Curriculum Vitae

Personal information

Sirpa Lohi

Work experience

1. Employer: Finnish Medicines Agency Fimea, Helsinki, Department of Pharmaco-chemical Section

- Start date: 1.1.2018
- End date: current position
- Position: Member of the Nordic packaging working group from 1.8.2020, expert for ePI issues, lead auditor (internal audits) from December 2024, Standardizing activities for the Pharmacopoeia (preparation of translations for the International Non- proprietary Names for Pharmaceutical Substances (INN), names of the monographs on pharmaceutical dosage forms, all name of monographs implemented in Finland and the name of Pharmaceutical and Technical tests, quality evaluation and coordination of variation applications, quality assessment of renewals, assessment of product information, assessment of exemption applications, expert for Pharmaceutical Excipients and Excipient Guideline translations, expert for pediatric and safety issues, expert for GxP issues, expert for formulations, pre-clinical and toxicological studies and the development of biological medicines, Tasks for the EMA QRD subgroup on PL improvement and product information
- Country: Finland

2. Employer: Finnish Medicines Agency, Helsinki, Department of Marketing Authorization, Unit 1

- Start date: 1.3.2017
- End date: 30.1.2018
- Position: Coordination of marketing authorizations (centralized), variations, yearly assessments, renewals, referrals (CHMP, PRAC–processes), assessment of clinical and quality parts for product information, tasks for medicines name assessment with cooperation with EMA Name Review Group, inform QRD member from the new guidelines quality defects and outcomes of the inspections, answer the QRD questions with QRD member, make Finnish translations for new excipients included to the Annex of the European Commission guideline, planning of meetings (pre-submission) and participating in meetings of scientific advice.
- Country: Finland

3. Employer: Finnish Medicines Agency, Helsinki, Department of Marketing Authorization, Unit 2

- Start date: 2.12.2016
- End date: 28.2.2017
- Position: Research Coordinator, assessment and coordination of variation applications, assessment of renewals, assessment of product information, assessment of exemption applications, expert for Pharmaceutical Excipients and Excipient Guideline translations, expert for pediatric and safety issues, expert for GxP issues
- Country: Finland

4. Employer: Finnish Medicines Agency, Department of Marketing Authorization, Unit 2

- Start date: 11.1.2016
- End date: 1.12.2016
- Position: Research Coordinator, assessment and coordination of variation applications, assessment of renewals, assessment of product information, assessment of exemption applications, expert for Pharmaceutical Excipients and Excipient Guideline translations, expert for pediatric and safety issues, expert for GxP issues
- Country: Finland

5. Employer: Finnish Medicines Agency, Department of Marketing Authorization, Unit 1

- Start date: 1.10.2014
- End date: 10.1.2016
- Position: Coordination of marketing authorizations (centralized), variations, yearly assessments, renewals, referrals (CHMP, PRAC–processes), assessment of clinical and quality parts for product information, tasks for medicines name assessment with cooperation with EMA Name Review Group, inform QRD member from the new guidelines quality defects and outcomes of the inspections, answer the QRD questions with QRD member, make Finnish translations for new excipients included to the Annex of the European Commission guideline, planning of meetings (pre-submission) and participating in meetings of scientific advice.
- Country: Finland

6. Employer: UCB Pharma Oy Finland, Espoo

- Start date: 15.3.2010
- End date: 12.7.2010
- Position: Local Safety Officer, Regulatory Affairs Specialist, audits, clinical trials, development of biological (Cimzia) and chemical medicines, product, defects, quality deviations, making translations for clinical and quality parts of product information, assessment of dossiers, responsibility of safety and regulatory issues, mentor for new employers for the safety and regulatory issues, meetings in Bryssel office.
- Country: Finland, Bryssel

7. Employer: Finnish Medicines Agency, Department of Marketing Authorization, Unit 1

- Start date: 10.4.2007
- End date: 15.3.2010

- Position: Coordination of generic and original medicines (marketing authorizations: NP, DCP, MRP), renewals, type II variations), classification of clinical variations in cooperation with clinical assessors, assessment of clinical and quality parts of national texts and labelling, responsible for training and education of new coordinators, co-operation with department of pharmacovigilance activities.
- Country: Finland

8. Employer: Pharmacy of Kontulankaari, Helsinki

- Start date: 1.3.2005
- End date: 28.2.2006
- Position: Manager, Pharmacist, deputy apothecary, ex tempore manufacturing, analyzing of substances, handling of applications for special permission, customer service, keeping presentations for medicines, dose-dispensing for the contract customers, updating SOPs
- Country: Finland

9. Employer: Pharmacy of Lapinjärvi, Lapinjärvi

- Start date: 2.10.2003
- End date: 9.1.2004
- Position: Manager, Pharmacist, deputy apothecary, analyzing of substances, customer service, keeping presentations for medicines, dose-dispensing for the contract customers, updating SOPs
- Country: Finland

10. Employer: Pharmacy of Helsinki XXIX Malmi, Helsinki

- Start date: 9.6.2003
- End date: 30.9.2003
- Position: Pharmacist, deputy apothecary, customer service, manufacturing of ex tempore medicinal products, keeping training
- Country: Finland

11. Employer: Biomedicum, Helsinki, Department of Pharmacology and Toxicology

- Start date: 1.12.2001
- End date: 31.5.2003
- Position: Independent Researcher for the doctoral dissertation. Preclinical studies were performed in mice and rats. The research plan was evaluated by the ethics committees of hospital districts. The new research equipment (EMKA Technologies) was validated so that it was suitable for trials of human umbilical veins. The research methods were developed and validated. The aim of the research was to study the reactivity of human umbilical veins in normal and abnormal pregnancies (the mother suffered from diabetes or pre-eclampsy). The umbilical arteries and veins of premature babies were investigated too. Endothelial contraction and relaxation of veins were the focus in research. Human umbilical vein endothelial cells represent a widely used source of primary endothelial cells for in vitro studies of the vasculature and angiogenesis. The test substances of endothelial contraction and relaxation were used. For the relaxation of smooth muscle were used SIN-1. In the pre-eclampsy the contraction of umbilical artery was stronger compared to normal umbilical arteries and the relaxation of umbilical veins was decreased. The writing of publications is pending. In addition, cooperation closely with the cell laboratory in Biomedicum for the development of biological medicines.
- Country: Finland

12. Employer: Pharmacy of University, Mannerheimintie 96, Mannerheimintie 5 and Kaivopiha, Helsinki

- Start date: 1.9.1998
- End date: 31.5.2003
- Position: Student of pharmacy (B.Sc, M.Sc), customer service, manufacturing of ex tempore medicinal products, analyzing of medicines, keeping training to employers

13. Employer: Pharmacy of Töölön Tulli, Helsinki

- Start date: 1.6.1998
- End date: 31.8.1998
- Position: Student of pharmacy, customer service, manufacturing of ex tempore medicinal products, analyzing of medicines, administration of the homeopathic medicines

14. Employer: Pharmacy of Munkki, Helsinki

- Start date: 26.5.1997
- End date: 31.8.1997
- Position: Student of pharmacy, manufacturing of ex tempore medicinal products, customer service, warehouse monitoring, ordering
- Country: Finland

15. Employer: Yliopiston apteekin toimintakeskus, Kalliolanrinne, Helsinki

- Start date: 1.9.1995
- End date: 30.4.1996
- Position: Technical person, manufacturing of tablets, analyzing, checking of labellings, distributing of raw material to the packages, checking of batch records
- Country: Finland

16. Employer: Pharmacy of Runeberginkatu, Helsinki

- Start date: 19.10.1994
- End date: 31.5.1995
- Position: handling of prescriptions, making orders
- Country: Finland

Education and training

1. Subject: Pharmacy, Doctoral degree student in Industrial Pharmacy (Doctoral Programme in Drug Research (DPDR), pediatrics, neonates

- Start date: 1.1.2024
- End date: writing of scientific articles on going, all theoretical additional studies completed (61cr)
- Qualification: Doctoral degree student (Industry Pharmacy)
- Organisation: University of Helsinki, Faculty of Pharmacy
- Country: Finland

2. Subject: Licentiate degree student, Pharmacy, University of Helsinki

- Start date: 8.7.2015
- End date: 31.7.2023, transition to the doctoral degree student
- Qualification: Special pharmacist studies for the Industry Pharmacy
- Organisation: Faculty of Pharmacy (Industry Pharmacy)
- Country: Finland

3. Subject: Pharmacy, University of Helsinki

- Start date: 1.9.2001
- End date: 13.6.2003
- Qualification: M.Sc (Pharm) (312 ECTS)
- Organisation: Division of Pharmacology and Toxicology, Faculty of Pharmacy
- Country: Finland

4. Degree program in Chemistry (Biochemistry and Chemistry), University of Helsinki

- Start date: 30.11.1999
- End date: 1.6.2001
- Qualification: student for chemistry and biochemistry
- Organisation: Department of Biochemistry and Chemistry
- Country: Finland

5. Pharmacy: University of Helsinki

- Start date: 1.9.1996
- End date: 11.6.1999
- Qualification: B.Sc (Pharmacy) (180 ECTS)
- Organisation: Division of Pharmacology and Toxicology, Faculty of Pharmacy
- Country: Finland

6. The Finnish Matriculation Examination in Helsinki

- Start date: August 1991
- End date: 1.6.1994
- Qualification: Upper secondary school, stipends for broad Physics and Chemistry
- Organisation: Maunulan Yhteiskoulu (specialized for Mathematics, Physics and Chemistry)
- Country: Finland

Additional information

Publications

SIC! 3/2018 Visions for the electronic package leaflet with changes and challenges by the authority.

Projects

Tasks for development of Nordic flex EN/EN pilot project from 1.8.2024.

EMA`s QRD subgroup: PL improvement and product information 1.9.2023 - 1.6.2024.

Participation in planning of program for the Regulatory Affairs Seminar, Fimea`s representative 2020-2024.

Classification of risk medicines, Fimea`s national project (eDelphi panel), Oct 2022 - Spring 2023

Clarification for medicinal data reserve in different systems), since 22.3.2021-

Participation for the office space project (new location of Fimea, Helsinki) in 2018 – 2020.

Working with the national program of OTC medicines in 2013 - 2015.

Memberships

Deputy of representative of Fimea for the Patient advisory board 2024-2025.

A Member of the Nordic package Group since July 2020.

Health and safety representative, Finnish Medicines Agency Fimea, Helsinki since 2016.

A member of Helsinki`s area management team in 2013 - 2017, the Association of Finnish pharmacies (AFP).

A member of Valfa`s board in 2010 - 2013. An Accountant of Valfa in 2009.

Other Relevant Information

Clinical research Associate (CRA) 2010 training program (8.2.2010 - 18.11.2010)

- focus: good theoretical skills to apply to CRA jobs, completed.