EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Dovile Zacharkiene

WORK EXPERIENCE

January 2019- Present

Advisor

State Medicines Control Agency under Ministry of Health of the Republic of Lithuania (Lithuania)

Participation in the planning and organization of the effective work of the Marketing Authorisation Unit under supervision of the Head of the Marketing Authorisation Unit. Participation in drafting of legislative documents in collaboration with Ministry of Health of the Republic of Lithuania. Leading the projects in marketing authorization procedures where Lithuania acts as reference member state. Evaluation and acceptation of clinical variations for authorized medicinal products. Evaluation of proposed names for medicinal products. Additional I am an expert in European medicines agency, European Directorate for the Quality of Medicines and country representative in the network of Heads of Medicines Agencies, in the Regulatory optimisation working group. STE in the Twinning Light Project Harmonisation of the legislation for medicinal products with EU legislation and building capacities for its implementation (2017-2019). Experience in preparation of legal framework and methodological tools in the field of medicines.
Experience in conducting trainings in the field of medicines.

January 2016-November 2017

Acting Head of Marketing Authorisation Unit

State Medicines Control Agency under Ministry of Health of Lithuania (Lithuania)
Responsible for planning, organizing, staffing, directing, and controlling functions. Evaluation of proposed names for medicinal products. NRG member (EMA).
Delegate from Lithuania in the Committee of Experts CD-P-PH/PHO (European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe).
Member of regulatory optimisation group.

September 2008-December 2018

State official, Deputy Head of Marketing authorization unit

State Medicines Control Agency under Ministry of Health of Lithuania (Lithuania)
Primary evaluation of the documentation for granting marketing authorization for medicinal products via MR, DC and national procedures and evaluation and acceptation of clinical variations for authorized medicinal products. Evaluation of proposed names for medicinal products. NRG member (EMA).
Delegate from Lithuania in the Committee of Experts CD-P-PH/PHO (European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe).

June 2007-May 2008

Director

PE ,,Inkocentras (Lithuania)
Acting on behalf of the company as director.

September 2006-June 2007

Assistant (science)

Vilnius College of Higher Education Faculty of Health Care (Lithuania)
Preparing and delivering lectures for students.

November 2004-June 2005

Assistant (science)

Vilnius College of Higher Education Faculty of Health Care (Lithuania)
Preparing and delivering lectures for students.

August 2002-June 2007

State official

Vilnius City Municipality Administration Department of Social Affairs Health Division (Lithuania)

Preparing documents records, legal documents, collaboration with Public Institutions, Outpatient clinics, Hospitals, Foreign partners, Municipalities. Responsible for primary health care and nursing.

September 2000-December 2002

Medical nurse

Vilnius University Hospital Santariki klinikos Centre of Anesthesiology, Intensive Therapy andPain Treatment Department of Pediatric Anesthesia, Reanimation and Intensive Therapy (Lithuania)

Responsible for providing nursing care, anesthesiological intensive therapy help (under doctors supervision) before and after the surgery for the newborns and children with inborn and acquired heart diseases.

EDUCATION AND TRAINING

September 2000-June 2003

Master degree

Kaunas University of Medicine (Lithuania)

Public health management

September 1996-June 2000

Bachelor degree

Vilnius University, Faculty of Medicine (Lithuania)

Medical nurse science

September 1993-June 1996

nurse

Vilnius College of Higher Education Faculty of Health Care (Lithuania)

Medical nurse science

ADDITIONAL INFORMATION

Expertise

Review the acceptabilty of names as NRG member and on a national level in my country (Lithuania).
Delegate from Lithuania in the Committee of Experts CD-P-PH/PHO (European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe).
Member of Regulatory optimisation group.The Regulatory Optimisation Group (ROG) is a an HMA subgroup focused on regulatory/business optimisation, under HMA Multi Annual Working Plan priority Optimisation of the regulatory operations, objective 2, Strive for operational excellence.

Publications

Projects

Manager 2002 - 2003 VINO (Vilnius nurses to Oslo) Vilnius and Oslo municipality project for unemployed nurses.
Active participation in the organization of the meetings during the Lithuanian Presidency 2013.
STE in the EU Twinning Project Harmonisation of the legislation for medicinal products with EU legislation and building capacities for its implementation Moldova (2017-2019).
STE in the EU Twinning project Harmonisation of the legislation for Medicinal Products with EU legislation and building capacities for its implementation The North Macedonia (2019-2020).

Memberships

Member of the NRG (Review the acceptability of names) group in the European Medicines Agency (EMA).
Delegate from Lithuania in the Committee of Experts CD-P-PH/PHO (European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe).
Member of the Regulatory Optimisation Group (ROG). ROG is a an HMA subgroup focused on regulatory/business optimisation, under HMA Multi Annual Working Plan priority Optimisation of the regulatory operations, objective 2, Strive for operational excellence.

Other Relevant Information