



## Curriculum Vitae

Personal information **Mervi Saukkosaari**

### Work experience

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1. Employer: Fimea
  - Start date: 06/2018
  - End date:
  - Position: Senior Pharmaceutical Inspector, Head of GXP Section (GMP, GDP, GLP, part of time also GCP, GVP)
  - Activities: Inspectorate of Finnish Medicines Agency
  - Country: Finland
2. Employer: Oy Medfiles Ltd
  - Start date: 08/2012
  - End date: 05/2018
  - Position: Senior Pharmaceutical Chemical Expert (consultant)
  - Activities: Project Lead for Pharma clients including setting\_up of new serialization system, new packaging site and manufacturing site transfers. Quality & regulatory consultancy for clients.
  - Country: Finland
3. Employer: Santen Oy
  - Start date: 06/2006
  - End date: 07/2012
  - Position: R&D Project Manager
  - Activities: Project Lead of new drug development programs and line extensions from early clinical phase until launch.
  - Country: Finland
4. Employer: Santen Oy
  - Start date: 06/2001
  - End date: 05/2006
  - Position: Group Manager, Pharmaceutical Development
  - Activities: Responsible of manufacturing process validations, sterilization methods of primary packaging materials, stability study programs and premises.
  - Country: Finland
5. Employer: Santen Oy
  - Start date: 09/1997
  - End date: 05/2001
  - Position: Scientist, Pharmaceutical Development
  - Activities: Formulation, manufacturing process development and validation, manufacturing of GLP and GCP study batches, primary packaging material development. Commercial production support, risk management and regulatory documentation.
  - Country: Finland
6. Employer: Private pharmacies (Nokia Härki Apteekki, Tampere I)
  - Start date: 11/2009
  - End date: 05/2018
  - Position: Pharmacist (temporary)
  - Activities: Customer service in private pharmacy
  - Country: Finland
7. Employer: Kuopio University
  - Start date: 12/1995
  - End date: 07/1997
  - Position: Assistant teacher (temporary)
  - Activities: Microbiology, manufacturing of medicines, pharmacognosia
  - Country: Finland

### Education and training

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1. Subject: Specialist Qualification in Business Management
  - Start date: 08/2006
  - End date: 12/2009
  - Organisation: Tampere Adult Education Center
  - Country: Finland
2. Subject: MSc (Pharm)
  - Start date: 09/1991
  - End date: 05/1997
  - Organisation: Kuopio University
  - Country: Finland

### Additional information

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#### Publications

#### Projects

In pharma industry: multiple tech transfer, R&D projects & life cycle projects.

As national competent authority (Fimea): international GXP harmonisation & remote inspection projects, legislation implementation projects, setting up PIC/S annual seminar.

### Memberships

EMA GMDP IWG member and member of subcommittees.

PIC/S Committee member and previous experience on several PIC/S sub-committees.

### Other Relevant Information