EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Maja Tabak-Slošić

Work experience

1. Employer: Agency for Medicinal Products and Medical Devices (HALMED), Croatia
   - Start date: 012022
   - End date:
   - Position: Senior Pharmaceutical Officer
   - Activities: Quality assessment of generics (NP and DCP) and WEU, participation in HALMED's Scientific advice group (quality topics), alternate member in QWP group for Croatia (till July 2023), Member of HALMED's Medicinal Products' Safety Committee, member of QWP support group on topic ICH Q1/Q5C
   - Country: Croatia
2. Employer: Agency for Medicinal Products and Medical Devices (HALMED), Croatia
   - Start date: 022012
   - End date: 012022
   - Position: Senior Scientific Advisor _ Specialist in the Regulatory Dpt
   - Activities: pre_ and post_approval activities: CADREAC procedures, preparation for EU legislation (MRP, DCP), validations of MA CMDh delegate for Croatia, QWP alternate member from July 2013
   - Country: Croatia
3. Employer: Agency for Medicinal Products and Medical Devices (HALMED), Croatia
   - Start date: 092010
   - End date: 022012
   - Position: Scientific Advisor, Pre_Authorisation Division
   - Activities: Quality assessment of generics (NP), handling with variations and renewals in NP, SOP_s, CMDh delegate for Croatia from September 2011
   - Country: Croatia
4. Employer: Agency for Medicinal Products and Medical Devices (HALMED), Croatia
   - Start date: 062010
   - End date: 092010
   - Position: Senior Scientific Associate _ Specialist, Quality assessor
   - Activities: Quality assessment of generics (NP), handling with variations and renewals in NP
   - Country: Croatia
5. Employer: PLIVA Croatia Ltd.
   - Start date: 011987
   - End date: 062010
   - Position: Stability and Audit Manager
   - Activities: quality of the products nominated for registration in EU, non_EU and USA: pre_approval stability studies of generics (solids, semi_solids, liquids), API_s and Biotechnological products, development and characterisation of drugs, compapibility studies, setting specifications, GMP compliance in analytics of drugs
   - Country: Croatia

Education and training

1. Subject: Faculty of Pharmacy and Biochemistry, University of Zagreb, Zagreb
   - Start date: 1982
   - End date: 1986
   - Qualification: Master of Pharmacy
   - Organisation: Pharmacy
   - Country: Croatia
2. Subject:
   - Start date: 011987
   - End date: 052010
   - Qualification: Mag. Pharm.
   - Organisation: Trainings: Visiongain Ltd 2009: Stability testing Conference Stability testing: Informa Life Sciences 2008; ECA 2005; APV 2001; The CfPA 1993 Skin product development; The CfPA 2007 Setting Specifications – Acceptance Criteria; ECA 2005 How to Prepare and Manage a Successful Regulatory Inspection; David Begg associates 2005 EU Regulatory Requirements; Croatian Pharmaceutical Society 2005 EU regulatory requirements; SMI Group Ltd. 2003. Documentum/myProcess application users course; Infotehna Lifescience 2003 Managing People MCE 2001 Generics in EU and CEE; European Generic Medicines Association 2001 Pharmaceutical Project Management Course; MCE 1999: Qualification/validation of Processes And Systems for Sterile Pharm Products; CfPA1998
   - Country:
3. Subject:
   - Start date: 062010
   - End date:
   - Qualification: Mag. Pharm.
   - Organisation: Trainings: Drug/Device and Device/drug combinations in the EU and USA _ on line Management Forum, UK, March 2022 GMP and Quality Requirements for Radiopharmaceuticals – Live Online Tranining _ ECA & Concept Heidelberg, 2021 2nd APV Continuous Manufacturing Conference _ APV, . 2020 6. Croatian congress on Pharmacy with international participation (poster presentation), 2019 EMQ QWP Seminar/training for senior

assessors Learn to develop and draft regulatory documents on quality, 2019 1st APV Cont Mnfc Conf, 2019 XII. Central EU Symp on Pharm Technology and RA, 2018 QWP Training for Advanced Quality Assessors (Mathematical models, ICH Q3D, GL on the selection of sterilisation processes for API, DP and Primary packaging, GMP related aspects, ICH M7, EMA Quality overview), 2018, EMA QWP training for sen assessors (Starting material, Medical errors, Sterile drugs and manufacturing, Diss testing, QbD and DoE); 2017, EMA Quality Assessment on specific types of products, EMA&QWP&AIFA, 2016 New generation of Pharmacovibilance, Halmed, 2016 DIA 28th Annual EuroMeeting, 2016 5th Croatian Congress on Pharmacy, 2015 Leachables & Extractables, ECA Academy, 2015 EDQM:50 years of leadership in the quality of medicines _ Paving the way for the future, 2014 New Inspector Training Course, IMB and PIC'S, 2014 Genotoxic Impurities; Informa Life Science; 2013 European RA; In_depth Review of Current Registration Procedures in the European Union, DIA 2011 Information on drugs; MZRH& HALMED&AFSSAPS&HFD&HUPL, 2011 Twinning light with Spanish Agency, 2011: MA procedure Europe, EMA & HALMED, 2011 Quality_assessors training on Efficient and Effective Quality Assessment 2011, EMA & AGES & BfArM H and Vet Pharm Regulation – Towards EU Accession: Serbia's Regulatory Challenges, Expectations and Opportunities", EMA & ALIMS, 2010 EMA IPT – 2010: Q Ass Training on sterile mnfc, QWP related activity

- Country:

Additional information

Publications

Croatian Pharmaceutical society journal (2002, author): Stability testing requirements

Abstracts of the 6th ESGENA Conference and 10th United European Gastroenterology Week (co_author): UEGW in: European Journal of Pharmaceutical Sciences (ISSN 0928_0987) 17 (2002) (Sl): Safety, tolerability and pharmacokinetics of PL 14736, a novel agent for treatment of ulcerative colitis, in healthy male volunteer

Projects

Memberships

Memberships:

- Croatian Pharmaceutical Society
- Medicinal Products' Safety Committee

- EMA QWP, alternate member (2013-2023)
- Editorial board of the Pharmaceutical gazette (Official Gazette of Croatian Pharmaceutical Society)

Oral presentations:

- 2011: First Congress on Pharmacy with International Participation, (Montenegro): Regulatory requirements for stability testing in EU
- 2009: Visiongain Ltd: Conference on Stability testing (London): Stress testing of APIs and drug products
- 2008: Informa Life Sciences (Vienna): Predict your stability results through well designed stress tests
- 2001: Second Croatian Congress on Pharmacy with International Participation (Cavtat, Croatia): Stability testing of Azithromycin injections

Posters

- 2024: 7th Croatian Congress on Pharmacy with International Participation (Dubrovnik, Croatia): Titanium dioxide in medicinal products - are there any changes in the regulation?
- 2019: 6th Croatian Congress on Pharmacy with International Participation (Dubrovnik, Croatia): Selection of sterilisation method – new EU guideline and HALMED's experiences
- 2015: 5th Croatian Congress on Pharmacy with interantional Paritcipation (Rovinj, Croatia): In-use shelf life of human medicinal products
- 2005: Third Croatian Congress on Pharmacy with International Participation (Cavtat, Croatia)
- 2002: 4th world Meeting on Pharmaceutics, Biopharmaceutcs and Pharmaceutical Technology (Florence, Italy)
- 1996: First Croatian Congress on Pharmacy with International Participation (Zagreb, Croatia)

Other Relevant Information

Oral presentations: 2011: First Congress on Pharmacy with International Participation, (Montenegro): Regulatory requirements for stability testing in EU 2009: Visiongain Ltd: Conference on Stability testing (London): Stress testing of APIs and drug products 2008: Informa Life Sciences (Vienna): Predict your stability results through well designed stress tests 2001: Second Croatian Congress on Pharmacy with International Participation (Cavtat, Croatia): Stability testing of Azithromycin injections