AUDIT

SERVICES PROPOSED

- Quality Management Systems (QMS) management which includes preparation, review, and support in the implementation of Quality Documents (Policies, Standard Operational Procedures (SOPs) and Working Instructions) as well as development and implementation of Training Management organization
- Quality Assurance Plans preparation
- Risk Identification, assessment and management, remediation plans development, performance indicators identification
- Regulatory Inspections readiness preparation and support during, after the inspection – ANSM, EMA, MHRA, BfArM, VMD, ANMV ….
- Review and analysis of Quality trends and communicating to the key stakeholders
- Root Cause analysis and Corrective and Preventive Actions (CAPA) : development, review, and management of all types of CAPAs raising from audits, inspections, and reported Quality Issues. Support on each step of the CAPA development process, including Root Cause Analysis, CAPA implementation, closure and effectiveness check, as well as subsequent trends review of identified nonconformities and findings.
- Vendors qualification, management and agreements review.
- Development and delivery of internal and external advanced and basic trainings, of lesson learned sessions and practical workshops for operational teams
- Audits (internal, vendors) and self-inspections
- Trial Master File (TMF) management, support, trainings and audits.
- Medical Writing (protocol, Clinical Study Report, PSMF, PQR, user guides …)
- Data Protection Officer (DPO) function for the EU and General Data Protection Regulation (GDPR) implementation
- Analysing information system needs of startup and TPE companies with adapted solutions proposal
- Regulated Systems Validation Process (Computer & Material – IQ, OQ, PQ)

AREAS OF EXPERTISE

- Quality Assurance (QA) & Quality Control (QC)
- Clinical trial and Low risk Studies, post-marketing activiies
- GCP, GMP, GDP, Pharmacovigilance and medical information, ISO 9001
- Human and Veterinarian Medicinal Products regulations
- Personal Data Protection, Computer Validation, Electronic Signatures
- Experience in working with a broad range of pharmaceutical companies including global pharma, biotechnology companies, Contract Research Organisations

WORK METHOD

- Integrate and work as a member of the client team, Following client working practices and culture where needed.
- Provide remote support to clients for main of the services proposed.