Alina Panourgia

Diligent, accountable and result-driven professional with extensive experience in leading regulatory submissions, pharmacovigilance projects and quality improvements initiatives; particularly well adapted in operating throughout the region of Asia, Europe, LATAM and Middle East.

Pharmacovigilance (PV)
Act as point of contact for all PV-related matters in pre- and post-marketing settings

- Risk Management and Safety Communication: preparation of RMP, REMS, USPI, SmPC, PIL, Patient Wallet (Alert) Card
- PV audits and preparation for inspections
- Project Lead in Clinical Trials; preparation of Safety Management Plans, study related documents
- Worked on various clinical research projects remotely
- SOPs, SMP, PSMF preparation; TQAs and SDEAs management;
- Signal Detection
- Registered QPPV in UAE

Regulatory Affairs (RA)

- Regulatory submissions/variations preparations in GCC, LATAM, EU, South Africa, Thailand, CIS
- CMC authoring and review of raw data (module 3)
- Medical writing for EU and US submissions (Clinical summaries)

Quality Assurance (QA)

- QMS Auditor; preparation for the audits and inspections
- Quality improvements initiatives

KEY INDUSTRY EXPERIENCE

Global Head Regulatory Affairs and PV, North Life Pharma: UAE

Freelancer in RA, PV, QA: UAE/Qatar - work as associate with various companies on project basis

Head of Quality & Regulatory, PureCircle Biotech: Malaysia

QUALIFICATION

B.Pharmacy,
First Moscow State Medical Academy,
Russia

Masters in Business Administration
Nottingham University
United Kingdom

Masters in Pharmacovigilance.
University of Hertfordshire
United Kingdom

CERTIFICATIONS

QMS Lead Auditor (ISO 9001:2015)

MedDRA: Medical Coding Training

MedDRA: SMQ and Query Building

GCC Regulatory Affairs/ PV Summit 2022 and 2023 – delegate/speaker
Drug Safety Symposium 2024 - speaker

TOPRA and ISoP organizations member

GCP training

GEOGRAPHIC EXPERIENCE

Asia
Europe
Latin America
Middle East
CIS

LANGUAGES

English
Russian
French