



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



PAOFarmacie

Netherlands Centre for Post Academic Education in Pharmacy

Quality management, the role of the qualified person Faculty

COURSE LEADER

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LECTURERS

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GENERAL INFORMATION

See last page for information on registration, dates and costs is available on the website of www.paofarmacie.nl

Select course **Quality Management**

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