EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Guðrún Stefánsdóttir

Work experience

1. Employer: Icelandic Medicines Agency
   - Start date: 03-2018
   - End date: current
   - Position: Team lead Pharmacovigilance and bioequivalence assessment
   - Activities: Pharmacovigilance, risk management, PSUR assessment, Signals, PRAC member, Assessment of a change in legal status (OTC)
   - Country: Iceland
2. Employer: Astellas Pharma B.V.
   - Start date: 04-2016
   - End date: 01-2018
   - Position: Senior Manager Signal Management
   - Activities: Maintain expert knowledge on Good Pharmacovigilance Practices, regulations and guidelines for signal detection. Scientific input on signal detection strategies. Translate guidelines and regulations into internal processes and continous process improvements. Provide training on signal detection and management and the Empirica Signal application in_house. Compliance monitoring of signal management system. Input into signal evaluation, PSUR and RMP. Lead in_house projects such as Eudravigilance for signal detection, evaluation and reporting of medication errors and real world evidence for signal detection. Software: Argus, Empirica Signal, SÆfetyWorks
   - Country: Netherlands
3. Employer: Astellas Pharma B.V.
   - Start date: 042014
   - End date: 032016
   - Position: Manager Signal Management
   - Activities: Maintain expert knowledge on Good Pharmacovigilance Practices, regulations and guidelines for signal detection. Scientific input on signal detection strategies. Translate guidelines and regulations into internal processes (e.g. European, American and Japanese regulations), set up process and internal trainings. Customization of the Empirica application environment. Develop and implement a process to monitor compliance to the signal management process. Harmonization of signal management processes between development and post_marketing. Software: Argus, Empirica Signal
   - Country: Netherlands
4. Employer: Astellas Pharma B.V.
   - Start date: 072012
   - End date: 032014
   - Position: Pharmacovigilance Science Manager
   - Activities: Safety management of assigned products. Supporting the design, conduct, analysis and reporting of clinical trials. Supporting global and regional clinical studies and participation in project teams in pharmacovigilance. Conduct safety reviews and providing scientific safety input to clinical trial protocols, clinical study reports, periodic safety reports (e.g. PSUR and DSUR), CCDS, SmPC. Collecting safety data for signal surveillance activities using AE reports, (pre_) clinical data, literature surveillance and Empirica Signal. Write and maintain safety reporting plans for global and regional clinical studies. Perform signal evaluation and write the reports. Co_author risk management plans Participate in signal management project team and provide training on signal management. Software: Argus, Cognos, Empirica Signal
   - Country: Netherlands
5. Employer: Vistor ehf.
   - Start date: 052008
   - End date: 082008
   - Position: Regulatory Affairs Specialist
   - Activities: Submission of variations and communication with local authorities Translation of SmPC, PIL, package materials, from Danish/English to Icelandic Communication with external stakeholders
   - Country: Iceland
6. Employer: GlaxoSmithKline ehf.
   - Start date: 022007
   - End date: 112007
   - Position: Regulatory Affairs Associate
   - Activities: Submission of variations to local authorities Translation of SPC, PIL, package materials from English to Icelandic Prepare data and transfer to a new regulatory database.
   - Country: Iceland
7. Employer: DAC ehf.
   - Start date: 052005
   - End date: 122006
   - Position: Pharmacy Technician
   - Activities: Computerized drug dispensing and wholesale. Various jobs regarding drug dispensing, re_packaging, translations of PILs, SmPCs and other texts
   - Country: Iceland

Education and training

1. Subject: Julius Center _ University Medical Center Utrecht
    - Start date: 092008
    - End date: 082012
    - Qualification: PhD pharmacoepidemiology
    - Organisation: The project was performed in the context of the Escher project (T6_202), a project of the Dutch Top Institute Pharma and resulted in a thesis entitled 'Innovations in post_marketing safety research'. Tasks _ Writing international publications, including a PhD thesis _ Collection of data, data analysis _ Presentation of results within internal as well as external meetings and conferences _ collaboration with external parties (other research groups inside and outside The Netherlands) _ Teaching assistant in Classical Methods in Statistical Analysis for 3 years _ 4 peer_reviewed publication as the first author Skills: _ presentation skills _ scientific writing skills _ statistical analysis (SPSS, R) _Teaching
    - Country: Netherlands
2. Subject: Universiteit Utrecht
    - Start date: 092008
    - End date: 082011
    - Qualification: MSc. pharmacoepidemiology
    - Organisation: Post_graduate masters program of pharmacoepidemiology. The final master research concerned cancer risk in patients with Type II diabetes that received diabetes treatment of different intensity.
    - Country: Netherlands
3. Subject: University of Iceland
    - Start date: 092003
    - End date: 062008
    - Qualification: MSc. Pharmacy
    - Organisation: Masters degree in pharmacy including summer internships in pharmacies. Topic of master thesis: The association between benzodiazepine use and the length of antidepressant treatment episodes, Written at Utrecht University, the Netherlands using data from the PHARMO database.
    - Country: Iceland
4. Subject: University of Iceland
    - Start date: 092017
    - End date: 062019
    - Qualification: Postgraduate diploma, public administration: Executie diploma in health administration
    - Organisation: Health administration/public administration
    - Country: Iceland

Additional information

Publications

Evidence synthesis in drug safety assessment: the example of rosiglitazone publication date Nov 28, 2017 publication descriptionFrontiers in medicine A Business Intelligence Solution to Pharmacovigilance Signal Tracking and Management: One Mid_Size Pharma's Experience publication date Aug 2015 publication descriptionPharmaceutical Medicine The post hoc use of randomised controlled trials to explore drug associated cancer outcomes: methodological challenges publication date Nov 2013 publication descriptionCurr Drug Saf. Safety learning from drugs of the same class: room for improvement publication date May 2012 publication descriptionClin Pharmacol Ther Randomized Controlled Trials of COX_2 Inhibitors: An analysis of doses used and trends over time to investigate implications for comparative safety publication date Sep 1, 2011 publication descriptionDrug Safety Intensive glucose control and risk of cancer in patients with Type II diabetes publication date Apr 21, 2011 publication descriptionDiabetologia Publications in Icelandic: Frá Lyfjastofnun og Landspítala. Aukaverkanatilkynningar og ný lyfjalög. November 2020. Læknablaðið _ The Icelandic Medical Journal Lyfjamál á tímum COVID_19 – Allt á fullu. May 2020 Læknablaðið _ The Icelandic Medical Journal Flixabi – aukaverkanir af nýju líftæknihliðstæðulyfi, undir sérstöku eftirliti Nov 2019 Læknablaðið _ The Icelandic Medical Journal

Projects

Memberships

Poster Prize Nomination 2011 FIGON _ Dutch Medicines Days, for the study on safety learning of same class drugs. Student travel grant October 2011 _ 11th Annual Meeting of ISoP International Society of Pharmacovigilance, oral presentation of the study on safety learning of same class drugs. September 2009 _ oral presentation at ICPE regarding the study of randomized controlled trials of COX_2 Inhibitors: An analysis of doses used and trends over time to investigate implications for comparative safety

Other Relevant Information

Standalone courses: Uppsala University _ Drug Safety and Pharmacovigilance; Preclinical safety assessment and pharmacovigilance DIA _ Signal management in Pharmacovigilance; Assessing Benefits & Risks of Medicines Part 3 _ Framing for Assessment & Communication TI Pharma _ Business and enterpreneurial skills; drug discovery and development cycle;