EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Elena Ukhatskaya

Work experience

1. Employer: Icelandic Medicines Agency
   - Start date: 052022
   - End date:
   - Position: _ Project Manager
   - Activities: _ Marketing license applications in full evaluation (RMS / Rapp, Co_Rapp, country), _ Project management of marketing authorization applications when Icelandic Medicines Agency is the managing country (RMS) in it (includes maintenance of job descriptions, communication with CMDh representatives and dissemination of information to project manager, mailbox monitoring, communication with CMS countries, EMA and applicant, Writing Public Assessment Report, _ Project management of national market license applications.
   - Country: Iceland
2. Employer: Icelandic Medicines Agency
   - Start date: 042018
   - End date: 042022
   - Position: _ Assessor of Bioequivalence Studies
   - Activities: _ Assessment of Bioequivalence Studies _ Responsible to follow current EMA guidelines in assessment _ Assessment of product information sections with clinical and non_clinical data _ Writing the corresponding BE assessment reports
   - Country: Iceland
3. Employer: Icelandic Medicines Agency
   - Start date: 022014
   - End date:
   - Position: Risk Management Plan Assessor
   - Activities: _ Risk Management Plan assessment _ Assessment of the medicinal product´s safety and efficacy in procedures for renewal of the marketing authorisation _ Assessment of data devoted to changes in Risk Management and safety specification within procedures for variation of marketing authorisation _ Assessment of: product information data; risk minimisation tools (routine and additional) _ Responsible to follow current EMA guidelines in assessment _ Writing the corresponding reports within aforementioned procedures _ PSUR assessment
   - Country: Iceland
4. Employer: Icelandic Medicines Agency
   - Start date: 022016
   - End date: 122017
   - Position: Expert in the RMS team
   - Activities: _ Assessment and all other coordination of work on RMS applications post_licensing (variations, renewals, PSURs), apart from those parts of the dossier that are delegated to specilised assessors _ Supervision of variations, renewals and PSURs and other life cycle management of the marketing authorisation when the IMA is acting as RMS _ CMS project management, i.e. follow up on certain CMS variations and renewals in accordance with the relevant SOP
   - Country: Iceland
5. Employer: University of Iceland, Faculty of Pharmaceutical Sciences
   - Start date: 102009
   - End date: 122013
   - Position: PhD student
   - Activities: _ Analysis of pharmaceutical substances and rw materials, medicines, excipients, etc. via different techniques _ Scientific, technical, laboratory work; carrying out experimental research _ Method development, data recieving, processing and analysis of results _ Scientific literature search, preparation of reports, presentations, scientific manuscripts _ Assisting, training and teaching of colleagues and students _ Collaboration with other research groups, work planning
   - Country: Iceland
6. Employer: University of Iceland, Faculty of Pharmaceutical Sciences
   - Start date: 032009
   - End date: 092009
   - Position: Laboratory Assistant
   - Activities: _ Orginising and preparing, setting up and performing experiments in vitro devoting to investigation of properties of pharmaceutical substances _ Assisting of colleagues in preparing and performing experiments
   - Country: Iceland
7. Employer: Pharmaceutical Organization
   - Start date: 102005
   - End date: 122008
   - Position: Tender Manager, Sales Manager, Office Manager
   - Activities: _ Preparing documentation for tender offers _ Performing of wholesale of medicnal products and medicinal goods; preparation of relevant documentation _ Contacting competent authorities, such as Departments of Public Health, in different regions of the country _ Managing and handling documentation related to delivery of medicines according to the tender offers _ Contacting customers, representatives of health facilities and hospitals with regard to wholesales of the medicines and tender sales.
   - Country: Russian Federation

Education and training

1. Subject: University of Iceland, Faculty of Pharmaceutical Sciences
   - Start date: 102009
   - End date: 122013
   - Qualification: PhD
   - Organisation: _ Research Project: Cationic amphiphilic quaternized aminocalix[4]arenes as novel potential drug delivery vehicles (vectors) _ Investigation of physico_chemical properties of macrocyclic molecules, cavitands, excipients, pharmaceutical substances. _ Molecular chemistry of macrocyclic molecules, cyclodextrins, calixarenes, polymers, pharmaceutical excipients. _ Laboratory animal Sciences course.
   - Country: Iceland
2. Subject: Ivanovo State University, Department of Biology and Chemistry
   - Start date: 092000
   - End date: 062005
   - Qualification: MSc in Biology
   - Organisation: Specialization: zoology; anatomy of animals. Main subjects: _ Chemistry (analytical, non_organic, organic, physical and colloidal chemistry) _ Biochemistry and molecular biology _ Biology (common biology, zoology, botany, microbiology) _ Anatomy and physiology of humans and animals _ Immunology _ Cell biology _ Histology _ Genetics _ Ecology _ Mathematics and statistics _ Physics
   - Country: Russian Federation

Additional information

Publications

1. Elena V. Ukhatskaya, Sergey V. Kurkov, Martha A. Hjálmarsdóttir, Vladimir A. Karginov, Susan E. Matthews, Roman V. Rodik, Vitaly I. Kalchenko, Thorsteinn Loftsson. Cationic quaternized aminocalix[4]arenes: cytotoxicity, haemolytic and antibacterial activities. Int J Pharm, 2013, 458 (1), 25_30. 2. Elena V. Ukhatskaya, Sergey V. Kurkov, Roman V. Rodik, Vitaly I. Kalchenko, Susan E. Matthews, Phatsawee Jansook, Torsteinn Loftsson. Surface_activity and self_aggregation ability of three cationic quaternized aminocalix[4]arenes. J Incl Phenom Macrocycl Chem, 2013. DOI: 10.1007/s10847_013_0370_6. 3. Elena V. Ukhatskaya, Sergey V. Kurkov, Susan E. Matthews, Thorsteinn Loftsson. Encapsulation of drug molecules into calix[n]arene nanobaskets. Role of aminocalix[n]arenes in biopharmaceutical field. (Review) J Pharm Sci, 2013, 102 (10), 3485_3512. 4. Elena V. Ukhatskaya, Sergey V. Kurkov, Susan E. Matthews, Thorsteinn Loftsson. Antifungal drug solubilizing activity and self_aggregation ability of cationic aminocalix[4]arene in comparison to SBEβCD: effect of addition of water_soluble polymer. J Incl Phenom Macrocycl Chem., DOI 10.1007/s10847_013_0302_5. 5. Sergey V. Kurkov, Elena V. Ukhatskaya, Thorsteinn Loftsson. Drug/Cyclodextrin: beyond inclusion complexation. J Incl Phenom Macrocycl Chem., 2011, 69, 297_301. 6. Elena V. Ukhatskaya, Sergey V. Kurkov, Susan E. Matthews, Amani El Fagui, Catherine Amiel, Florent Dalmas and Thorsteinn Loftsson. Evaluation of a cationic calix[4]arene: solubilization and self_aggregation ability. Int J Pharm, 2010, 402, 10_19.

Projects

Memberships

Member of Pharmacovigilance Work Sharing Procedures Working Party (PhV WS WP), April 2018 _ April 2022. Member of American Association of Pharmaceutical Scientists (AAPS), 2010_2011

Other Relevant Information

Trainings: 14 May 2014: Webinar on procedural aspects of the PSUR/PSUSA procedure in the new EMA structure. 27 June 2014: SmPC Advisory Group webinar: Paediatric information. EMA 13 October 2014: SmPC Advisory Group webinar: SmPC safety information. EMA 22 October 2014: Ad Hoc Meeting of the PSUR Work Sharing Working Party – Summary Assessment Reports. EMA 23 October 2014: PhV assessments. Challenges and solutions for PhV assessors. Webinar, EMA. 5 December 2014: SmPC Advisory Group webinar: Update and case studies. EMA 30 January 2015: Single assessmnet of Periodic Safety Update Reports with nationally authorised medicinal products. EMA 19 March 2015: Webinar from EDQM: Biologicals of the twenty_PhEur_st century". 31 March 2015: Training for assessors: Webinar on the review of the English Product Information for initial MA. EMA. 12 October 2015: Regulatory Awareness Session on Post_authorisation safety studies. Webinar. EMA. 12 October 2015: SmPC Advisory Group webinar: Consistency of SmPC efficacy information within therapeutic class. EMA. 19_20 November 2015: NCA assessors´training, teleconference. Pharmacovigilance assessments – challenges and solutions for PhV assessors. EMA. 7 December 2015: SmPC Advisory Group webinar: SmPC safety information: guideline and „class" consistency. EMA 19 January 2016: PSUR Repository – training of member state users on the new functionality. Webinar. EMA 22 April 2016: Pharmacovigilance training (Eudravigilance, PASS, Signal Management, RMP, PSURs). EMA. Webinar. 17 May 2016 PSUR Repository NCA training. Webinar. EMA 26 May 2016. PSUR Repo Interactive Q&A session with NCAs (member states). Webinar. EMA 13 June 2016. Mandatory use of PSUR Repository. Webinar. EMA 20_21 September 2016: SCOPE Work Package 8 (WP8) – Lyfecycle Pharmacovigilance – training course. Lisbon, Portugal. Webinar. 24 February 2017: SmPC Advisory Group webinar: Review of SmPC safety information. EMA. Webinar. 27 April 2017: SmPC Advisory Group webinar: Labelling and Package Leaflet: readability and consistency with SmPC. EMA. Webinar. 22 September 2017: SmPC webinar: Interpolation of interactions. EMA. Webinar. 13_14 November 2017: Pharmacovigilance assessments – challenges and solutions for pharmacovigilance assessors. EMA. Webinar. 24 November 2017: SmPC webinar: EudraSmPC website – What´s new? EMA. Webinar 17 May 2018: CTS dedicated features training. EMA. Webinar 20 June 2018: Pharmacovigilance Training. EMA. Webinar. 15_16 November 2018: Pharmacovigilance assessments – challenges and solutions for pharmacovigilance assessors. EMA. Webinar 30_31 January 2019: ICP Pharmacovigilance Training, MEB. 7 May 2019: Webinar: EU Network Regulatory Assessors´ Training Session on Orphan Similarity. 11_12 November 2019: F2F_ Pharmacovigilance assessments_challenges and solutions for pharmacovigilance assessors 2019, EMA, 17 hours. 17_18 November 2020 – Forum on Bioequivalence Inspection 2020, Webinar. 12 December 2020 – Public stakeholder meeting: development and authorisation of safe and effective COVID_19 vaccines in the EU; EMA, broadcasting. 18 February 2021 – MEB Science Day 2021 – The evolution of 25 years of PhV, NL, Broadcasting and teleconference 17th September 2021 _ Instrument for Pre_accession Assistance (IPA) Advanced Virtual EMA Training on the EU Regulatory System for medicines, Webinar "Risk Management Plans: Theory and Practice". 21 Sept 2021 – Uppsala Monitoring Centre Course – "Communicating the importance of PhV and your work", self_paced course. 24 Sept 2021 _ Uppsala Monitoring Centre Course – "Collecting high quality ADR reports", self_paced course 29 Sept 2021 _ Uppsala Monitoring Centre Course – "PhV management systems and terminologies", self_paced course 4_5 Oct 2021 – Bioequivalence and IVIVC, online training course by SYMMETRIC. 20 Oct 2021 _ Uppsala Monitoring Centre Course "Signal detection and assessment", self_paced course. 7 Dec 2021 _ Pharmacovigilance assessments – challenges and solutions for pharmacovigilance assessors, Webinar, EMA, 8 hours 8 Dec 2021 _ Instrument for Pre_accession Assistance (IPA) Advanced Training on the "EU Regulatory System for medicines" Risk Management Plans: Case Studies; 09.30 – 11.00 Conferences: 29 January 2020 – 13th Pharmacovigilance conference, Amsterdam, Medicines for Europe 30_31 January 2020 – 19th Regulatory and Scientific affairs conference, Amsterdam, Medicines for Europe 23rd of November 2020 – CORS conference (Copenhagen Centre for Regulatory Science) "Pandemics as driver for regulatory innovation – regulatory changes in times of disaster", broadcasting. 29th January 2021 – Medicines for Europe conference 2021; Session 5 – PhV in 2021: what can we expect? NL, Webinar. Trainings in Project Management: 1. Basic knowledge of EU Medicines Regulation – 17.05.2022 2. Basic principles of the MRP and DCP – 17.05.2022 Trainings on EU NTC Learning Management System: _ Bioequivalence inspectors online videos _ Forum on BE Inspection _ Pharmacovigilance: Risk Management Plan _ Pharmacovigilance: Periodic Safety Update Reports _ The EU Pharmacovigilance Network _ Pharmacovigilance: Signal Management _ Pharmacovigilance: Post Authorisation Safety Studies _ Recording: PhV assessments _ challenges and solutions for PhV assessors (2017) _ Audio recording of Benefit/Risk Training (CHMP) _ Additional Monitoring _ Risk Management Plan Assessment _ Good Practice in the Exchange of Information between PV Assessors and Pharmacovigilance

Inspectors _ Recording: Pharmacovigilance: Concepts, Definitions and Methods (20/06/2018) _ EV_M8 _ Accessing Article 57 data via the Eudravigilance Data Analysis System (EVDAS) _ PSUR repository training for NCA users _ Periodic Safety Update Report (PSUR) and PSUR Single Assessment (PSUSA)