PHARMALIGENT LLC

Global Quality Assurance & Compliance Consulting

Pharmaligent LLC is a firm that specializes in global Quality Assurance, Quality Control for Biotechnology/Pharmaceutical products with the mission to build and maintain GxP Quality systems and processes that are fit for purpose. We serve as your quality expert representative before, during and after regulatory agency inspections including FDA, EMA, TGA, AMPS, PMDA, HEALTH CANADA, MHRA, Genzyme, Lybian Health Authority, etc.

The team comprises industry experts and ex-FDAs with 20+ years of experience and responsibilities including GMP, GCP, GLP, GDP and GVP programs and processes to assure compliance in clinical trials, commercial operations and distribution of therapy drugs. Our expertise includes small and large molecule dosage forms for portfolios of biotechnology/pharmaceutical drugs in late stage discovery through the various clinical stages, with assets moving into Phase I, Phase II, Phase III clinical trials and commercial.

Expertise

GCP Clinical Trial Quality

- *Clinical Quality System design*
- *Risk Management*
- *Clinical Quality Manuals and SOPs*
- *CAPA initiation and Management to closure*
- *Clinical Quality System implementation*
- *GCP qualifying audits for sites and vendors*
- *GCP audits for ongoing trials, routine and/or for-cause*
- *Audits of Contract Research Organizations (CROs), Central Labs, IRBs, and Data Management.*

GLP/GCP PK & Tox Laboratory Quality

- *Nonclinical and clinical laboratory GLP Audit*
- *Protocol Reviews/ Investigations per QTA*
- *Study Data and Report Audits*
- *In-Process Study Inspections*
- *Facility Inspections*
- *Standard Operating Procedures*
- *GLP Implementation*
- *GLP Training*
- *Regulatory Inspection Preparation*

GVP Pharmacovigilance Quality

- *Designing a risk-based and robust audit program*
- *Global health authorities (European GVP Modules I and IV)*
- *Audits of PV systems per Good Pharmacovigilance Practices*
- *Perform a PV system or Clinical Program "diagnostic" review*
- *Development and execution of action plans to close gaps*
- *Regulatory Inspection Readiness/ GVP Audits*

CMO/CRO Oversight and Quality Leadership

- *Collaboration with senior management to accomplish objectives*
- *Global Quality Technical Agreements/ QP-QP Agreements*
- *Building and scaling the global Quality team to resolve issues*
- *Sponsor response to regulatory inspectors worldwide*
- *Management of annual budgets for Quality Unit functions*
- *Relationship development with CMOs/CROs and negociations*

GMP Quality Systems & CMC Quality

- *Phase-appropriate Quality Management System (eQMS) creation*
- *Policies and Procedures development*
- *Change Controls, CAPAs, Deviations, OOS/OOT, Investigations*
- *QP Release; Sponsor Quality Assurance Release per the QTA*
- *Stability Studies*
- *GMP Training*
- *Technology transfer from R&D to commercial*
- *GMP Process validation/method qualification*
- *Cleaning validation and critical utilities*
- *Quality System and Computer System Audit per Part 11/ICH*
- *GMP Supplier qualification / cGMP Audits*
- *Regulatory Inspection Readiness*

Professional Experience

- *GMP Operations*, QA/QC – **Sun Pharmaceuticals**
- *GMP Operations*, QA/QC – **Dr. Reddys Labs**
- *GCP*, *GMP*, *GLP* QA/QC–**Shire Pharmaceuticals**
- *GCP Clinical*, *GMP Commercial* – **Avedro Inc.**
- *GMP Commercial Quality* – **Pharmalucence Inc.**
- *Clinical*, *CMC/GMP*– **Lantheus Medical Imaging**
- *Preclincal Development* – **Bristol Myers Squibb**
- *GMP Commercial*– **Instrumentation Laboratory**
- *GLP*, *GMP*, QA/QC–**Alkermes Pharmaceuticals**
- *GLP*, *GMP*, *GCP*, *CMC*, QA/QC – **Pfizer Inc.**
- *GMP*, *GLP*, QA/QC – **Alexion Pharmaceuticals**
- *GCP*, *GMP*, QA/QC – **Cytori Nanomedicine**
- *GCP*, *GMP*, *GLP*, QA/QC – **Bluebirdbio Inc.**
- *GCP*, *GLP*, *GMP*, QA/QC – **Concert Pharma**
- *GCP*, *GLP*, *GMP*, QA/QC – **Northern Biologics**
- *GCP*, *GLP*, *GMP QA* – **Roivant Sciences**
- *GCP*, *GMP*, *QA* – **Karyopharm Therapeutics**

Professional Affiliations

- *ISPE, PDA,ASQ, ISPOR*

Contact Information

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