TRAINING COURSE
QUALITY MANAGEMENT
IN PHARMA AND BIOTECH
2012

M1 M2 M3 M4

Quality Management, the role of the Qualified Person
Drug development from Quality by Design to clinical studies: an integrated course for the pharmaceutical industry and hospital pharmacy
Sterile manufacturing
Quality and safety for the manufacturing of biopharmaceuticals: from cell line development to downstream processing and formulation
TRAINING COURSE QUALITY MANAGEMENT IN PHARMA AND BIOTECH

QUALITY MANAGEMENT, THE ROLE OF THE QUALIFIED PERSON

PROGRAM 6 - 8 February 2012
Hotel Bergse Bossen, Driebergen, the Netherlands

MONDAY, 6 FEBRUARY 2012

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

09.15 Welcome and Introduction
Vivien Moffat

09.30 Responsibilities of the Qualified Person (QP):
International regulations
Hans Smalenbroek

10.15 The role and duties of the Qualified Person in
Pharmaceutical Quality Management and the supply
of medicines to the European Community
Marijke Pubben

12.00 Lunch

13.00 Case study addressing the issues facing the QP in an
integrated approach to Quality Assurance
in a pharmaceutical environment
Saskia Sturm and Marijke Pubben

14.15 Presentations and discussions

15.00 Validation principles in the pharmaceutical industry
Saskia Sturm

16.15 Case study: Risk management
Vincent Coolen and Jan Damm

17.45 Social drink and dinner

TUESDAY, 7 FEBRUARY 2012

Theme: Maintaining compliance in the current
Quality environment

09.00 Quality systems
Sue Mann

10.00 Compliance, change control and audits
Jolande Schoemaker

11.00 Case study: in compliance or not in compliance?
Jolande Schoemaker

12.30 Lunch

13.30 The role of the QP in the manufacture of Active
Pharmaceutical Ingredients (APIs) and finished
products for investigational purposes (IMPs)
Speaker to be announced

14.30 Introduction to the case study ‘Creatis and BODL 2000’
Dominique Mudde and Carin Huibers

15.00 Case study:
preparation for an inspection of the manufacturing
of the antidepressant BODL 2000
Dominique Mudde and Carin Huibers

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
Pedro Tetteroo, Vivien Moffat and Mirjam te Koppele

WEDNESDAY, 8 FEBRUARY 2012

Theme: Operating effectively as a QP in the complex
world of pharmaceutical manufacturing

09.00 “The international QP”
Tesh Patel

11.00 Experiences from a QP in industry:
Eric van Wensveen
in a hospital pharmacy:
Katja van Rij

12.30 Lunch

13.30 Workshop: the real world
Pedro Tetteroo, Mirjam te Koppele, Vivien Moffat,
Eric van Wensveen and Katja van Rij

15.30 Lessons from the workshop

16.00 Evaluation of the course and concluding remarks
Vivien Moffat

16.15 Farewell drink
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Dr. V.L.C. Moffat
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Drs. A.J. Smallenbroek
Health Care Inspectorate, Den Haag, the Netherlands

Drs. S.E. Sturm
Merck, Sharp & Dohme BV, Haarlem, the Netherlands

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Tetteroo Coaching & Consulting, Oegstgeest, the Netherlands

Drs. E. van Wensveen
Covidien, Petten, the Netherlands

GENERAL INFORMATION
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TRAINING COURSE QUALITY MANAGEMENT IN PHARMA AND BIOTECH

DRUG DEVELOPMENT FROM QUALITY BY DESIGN TO CLINICAL STUDIES: AN INTEGRATED COURSE FOR THE PHARMACEUTICAL INDUSTRY AND HOSPITAL PHARMACY

PROGRAM

Hotel Bergse Bossen, Driebergen, the Netherlands

16 - 19 April 2012

MONDAY, 16 APRIL 2012

Theme: **Medicinal chemistry, pharmaceutical formulations, large scale production**

10.00 Welcome and introduction
Erik Frijlink and Leo de Leede

10.15 Introduction of the case study: antidepressant BODL 2000
- the profile of BODL 2000; R&D steps and R&D data
- registration of BODL 2000; role of RA department
- the quality of the registration dossier for BODL 2000
- Good Regulatory Practice (GRP) and the quality of the company
Leo de Leede

11.30 Medicinal chemistry: quality in lead finding and lead optimization
Jan-Jaap Scherpbier

12.30 Lunch

14.00 Quality requirements from process chemistry to large scale production
Michel Guillaume

15.00 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

18.00 Social drink and dinner

TUESDAY, 17 APRIL 2012

Theme: **Quality by Design in industry and hospital pharmacy, GMP applied**

09.00 Objectives of the day, focus on GMP:
Jan-Jaap Scherpbier

09.15 Quality part of registration dossier
Frans Metzers

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
Ben van Beek

12.30 Lunch

13.30 Case study BODL 2000: GMP/Quality:
- deviations and changes during manufacturing of clinical supplies
- impurity profile drug substance
- specifications and batch analysis data
- deviations during commercial manufacturing
Jan-Jaap Scherpbier and Frans Metzers

15.15 Group presentations
Wrap up of the case

17.00 The development of oncolytic drug products: the Slotervaart case
Jos Beijnen

18.00 Social drink and dinner

WEDNESDAY, 18 APRIL 2012

Theme: **Pre-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, BODL 2000 in focus
Eric de Waal

12.00 Lunch

13.00 Case study BODL 2000: GLP and regulatory aspects of pharmacokinetics, pharmacodynamics and toxicological studies:
- action steps for the preparation and execution of the toxicological study to guarantee that it will be a GLP compliant study
- is there a need for additional requirements from GLP perspective for a multi-site study?
- are additional data from tox studies required for registration of BODL 2000?
Ineke Jonker-Hoogerkamp and Chris Mitchell

14.30 Group presentations
Wrap up of the case study

15.30 Events occurring in industry and hospital pharmacy, not appreciated by inspectors
Discussion
Annie Rietveld

16.15 Workshop skills required in drug development
Real life example: mix-up in a wallet
Annie Rietveld, Erik Frijlink and Leo de Leede

16.30 Role play by acting as company experts and authorities
Experts: representative from R&D (and site) management, the QP, Head of pharmaceutical development, clinical production and packaging, Head of clinical development and Head of quality control
Annie Rietveld, Erik Frijlink and Leo de Leede

19.00 Dinner

THURSDAY, 19 APRIL 2012

Theme: **Clinical development, GCP applied**

08.30 Objectives of the day, focus on CP
Luuk Promes and Lisette Vromans

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

10.45 Clinical development Phase II and III
- clinical development plan
- regulatory requirements clinical trials
- issues (design, submissions, conduct)
- investigator initiated studies (including case study)
Petra Matthijssse

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 clinical program
- outline for a clinical trial
- possible deficiencies in the informed consent
- audit report
Luuk Promes and Lisette Vromans

15.30 Group presentations
Wrap up of the case study

16.00 Evaluation of the course and learned lessons
Erik Frijlink and Leo de Leede

17.00 Farewell drink
COURSE LEADERS
Prof. dr. H.W. Frijlink
Groningen University Institute for Drug Exploration (GUIDE),
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Janssen, Beerse, Belgium

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Drs. P.C. Matthijsse
Trial Form Support, Berghem, the Netherlands

Ing. F.A.A.J. Metsers
Merck, Sharp & Dohme, Oss, the Netherlands

C. Mitchell, BSc
NOTOX BV, 's-Hertogenbosch, the Netherlands

Drs. L.W. Promes
Merck, Sharp & Dohme, Oss, the Netherlands

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Health Care Inspectorate, Utrecht, the Netherlands

Drs. J.J. Scherpber
Merck, Sharp & Dohme, Oss, the Netherlands

P. Vis
Janssen, Beerse, Belgium

Ms. E.W.M. Vromans
Merck, Sharp & Dohme, Oss, the Netherlands

Dr. E.J. de Waal
Janssen, Beerse, Belgium

Dr. J.C.H.M. Wijkmans
Formerly, Merck, Sharp & Dohme, Oss, the Netherlands

GENERAL INFORMATION
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MONDAY, 8 OCTOBER 2012

Theme: Microbiology

09.30 Welcome and outline of the course
Hans van Doorne

09.45 Biology of microorganisms
Implications for pharmaceutical production and quality control
Hans van Doorne

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

12.30 Lunch

13.30 Environmental monitoring methods:
- what are the risks we need to recognize and which methods are available?
- what are the results we obtain, how to evaluate them, how to recognize the risks and how to mitigate them
- introduction to the case study
Klaus Haberer

15.30 Heat sterilization
Exercises
Hans van Doorne

17.30 Film: Parenteral production at Medimmune, Nijmegen
Mirjam te Koppele

18.00 Social drink and dinner

19.30 The gowning procedure
Mirjam te Koppele

TUESDAY, 9 OCTOBER 2012

Theme: Water systems and parenteral production
Sterility assurance in practice

08.30 Case study: Environmental monitoring methods
Klaus Haberer

10.00 Pharmaceutical water systems
Frank van Ede

11.30 Environmental monitoring methods:
- water monitoring
Klaus Haberer

12.30 Lunch

13.30 Membrane filtration
Hans van Doorne

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
- new requirements for vial capping
Jos Mathôt

16.00 Presentations of the case study results
Evaluation

18.00 Social drink and dinner

WEDNESDAY, 10 OCTOBER 2012

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 Massens

16.00 Evaluation of the course
Hans van Doorne

16.30 Farewell drink
M3

FACULTY

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Dr.ir. J.L.M. van der Lubbe
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Drs. R.H.L.M. Maassen
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## PROGRAM

### MONDAY, 26 NOVEMBER 2012

**Theme:** Cell line development, upstream and downstream

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<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<td>09.30</td>
<td>Welcome</td>
<td>Aad van de Leur</td>
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<tr>
<td>09.45</td>
<td>Introduction to biotechnology: applications and elements of the biotechnological production process, quality and regulatory aspects</td>
<td>Aad van de Leur</td>
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<tr>
<td>11.00</td>
<td>Upstream process development for biopharmaceutical products: different expression systems and unit operations</td>
<td>Wout van Grunsven</td>
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<td>12.30</td>
<td>Lunch</td>
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<tr>
<td>13.30</td>
<td>Cell line development and cell bank preparation</td>
<td>Nienke Vriezen</td>
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<td>Theory and case study</td>
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<td>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.</td>
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<td>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)</td>
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<td>17.00</td>
<td>Purification survey of unit operations and process integration</td>
<td>Marcel Ottens</td>
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<td>18.30</td>
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### WEDNESDAY, 28 NOVEMBER 2012

**Theme:** Quality issues

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<td>09.00</td>
<td>Protein analytics of biopharmaceuticals: relevant assays and their principles</td>
<td>Martijn Pinkse and Peter Verhaert</td>
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<td>10.00</td>
<td>Critical attributes and comparability studies</td>
<td>Prathima Acharya</td>
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<td>11.15</td>
<td>Specific quality issues around ATMPs</td>
<td>Arnold Vulto</td>
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<td>12.15</td>
<td>Lunch</td>
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<td>14.00</td>
<td>Biosimilars</td>
<td>Arnold Vulto</td>
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<tr>
<td>15.15</td>
<td>Immunogenicity and formulation of biopharmaceuticals</td>
<td>Wim Jiskoot</td>
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<td>16.15</td>
<td>Evaluation of the course</td>
<td>Aad van de Leur</td>
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<td>16.30</td>
<td>Farewell drink</td>
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### TUESDAY, 27 NOVEMBER 2012

**Theme:** The practice

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<tr>
<td>09.00</td>
<td>Design of an industrial process for purification of biologicals</td>
<td>Michel Eppink</td>
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<td>10.15</td>
<td>Development, tech transfer and commercial production of monoclonal antibodies: theory and case studies</td>
<td>Prathima Acharya</td>
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<td></td>
<td>- The use of platform technology</td>
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<td>12.30</td>
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<td></td>
<td>- Critical quality attributes and critical process parameters</td>
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<td>- Spec setting and the consequences for routine manufacturing</td>
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<td>- Case study 1</td>
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<td>- Technology transfer and process validation</td>
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<td>- Pre-approval inspections</td>
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<td>- Process Fit to Plant</td>
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<td>- Case study 2</td>
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<td>- Changes, deviations and CAPAs in manufacturing</td>
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<td>- Process Excellence for continuous cost reduction</td>
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<td>Linda Bus-Jacobs, Diana der Graaf-Harris and Maaike Poppema</td>
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<td>18.00</td>
<td>Viral safety</td>
<td>Klaus Kellings</td>
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<td>19.30</td>
<td>Dinner</td>
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Pharm D and CEO of the Netherlands Centre for Post Academic Education in Pharmaceutical Sciences.

PARTNERSHIP
The Netherlands Centre for Post Academic Education in Pharmaceutical Sciences (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.

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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Dr. F. Moolenaar secretary
Drs. R.J. Wolters chairman of finance
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Drs. M.M. Tjoeng board member

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Members of the Scientific Advisory Board (WAR) are linked to national universities and pharmaceutical associations.
Their aim is to further develop the curriculum of PAOFarmacie. In the WAR members of science and practice meet.
They propose new topics for further training, continue development of existing topics and guarantee the scientific quality.

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Dr. T. Schalekamp representing the UU
Dr. H. Buurman representing the Director of studies for the KNMP
Drs. B.J.F. van den Bemt representing the Dutch Association of Polyclinic Pharmacy (NVFF)
Dr. K. Taxis representing the RuG
Dr. F.J. van de Vaart representing KNMP
Drs. A. Nooij representing the KNMP
Ms. A. Hildebrand representing the Association for Registration of Industrial Pharmacists (StRIA / NIA)

THE ISO STANDARD
PAOFarmacie is certified to the ISO standard since 2009
ISO9001
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 Inspectories. 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.

ACREDITATION
For hospital pharmacists in the Netherlands: 20 accreditation-hours for each course module attended.