EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Mieke van der Meulen

WORK EXPERIENCE

June 2013- Present

Coordinating/Specialist Inspector

Ministry of Health, Welfare and Sport (Netherlands)

GMP inspections

GDP inspections

January 2004-April 2013

Senior Consultant / Managing Consultant

Xendo B.V. (Netherlands)

As senior consultant:

- Writing GMP, GDP and GcLP SOPs
- Review of manufacturing and packaging batch records
- Release as QP for the Netherlands and EU (including CTM)
- Responsible Person on Wholesale dealers license
- GMP & GDP auditing
- Stability studies
- Review validation documentation
- Training courses (create training material and presentation)
- Interim manager QA

From 2008-2013 services were performed at: Apotex Nederland B.V., Abbott Healthcare B.V., DHL Supply Chain B.V., Forest Laboratories Nederland B.V., Merck B.V. (division Merck Serono), Omega Pharma Nederland B.V., Xendo Clinical Trial Material B.V. (all companies located in the Netherlands)

As manager

- Manager of group of consultants (direct report)
- Knowledge expert on QA, GMP, GDP, QP
- Trainer

July 2002-December 2003

Manager QA/QP

Hexal Pharma Nederland B.V. (Netherlands)

Create/maintain QA documentation system

Auditing/approval third party manufacturers

Complaints

Qualified Person

January 1996-June 2002

Manager QA/QP

Katwijk Farma B.V. (Netherlands)

Create/maintain QA documentation system

Auditing/approval third party manufacturers/packagers and suppliers

Complaints

Review batch manufacturing/packaging records

Qualified Person

Pharmaceutical training

Validation

Calibration

January 1996-December 2001

Responsible Person

Sameko Farma B.V. (Netherlands)

All activities related to the position of Responsible Person (wholesale dealer), including creation/maintenance of QA documentation system

July 1992-December 1995

Manager QA/QC and QP

Katwijk Farma B.V. (Netherlands)

Refer to position of Manager QA/QP at Katwijk Farma listed above in Work Experience 4.

Additional: Responsible for quality control laboratory and quality inspection.

January 1989-June 1992

Head Regulatory Affairs

Katwijk Farma B.V. (Netherlands)

Update/submission of registration dossiers (mainly CMC part)

Create/update SPCs and PILs

Medical information (responses to questions from pharmacists and patients)

EDUCATION AND TRAINING

October 1987-January 1989

Pharmacist

University of Groningen (Netherlands)

Pharmacist education

September 1981-September 1987

Master Degree

University of Leiden (Netherlands)

Pharmaceutical Sciences

ADDITIONAL INFORMATION

Expertise

GMP and GDP compliance

Qualified Person

Manufacturing and packaging of solid dosage forms (including for clinical trial material).

Packaging of sterile dosage forms.

QA systems

Validation

Training

Auditing

Pharmaceutical storage and distribution

Safety Features

Publications

Projects

Memberships

Royal Dutch Pharmaceutical Society

Dutch Industry Pharmacists

Other Relevant Information