



Curriculum Vitae

Personal information Xinyi Xian-Snepvangers

Work experience

1. Employer: CBG
 - Start date: 052022
 - End date:
 - Position: quality assessor
 - Activities: • Analyzing the chemical_pharmaceutical quality of drug products (module 3) • Preparation of assessment reports of National, DCP and CP procedures, as well as variations.
 - Country: Netherlands
2. Employer: Eurodrug Laboratories B.V.
 - Start date: 012014
 - End date: 122021
 - Position: Regulatory Affairs Officer & Quality assurance manager
 - Activities: Tasks as a Regulatory Affairs Officer: • Preparation and submission of dossiers (CTD, ACTD, cosmetic dossier, medical device dossier) and variations according to the country specific guidelines for registration/notification or renewal purpose in various countries. • Preparing/editing module 3. • Preparing/Updating of SPC, PIL and mock_ups according to requirements per country and product status (registered medicine, cosmetics, medical devices). Tasks as QAM: • In case of deviations/complaints, ensure that the root_cause analysis is carried out and CAPA's implemented. • Ensure that the required initial and continuing training of all personnel is carried out and adapted according to need. • Authorize /edit written procedures and other documents, including amendments; monitor compliance with the requirements of GMP. • Ensure that a recall or mock_recall is carried out swiftly and accurately. • Participate in management reviews and advocating continual improvement. • Ensure that product quality review of all products are requested and send annually. Making conclusions of these reviews. • Ensure that the overview of capas/deviations/changes are updated quarterly and reports can be closed.
 - Country: Netherlands
3. Employer: Apotex Nederland B.V.
 - Start date: 042013
 - End date: 112013
 - Position: Regulatory Affairs Officer
 - Activities: • Updating and renewing of registration dossiers with regard to pharmaceutical technical_ and analytical documentations (module 3) according to the (inter)national guidelines. • Preparation and submission of variations.
 - Country: Netherlands
4. Employer: VSM geneesmiddelen B.V.
 - Start date: 082010
 - End date: 032013
 - Position: Regulatory Affairs Officer
 - Activities: • Preparation and submission of dossiers (CTD) and variations according to the (inter)national guidelines. • Preparation of dossiers of health care products, e.g cosmetic dossiers or food supplements. • Managing and monitoring of stability studies of all products • Correction of SPC, PIL and mock_ups according to QRD and new claims for products of different status (registered medicine, cosmetics, medical devices).
 - Country: Netherlands

Education and training

1. Subject: university of utrecht
 - Start date: 012004
 - End date: 042009
 - Qualification: PhD
 - Organisation: PhD at the University of Utrecht within the department of Crystal and Structural Chemistry on Eval15, data integration using profile prediction. Defence in April 2009
 - Country: Netherlands
2. Subject: University of Utrecht
 - Start date: 091998
 - End date: 082003
 - Qualification: Master of Science (Drs)_Chemistry
 - Organisation: Chemistry study at the University of Utrecht Master thesis: Wall Crystals: Depletion_induced growth and X_ray characterization within the Van 't Hoff laboratory for Physical and Colloid Chemistry. Graduated in august 2003
 - Country: Netherlands

Additional information

Publications

Projects

Memberships

Other Relevant Information