Curriculum Vitae

Personal information

Birna Kristín Eiríksdóttir

Work experience

VISTOR EHF, Garðabær, Iceland (2024-2025)

May 2024 – Aug 2025 ***Regulatory Affairs Specialist. Department of Regulatory Affairs and Clinical Operations.***

Responsibilities include translation of product information, educational material and review of promotional material for various marketing authorisation holders in Iceland. Creation, review and approval of product information leaflets and labels.

ASTRAZENECA AB, Gothenburg, Sweden (2018-2024)

Nov 2023-May 2024 ***Associate Director, Senior Scientist, Patient Safety Biopharma (PS Biopharma).***

The Associate Director, Senior Pharmacovigilance Scientist, role leads the review of safety data and related documents for potential safety issues in collaboration with the Global Safety Physician (GSP) and (Associate) PV Scientist. Authors and leads PV input to safety documents and regulatory reports. Associate Director, Senior Patient Safety Scientist leads meetings and presents safety data and analyses.

Nov 2023-May 2024 (tezepelumab) **Safety Strategy and Management Lead for TEZSPIRE**

The SSaMTL chairs the Safety Strategy and Management team, including the global safety physician (GSP), global clinical lead and global regulatory lead, where safety topics are discussed and escalated as relevant to safety information committee, for labelling discussions. As SSaMTL, I also lead the TEZSPIRE safety team, which included 10 people.

This included accountability for all global safety activities for TEZSPIRE (shared with GSP) registered for indication severe asthma and under development for chronic obstructive pulmonary disease (COPD) and chronic rhinosinusitis with nasal polyps. The role including oversight of safety in ongoing clinical trials, management of safety information for study reports and the subsequent clinical trial submissions, delivery of aggregate reports (PBRER and DSUR), risk management plans, routine safety surveillance and signal detection and management.

Additional responsibilities

2023-2024 **Executive Safety Board, Operational Lead (ESB Op Lead)**

Responsibilities include scheduling meetings with senior vice presidents for clinical development, regulatory, quantitative pharmacology, QPPV, statistics, labelling, relevant safety knowledge groups (depending on the topic) to discuss and make executive decisions on important, emerging safety issues. The ESB Op Lead supports ESB chair and project teams with agenda, appropriate level of detail and documents the discussions.

2022-2024 **Subject Matter Expert – Signal Detection and Management**

Participated in the „AZALEA“ project, integration activities with Alexion and AstraZeneca with regards to signal detection and safety surveillance processes, in close collaboration with process owners.

Mar 2023-Nov 2023 ***Director, Principal Pharmacovigilance Scientist, Patient Safety Vaccines and Immune Therapies (PS V&I) – COVID-19***

The Director, Principal Patient Safety Scientist role provides expertise to multiple and/or single but complex products in different stages of development as needed. Provides oversight of safety documents and deliverables for these projects in collaboration with the Global Safety Physician (GSP) and other PV Scientists. Leads PV strategy for safety documents and regulatory reports. Applied in the role of leading the safety strategy and management for EVUSHELD, see below.

Oct 2022-Oct 2023 **Safety Strategy and Management Lead for EVUSHELD (tixagevimab/cilgavimab) COVID-19 mABs**

The EVUSHELD project team counted all up to 13-14 people, based in 4 countries. The role included team leadership and accountability of all global safety activities for EVUSHELD (combination of 2 mAbs for prophylaxis and treatment of COVID-19), including oversight of safety in 9 ongoing clinical trials, management of safety information for interim and final study reports and the subsequent clinical trial submissions, delivery of monthly safety update reports, aggregate reports (PBRER and DSUR), risk management plans, routine safety surveillance and signal detection and management.

July 2022-Mar 2023 ***Associate Director, Senior Pharmacovigilance Scientist, PS V&I***

The Associate Director, Senior Pharmacovigilance Scientist, role leads the review of safety data and related documents for potential safety issues in collaboration with the Global Safety Physician (GSP) and (Associate) PV Scientist. Authors and leads PV input to safety documents and regulatory reports. Associate Director, Senior Patient Safety Scientist leads meetings and presents safety data and analyses. Applied in both EVUSHELD and VAXZEVRIA (Covid-19 vaccine AstraZeneca)

projects.

June – Aug 2022 **COVID-19 Vaccine PBRER lead for VAXZEVRIA**.
Responsibilities include leadership and alignment of overall strategy for the delivery of the aggregate report. Strategy, delegation and coordination with authoring team involving 40+ people, assuring that 15+ requests from European Medicines Agency´s Pharmacovigilance assessment committee (EMA PRAC) are addresed, collaborating with process owners and QPPV in finding innovative ways in planning review cycles involving global safety, clinical and regulatory leads, QPPV and executive director for V&I for this extensive document.

Feb 2018- Jun 2022 ***Associate Director, Pharmacovigilance Scientist, Patient Safety Cardiovascular, Metabolic and Renal Diseases (PS CVRM)***
The Pharmacovigilance (PV) Scientist role works collaboratively with the Global Safety Physician and (Senior/Principal) PV scientist with the review of safety data and related documents for potential safety issues. Ability to provide authoring and PV input to safety documents and regulatory reports. PV Scientist also has the ability to lead meetings and present safety data and analyses.

Jan 2021-Oct 2022 **VAXZEVRIA (AZD1222) COVID-19 Vaccine Safety Surveillance & Signal Detection Team Member**
Jan-April 2021 Main tasks involve safety surveillance for hypersensitivity and neurological events, leading safety surveillance team, manage safety management tool, respond to health authority questions and participating in authoring the monthly safety summary report (MSSR) and periodic benefit-risk assessment report (PBRER).

Safety Surveillance & Signal Detection Team Lead
April 2021 Oct 2022 Leadership of weekly surveillance meeting to review global post-marketing adverse event reports in collaboration with the deputy Global Safety Physician for surveillance. Set-up a team structure for a fast expanding surveillance team, involving up to 35 people in various time zones and create effective teams working against different adverse events of special interest (AESIs). Topic lead for neurological disorders involving leadership and strategy for internal monitoring and evaluation, respond to health authority questions and write summaries in aggregate reports involving any neurological topic.

2018-2020 **Member of Lokelma Patient Safety (PS) team**.
Main responsibilities were surveillance, driving development safety update reports (DSUR) and risk management plan (RMP) updates, representing safety on epidemiological study meetings meetings, reviewing clinical and epidemiological study protocols and study reports and document management. Participated in the Patient Safety Document Management (PSDM) development

team during autumn 2018, as patient safety representative for the therapeutic area of cardiovascular, metabolic and renal diseases (CVRM).

ACTAVIS GROUP PTC ehf, Hafnarfjörður (during period part of Watson, Allergan then Teva Pharmaceuticals).

2013-2018 ***Senior Regulatory Affairs Manager***
In addition to the life cycle management of the company's products, the job included keeping oversight of priority projects within a team and help with prioritization and delegation, attending meetings with senior management, training of new employees and managing and/or participating in larger development projects and process improvements, often cross-functional and acquisition related between various departments and manufacturing sites. Responsible for yearly performance interviews with team members.

2012-2013 ***Regulatory Affairs Product Manager – Life Cycle Management*** *(role was later renamed to Regulatory Affairs Associate - Maintenance)*
Responsibility for all regulatory post approval activity of products after marketing authorisation i.e. submitting safety, administrative and quality variations and renewal application. Supporting national market offices/marketing companies and 3rd Party clients with license maintenance. Responsible for quality publishing, i.e. compilation of eCTD/NeeS and communication with health authorities.

2011-2012 ***Variations Project Manager***
Compilation of quality variation packages and distributing to own brand markets/marketing companies, publishing team and 3rd Party clients. Provide support and guidance to meet regulatory requirements.

LYFJA PHARMACY

2011 *Accountable Pharmacist.* Rotation position within different Lyfja pharmacies, both in the capital and more rural areas

2010-2011 *Associate Pharmacist*. Full time in a large shift/emergency pharmacy Lyfja,Smáratorg summer 2010. Occasional evenings, weekends and during school holidays

2006-2010 *Pharmacy Associate*, prescriptions
Full-time in Lyfja, Smáratorgi during summers 2006 and 2007

Summer 2008 Landspitali University Hospital, Hospital Pharmacy, *Pharmacy Associate, Internship*

Summer 2009 Landspitali University Hospital, Hospital Pharmacy, *Pharmacy Associate, Internship*

Education and training

2005-2008	University of Iceland, School of Health Sciences, Faculty of Pharmacy. ***B.Sc in Pharmaceutical Sciences – First grade***
2009-2011	University of Iceland, School of Health Sciences, Faculty of Pharmacy ***M.Sc. in Pharmaceutical Sciences - First grade***
2015	University of Reykjavík (program for Actavis Employees), Project Management, IPMA level D.
2016-2017	University of Iceland Continuing Education Institute, *Positive Psychology*, Diploma on a master level

Additional information

Publications

Evaluation of Performance and Approval of a Medication Reconciliation Program in Admission to Orthopedic and Trauma Surgery Ward. Co-authors: Hernández, Eduardo L. Mariño (Univeristy of Barcelona), Sveinbjörn Gizurarson 1962 (University of Iceland), Fernández Lastra, Cecilia (University of Barcelona), Bonafont, Xavier (Hospital Germans Trial I Pujol)

Projects

Memberships

Other Relevant Information

Participation in conferences:

10th Annual Risk Management and Pharmacovigilance Summit, Vienna 10-11 May 2023. ***Key Note Speaker and panel discussions.*** *„Applying WHO-UMC Causality Criteria to Vaccinations: A COVID-19 vaccine experience".*

9th Annual Global Pharmacovigilance Summit, Prague 12-13 June 2025. ***Panel discussions.*** *"TRANSITIONING FROM PAPER-BASED TO DIGITAL DISTRIBUTION OF DHCPS AND EDUCATIONALMATERIALS TO ENHANCE PATIENT CARE AND SAFETY.**"***