Curriculum Vitae

Personal information

Laura Van Hoyweghen

Work experience

Job title	Company	Period	Responsibilities
GMP inspector	Federal Agency of Medicines and Health Products (FAMHP, Belgium)	Mar 2024 - Current	Inspection of pharmaceutical manufacturers and importers on compliance with cGMP
Qualified Person	Ablynx NV (Belgium)	Apr 2022 - Feb 2024	Responsible for batch certification and release of small molecule and biological DP intermediates and Finished Products, in compliance with 2003/94/EC, for MIA of Ablynx NV and Sanofi BV. Supporting Quality System related activities (including change control, deviations and complaints). Approval of Quality Agreements. Performing external GMP audits. Training of personnel in batch record review. Review and approval of procedures.

Sr Contract Manufacturing Quality Specialist	Ablynx NV (Belgium)	Jul 2019-Mar 2022	Quality oversight of Contract Manufacturing Organizations (CMO) of small molecules and Biologics. Quality System management, including writing, evaluation and approval of change controls, deviations and product technical complaints. GMP Audits of contract manufacturers and contract laboratories. Batch record review and preparation of release. Technology transfer. Creation of Quality Agreements with CMO's.
GMP QA Officer	Ablynx NV (Belgium)	Feb 2018 - Jun 2019	Management of internal and external change controls, deviations and CAPA's. QA review of method and process validation activities. Batch Record review of Biologics (DS, DP). Performing internal and external GMP audits at manufacturer's of Biologic DS and DP. Establishment of Quality Agreements with CMO's.
QA Officer	Q Biologicals (Eurofins Amatsigroup, Belgium)	Aug 2017 -Nov 2017	QA review of batch records of Biologics (DS). Maintenance and performance improvement of the Quality Management System (deviations, CAPA's & procedures).

			Supplier and material qualification for GMP production. Quality Control of incoming materials. Support in the preparation of and during authority inspections.
Site Compliance network member	Pfizer Manufacturing NV (Belgium)	Feb 2014 - Jul 2017	Authoring of CTD-sections (module 3). Submission of CTD dossiers in collaboration with regulatory affairs. Answering of queries coming from competent authorities. Facilitating implementation timelines at the production site in line with regulatory timelines. Trainer for regulatory change management. GMP QA oversight of process validation, filter validation, material & component qualification and risk assessments.
Pharmacist, head of a public pharmacy	Vooruit CVBA (Belgium)	Jan 2012 - Feb 2014	Delivery of medicines to patients. Give advice and counsel patients. Preparation and delivery of magistral and officinal preparations. Pharmacy administration and stock management.
Doctoral fellowship	Ghent University (Belgium)	Sep 2007 - Dec 2011	HPLC analysis of herbal extracts. Purification and identification of phytochemical components. Set up and performance of in vitro bioactivity studies. Scientific writing and scientific publication of research results. Oral presentations of research results at

			international conferences. Train Master students and accompany students for their master thesis. Writing, presenting and defending successfully a PhD thesis.

Education and training

Education	Diploma/Degree Awarded
Qualified Person internship at Genzyme Flanders BVBA	Registered as Qualified Person N° 2690 at the FAMHP (2022)
Ghent University: Master of Science in the Industrial Pharmacy_credit student	Credit certificate obtained for Pharmaceutical Technology, Biotechnology, Regulatory Affairs, Analytics & Quality Control (JUN 2021)
Ghent University: PhD in Pharmaceutical Sciences	Doctor in the Pharmaceutical Sciences (APR 2012)
Ghent University: Master in Pharmaceutical Sciences	Master in the Pharmaceutical Sciences (JUN 2007)

Courses	Institution
QP forum (2023)	European Compliance Academy (ECA) (certificate of attendance)
Handling Changes and Variations (2019)	European Compliance Academy (ECA) (certificate of attendance)
ICH Q7 Compliance for API's manufactured by cell culture/fermentation (2018)	European Compliance Academy (ECA) (certificate of attendance)

Additional information

Publications

Title, date	Journal
Antioxidant Capacity and Secondary Metabolites of 12 Bamboo Species	International Society for Horticultural Science, Aug 2013
In vitro inhibition of the Transcription Factor NF-κB and Cyclooxygenase by Bamboo Extracts	Phytotherapy Research, Apr 2013
Phenolic Compounds and Antioxidant Capacity of twelve Morphologically heterogeneous Bamboo Species	Phytochemical Analysis, Jan 2012
Antioxidant Flavone Glycosides from the leaves of *Fargesia robusta*	ACS Journal of Natural Products, Aug 2010
Radical Scavenging Capacity of hop-derived products	Brewing Science, Jan 2010

Projects

Memberships

Other Relevant Information