

PERSONAL INFORMATION

Katrin Kiisk

WORK EXPERIENCE

January 2012- Present

Deputy Director General

State Agency of Medicines (Estonia)

Overall coordinating and controlling for pre- and post-authorisation control, biological products, supervision of the manufactures, distributors and pharmacies.

Work-flow management in the departments (5).

Advice on clinical trials evaluation and marketing authorisation processes.

2003- 2012

Head of the Department of Human Medicines

State Agency of Medicines (Estonia)

Overall responsibility for pre- and post-authorisation control of human medicines, national and EU procedures.

Work-flow management in the Department of Human Medicines

Assessment of safety and clinical data of the human medicinal products, assessment of user testing of PILs. Advice on clinical trial application assessment.

National and EU marketing authorisation procedures for human medicinal products, EU

requirements for safety and clinical evaluation of human medicines. National and EU requirements for clinical trials.

EU system and requirements of pharmacovigilance of the human medicinal products.

2002- 2003

Head of the Bureau of Clinical Trials

State Agency of Medicines (Estonia)

Clinical trial application evaluation, assessment of safety data from clinical trials.

2002- 2003

Director

Tartu University Lung Clinic (Estonia)

Overall coordinating and controlling, responsible for clinic budget and use of the clinic budget from Health Insurance Fund.

EDUCATION AND TRAINING

2000- 2003

Master of Public Health

Tartu University, Medical Faculty (Estonia)

The aim of the master programme is to provide knowledge, skills and competence for expert decision-making, implementation of decisions, management and independent research and development work in the fields of health care and public health.

1997- 1998

internship

Tartu University, Medical Faculty (Estonia)

The aim of the programme is to acquire the practical skills required for the profession of a doctor.

1991- 1997

Degree in Medicine

Tartu University, Medical Faculty (Estonia)

The aim of the programme is to acquire the theoretical knowledge and practical skills required for the profession of a doctor.

ADDITIONAL INFORMATION

Expertise

- Drug regulation
- Clinical trials and GCP
- Efficacy and safety evaluation of human medicinal products

Publications

Projects

Memberships

- PRAC Alternate member
- Alternate member of the Estonian Treatment Guidelines Council

Other Relevant Information

- Continuous professional education
- EMA Training Session for Junior Assessors, London, UK, 2001
- BfArM Methodological and Biostatistical Points to Consider Documents of the CPMP, Bonn, 2003
- EMA GCP Inspectors Training Seminar, Netherlands, 2003
- EMA Workshop Methodological Aspects of Clinical Trials for Efficacy Evaluation in small populations, London, 2003
- EMA Eudravigillance User Training Course, London, 2004
- Symposium EU Regulatory Environment, Croatia, 2005 (presentation Pharmacovigilance The Role of the Authority)
- EMA The EU Clinical Trials Directive, London, 2005
- FDA CDER Forum for International Drug Regulatory Authorities, US, 2006
- Joint EMA/TOPRA meeting New Medicines Legislation, London, 2006
- Pharmaceutical Innovation, Portugal, 2007
- DIA (Drug Information Association) 20th Euromeeting 2008 and 2009
- Evidence-based pharmacotherapy Tartu University, 2007
- Epidemiology studies and analysis of health information Tartu University, 2009