PHARMA-BIO SERV

Your global source for efficient and

COMPLIANT OPERATIONS

Regulatory Compliance

Quality Systems Support

- Remediation Activities associated to FDA 483's, Warning Letters, Consent Decrees
- PAI Readiness/Mock-ups
- QS Compliance Audits
- CAPA, APR Investigations, Change Control, Deviation Management
- Complaints Management
- SOP Development / Revisions
- Gap Analysis, Remediation & Implementation Plans
- Development and Execution of GMP Training Programs
- Supplier Quality Management
- Stability Protocols & Programs

Regulatory Affairs

- US Agents
- Establishment Registrations
- Listing of Products
- Preparation of CTD (all 5 modules)
- Regulatory Dossiers Compliance Assessments
- Preparation of responses to FDA for 483's, Warning Letters, and Consent Decrees
- Preparation of 510k and Pre-Market Approval Packages
- Preparation of Regulatory Meetings and Briefing Packages
- Filings Requirements and Post Approval Supplement (APR, AR, CBE, IND, NDA, ANDA, etc.)
- Process Change Filings
- Preparation and submission of New Dietary Ingredients Notifications

Risk-Based Validation Services

- Validation Master Plans
- Risk Based Validation
- Equipment/Manufacturing Changes & Qualification
- Manufacturing Process Validation (PV)
- Packaging Process Validation (Pkg V)
- Cleaning Validation (CV) & Calculation of PDE's
- Analytical Methods Validation (AMV)
- Software Validation & Computer Software Validation (CSV) – 21 CFR Part 11
- Capital Projects Management
- Shipping Validation
- Commissioning and Qualification
- Design (DQ), Maintenance Systems & Facilities Qualification
- Validation Protocols, Validation Reports
- Sterility Validation

Quality Risk Management

- Preliminary Hazard Analysis (PHA)
- Product and Process Risk Assessment
- Critical Process Parameters (CPP) Assessment
- Critical Quality Attributes (CQA) Assessment
- Quality Risk Management (QRM) Tools Implementation
- Sustainability Strategy Development
- QRM Integration to Quality Systems
- Interpretation and Application of QRM Guidelines
- Risk Analysis & Assessment
- Risk ID & Control (FMEA, FMECA, FTA, HAZOP, HACCP)
- ICH Guidelines Compliance – Q8, Q9, Q10
- Development of Risk-Based Supplier Quality Programs and Execution
- Training & Education
- Change Management & Control
- Process Validation
- Process Excellence
- 6-Sigma Methodology
- Cross-Contamination Risk Analysis

On-Time Workforce Enhancement

Flawless Project Execution

- Project Management
- Project Controls
- Organizational Improvement
- Strategic Planning and Execution

Technical Resources As Needed

- Contract to Hire Services
- Placement Services
- Project Based Consulting

Technology Transfer

- Technology Transfer Strategy Plans
- Quality by Design
- NPI/New Technology Introduction
- Manufacturing Process Gap Analysis
- Site, Component, Packaging, Batch Size Changes
- Process Research, Development, Characterization & DOE
- SUPAC Management

27 YEARS OF EXCELLENCE IN COMPLIANCE

WHO WE ARE

Since our inception over twenty-seven years ago, we have focused on developing a technical, administrative, and human resources infrastructure with a single purpose: **To provide integrated quality, productivity, and compliance services to highly-regulated manufacturers throughout the globe.**

We provide **Consulting & Quality Professional Services** to the

Life Sciences Industries

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