

Curriculum Vitae

Personal information **Viktoriia Starokozhko**

Work experience

1. Employer: Medicines Evaluation Board
 - Start date: 2022
 - End date: current
 - Position: Project Lead Parallel Procedures CBG_ZIN
 - Activities: Coordinate Parallel Procedure Project and collaboration between the Dutch Medicines Evaluation Board and Dutch National Health Care Institute.
 - Country: Netherlands
2. Employer: Medicines Evaluation Board
 - Start date: 2018
 - End date: current
 - Position: Clinical assessor
 - Activities: Assessment of national or European marketing authorisation applications for pharmaceuticals, as well as post_authorisation changes to the drug label. Provision of national or European scientific advices, and qualification advices. Particular expertise in benign haematology and ATMPs, including multiple Rapporteurships. Member of the Haematology Working Party at the European Medicines Agency. Dutch representative of the EU-IN at the European Medicines Agency.
 - Country: Netherlands
3. Employer: University Medical Center Groningen & Medicines Evaluation Board
 - Start date: 2019
 - End date: current
 - Position: Researcher and teacher
 - Activities: Teaching pharmacotherapy. Co-promotor of PhD students, supervising master students. Author of multiple publications.
 - Country: Netherlands
4. Employer: University of Groningen
 - Start date: 2017
 - End date: 2018
 - Position: Post-doctoral researcher in Toxicology
 - Activities: Translational research (from animals to human)
 - Country: Netherlands
5. Employer: University of Groningen
 - Start date: 2013
 - End date: 2017
 - Position: PhD candidate
 - Activities: Pharmacy and toxicology. Investigating mechanisms of drug toxicity. Translational research. Developing new in vitro models.
 - Country: Netherlands
6. Employer: Regional Clinical Hospital
 - Start date: 2010
 - End date: 2011
 - Position: Clinical pharmacist
 - Activities: Providing patient care. Consulting treating physicians. Working at the hospital pharmacy.
 - Country: Ukraine

Education and training

1. Subject: BIG registry
 - Start date: 2017
 - End date: 2019
 - Qualification: BIG registration
 - Organisation: BIG register
 - Country: Netherlands
2. Subject: EUROTOX
 - Start date: 2013
 - End date: 2017
 - Qualification: European Registered Toxicologist
 - Organisation: EUROTOX
 - Country: Netherlands
3. Subject: PhD
 - Start date: 2013
 - End date: 2017
 - Qualification: PhD in Pharmacy and Toxicology
 - Organisation: University of Groningen
 - Country: Netherlands
4. Subject: Master
 - Start date: 2011
 - End date: 2013
 - Qualification: MSc Medical Pharmaceutical Sciences (Cum Laude)
 - Organisation: University of Groningen, Internship at the Queen's Medical Research Institute,

- University of Edinburgh, Scotland
- Country: Netherlands
- 5. Subject: Master
 - Start date: 2010
 - End date: 2011
 - Qualification: MSc Clinical Pharmacy (Cum Laude)
 - Organisation: National University of Pharmacy.
 - Country: Ukraine
- 6. Subject: Bachelor
 - Start date: 2005
 - End date: 2010
 - Qualification: BSc Clinical Pharmacy (Cum Laude)
 - Organisation: National University of Pharmacy
 - Country: Ukraine

Additional information

Publications

Starokozhko V, Heß A, Löbker W, Ballensiefen W, Agricola E, Ziegele B, Kallio MJ, O'Dwyer L, Nuevo Y, Mol PGM, Pasmooij AMG. Strategic recommendations from the STARS project to foster academic drug development. *Nat Rev Drug Discov.* 2023 Apr;22(4):251-252. doi: 10.1038/d41573-023-00021-z. PMID: 36755155.

Starokozhko V, Tarrahi F, Vrijlandt PJWS, Mol PGM. Safety-Related Drug Label Changes Following Large Post-Marketing Cardiometabolic Trials: A Review of European Public Assessment Reports. *Clin Pharmacol Ther.* 2023 Apr;113(4):859-866. doi: 10.1002/cpt.2840. Epub 2023 Jan 18. PMID: 36606727.

Kallio MJ, Starokozhko V, Agricola E, Burggraf M, Heß A, Ballensiefen W, Löbker W, Nuevo Y, Pasmooij AMG, Mol PGM; STARS consortium. Translating Academic Drug Discovery Into Clinical Development: A Survey of the Awareness of Regulatory Support and Requirements Among Stakeholders in Europe. *Clin Pharmacol Ther.* 2023 Feb;113(2):349-359. doi: 10.1002/cpt.2789. Epub 2022 Nov 21. PMID: 36326573; PMCID: PMC10099080.

Bakker E, Plueschke K, Jonker CJ, Kurz X, Starokozhko V, Mol PGM. Contribution of real-world evidence in EMA regulatory decision making. *Clin Pharmacol Ther.* 2022 Oct 17. doi: 10.1002/cpt.2766. Epub ahead of print. PMID: 36254408.

Estrada-Ortiz N, Starokozhko V, van Steenwijk H, van der Heide C, Permentier H, van Heemskerck L, Prins GH, Heegsma J, Faber KN, Bressers S, Steiblen G, de Groot A, Groome S, van Miert E, Groothuis G, de Graaf IAM. Disruption of vitamin A homeostasis by the biocide tetrakis(hydroxymethyl) phosphonium sulphate in pregnant rabbits. *J Appl Toxicol.* 2022 Jul 20. doi: 10.1002/jat.4364. Epub ahead of print. PMID: 35857281.

de Vries ST, Starokozhko V, Schellens IMM, et al Attention for sex in COVID-19 trials: a review of regulatory dossiers. *BMJ Global Health* 2022;7:e008173.

Bakker E, Hendrikse N. M, Ehmann F, Van der Meer D.S, Llinares Garcia J, Vetter T, Starokozhko V, Mol P.G.M. Biomarker qualification at the European Medicines Agency: a review of biomarker qualification procedures from 2008 to 2020. *Clinical Pharmacology & Therapeutics*, 2022.

Starokozhko V, Kallio M, Kumlin Howell Å, Mäkinen Salmi A, Andrew_Nielsen G, Goldammer M, Burggraf M, Löbker W, Böhmer A, Agricola E, de Vries C.S, Pasmooij A.M.G, Mol P.G.M., on behalf of the STARS consortium. Strengthening regulatory science in academia: STARS, an EU initiative to bridge the translational gap. *Drug Discovery Today*, 2020.

Starokozhko V*, Hemmingsen M*, Larsen L, Mohanty S, Merema MT, Pimentel C, Wolff A, Ernénus J, Aspegren A, Groothuis GM#, Dufva M#. Differentiation of Human Induced Pluripotent Stem Cell under Flow Conditions to Mature. * Shared first author. # Shared last author. *Tissue Engineering and Regenerative Medicine*, 2018; 12(5):1273_1284.

Starokozhko V, Greupink R, van de Broek P, Soliman N, Ghimire S, de Graaf IAM, Groothuis GM. Rat precision_cut liver slices predict drug_ induced cholestatic injury. *Archives of Toxicology* , 2016; 91(10), 3403–3413.

Starokozhko V, Vatakuti S, Schievink B, Merema MT, Asplund A, Synnnergren J, Aspegren A, Groothuis GM. Maintenance of drug metabolism and transport functions in human precision_cut liver slices during prolonged incubation for 5 days. *Archives of Toxicology*, 2016; 91 (5), 2079_2092.

Starokozhko V, Groothuis GM. Judging the value of "liver_on_a_chip" devices for prediction of toxicity. *Expert Opinion on Drug Metabolism & Toxicology*, 2016; 13 (2), 125_128. Starokozhko V, Groothuis GM. Challenges on the road to a multicellular bioartificial liver. *Tissue Engineering and Regenerative Medicine*, 2016; 12 (1), e227_e236.

Starokozhko V, Abza GB, Maessen HC, Merema MT, Kuper F, Groothuis GM. Viability, function and morphological integrity of precision_cut liver slices during prolonged incubation: Effects of culture medium. *Toxicology in Vitro*, 2015; 30: 288_299.

Hadi M, Westra IM, Starokozhko V, Dragovic S, Merema MT, Groothuis GM. Human precision_cut liver slices as an ex vivo model to study idiosyncratic drug_induced liver injury. *Chemical research in toxicology*, 2013; 26: 210_220.

Hadi M, Chen Y, Starokozhko V, Merema MT, Groothuis GM. Mouse precision_cut liver slices as an ex vivo model to study idiosyncratic drug_induced liver injury. *Chemical research in toxicology*, 2012; 25:1938_1947.

Projects

PRIME-CKD project, IMI EPND project

Memberships

Member of the Dutch Society of Toxicology, Section Pharmaceutical Toxicology

Other Relevant Information

Languages: English, Dutch, Ukrainian, Russian.