Curriculum Vitae

Personal information

Ivana Matelic

Work experience

Sep-2024 - present

Senior Advisor at Ministry of Health of Republic of Croatia, Croatia

CLINICAL TRIALS MANAGEMENT:
- processing, assessing and evaluating clinical trial documentation according to CTR
- supported and executed the final stage of transition process of conducting Clinical Trial from CTD to the CTR regulatory framework
- CTCG member

Jan-2023 - Feb-2024

Quality Asssurance Associate at Krka-Farma d.d., Croatia

CHANGE CONTROL MANAGEMENT:
- the main responsible person for monitoring and evaluation of change controls; including maintaining the oversight of respective process, keeping documentation records, tracking monthly metrics and maintaining related SOPs.
- Projects initiatives (leading the execution): implementation of the new digital system for Change Control management, educating employees of the system use and process flow, providing operational support)

CLEANING VALIDATION
- supporting role; monitoring of the execution of the annual cleaning validation plan, maintaining related documentation and SOPs

Oct 2016 - Oct 2021

GxP QA Specialist at Novartis d.o.o., Croatia

Ensuring and supporting compliance of Novartis Quality Management Systems with cGxP requirements and managing/supporting various quality aspects and projects for several countries, including:
- QMS (document and training management)
- EU Batch Certification release activities of commercial and clinical products (IMPs/non-IMPs)
- quality issues, deviations, complaints, CAPAs, recalls, counterfeits, escalations, audits
- Vendor Management (quality oversight of GMP/GDP third parties, Quality Agreements)
- Change Control / Change Management
- other activities, as required

Feb 2014 - Oct 2016

QA Assistant at Novartis d.o.o., Croatia

Supporting compliance of Novartis Quality Management Systems with cGxP requirements and managing/supporting various quality aspects and projects for Croatia, including:
- QMS (document and training management)
- EU Batch certification release activities of commercial and clinical products (IMPs/non-IMPs)
- quality issues, deviations, complaints
- other activities, as required

May 2013 - Jan 2014

Clinical Trial Administrator at Novartis d.o.o., Croatia

- processing clinical trial related documentation (collecting and archiving of clinical trial documentation, both paper based and electronic, and uploading documentation in eTMF
- providing other administrative support to CRAs and CSMs, as required

Education and training

Oct-2008 - Mar-2015
Master of Pharmacy, Pharmacy
Faculty of Pharmacy and Biochemistry, University of Zagreb, Croatia

Additional information

Publications