

# Curriculum Vitae

# Personal information Veronique Begerem

## Work experience

#### February 2024 - Present

GCP Inspector at FAMPS (Federal Agency for Medicines and Health Products) - Belgium

rming GCP inspections at investigator sites, sponsors and ethics committees

# August 2022 - February 2024 (non-pharmaceutical job) HR Business Partner at HOGENT - University of Applied Sciences and Arts - Belgium

ported executives in HR-related matters, including recruitment and the development of HR policies

#### November 2021 - August 2022 (non-pharmaceutical job) Jobcoach at Divergent - University of Ghent - Belgium

orted people with a distance to the labor market in their job search

#### April 2013 - November 2021

Qualified Person (QP) at UZ GENT (University Hospital of Ghent) - Belgium

- Set up and led a GMP unit for the manufacturing of non-sterile IMPs (Investigational Medicinal Products) in
- support of academic researchers and sponsors Developed the quality system within the unit
- Translated applicable regulations and quality standards to the GMP unit Followed up on inspections by national authorities and implemented CAPAs
- Batch release and Certification of IMP's: certified that the IMP's were manufactured in accordance with the GMP guidelines and other applicable laws
- Performed internal audits at the phase I center of the hospital

# May 2006 - March 2013

Compliance Pharmacist and SQA (Supplier Qualification) Pharmacist at Novartis (previously Alcon-Couvreur) - Belgium

### **Compliance Pharmacist:**

- Evaluated/prepared CTD dossiers (QA and manufacturing) and CE dossiers
- Responded to registration queries from various agencies and authorities
- Evaluated changes to QA systems and R&D documents, including risk analyses
- Drafted SOPs and other quality documents
- Initiated and followed up on CAPAs and evaluated process deviations

- Implemented quality assurance processes to ensure that supplier products and services comply with company standards and regulatory requirements
- Worked closely with suppliers to address quality issues, provide technical guidance, and support process improvements Evaluated and mitigated risks associated with supplier quality, including conducting risk analyses and
- Coordinated, implemented, and translated the impact of changes to components in the production process
- Conducted regular audits of supplier facilities and processes to assess their capabilities and identify areas for improvement
- Approved or rejected incoming goods after the evaluation of the specifications

### August 2003 - May 2006

Pharmacist in various public pharmacies - Belgium

## Education and training

### February 2025

ACT EU Workshop on ICH E6 R3 (Principles and Annex 1)

# March 2024 - February 2025 Internship for GCP Inspectors

2024 EU Good Clinical Practice Inspectors Working Group Workshops

## September 1998- June 2003

Master in Pharmaceutical Sciences University of Ghent - Belgium

## Additional information

Publications
Projects
Memberships
Other Relevant Information