Curriculum Vitae

Personal information

Gordana Savic

Work experience

09.02.2024. - today: Principal Advisor for Quality Assessment, Agency for Medicinal Products and Medical Devices of Croatia (assessment of Module 3 for chemical substances)

01.06.2012. - Senior Advisor, Specialist for Quality Assessment, Agency for Medicinal Products and Medical Devices of Croatia (assessment of Module 3 for chemical substances)

07.09.2009. – 31.05.2012. - Head of Regulatory Affairs and Development department, Genera inc., Croatia (organizing and coordinating teams in the field of research and development of veterinary immunobiological drug product (vaccines) and regulatory activities for product registration on various markets)

31.12.2007. – 06.09.2009. - Regulatory Affairs Specialist, Pliva Croatia – Member of the Teva Group, Croatia (preparation and completion of Module 3 of humane medicine documentation)

01.01.2001. – 30.12.2007. - Regulatory Affairs Specialist, Veterina Animal Health ltd., Member of Pliva Group, Croatia (preparation and completion of dossier for animal health products)

20.01.1998. – 31.12.2000. - Coordinator of the R & D Laboratory for Animal Health, Veterina Animal Health ltd., Member of Pliva Group, Croatia (coordination of R & D activities in immunobiological lab.)

10.09.1992. – 19.01.1998. - Associate/Specialist in the R & D Laboratory for Animal Health, Pliva Inc. Croatia (research and development of veterinary vaccines)

Education and training

2024. EDQM Webinar: CEP 2.0: Fresh feedback from stakeholders

2023. PharmaCRO Conference, Vodice, Croatia

2022. QWP on-line training: Nitrosamines

2022. ICH Q6A Specifications (Kings College, London, on line training)

2021. EU NTC on-line course: Review of Pharmaceutical information in SmPC and Package Leaflet (Product Information)

2021. EDQM Webinar: Approaches for CEPs and the Ph. Eur. strategy with regard to nitrosamine control: Current guidance and practical implementation

2021. EDQM Webinar: Impurity Control in the European Pharmacopoeia

2020. EMA QWP on-line training: Nitrosamines; Transdermal Patches

2019. ECA - „Granulation & Tableting", Vienna, Austria

2018. ECA - ICH Q8 and Q11 Training Course: From QbD to Process Validation, Heidelberg, Germany

2017. EMA - QWP Assessor Training on writing Assessment Reports, Dublin, Ireland

2017. ECA - GMP for Beginners in sterile manufacturing + Process Simulation / Media Fills, Berlin, Germany

2016. EDQM - European Pharmacopoeia: Tackling future challenges of the quality of medicines together, Tallinn, Estonia 2023.

2015. ECA - API Regulatory Starting Materials, Barcelona, Spain

2014. ECA - Spray Drying/Solutions for Pharmaceutical Industry, Lisbon, Portugal

2013. IIR - Stability testing for pharmaceuticals, London, UK

2011. CIR, Informa Life Sciences - Regulation of Veterinary Medicine, , Barcelona, Spain

2010. EDQM - Guide for the elaboration and use of monographs on IVMPs, Strasbourg, France

2008. PTI - Introduction to European Regulatory Affairs (Pharmaceutical Training International), London, UK

2007. EMEA - Pharmaceutical Regulation – Croatia's Road to EU Membership, Split, Croatia

10.1985.-07.1992. - Doctor of Veterinary Medicine; Faculty of Veterinary Medicine, University of Zagreb, Croatia

Additional information

Publications

Projects

Memberships

Other Relevant Information