



Curriculum Vitae

Personal information Tamara Mandusic Nazor

Work experience

1. 1. Employer: Agency for Medicinal Products and Medical Devices
2.
 - Start date: 01/2023
 - End date: present
 - Position: Expert Assessor for Biological Medicinal Products
 - Activities: Quality Assessment (quality parts of documentation) of Vaccines, Biotech Medicinal Products, Blood Products, and for conventional Medicinal Products/Chemicals (assessment of quality parts of documentation for Variations); Scientific Advices
 - Country: Croatia
3. Employer: Agency for Medicinal Products and Medical Devices
4.
 - Start date: 11/2017
 - End date: 01/2023
 - Position: Senior Advisor Specialist II for Quality Assessment
 - Activities: Quality Assessment of Vaccines (quality parts of documentation for MA/Renewal/Variations), Biotech Medicinal Products (assessment of quality parts of documentation), Blood Products and for conventional Medicinal Products/Chemicals (assessment of quality parts of documentation for Variations); Scientific Advices
 - Country: Croatia
5. Employer: Agency for Medicinal Products and Medical Devices
6.
 - Start date: 11/2015
 - End date: 11/2017
 - Position: Senior Advisor Specialist I for Quality Assessment
 - Activities: Quality Assessment of Vaccines (quality parts of documentation for MA/Renewal/Variations), Biotech Medicinal Products (assessment of quality parts of documentation), and for conventional Medicinal Products/Chemicals (assessment of quality parts of documentation for Variations)
 - Country: Croatia
7. Employer: Agency for Medicinal Products and Medical Devices
8.
 - Start date: 04/2013
 - End date: 11/2015
 - Position: Senior Advisor for Quality Assessment
 - Activities: Quality Assessment of Vaccines (quality parts of documentation for MA/Renewal/Variations), Biotech Medicinal Products (assessment of quality parts of documentation and further education), and for conventional Medicinal Products/Chemicals (assessment of quality parts of documentation for Variations)
 - Country: Croatia
9. Employer: Agency for Medicinal Products and Medical Devices
10.
 - Start date: 04/2012
 - End date: 04/2013
 - Position: Advisor for Quality Assessment
 - Activities: Quality Assessment of Vaccines (quality parts of documentation for MA/Renewal/Variations), Biotech Medicinal Products (education in assessment of quality parts of documentation), and for conventional Medicinal Products/Chemicals (assessment of quality parts of documentation for Variations)
 - Country: Croatia
11. Employer: Agency for Medicinal Products and Medical Devices
12.
 - Start date: 05/2010
 - End date: 04/2012
 - Position: Senior Scientific Associate _ Specialist
 - Activities: Quality Control of Immunobiologicals (vaccines, allergenes, blood/plasma derivatives) for batch release, Participation in GMP Inspection for Vaccines and Blood derivatives governed by Pharmaceutical Inspector from Ministry of Health and Welfare, Reconstruction of Biological Laboratory
 - Country: Croatia
13. Employer: Agency for Medicinal Products and Medical Devices
14.
 - Start date: 09/2006
 - End date: 05/2010
 - Position: Quality Control Senior Associate for Viral Vaccines
 - Activities: Quality Control of Immunobiologicals (for batch release), Quality Assessment of Immunological Medicinal Products (quality parts of documentation for MA/Renewal/Variation), Quality Control of Medicinal Products (sterility, LAL gel clot), Participation in GMP Inspection for Immunologicals and Medical Devices governed by Pharmaceutical Inspector from Ministry of Health and Welfare
 - Country: Croatia
15. Employer: Agency for Medicinal Products and Medical Devices
16.
 - Start date: 10/2004
 - End date: 09/2006
 - Position: Quality Control Associate
 - Activities: Quality Control of Immunobiologicals (for batch release), Quality Assessment of Immunological Medicinal Products (quality parts of documentation for MA/Renewal/Variation), Participation in GMP Inspection for Immunologicals and Medical Devices governed by Pharmaceutical Inspector from Ministry of Health and Welfare
 - Country: Croatia

- 17. Employer: Agency for Medicinal Products and Medical Devices
- 18.
 - Start date: 02/2004
 - End date: 10/2004
 - Position: Quality Control Associate
 - Activities: Education in the viral vaccines QC, MEDICAL DEVICES ACTIVITIES: Approvals for Importing Medical Devices, Conformity Assessment of Medical Devices, Participation in development of draft legislation from the scope of work of the Agency
 - Country: Croatia
- 19. Employer: University Hospital "Merkur"
- 20.
 - Start date: 09/2002
 - End date: 09/2003
 - Position: Intern
 - Activities: All fields of general medical biochemistry and hematology, including relevant immunochemistry in Emergency room. Other responsibilities included specialized units for: Molecular diagnostics, Flow cytometry, Proteins and markers of tumor, Enzymes, drugs and narcotics, Hormones, Hematology, Coagulation; Preparation for accreditation of Laboratory according to ISO Norm, Handling of biological material.....
 - Country: Croatia

Education and training

- 1. Subject: Bioassays and Bioanalytical Methods
- 2.
 - Start date: 03/2021
 - End date:
 - Qualification: _
 - Organisation: Fleming
 - Country: Austria
- 2. Subject: Principles of Proteomics
 - Start date: 02/2020
 - End date:
 - Qualification: _
 - Organisation: BIOCentre, Zagreb
 - Country: Croatia
- 3. Subject: Essential Aspects of Biopharmaceutical Manufacturing
 - Start date: 10/2019
 - End date:
 - Qualification: _
 - Organisation: Biotech Training Facility, Leiden
 - Country: Netherlands
- 4. Subject: EU and International assessors training on biosimilars
 - Start date: 11/2016
 - End date:
 - Qualification: _
 - Organisation: EMA
 - Country: Austria
- 5. Subject: Quality by Design_Design – New concepts for chemical and biotech product development and optimisation
 - Start date: 09/2015
 - End date:
 - Qualification: _
 - Organisation: DIA
 - Country: Germany
- 6. Subject: Biotechnology for non Biotechnologist _ all about manufacturing and quality control of biotech
 - Start date: 04/2013
 - End date:
 - Qualification: _
 - Organisation: Managment Forum
 - Country: France
- 7. Subject: HALMED _ AEMPS
 - Start date: 02/2011
 - End date: 03/2011
 - Qualification: _
 - Organisation: Twinning Light project IPA/2007/IB/SO/01TL "Strengthening the expert capacity in the implementation of European legislation in the Agency for Medicinal Products and Medical Devices", in the area of quality control and quality assessment of blood/plasma derivatives and vaccines; training in Zagreb and training and vist to OMCL in AEMPS, Spain
 - Country: Croatia
- 8. Subject: GMP for vaccine manufacturers
 - Start date: 10/2010
 - End date:
 - Qualification: _
 - Organisation: ECA
 - Country: Germany
- 9. Subject: Human mistakes and how to avoid them (in analytical laboratory)
 - Start date: 09/2010
 - End date:
 - Qualification: _
 - Organisation: Supera
 - Country: Croatia

10. Subject: Biological Safety Cabinets
 - Start date: 01/2010
 - End date:
 - Qualification: _
 - Organisation: Farmago
 - Country: Croatia
11. Subject: Batch Release for Human Vaccines
 - Start date: 10/2009
 - End date:
 - Qualification: _
 - Organisation: EDQM
 - Country: France
12. Subject: Quality assurance of analytical results
 - Start date: 05/2009
 - End date:
 - Qualification: _
 - Organisation: Supera
 - Country: Croatia
13. Subject: Harmonisation of Ph. Eur. Methods (Ph. Eur./USP/JP)
 - Start date: 02/2009
 - End date:
 - Qualification: _
 - Organisation: Faculty of Pharmacy and Medical biochemistry, Zagreb
 - Country: Croatia
14. Subject: Uncertainty of measurement Croatian metrology society
 - Start date: 06/2007
 - End date:
 - Qualification: _
 - Organisation: Croatian metrology society
 - Country: Croatia
15. Subject: GTN on Vaccine Quality "Good Manufacturing Practice", WHO training course for inspectors WHO/KFDA
 - Start date: 11/2006
 - End date:
 - Qualification: _
 - Organisation: WHO/KFDA
 - Country: South Korea (Republic of Korea)
16. Subject: New Assessors` Training
 - Start date: 11/2006
 - End date:
 - Qualification: _
 - Organisation: EMEA
 - Country: United Kingdom
17. Subject: Good laboratory practice (analytical methods)
 - Start date: 05/2006
 - End date:
 - Qualification: _
 - Organisation: Supera
 - Country: Croatia
18. Subject: Workshop: LAL test (Gel Clot method)
 - Start date: 05/2006
 - End date:
 - Qualification: _
 - Organisation: Sopex _ Charles River
 - Country: Croatia
19. Subject: Laboratory equipment qualification
 - Start date: 04/2006
 - End date:
 - Qualification: _
 - Organisation: Supera
 - Country: Croatia
20. Subject: OMCL Network Technical Training Session for Biologicals
 - Start date: 02/2006
 - End date:
 - Qualification: _
 - Organisation: EDQM
 - Country: France
21. Subject: Preparation and Management of successful regulatory inspection
 - Start date: 10/2005
 - End date:
 - Qualification: _
 - Organisation: Supera
 - Country: Croatia
22. Subject: Alternatives 2005, International workshop on promotion of the three R`s (reduction, refinement, replacement) concept in relation to animal experimentation
 - Start date: 09/2005
 - End date:
 - Qualification: _

- Organisation: Agency
 - Country: Slovenia
23. Subject: Serological potency tests for diphtheria and other vaccines EDQM
- Start date: 10/2004
 - End date:
 - Qualification: _
 - Organisation: EDQM
 - Country: Hungary
24. Subject: Validation of Microbiological Methods Croatian metrology society, Zagreb
- Start date: 06/2004
 - End date:
 - Qualification: _
 - Organisation: Croatian metrology society, Zagreb
 - Country: Croatia
25. Subject: Medical Biochemistry, Hematology (biological, biochemical, immunochemical methods), diagnostic, Organization of the processes in the laboratory, Handling of biological material... Ministry of Health, Republic of Croatia
- Start date: 12/2003
 - End date:
 - Qualification: Master of Medical Biochemistry, Licence for independent work as medical biochemist
 - Organisation: Ministry of Health, Republic of Croatia
 - Country: Croatia
26. Subject: All fields of general medical biochemistry and hematology, including relevant immunochemistry in Emergency room. Other responsibilities included specialized units for: Molecular diagnostics, Flow cytometry, Proteins and markers of tumor, Enzymes, drugs and narcotics, Hormones, Hematology, Coagulation; Preparation for accreditation of Laboratory according to ISO Norm, Handling of biological material..... University Hospital "Merkur", Zajčeva 19, Zagreb
- Start date: 09/2002
 - End date: 09/2003
 - Qualification: Master of Medical Biochemistry (Clinical Chemistry and Laboratory Medicine), INTERN
 - Organisation: University Hospital "Merkur", Zajčeva 19, Zagreb
 - Country: Croatia
27. Subject: Medical Biochemistry, Hematology, Biochemistry, Analytical chemistry, Pharmacology.
- Start date: 09/1996
 - End date: 09/2002
 - Qualification: Master of Medical Biochemistry (Clinical Chemistry and Laboratory Medicine)
 - Organisation: Faculty of Pharmacy and Medical biochemistry, University of Zagreb
 - Country: Croatia

Additional information

Publications

T. Mandušić Nazor, P. Sokol, I. Jurač, S. Tomić, "Quality of biological medicinal products", Farmaceutski glasnik 79, 9-10/2023

Mandušić Nazor T., Pipić Kosanović M., Tomić S., „Quality Control of Seasonal Influenza Vaccines“, Arh Hig Rada Toksikol 2010:61; Professional Paper

Bobetić Vranić, T., Marušić Vrsalović M., Mandušić T., Šiftar Z., Nazor A., Flegar Meštrić Z., Kardum Skelin I., Dominis M., Jakšić B., Minigo H., Kušec R., „Frequency of Bcr/Abl p210 molecular isoforms in chronic myeloid leukemia and its clinical significance“, Biochemia medica 14 (2004); 37_45

Projects

I have been involved in full reconstruction of OMCL biological laboratory (within Agency) and in organisation and coordination of official visit of the experts from HALMED to AEMPS (Agencia Espanola de Medicamentos y Productos Sanitarios) in the Twinning Light Programme

Memberships

Member of Croatian Chamber of Medical Biochemist since 2003. (part of the Croatian education process, necessary for maintaining the license for work after graduation)

Other Relevant Information

EU NTC, lecturer: _February 2020., Madrid, Spain "The Risk Assessment Tool for Sampling and Testing of Human and Veterinary Medicinal Products" _October 2023., Tallinn, Estonia, "HMA Risk Assessment Tool of Human and Veterinary Medicinal Products"

Conferences attended/speaker: _ October 2005., 2nd Croatian Epidemiological Congress, Rovinj, Croatia, international congress, speaker: "The way for getting Marketing Authorisation for Immunobiologicals" _ June 2006. Round table about quality assessment of medicines, ALMP, Osijek, Croatia, speaker: "Quality of vaccines" _ April 2007, Croatian Pharmacopoeia symposium _ May 2010, Annual Meeting of the OMCL Network, Split, Croatia, speaker: „QC – Overview of the results for seasonal Flu vaccines“ _ September 2010, 6th Croatian Congress of Pharmacology with International participation, Croatia, speaker: „Special Quality Control of Vaccines in the Croatian Agency for Medicinal Products and Medical Devices“