Curriculum Vitae

Personal information

Ivana Zadro Grahovac

Work experience

02.2024 - present: Principal Advisor for Regulatory Affairs, Agency for Medicinal Products and Medical Devices (HALMED)

12.2019 – 02.2024: Senior Advisor - Specialist II for Validation of Applications, Agency for Medicinal Products and Medical Devices (HALMED)

12.2018 – 12.2019: Senior Advisor - Specialist I for Validation of Applications, Agency for Medicinal Products and Medical Devices (HALMED)

10.2017 – 12.2018: Senior Advisor for Validation of Applications, Agency for Medicinal Products and Medical Devices (HALMED)

11.2015 – 10.2017: Scientific Advisor for Validation of Applications, Agency for Medicinal Products and Medical Devices (HALMED)

01.2014 – 11.2015: Senior Regulatory Affairs Specialist, Agency for Medicinal Products and Medical Devices (HALMED)

03.2013 – 01.2014: Senior Regulatory Affairs Associate , Agency for Medicinal Products and Medical Devices (HALMED)

07.2012 – 03.2013: Regulatory Affairs Associate, Agency for Medicinal Products and Medical Devices (HALMED)

activities and responsibilities in HALMED (from July 2012 till now)

- validation of applications for marketing authorisation for national and MRP/DCP procedures where Croatia acts as CMS and RMS
- validation of simplified repeat use procedures (sRUP) in which Croatia was included as CMS
- validation of applications for renewal of marketing authorisation for national and MRP/DCP procedures
- validation of applications for upgrade of marketing authorisation for national procedures
- validation and assessment of applications for administrative variations and validation of applications for quality and safety variations
- communication with experts from European regulatory agencies and marketing authorisation holders in Croatia and in the EU
- mentoring of new employees

10.2007 – 07.2012: Associate in Viral Vaccine and Interferon Quality Control Unit, Institute of Immunology Inc., Zagreb, Croatia

- Preparation of documentation for marketing authorisation application for viral vaccines
- Preparation of standard operating procedures
- Preparation of validation plans for laboratory methods and laboratory equipment

Work with microscope (quality control tests for viral vaccines)

Education and training

02.2015 – 05.2017: univ. mag. pharm., University of Zagreb, Faculty of Pharmacy and Biochemistry, Zagreb, Croatia (Postgraduate Specialist Studies)

09.1998 – 09.2004: B.Sc. molecular biology, University of Zagreb, Faculty of Science, Division of Biology, Department of Molecular Biology, Zagreb, Croatia

Additional information

Publications

-Kutle L, Pavlović N, Dorotić M, Zadro I, Kapustić M, Halassy B: Robustness Testing of Live Attenuated Rubella Vaccine Potency Assay using Fractional Factorial Design of Experiments. Vaccine. 28 (2010)

-Balen B, Krsnik-Rasol M, Zamfir A, Zadro I, Vakhrushev S, Peter-Katalinić J: Assessment of N-glycan Heterogeneity of Cactus Glycoproteins by One Dimensional Gel Electrophoresis and Matrix Assisted Laser/Desorption Time-of-Flight Mass Spectrometry. Journal of Biomolecular Techniques 18 (2007)

-Balen B, Krsnik-Rasol M, Zadro I, Simeon-Rudolf V: Esterase activity and isoenzymes in relation to morphogenesis in Mammillaria gracillis Pfeif. Tissue culture. Acta Bot Croat,Vol 63 (2004)

Projects

Memberships

Other Relevant Information

Presentations

- Zadro Grahovac I: 11. Croatian congress of pharmacology with international participation, Amended variation regulation – overview and practical experiences, Split, September 25 - September 28, 2025
- Zadro I: EU Twinning Project "Support to the Agency for Medicines and Medical Devices of Montenegro (CALIMS)"; Activity 3.1.1 - Assessment of documentation for medicinal products: EU variation system, July 7 - July 8, 2021
- Zadro I: DIA Conference - Sharing post EU Accession Experience, Croatian Regulatory Perspective (online workshop), October 29 - October 30, 2020
- Zadro I, Čačić L: Variation Workshop (Medicademy in collaboration with HALMED and the Croatian Pharmaceutical Industry): Variations - preparation and submission, Zagreb, May 4 - May 5, 2017
- Zadro I: Science & Standards Symposium on Biologics & Biotechnology: Advancing Quality Standards through Analytics and Assays, USP, Seattle, Washington, October 3 – October 6, 2011 (invited presentation: Vaccine case study)

Seminars

- Atrium Module 6: Quality - Drug Substance and Drug Product, Copenhagen, Denmark, 04-06 November 2019
- DIA CMC Workshop, Basel, Switzerland, 20-21 June 2018
- Atrium Module 9: Product Life Cycle Activities, Copenhagen, Denmark, 28-30 November 2017
- “ECA - API Regulatory Starting Materials”, Prague, Czech Republic, 23- 24 February 2016
- “Advanced European Regulatory Affairs” London, UK, 11-14 February 2014
- "Global eSubmissions” Hamburg, Germany, 21-22 October 2014
- “ECA - Handling Changes and Variations” Barcelona, Spain, 28- 29 April 2015