ABOUT US

PharmEng has been serving the regulated life science industry for over 25 years. It counts with offices in North America, South America, Asia and Europe. Our expertise involve current regulatory practices from around the globe. We provide services to the manufacturers of pharmaceuticals, biotech products, medical devices, nutraceuticals and supply chain functions to numerous clients.

Our team of highly qualified specialists are assembled from various disciplines to meet all of your project needs. We provide cost-effective and timely solutions proven to deliver exceptional results. Working collaboratively with our clients' personnel, we ensure a cooperative relationship that maximizes productivity and efficiency. By delivering quality in every facet of our services, ensures our success through your satisfaction.

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PharmEng Technology

Your cGMP Partner

OUR SERVICES

PROJECT MANAGEMENT & ENGINEERING SERVICES

- Occupational Health & Safety Management
- Facility, Process Planning & Design
- Modelling, Simulation and Scheduling
- Budget & Cost
- Risk Assessment
- Bio-Pharmaceutical Process Engineering
- Environmental Impact Management
- Automation and Process Controls

TOXICOLOGY SAFETY ASSESSMENTS

- Toxicology Data & Safety Assessment
- Hazard Identification – Safety Assessments
- Critical Effects – Evaluation of Chemicals and Potential Effects (ADEs, PDEs, OELs)
- Determination of No Observed Adverse Effect Level (NOAEL)
- Uncertainty and Modifying Factors
- Pharmacokinetic Adjustment(s)
- Cleaning Validation Development & Support
- Extractables and Leachables
- Safety Development & Training

QUALITY SYSTEMS & COMPLIANCE

- Quality Management Consultation and Training
- Gap and Quality Performance Analysis
- Audit and Inspection Management
- ISO and cGMP Implementation
- Quality System Documentation
- Risk / Crisis And CAPA / Deviation Management
- Environment Monitoring
- ALCOA+ Assessment
- Dealing with Regulatory Organizations (FDA, EMA, AEMPS, Etc.)
- Trackable and Traceability Projects For Unforeseen Incidents

MANUFACTURING SUPPORT SERVICES

- Commissioning/Qualification/Validation
- Technology Transfer
- Process Validation
- Manufacturing Systems
- Cleaning Validation
- Facility / Utility /Equipment / Instrument Qualification
- Computer System Validation (CSV)
- Packaging
- Data Integrity Assurance

REGULATORY AFFAIRS

- Master File Preparation (DMF, SMF, MFA, VMF)
- eCTD / CTD Submission
- Prepare and Submit Post Approval Reports
- Establishment Registration and Renewal
- Product Assessment and Regulation
- Regulatory Strategy and Intelligence
- CMC Preparation

LABORATORY COMPLIANCE

- Method / Assay Validation
- Documentation Audits, Review and Remediation
- Documentation Traceability and Review

TRAINING

- Qualification: Computer / Cleaning / Process / Equipment / Utilities
- RA: Biotechnology, Pharmaceuticals and Medical Devices
- QA: Audit Programs and CAPA
- cGMPs/GLPs: FDA, Health Canada and EU