PAOFarmacie

Netherlands Centre for Post Academic Education in Pharmacy

Training course Quality Management in Pharma and Biotech 2019

MODULES

M1 **Quality management, the role of the Qualified Person**

M2 **Drug development from Quality by Design to clinical studies: an integrated course for the pharmaceutical industry and hospital pharmacy**

M3 **Sterile manufacturing: a thorough discussion on sterility assurance challenges**

M4 **Quality and safety for the manufacturing of biopharmaceuticals: from cell line development to downstream processing and formulation**

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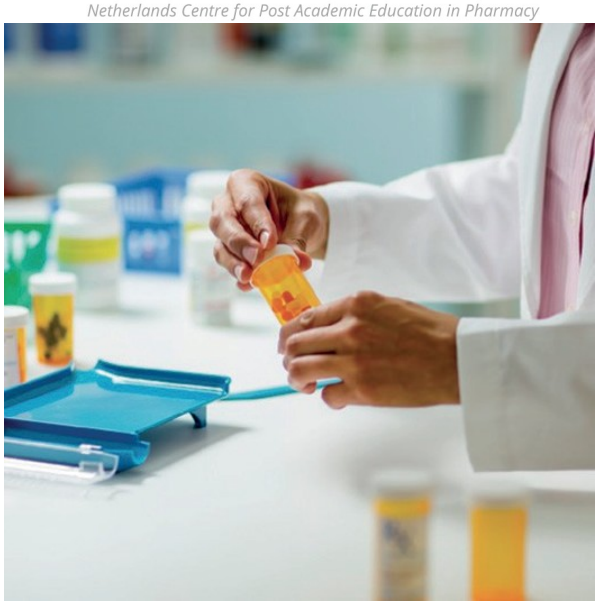

Module1: Quality Management, the role of the qualified person

PROGRAM
4 - 6 March 2019
Hotel Bergse Bossen, Driebergen, the Netherlands

Monday, 4 March 2019
Theme: ***The role and legal obligations of the Qualified Person***
Introduction to current concepts in Quality Management

09.00: Welcome and Introduction
Jan Henk Brinkman
09.30: The role and duties of the Qualified Person in Pharmaceutical Quality Management and the supply of medicines to the European Community
Jan Henk Brinkman
10.30: Break
10.45: The role and duties of the Qualified Person in Pharmaceutical Quality Management and the supply of medicines to the European Community
Jan Henk Brinkman
12.00: Lunch
12.45: Responsibilities of the Qualified Person (QP): International Regulations Current views from the Inspectorate
Mieke van der Meulen
13.45: Responsibilities of the Qualified Person (QP) for batch release of commercial products
Mieke van der Meulen
14.30: Case study addressing the issues facing the QP in an integrated approach to Quality Assurance in a pharmaceutical Environment
Jan Henk Brinkman
15.30: Presentations and discussions
16.15: Break
16.30: Good Distribution Practice: the new EU requirements and the role of the Responsible Person
Mieke van der Meulen
17.30: Dinner

Tuesday, 5 March 2019
Theme: ***Quality management and maintaining compliance in the current Quality environment***

08.30: Compliance verification and Auditing
Désirée Vendrig
09.15: Case study: in compliance or not in compliance?
Désirée Vendrig
10.15: Break
10.30: Active pharmaceutical ingredients (APIs) and the QP Declaration
Désirée Vendrig
12.00: Lunch
13.00: Quality Systems: Deviation management and Change control
Mirjam te Koppele
15.00: GMP inspections and case study on inspection readiness
Dominique Mudde
16.45: Break
17.00: The fight against counterfeit medicines: The new falsified medicines directive and securing the supply chain for patients
Jean-Michel Guirado
18.00: Dinner
19.00: Introduction to the Workshop: the real world
Eric van Wensveen and Pedro Tetteroo

Wednesday, 6 March 2019
Theme: ***Operating effectively as a QP in the complex world of pharmaceutical manufacturing***

09.00: "The international QP"
Bart van Osch
09.45: Break
10.00: Continuation of the lecture and discussions
10.45: Break
11.00: Challenges from a QP in industry
Eric van Wensveen and in a hospital pharmacy Katja van Rij
12.30: Lunch
13.15: Workshop: the real world
Eric van Wensveen, Mirjam te Koppele, Pedro Tetteroo and Jan Henk Brinkman
16.00: Lessons from the workshop
Jan Henk Brinkman
16.30: Evaluation of the course and concluding remarks
Jan Henk Brinkman
16.45: Close

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Netherlands Centre for Post Academic Education in Pharmacy

Quality management, the role of the qualified person
Faculty

COURSE LEADER

Drs. J.H.W. (Jan Henk) Brinkman
ProPharma Group, Leiden, the Netherlands

LECTURERS

Ir. J-M. (Jean-Michel) Guirado
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Drs. M.A. (Mirjam) te Koppele
MSD, Oss the Netherlands

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

D.M. (Dominique) Mudde
MSD, Haarlem, the Netherlands

Dr. T.K. (Tesh) Patel
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Clinical Pharmacy, UMC St Radboud, Nijmegen, the Netherlands

Dr. P.A.T. (Pedro) Tetteroo
Tetteroo Coaching & Consulting, Oegstgeest, the Netherlands

Drs. D. (Désirée) Vendrig
Vendrig in Pharma, Heemstede, the Netherlands

Drs. E. (Erik) van Wensveen
Mallinckrodt, Petten, the Netherlands

GENERAL INFORMATION

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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

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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

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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

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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

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Module 3:
Sterile manufacturing:
a thorough discussion on sterility assurance challenges

PROGRAM
7 – 9 October 2019
Hotel Bergse Bossen, Driebergen, the Netherlands

Monday, 7 October 2019
Theme*: Microbiology and design for sterility Environmental monitoring and utilities*

09.30: Welcome and outline of the course
Jos Mathôt
09.45: Biology of microorganisms
Implications for pharmaceutical production and quality control
Vincent Hamers
10.45: Sterile manufacturing:
a philosophy on design and control
Jos Mathôt
12.30: Lunch
13.30: Environmental monitoring
Marco Rijnbeek
15.00: Case study Environmental Monitoring
Marco Rijnbeek
16.00: Pharmaceutical water systems and utilities
Peter Vleugel
17.30: The gowning procedure
Harm de Beer
18.30: Dinner

Tuesday, 8 October 2019
Themes: *Sterilsation and desinfection*
Sterility assurance in practice

08.30: Environmental monitoring: water monitoring
Marco Rijnbeek
09.30: Sterilization methods: steam, dry heat
Exercises for steam
Wim van der Boon
10.30: Cleaning and desinfection
Marco Rijnbeek
11.30: Sterilization methods: Filtration and alternative methods
Wim van der Boon
12.30: Lunch
13.30: Case studies: Sterility Assurance in practice
Jos Mathôt
15.45: Lean: application in sterility Assurance
Marc Stegeman
18.00: Dinner

Wednesday, 9 October 2019
Themes: *Validation and qualification*
The role of the QP

09.00: Validation of aseptic processes
Jos van der Lubbe
11.30: Validation of analytical methods
Jos van der Lubbe
12.15: Operator Qualification, incl. case studies
Jos van der Lubbe
13.00: Lunch
14.00: Workshop: the role of the QP in assuring the quality of sterile pharmaceuticals
René Maassen
16.00: Evaluation of the course
Jos Mathôt
16.30: Close

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Sterile manufacturing: a thorough discussion on sterility assurance challenges
Faculty

COURSE LEADER

Drs. J.H.A. (Jos) Mathôt
Mathôt Pharma Support, the Netherlands

LECTURERS

Ing. H. (Harm) de Beer
GE Healthcare BV, Eindhoven, the Netherlands

Drs. W. (Wim) van der Boon
Medster Advise bureau, Amersfoort, the Netherlands

Ing. V. (Vincent) Hamers
AstraZeneca, Nijmegen, the Netherlands

Ir. D. (Douwe) Hoekstra
GE Healthcare BV, Eindhoven, the Netherlands

Dr.ir. J.L.M. (Jos) van der Lubbe
Pharming Technologies BV, Leiden, the Netherlands

Drs. R.H.L.M. (René) Maassen
Pharmaceutical Consultancy Services, PCS, Haastrecht, the Netherlands

Ing. M. (Marco) Rijnbeek
PROXY Laboratories BV, Dept. MicroSafe Laboratories, Leiden, the Netherlands

Drs. M. (Marc) Stegeman
ProPharma Group, Leiden, The Netherlands

Ing. P. (Peter) Vleugel
Vleugel Engineering, Anna Paulowna, the Netherlands

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Module 4: Quality and safety for the manufacturing of biopharmaceuticals:

from cell line development to downstream processing and formulation thorough discussion on sterility assurance challenges

PROGRAM
11 – 13 November 2019
Hotel Bergse Bossen, Driebergen, the Netherlands

Monday, 11 November 2019
Theme*: Cell line development, upstream and downstream*

09.30: Welcome
09.45: Introduction to biotechnology: applications and elements of the biotechnological production process; quality and regulatory aspects
Aad van de Leur
11.00: Upstream process development for biopharmaceutical products
Jürgen van de Lagemaat
12.30: Lunch
13.30: Cell line development and cell bank preparation
Theory and case study
-Genetics: gene of interest; description of the starting strain(s) or cell line(s); preparation and description of the product strain or cell line; genetic stability during storage of cell bank and during production.
-Cell Bank system: preparation and description of the Master Cell Bank (MCB); testing / in-process controls; protocol for preparation of subsequent Working Cell Bank (WCB).
Nienke Vriezen
16.00: Purification survey of unit operations and process integration
Marcel Ottens
18.30: Dinner

Tuesday, 12 November 2019
Theme: *The practice*

09.00: Design of an industrial process for purification of biologicals
Michel Eppink
10.15: Development, tech transfer and commercial production of monoclonal antibodies by cell culture
-Introduction Janssen Biologics
-Upstream Processing
-Downstream Processing
-Changes, deviations and CAPA's
-Case study 1: PGCS contamination
12.30: Lunch
13.30: Part 2
-Continue case study 1: PGCS Contamination
-Technology transfer & process Validation
-Process fit to plant and platform Technology
-Case study 2: IgG retention
-CQA's, CPP's and CMA's
-Spec settings
-Case study 3: Spec settings
-Closure
Marit Heblij and Martijn Wapenaar
18.00: Pathogen safety
Olaf Stamm
19.30: Dinner

Wednesday, 13 November 2019
Theme: *Quality issues*

09.00: Protein analytics of biopharmaceuticals:relevant assays and their principles
Peter Verhaert
10.30: Critical attributes and comparability studies to be announced
11.45: Quality challenges for Advanced Therapy Medicinal Products (ATMPs)
Anna de Goede
12.45: Lunch
14.00: Biosimilars: a new class of licensed biotech products
Arnold Vulto
15.15: Immunogenicity and formulation of biopharmaceuticals to be announced
16.15: Evaluation of the course
Aad van de Leur
16.30: Close

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Quality and safety for the manufacturing of biopharmaceuticals
Faculty

COURSE LEADER

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Synthon Biopharmaceuticals BV, Nijmegen, the Netherlands

LECTURERS

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Synthon Biopharmaceuticals BV, Nijmegen, the Netherlands

Dr. A. (Anna) de Goede
Radboud UMC, Nijmegen, the Netherlands

M. (Martijn) Wapenaar, PDEng
Janssen Biologics B.V., Leiden, the Netherlands

J. (Jürgen) van de Lagemaat, PhD
Merck, Sharp & Dohme BV, Oss, the Netherlands

Dr. ir. M. (Marcel) Ottens
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Charles River Biopharmaceutical Services GmbH, Erkrath, Germany

Dr. N. (Nienke) Vriezen
Synthon Biopharmaceuticals BV, Nijmegen, the Netherlands

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Honorary professor at the Erasmus MC, Rotterdam, the Netherlands and at the KU Leuven, Belgium

Prof. dr. P.D.E.M. (Peter) Verhaert
Founder of ProteoFormiX, Beerse, Belgium

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Committee and board

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PARTNERSHIP

The Netherlands Centre for Post-Academic Education in Pharmacy (PAOFarmacie) is a professional partnership between Pharmaceutical Sciences at Utrecht University (UU), the faculty of Medical Sciences of the University of Groningen (RuG), the faculty of Medical Sciences of the Leiden University, the Royal Dutch Pharmacists Association (KNMP), the Association of Dutch industrial Pharmacists (NIA) and the Dutch Association of Hospital Pharmacists (NVZA). The Board and Scientifi c Board of PAOFarmacie are formed by representatives of this professional partnership.

BOARD

Representatives of state universities and pharmaceutical associations form the board of PAOFarmacie. The board is responsible for policy, finance and personnel.

Members

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Prof. dr. B. (Bob) Wilffert secretary
Drs. Ch.F. (Charles) Gusdorf chairman of finance
Dr. F.G.A. (Frank) Jansman boardmember
Prof. dr. H.J. (Henk Jan) Guchelaar boardmember
Dr. R.J. (Robbert Jan) Kok boardmember

The trainingcourse is owned by the Stichting Training Course Quality Management in Pharma and Biotech.
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Dr. ir. J.L.M. (Jos) van der Lubbe, secretary and treasurer
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Dr. A. (András) Vermes, representative NVZA
Prof. dr. M. (Meindert) Danhof, representative LACDR

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General information

Module 1: Quality Management, the role of the Qualifi ed Person
4 –6 March 2019
Module 2: Drug development from Quality by Design to clinical studies: an integrated course for the pharmaceutical industry and hospital pharmacy
17 – 19 Juni 2019
Module 3: Sterile manufacturing: a thorough discussion on sterility assurance challenges
7 - 9 October 2019
Module 4: Quality and safety for the manufacturing of biopharmaceuticals: from cell line development to downstream processing and formulation
11 - 13 November 2019

AIM
The course offers an integrated approach on quality management in the pharmaceutical, biotechnological, medical device industries and hospitals to safeguard the quality of their products. Expert knowledge and real life case studies are combined and presented and coached by professionals from Industry, Universities and Health Care Inspectorates. The training is interactive.

TARGET GROUPS
- Professionals in pharmaceutical, biotechnological and medical device industries
- Professionals in institutions and Contract Research Organisations (CRO's)
- Hospital pharmacists
- Postgraduate students

For (young) professionals in Research and Development, Production, Packaging, Quality Control and Quality Assurance or Regulatory Aff airs, who are dealing with the complexity of quality systems, it is important to have an overview of these systems in order to improve quality management in their own environment. It is advised dat participants at least have a BSc degree or equivalent level of thinking.

CERTIFICATES
You can select individual course modules best suited to complement your education or experience. After attending a module, you will receive a certificate for attendance. In addition, the participants are offered the possibility to complete the modules through an examination. The examination sessions will be scheduled twice per year. In combination with a university degree in e.g. pharmacy, biology, chemistry or engineering, and with industrial experience, successful completion of the modules of the training course forms a good starting point to apply for Qualified Person (QP) status.

ACCREDITATION
For hospital pharmacists in the Netherlands: accreditation-hours are requested for each course module attended.

ORGANISATION
The training course is organized by Netherlands Centre for Post-Academic Education in Pharmacy: www.paofarmacie.nl In close collaboration with:
- Leiden/Amsterdam Center for Drug Research (LACDR): www.lacdr.nl
- Groningen University Institute for Drug Exploration (GUIDE): www.rug.nl/guide
- Biotechnology Studies Delft Leiden (Biotech Delft): www.biotechnologycourses.nl
- Top Institute Pharma: www.tipharma.com
- European Federation of Pharmaceutical Sciences (EUFEPS):www.eufeps.org
- International Pharmaceutical Federation (FIP):www.industrialpharmacy.org

WHERE?
All modules are organized in :
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