Curriculum Vitae

Personal information

Lina Čačić

Work experience

Principal Advisor for Regulatory A**ffairs**
HALMED (Croatian Agency for Medicinal Products and Medical Devices) [Aug 2022 – Present]
- International cooperation in the field of medicines
- Development of national legislation supplementing VMP Regulation
- Regulatory A**ffairs Advice**

Various positions (Advisor to Senior Advisor) in Department for Validation of Applications
HALMED (Croatian Agency for Medicinal Products and Medical Devices) [Aug 2015 – Aug 2022]
- Assessment of validity of applications for variations for human medicines
- Preparation and delivery of training in the field of validation of documentation for medicines for HALMED st**aff and applicants**
- Participation in database improvements (National Registry for Medicinal Products and Medical Devices)

Various positions (Associate to Senior Associate – Specialist) in Department for Quality, Safety and E**fficacy Assessment; Regulatory Affairs Department and Department for Quality Control and Quality Assessment of Immunologicals**
HALMED (Croatian Agency for Medicinal Products and Medical Devices) [Jul 2007 – Aug 2015]
- Assessment (Quality) of applications for Marketing Authorisations / Renewals / Variations for Biologicals
- Assessment (Quality) of applications for Variations for Human Medicines (Chemicals)
- Participation in database development (National Registry for Medicinal Products and Medical Devices)
- Participation in development of secondary legislation, guidelines, instructions and internal SOPs in the field of medicines to ensure approximation with the EU legislation and other international acts / guidelines
- Quality control of vaccines for human use

Education and training

Dipl. Ing. Biology (MSc)
University of Zagreb, Faculty of Science, Croatia [Jul 1999 – Mar 2005]

Additional information

Publications

Projects

EU4Health Joint Action (JA) on increasing capacity building of the EU medicines regulatory network (IncreaseNET): JA addresses two major challenges in the EMRN: Lack of resources in NCAs to deal with all applications (EMA/MRP/DCP/national) and Rapid evolution of science and innovative technologies for which sufficient expertise and frameworks are not currently available. The project is co-financed by the EU and MSs with the value of EUR 10 000 000 and the implementation period is 36 months (TBD – Present).
Role in the JA: Work Package 2 Leader (Dissemination and communication).

EU Twinning Project "Support to the Institute for Medicines and Medical Devices of Montenegro", Montenegro, Podgorica: The overall objective of the project was to assist Montenegro in the process of accession to the EU by contributing to legislation alignment and enforcement in the field of free movement of goods (Chapter 1), with special focus on finalising the transposition of the Union acquis and supporting the application of the EU and international good practices (ICH, PIC/S …) in the field of pharmaceuticals and medical devices. The specific objective of the project was to enhance and consolidate the institutional and operational capacities of the Institute for Medicines and Medical Devices of Montenegro (CInMED) to perform its statutory duties and contribute to the health care system improvement and patients' protection, by ensuring compliance with the EU standards, guidelines and good practices relevant to Chapter 1 of the Union acquis – 'Free Movement of Goods' concerning registration, marketing and consumption of medicines and medical devices. The project was co-financed by the EU and Montenegro with the value of EUR 400 000 and the implementation period was 18 months (29 January 2021 – 28 July 2022).
Role in the project: Resident Twinning Advisor

EU Twinning Light Project "Strengthening of expert capacity in implementation of EU legislation on medicines in the Croatian Agency for Medicinal Products and Medical Devices" with MS partner Agencia Española de Medicamentos y Productos Sanitarios (AEMPS): Goal of the Project: Support in continuing development and strengthening of operational capacities of HALMED, which will contribute to continuation of harmonisation of national legislation with EU and thus ensure full compliance with European standards. The project was financed by the EU with the value of EUR 250 000 and the implementation period was 6 months (Dec 2010 – June 2011).
Role in the project: Croatian (beneficiary) Team Leader for activities related to Assessment of biological products (Vaccines and Sera)

Memberships

HMA Veterinary Strategy Focus Group (VSFG) member (April 2023 - Present)
EDQM Group of Experts No 15 (Sera and Vaccines) Croatian delegate (2012 - 2015)

Other Relevant Information