Program Quality Management, module 1 – Draft (2019)

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, 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** Janine van der Linden
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**