krijger and Lisette Vromans*
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	**Clinical development Phase II and III** **- Regulation of clinical trials in historical context** **- Practical and methodological aspects of clinical trials** **- Clinical development strategy, label as driver** *Tjeerd Korver*
12.30	*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	Coffee
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**

FACULTY

Course Leaders

Dr. A. Jonker-Hoogerkamp
Eagle Pharma Consult, the Netherlands
Drs. J.J. Scherpbier
Sonsbeek Pharma Consultancy BV and Garden State Pharmatech, the Netheralnds

Lecturers

Prof.dr. H.W. Frijlink
Groningen University Institute for Drug Exploration (GUIDE), Dept. of Pharmaceutical Technology and Biopharmacy, the Netherlands
Tj. Korver, PhD
ReproVision Consultanty in Clinical Development, Oss, the Netherlands
Ir. E.M. Krijger
Kite Pharma Inc., Amsterdam, the Netherlands
Dr. L.G.J. de Leede
Exelion Bio-Pharmaceutical Consultancy BV, Waddinxveen, the Netherlands
Dr. M. van der Meulen
Inspectie voor de Gezondheidszorg, Den Haag, the Netherlands
C. Mitchell, BSc
Charles River Laboratories, Den Bosch, the Netherlands
Dr. W. Oostra
Abbot Healthcare Products BV, Weesp, the Netherlands
Drs. P. Vis
LAP&P Consultants, Leiden, the Netherlands
Ing. E.W.M. Vromans
Zwiers Regulatory Consultancy BV, Oss, the Netherlands
Dr. E.J. de Waal
JanssenPharmaceutica N.V., Beerse, Belgium
Dr. J. Wijkmans
Griffin Discoveries, Amsterdam, the Netherlands