

### PERSONAL INFORMATION

Simona Kudeliene

### WORK EXPERIENCE

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March 2014- Present

#### Chief specialist of Pharmacovigilance and Poison Information Unit

The State Medicines Control Agency of Lithuania (Lithuania)

Activities in pharmacovigilance: evaluation of ICSRs, evaluation of safety signals, evaluation of periodic safety update reports; inspector of pharmacovigilance inspections.

July 2013-February 2014

#### Pharmacist

Camelia Pharmacy (Lithuania)

Dispensing of medicines

### EDUCATION AND TRAINING

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September 2008-June 2013

#### Pharmacist

Lithuanian University of Health Sciences (Lithuania)

September 2014-January 2016

#### Biolawyer

Mykolas Romeris University (Lithuania)

Master thesis: "Post-authorization drug surveillance"

### ADDITIONAL INFORMATION

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#### Expertise

1. Prepared assessment of "Nitrofurantoin" periodic safety update report in 2015;
2. Prepared assessment of "Dalteparinum" periodic safety update report in 2016;
3. Prepared assessment of "Cefoperazone" periodic safety update report in 2016;
4. Prepared assessment of "Cefoperazone/sulbactam" periodic safety update report in 2016;
5. Prepared assessment of "Granisetron" periodic safety update report in 2019;
6. Prepared assessment of "Cidofovir" periodic safety update report in 2021;
7. Prepared assessment of "Fluciclovine 18F" renewal 2021;
8. Prepared assessment of "Octenidine dihydrochloride/phenoxyethanol" periodic safety update report in 2022;

#### Publications

1. Published article "Statins consumption tendencies (2005-2012);
2. Kadusevicius E., Kasciuskeviciute S., Kudeliene S. Gydymas statiniais: vaistu saveika, nepageidaujamos reakcijos, saugaus medikamentu derinimo principai. Practice of Cardiology. 2017/4; 21-26p.

#### Projects

#### Memberships

Alternate member of Pharmacovigilance Inspectors Working Group

#### Other Relevant Information

#### Certifications:

Eudravigilance - electronic reporting of ICSRs

European Medicines Agency

November 2014;

Eudravigilance data analysis system

European Medicines Agency

January 2015;

The prevention of corruption in the field of healthcare

February 2015;  
Basics of quality management in healthcare system and internal medical audit  
EVS Group, UAB  
December 2017.