

Curriculum Vitae

Personal information Katarina Tepsic Stupica

Work experience

1. Employer: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

- Start date: 2019
- End date:
- Position: Pharmaceutical Inspector for GCP
- Activities:

_ leads and decides in the inspection supervisions in accordance with the applicable legislation and regulations, guidelines and code of ethics

- Country: Slovenia

2. Employer: Astellas Pharma d.o.o

- Start date: 2012
- End date: 2018
- Position: Clinical Operations Manager for South East Europe
- Activities:

· Project Management of Clinical trials Phase III & IV and Non-interventional studies (NIS) throughout SEE region, oversight of investigator sponsored research (ISR), development & approval of study documentation in collaboration with MA colleagues for NIS, evaluation of potential studies proposed by Research & Development in SEE region, investigator meeting organisation and participation, training of study staff at sites, managing, training & supervision of international study teams of 18 members (MSL, MAM, CRA, CRO team members), building & maintaining good relationship with respective KOLs, collaboration with multidisciplinary teams (Pharmacovigilance, Regulatory, QA, Finance, Legal & Compliance), active collaboration within EMEA MA organization, lead regular conference calls with study teams, ensuring high quality standards are adhered in all studies (adherence to Protocol, GCP, Declaration of Helsinki, Regulatory requirements, Codes of practice and Study procedures) and progress of studies to schedule & budget, management of statistical study data analysis & Final clinical study reports preparation, publication of study results, writing and reviewing applicable Standard operating procedures (SOPs), holding people management responsibilities.

- Country: Slovenia

3. Employer: Medica d.o.o

- Start date: 2010
- End date: 2012
- Position: Product specialist for Medical Devices for Intensive Care Unit & Interventional Radiology_Slovenia & BIH
- Activities:

· Demonstrating-presenting medical devices to ICU specialists and Interventional radiologists in Slovenia and BIH, organisation of education courses & presentations in Slovenia & abroad, building & maintaining good relationship with respective KOLs.

- Country: Slovenia

4. Employer: Janssen, Pharmaceutical part of Johnson & Johnson

- Start date: 2008
- End date: 2009
- Position: Clinical Research Associate (CRA)
- Activities:

· Planning and execution of non-interventional studies (NISs) in Slovenia (4 Therapeutic areas; > 50 participating sites), development of study concepts and study documentation, preparation submissions and obtaining approvals from independent CEC & RA, conducting sites visits & site management, reporting to management, PV & QA (preparation of visit reports, study progress & Adverse events, PQC), building & maintaining good relationship with respective KOLs, managing the compilation, maintenance and archiving of the TMF, working with studies responsible physicians in the development, approval and publication of final studies results.

- Country: Slovenia

5. Employer: Janssen, Pharmaceutical part of Johnson & Johnson

- Start date: 2004
- End date: 2008
- Position: Senior product specialist_Neurology, Psychiatry
- Activities:

· Participation in planning and execution of Neurology non-interventional study (12 centres & 30 investigators in Slovenia), professional marketing of antidementive drug & antipsychotics in Slovenia, management of antidementive drug (premarketing activities, analysing market & sales data, preparation of Business plan), conducting projects with KOLs (case reports, realisation of professional psychiatric magazine, workshops), trainings of new medical representatives & head nurses, developing promotional & educational materials, lecturing at local events and workshops, customer segmentation, targeting & positioning, achieve sales targets on designed territory.

- Country: Slovenia
6. Employer: Janssen, Pharmaceutical part of Johnson & Johnson
- Start date: 2001
 - End date: 2004
 - Position: Hospital medical representative & Product specialist Pain
 - Activities:
- Successfully launch a new product on the market; building & maintaining good relationship with respective KOLs (oncologists, anaesthesiologists, internists, gynaecologists, surgeons), organisation of palliative medicine workshops, writing articles for bulletins, lecturing at local events and workshops.
7. Employer: Institute of Microbiology, Biotechnical Faculty, University of Ljubljana
- Start date: 1996
 - End date: 2001
 - Position: Young Researcher
 - Activities:
- Researches in the microbiological lab, lectured in Slovenia & abroad, published articles in scientific journals.
- Country: Slovenia

Education and training

1. Subject: University of Ljubljana, Faculty of Medicine & Biotechnical Faculty
 - Start date: 1999
 - End date: 2001
 - Qualification: PhD of Microbiology Science
 - Organisation:
 - Country: Slovenia
2. Subject: University of Ljubljana, Faculty of Medicine & Biotechnical Faculty
 - Start date: 1996
 - End date: 1999
 - Qualification: M.Sc. of Microbiology Science
 - Organisation:
 - Country: Slovenia
3. Subject: University of Ljubljana, Biotechnical Faculty, Molecular_Genetic block
 - Start date: 1989
 - End date: 1996
 - Qualification: B.Sc. of Biology
 - Organisation:
 - Country: Slovenia

Additional information

Publications

Arnol M, Naumovic R, Dimitrov PE, Racki S, Bucsa AC, Covic A, Mitic I, Vavic N, Velickovic Radovanovic MR, Zibar L, Bizilj S, Erculj V, Supanc Missoni T, Tepsic Stupica K, Knotek M. (2020) Immunosuppressive regimens following kidney transplantation in five European countries: The observational RECORD study. Transplantation Reports 5 100061 Mrazek, J., Tepsic, K., Kopecky J. and Augustin G. (2006) Diet-Dependent Shifts in Ruminant Butyrate-Producing Bacteria. Folia Microbiologica 51(4), 294-298 Peterka, M., Tepsic, K., Accetto T., Kostanjsek R., Ramsak A., Lipoglavsek L. and Augustin G. (2003) Molecular Microbiology of Gut bacteria: Genetic diversity and Community structure analysis Acta Microbiologica et Immunologica Hungarica 50(4), 395-406 Tepsic, K., Auguštin G. (2001) Molecular monitoring of Ruminant Prevotellas Folia Microbiologica 46(1), 87-90 Tepsic, K., Gunde Cimerman, N. and Frisvad J.C. (1997) Growth and mycotoxin production by *Aspergillus fumigatus* strains isolated from a saltern FEMS Microbiology Letters 157, 9-12

Projects

Memberships

Other Relevant Information

March 2023_ECA Academy training GMP meets GCP; Courses/Meetings 2020_Clinical Trials Quality & Inspection Updates (Mark Poulton Quality Solutions, UK) 2020_MHRA FDA GCP Symposium 2019_GCP IWG meeting at EMA 2019_Professional exam for inspector (The law on inspection procedure, Conduct and decision making in the misdemeanor) 2018_GCP Fundamentals v1.0 (Astellas Pharma EU on line training) 2018_Leadership Academy (Gustav Kaser Training International), Slovenia 2018_Change Management_Ownership/Authority (Željko Čurić, MD; OK Consulting), Croatia 2017_Ethics in Regulatory affairs for Drugs and Medical devices; raPharm seminar, Slovenia 2016_2017_Learn to speak stats: Statistics in Clinical Trials & Descriptive Statistics (On line training; Astellas Pharma EU) 2015_GCP Fundamentals v1.0 (Astellas Pharma EU on line training) 2014_Feasibility training, SME, London, UK 2014_Medical Biostatistics training; Astellas Pharma EU, Slovenia 2014_Slovenian Medical Products & Devices Act_What's new? raPharm seminar, Slovenia 2014_Monitor and Investigator meeting, London, UK 2014_Introduction to GCP (Astellas Pharma EU on line training) 2014_Leadership through integrity in multicultural organisation (OK Consulting), Slovenia 2013_DISK & communication with HCP (Pharma Consult) 2013_Oncology & Antiinfectives Therapy Area Training, London UK 2013_Publication Champion training, London, UK 2012_Slovenian Medical Products & Devices Act_What is new? raPharm seminar, Slovenia 2002 & 2009_Course in business protocol (European school of Protocol, Duša Adamič Vidanovič), Slovenia 2003_2008, 2010_Professional rhetoric (NLP communication, Effective persuasion, negotiation, closing, professional presentation) by prof. Tatjana Gale Zidar