Training course Quality Management in Pharma and Biotech 2018

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
Quality Management, the role of the qualified person

PROGRAM MODULE 1
5 - 7 March 2018
Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 5 MARCH 2018
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 Responsibilities of the Qualified Person (QP): International regulations
Mieke van der Meulen
10.30 Break
10.45 Responsibilities of the Qualified Person (QP) for batch release of commercial and investigational products (IMPs)
Mieke van der Meulen
11.30 The role and duties of the Qualified Person in Pharmaceutical Quality Management and the supply of medicines to the European Community
Jan Henk Brinkman
12.30 Lunch
13.30 The role and duties of the Qualified Person in Pharmaceutical Quality Management and the supply of medicines to the European Community (continued)
Jan Henk Brinkman
14.30 Case study addressing the issues facing the QP in an integrated approach to Quality Assurance in a pharmaceutical environment
Jan Henk Brinkman
15.15 Presentations and discussions
16.00 Break
16.30 Good Distribution Practice: the new EU requirements and the role of the Responsible Person
Riekert Bruinink
17.45 Dinner

TUESDAY, 6 MARCH 2018
Theme: Quality management and maintaining compliance in the current Quality environment
08.30 Quality Systems: Deviation management and Change control
Mirjam te Koppele
10.30 Break
10.45 Compliance verification and Auditing
Désirée Vendrig
11.30 Case study: in compliance or not in compliance?
Désirée Vendrig
12.30 Lunch
13.30 Active pharmaceutical ingredients (APIs) and the QP Declaration
Désirée Vendrig
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
19.30 Introduction to the Workshop: the real world
Eric van Wensveen and Pedro Tetteroo

WEDNESDAY, 7 MARCH 2018
Theme: Operating effectively as a QP in the complex world of pharmaceutical manufacturing
09.00 “The international QP”
Tesh Patel
09.45 Break
10.00 Continuation of the lecture and discussions
10.45 Break
11.00 Experiences from a QP in industry
Eric van Wensveen
And in a hospital pharmacy
Katja van Rij
12.30 Lunch
13.30 Workshop: the real world
Eric van Wensveen, Pedro Tetteroo and Jan Henk Brinkman
15.30 Lessons from the workshop
Jan Henk Brinkman
16.00 Evaluation of the course and concluding remarks
Jan Henk Brinkman
16.30 Close
Quality management, the role of the qualified person

Faculty

COURSE LEADER
Drs. J.H.W. (Jan Henk) Brinkman
Xendo BV, Leiden, the Netherlands

LECTURERS
Drs. R. (Riekert) Bruinink
Health Care Inspectorate (IGJ) Utrecht, the Netherlands

Ir. J-M. (Jean-Michel) Guirado
Amgen BV, Breda, the Netherlands

Drs. M.A. (Mirjam) te Koppele
Novartis Pharma BV, Arnhem, the Netherlands

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

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

Dr. T.K. (Tesh) Patel
Astellas Pharma Europe Ltd., Staines, United Kingdom

Drs. C.M. (Katja) van Rij
Clinical Pharmacy, UMC St Radboud, Nijmegen, the Netherlands

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

Drs. D. (Désirée) Vendrig
TEVA Pharmaceuticals, Haarlem, the Netherlands

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

GENERAL INFORMATION
All the information on registration, cost and starting dates can be found on the page "General Information" and is also available on the website of www.paofarmacie.nl
select course Quality Management
Drug development from quality by design to clinical studies:
an integrated course for the pharmaceutical industry and hospital pharmacy

PROGRAM MODULE 2
11 - 14 June 2018
Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 11 JUNE 2018
Theme: Drug substance, Regulatory requirements, GMP during development
10.00 Welcome and introduction
Ineke Jonker-Hoogerkamp and Jan-Jaap Scherpbier
10.15 Introduction of the case study: antidepressant BODL 2000
- The profile of BODL 2000; R&steps and R&D data
- Registration of BODL 2000; role of RA department
- The quality of the registration dossier for BODL 2000
Ineke Jonker-Hoogerkamp
11.30 Medicinal chemistry: quality in lead finding and lead optimization
Jac Wijkmans
12.30 Lunch
14.00 Quality requirements from process chemistry to large scale production
Jac Wijkmans
15.15 The importance of Quality
- Quality from a regulatory and GMP perspective
- Legislation
- ICH and regional guidelines
Jan-Jaap Scherpbier
16.00 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
17.00 GMP during development including process validation

TUESDAY, 12 JUNE 2018
Theme: Quality by Design in industry and hospital pharmacy, Drug product, GMP applied
09.00 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
09.30 From R&D to production
- Quality by Design
- PAT and PCT in industry and hospital pharmacy
Erik Frijlink
11.30 Total Quality Management obtained by Quality by Design
- Real life examples in industry
Win Oostra
12.30 Lunch
13.30 Case study BODL 2000:
- GMP/Quality:
  - Changes and deviations during manufacturing of clinical supplies
  - Impurity profile drug substance
  - Specifications and batch analysis data
  - Implementation of QBD aspects during development
Ineke Jonker-Hoogerkamp and Erik Frijlink
18.00 Dinner

WEDNESDAY, 13 JUNE 2018
Theme: Non-clinical development, GLP applied, Personal skills
08.30 Objectives of the day, focus on GLP
Ineke Jonker-Hoogerkamp
08.45 Introduction to GLP
Chris Mitchell
09.00 Pharmacokinetics and pharmacodynamics (PK/PD) in industrial practice
Peter Vis
10.30 Toxicology
Eric de Waal
12.00 Lunch
13.00 Case study BODL 2000: GLP and nonclinical development program:
- Action steps preparation and execution of a GLP compliant study
- GLP in a multi-site study
- Deficiencies for registration in the BODL 2000 nonclinical program
Ineke Jonker-Hoogerkamp and Chris Mitchell
14.30 Group presentations
Wrap up of the case study
15.30 Perspectives from the Dutch Inspectorate
Mieke van der Meulen
16.15 Workshop personal skills required in drug development
- Real life example: mix-up in a wallet
- Role play by acting as company experts and authorities
17.00 Group presentations
Wrap up of the case study
18.00 Dinner
> An integrated course for the pharmaceutical industry and hospital pharmacy

- Experts: representative from R&D (and site) management, QP, Head of pharmaceutical development, clinical production and packaging, Head of quality control
- Regulatory requirements clinical trials
- Issues (design, submissions, conduct)
- Investigator initiated studies (including case study)

Erik Frijlink and Mieke van der Meulen
19.00 Dinner

THURSDAY, 14 JUNE 2018
Theme: Clinical development, GCP applied

08.30 Objectives of the day, focus on GCP
Eveline Krijger and Lisette Vromans

09.00 Clinical development Phase I
- Principles, clinical study documents, requirements for a Phase I
- Clinic, clinical pharmacology, types of Phase I studies
Leo de Leede

10.00 Clinical development Phase II and III
- Clinical development plan

12.15 Lunch

13.30 Reflection to the lectures and the case study
14.00 Case study BODL 2000: GCP and clinical development program
- Possible deficiencies in the BODL 2000 clinical program
- Outline for a clinical trial
- Possible deficiencies in the informed consent
- Audit report
Eveline Krijger and Lisette Vromans

15.30 Group presentations
Wrap up of the case study

16.00 Evaluation of the course and learned lessons
Jan-Jaap Scherpber and Ineke Jonker-Hoogerkamp

17.00 Close

Faculty

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

Drs. J.J. (Jan-Jaap) Scherpber
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

Ir. E.M. (Evelien) Krijger
Merck, Sharp & Dohme, Oss, the Netherlands

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

Drs. P.C. (Petra) Matthijsse
TFS Trial Form Support, Berghem, the Netherlands

Dr. M. (Mieke) van der Meulen
Inspectie voor de Gezondheidszorg en Jeugd, Den Haag, the Netherlands

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

W. (Wim) Oostra
Abbot Healthcare Products BV Weesp

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

Ing. E.W.M. (Lisette) 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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select course Quality Management
Sterile manufacturing: a thorough discussion on sterility assurance challenges

PROGRAM MODULE 3
1 – 3 October 2018
Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 1 OCTOBER 2018
Theme: Microbiology and design for sterility
environmental monitoring
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
15.30 Case study Environmental monitoring
Marco Rijnbeek
16.00 Cleaning and disinfection
Marco Rijnbeek
17.00 The gowning procedure
Harm de Beer
18.30 Dinner

TUESDAY, 2 OCTOBER 2018
Theme: Sterilization and utilities
Sterility assurance in practice
08.30 Sterilization methods: steam, dry heat Exercises for steam
Wim van der Boon
09.30 Pharmaceutical water systems and utilities
Peter Vleugel
11.00 Sterilization methods: Filtration and alternative methods
Wim van der Boon
12.30 Lunch
13.30 Environmental monitoring: water monitoring
Marco Rijnbeek
14.15 Case studies: Sterility Assurance in practice
Jos Mathôt
16.30 Lean: application in sterility assurance
Marc Stegeman
18.00 Dinner

WEDNESDAY, 3 OCTOBER 2018
Theme: Validation and qualification of processes and personnel
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
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
Xendo BV, Leiden, The Netherlands

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

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select course Quality Management
Quality and safety for the manufacturing of biopharmaceuticals:
from cell line development to downstream processing and formulation

PROGRAM MODULE 4
12 – 14 November 2018
Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 12 NOVEMBER 2018
Theme: Cell line development, upstream and downstream
09.30 Welcome
Aad van de Leur
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: different expression systems and unit operations
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
17.00 Purification survey of unit operations and process integration
Marcel Ottens
18.30 Dinner

TUESDAY, 13 NOVEMBER 2018
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: theory and case studies
- the use of platform technology
Claartjie Jonker-Exler
12.15 Lunch
14.00 Biosimilars
Claartjie Jonker-Exler
15.15 Immunogenicity and formulation of biopharmaceuticals
Vera Brinks
16.15 Evaluation of the course
Aad van de Leur
16.30 Close

WEDNESDAY, 14 NOVEMBER 2018
Theme: Quality issues
09.00 Pathogen safety
Olaf Stamm
10.30 Critical attributes and comparability studies
Corné Stroop
11.45 Specific quality issues around ATMPs
Anna de Goede
12.15 Lunch
14.00 Biosimilars
Claartjie Jonker-Exler
15.15 Immunogenicity and formulation of biopharmaceuticals
Vera Brinks
16.15 Evaluation of the course
Aad van de Leur
16.30 Close
Faculty

COURSE LEADER
Drs. A.C.A.J. (Aad) van de Leur
Synthon Biopharmaceuticals BV, Nijmegen, the Netherlands

LECTURERS
Dr. M.H.M. (Michel) Eppink
Synthon Biopharmaceuticals BV, Nijmegen, the Netherlands

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

M. (Marit) Heblij, PhD
Janssen Biologies BV, Leiden, the Netherlands

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

Dr. ir. M. (Marcel) Ottens
Delft University of Technology, Dept. of Biotechnology, the Netherlands

Dr. O. (Olaf) Stamm
Charles River Biopharmaceutical Services GmbH, Erkrath, Germany

Dr. C.J.M. (Corné) Stroop
Merck, Sharp & Dohme BV, Oss, the Netherlands

Prof. dr. P.D.E.M. (Peter) Verhaert
Delft University of Technology, Dept. of Biotechnology, the Netherlands

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

Prof. dr. A.G. (Arnold) Vulto
Erasmus MC, Rotterdam, the Netherlands

M. (Martijn) Wapenaar, PDEng
Janssen Biologies BV, Leiden, the Netherlands

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select course Quality Management
### Committee and board

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Pharming Technologies BV, Leiden, the Netherlands

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

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

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

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

Drs. A.C.A.J. (Aad) van de Leur
Synthion Biopharmaceuticals BV, Nijmegen, the Netherlands

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

Dr. V.L.C. Moffat
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Drs. J.J. (Jan-Jaap) Scherpieber
Sansbeek Pharma Consultancy BV, Arnhem, the Netherlands

Prof. dr. P.D.E.M. (Peter) Verhaert
Delft University of Technology, Dept. of Biotechnology, Delft, the Netherlands

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Apotheek Haagse Ziekenhuizen, Den Haag, the Netherlands

Dr. N. (Nettie) Buitelaar, MBA
BioSana Pharma BV, Haarlem, the Netherlands

Prof.dr. M. (Meindert) Danhof
Leiden/Amsterdam Center for Drug Research (LACDR), Leiden University, the Netherlands

Drs. P.M.J.M. (Peter) Jongen,
CBG-MEB, Utrecht, the Netherlands

Drs. E. (Erik) Ligtenberg
Abbott Healthcare Products BV, Weesp, the Netherlands

Drs. M.M. (Mieke) van der Meulen
Health Care Inspectorate (IGJ), Den Haag, the Netherlands

Drs. M.G.A.M. (Marcel) Moester
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Drs. M.M.G. (Marijke) Pubben
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Apotheek Albert Schweitzerziekenhuis, Dordrecht, the Netherlands

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Utrecht University, Pharmaceutical Sciences, Utrecht, the Netherlands

Dr. J. (Joost) van Zutven
MSD, Oss, the Netherlands
PAOFarmacie offers Post-Academic Education in Pharmacy

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 Scientific 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.

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THE ISO STANDARD
PAOFarmacie is certified to the ISO standard since 2009
General information

Module 1 Quality Management, the role of the Qualified Person
5 – 7 March 2018
Module 2 Drug development from Quality by Design to clinical studies: an integrated course for the pharmaceutical industry and hospital pharmacy
11 - 14 June 2018
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1 - 3 October 2018
Module 4 Quality and safety for the manufacturing of biopharmaceuticals: from cell line development to downstream processing and formulation
12 - 14 November 2018

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 Affairs, 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 that participants at least have a BSc degree or equivalent level of thinking.

CERTIFICATES & DIPLOMA
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

WHERE?
All modules are organized in:
Hotel Bergse Bossen, Driebergen, the Netherlands
Traaij 299
3971 GM DRIEBERGEN
T +31 (0)343 528150
E info@bergsebossen.nl
www.bergsebossen.nl

STANDARD COURSE FEE
The standard fee of Module 1, 3 and 4 is € 1700,00 excl. 21% VAT.
The standard fee of Module 2 is € 2100,00 excl. 21% VAT.
The fee includes hotel accommodation, course notes, drinks, lunches and dinners. In the event of cancellation we refer to the general terms of condition of PAOfarmacie (www.paofarmacie.nl).

REDUCED COURSE FEE
Upon subscription by the same person for the modules 1, 2, 3 and 4, the total fee is € 5760,00 excl. 21% VAT.
For PhD-students and and PDEng-trainees a limited number of fellowships (25% of the standard fee) is available.
To apply, send a copy of your registration as a PhD-student or PDEng-trainee to info@paofarmacie.nl

REGISTRATION
For registration, please submit your application on-line via www.paofarmacie.nl select course Quality Management

INFORMATION
PAOFarmacie, Bilthoven, the Netherlands
T: +31 (0)30 3040100
E: info@paofarmacie.nl
www.paofarmacie.nl

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