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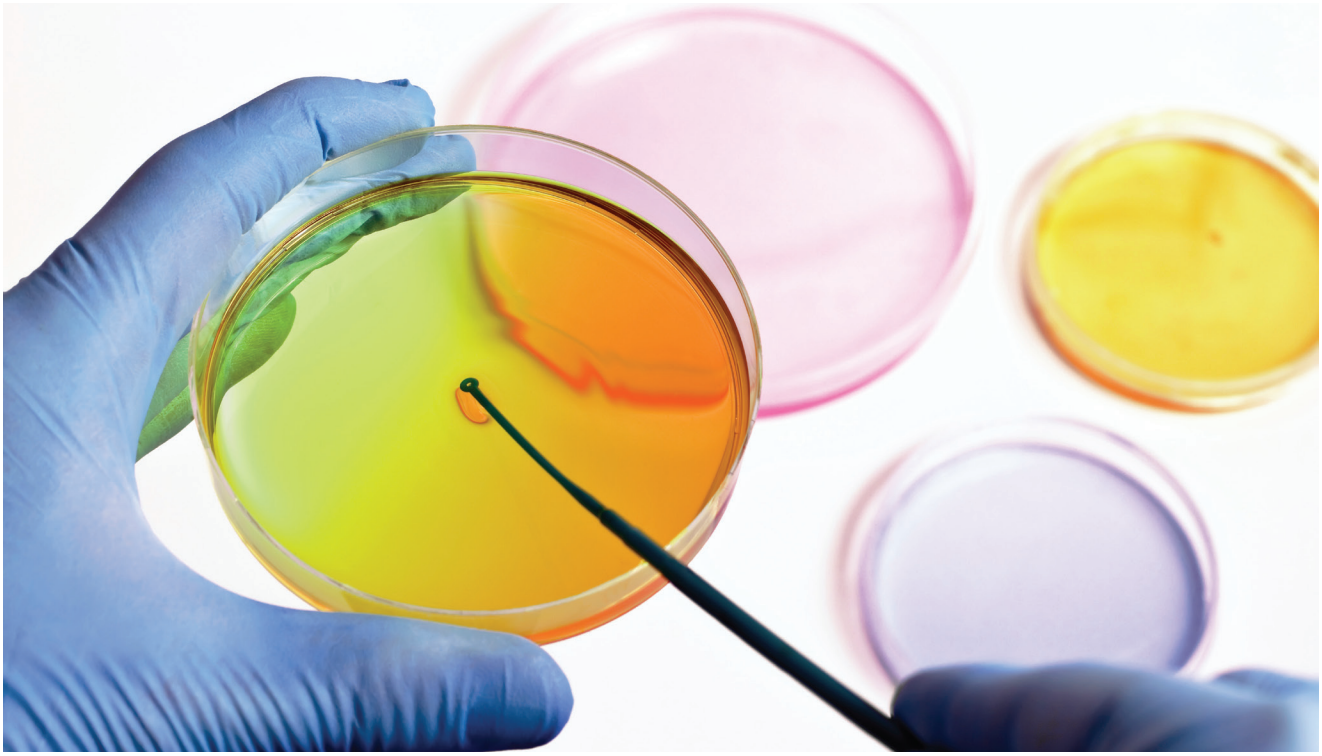

Training course Quality Management in Pharma and Biotech 2017

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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Quality Management, the role of the qualified person

PROGRAM MODULE 1

6 - 8 March 2017

Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 6 MARCH 2017

Theme: The role and legal obligations of the Qualified Person
Introduction to current concepts in Quality Management

09.00 Welcome and Introduction
Marijke Pubben

09.30 Responsibilities of the Qualified Person (QP): International regulations
Current views from the Inspectorate
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
Marijke Pubben

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)
Marijke Pubben

14.30 Case study addressing the issues facing the QP in an integrated approach to Quality Assurance in a pharmaceutical environment
Marijke Pubben

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, 7 MARCH 2017

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, 8 MARCH 2017

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 Marijke Pubben

15.30 Lessons from the workshop
Marijke Pubben

16.00 Evaluation of the course and concluding remarks
Marijke Pubben

16.30 Close

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> *Quality management, the role of the qualified person*

Faculty

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GENERAL INFORMATION

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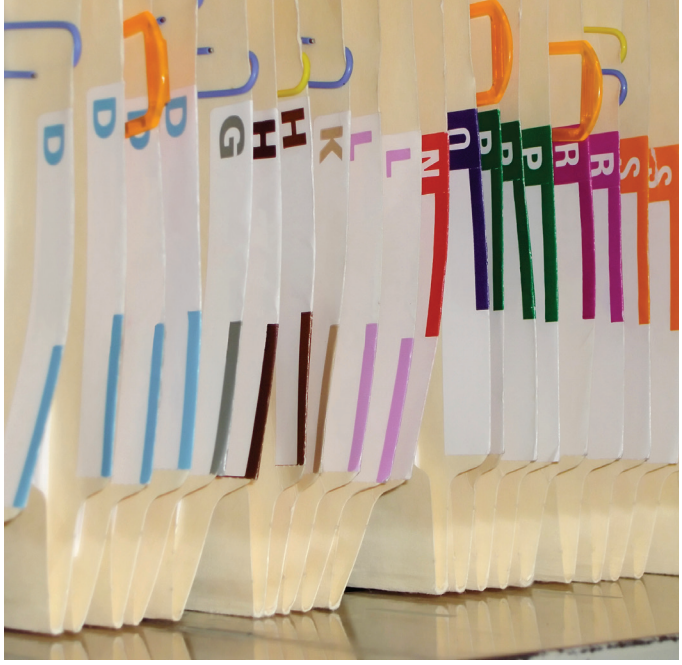
Drug development from quality by design to clinical studies:

an integrated course for the pharmaceutical industry and hospital pharmacy



PROGRAM MODULE 2

12 - 15 June 2017

Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 12 JUNE 2017

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 registrati dossier for BODL 2000
Ineke Jonker-Hoogerkamp

11.30 Medicinal chemistry: quality in lead finding and lead optimiztion
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 Docu ment(CTD)
-Development and manufacture of Drug substance and Drug product
-Clinical Trial Applications; quali ty requirements during deve lopment
Jan-Jaap Scherpbier

17.00 GMP during development inclu ding process validation
Ineke Jonker-Hoogerkamp and Jan-Jaap Scherpbier

18.00 Dinner

TUESDAY, 13 JUNE 2017

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

9.30 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

Wim 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

Jan-Jaap Scherpbier, Ineke Jonker-Hoogerkamp and Erik Frijlink

15.15 Group presentations
Wrap up of the case study

17.00 Drug development in Dutch hospital pharmacies
to be announced

18.00 Dinner

WEDNESDAY, 14 JUNE 2017

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

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- Experts: representative from R&D (and site) management, QP, Head of pharmaceuti cal development, clinical production and packaging, Head of clinical development and Head of quality control
  Erik Frijlink and Mieke van der Meulen

19.00 Dinner

THURSDAY, 15 JUNE 2017

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
- Regulatory requirements clinical trials
- Issues (design, submissions, conduct)
- Investigator initiated studies (including case study)
Petra Matthijsse

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 Scherpbier 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) Scherpbier
Sonsbeek Pharma Consultancy BV and Garden State Pharmatech, the Netherlands

LECTURERS

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

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Sterile manufacturing:

a thorough discussion on sterility assurance challenges

PROGRAM MODULE 3

2 – 4 October 2017

Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 2 OCTOBER 2017

Theme: Microbiology and sterility: execution and control

09.30 Welcome and outline of the course
Jos Mathôt

09.45 Biology of microorganisms
Implications for pharmaceutical production and quality control
Speaker to be confirmed

10.45 Sterile manufacturing: a philosophy on design and control
Jos Mathôt

12.30 Lunch

13.30 Environmental monitoring:
- which sterility risks to be recognized and how to mitigate
- which methods are available?
- what are the results, how to evaluate and to thrend them
- which actions to take in case of adverse results
Marco Rijnbeek

15.00 Case study Environmental monitoring:
Marco Rijnbeek

16.00 Sterilization methods: steam, dry heat Exercises for steam
Douwe Hoekstra

17.30 Film: Parenteral production at MedImmune, Nijmegen
Marco Rutten

18.00 Dinner

19.30 The gowning procedure
Marco Rutten

TUESDAY, 3 OCTOBER 2017

Theme: Water systems and parenteral production
Sterility assurance in practice

08.30 Pharmaceutical water systems
Frank van Ede

10.00 Environmental monitoring: water monitoring
Marco Rijnbeek

11.00 Cleaning and desinfection
Marco Rijnbeek

12.30 Lunch

13.30 Sterilization methods: Filtration and alternative methods
Douwe Hoekstra

14.30 Case studies: Sterility Assurance in practice
- selection of formulation and process
- combination of production and QC activities
- isolator application in unclassified environment
- validation of visual inspection
- environmental monitoring trend
- start-up after power failure
- HEPA filter failure
- requirements for vial capping
- Fungal contamination in clean room
Jos Mathôt

16.00 Presentations of the case study results Evaluation

18.00 Dinner

WEDNESDAY, 4 OCTOBER 2017

Theme: Validation and qualification of processes and personnel
The role of the QP

09.00 Validation of aseptic processes
- introduction
- technologies
- qualification
- validation
- case studies aseptic processing
Jos van der Lubbe

11.30 Validation of analytical methods
- introduction
- validation
- specifications
Jos van der Lubbe

12.15 Operator Qualification
- introduction
- training
- case studies analytical methods and operator qualification
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

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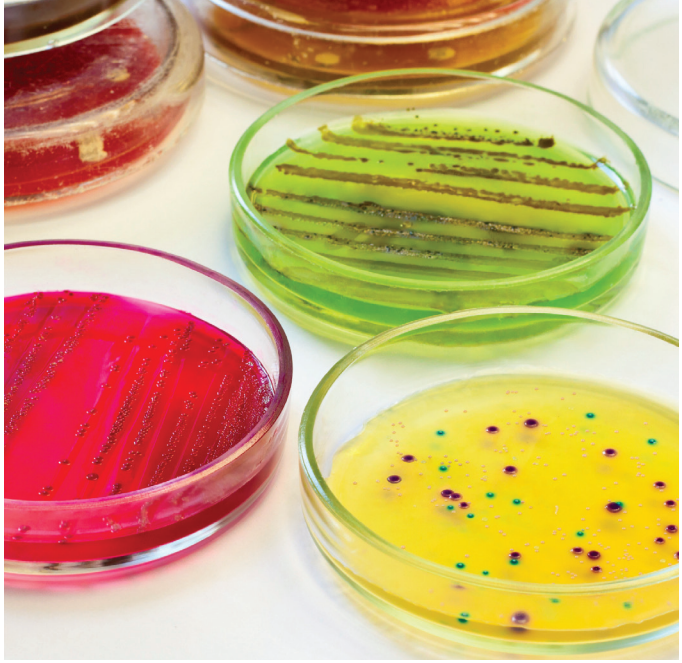

Quality and safety for the manufacturing of biopharmaceuticals:

from cell line development to downstream processing and formulation

PROGRAM MODULE 4

20 – 22 November 2017

Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 20 NOVEMBER 2017

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
Jurgen van de Langemaat

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, 21 NOVEMBER 2017

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

12.30 Lunch

13.30 Continuation of the theory
- critical quality attributes and critical process parameters
- spec setting and the consequences for routine manufacturing

14.15 Case study 1

15.00 - technology transfer and process validation
- pre-approval inspections
- Process Fit to Plant

16.00 Case study 2

16.45 - changes, deviations and CAPAs in manufacturing
- Process Excellence for continuous cost reduction
Marit Heblij and Martijn Wapenaar

18.00 Pathogen safety
Olaf Stamm

19.30 Dinner

WEDNESDAY, 22 NOVEMBER 2017

Theme: Quality issues

09.00 Protein analytics of biopharmaceuticals: relevant assays and their principles
Peter Verhaert

10.00 Critical attributes and comparability studies
Corne Stroop

11.15 Specific quality issues around ATMPs
Anna de Goede

12.15 Lunch

14.00 Biosimilars
Claartje Jonker-Exler

15.15 Immunogenicity and formulation of biopharmaceuticals
Vera Brinks

16.15 Evaluation of the course
Aad van de Leur

16.30 Close

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Netherlands Centre for Post Academic Education in Pharmacy

> *From cell line development to downstream processing and formulation*

Faculty

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Netherlands Centre for Post Academic Education in Pharmacy

CHIEF EXECUTIE OFFICER Sharon Schouten-Tjin A Tsoi, Pharm D
Netherlands Centre for Post-Academic Education in Pharmacy

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 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.

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Drs. Ch.F. (Charles) Gusdorf chairman of finance
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Prof. dr. H.J. (Henk Jan) Guchelaar boardmember

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General information

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6 – 8 March 2017
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12 – 15 June 2017
Module 3 Sterile manufacturing: a thorough discussion on sterility assurance challenges
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20 – 22 November 2017

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.

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
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 (BSDL): **www.bsdl-edu.bt.tudelft.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 :
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 accomodation, course notes, drinks, lunches and dinners. In the event of cancellation we refere 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

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