

PharmTech, Inc. is a Compliance consulting services company. We are customer-focused and dedicated to providing professional, comprehensive, and flexible services.

Our team of engineers, scientists, project leaders, quality and management professionals provide valuable insight and experience-based knowledge to plan and lead or support you in satisfying your organization's compliance-related project objectives.

We offer the following core services:

- Supply Chain Efficiency Management
 - Supply Chain Workflow Management.
 - GS1 and Serialization Compliance services.
 - Long Range Planning.
 - Process Evaluation.
 - Execution Plan Coordination.
 - Success Criteria and Measurement.
 - Project Execution and Oversight.
 - Business Process Mapping.
- Equipment and Automated Systems Validation, including:
 - Equipment/Utility/Facility/Building Management Systems/Laboratory Qualification.
 - Automation/Control System Validation.
 - Test Method Validation and Design of Experiments (DOE).
 - FAT, SAT, and Commissioning Services and Engineering Studies.
 - Validation Master Planning.
- Computer System Validation, including:
 - Computer System Validation Assessments/Protocol Development and Execution.
 - User Requirement Specification and System Functional Specification Documents.
 - 21 CFR Part 11 Compliance Services: risk assessments, compliance plans, policy and procedure development, system gap analysis.
 - SDLC Compliance Policies.
 - Vendor Audits.
- Quality Lifecycle Management, including:
 - Compliance-Related Workflow Management.
 - Business Process Re-engineering.
 - Quality Data Management System Designs.
 - Policy and SOP Document Authoring.
 - Quality System Audits.
 - Compliance Project Management.

INDUSTRIES SERVED

Pharmaceutical, Diagnostic and Medical Devices, BioTech, Specialty Chemical, Food, Nutritional, Cosmeceuticals and all other regulated Industries.

SELECTED PROJECT HIGHLIGHTS**Ongoing Drug Traceability Trace Consulting. Responsibilities include:**

- Process map of all distribution activities and performed gap analysis against current SOP's.
- Perform impact assessment of Traceability legislation, focusing on California Senate Bill 1307.
- Generate User Requirements for the future implementation of a Traceability system within the Distribution Center and also with consideration of third-party logistics and third-party destruction sites.
- Perform end-to-end product flow mapping to establish requirements for meeting Good Distribution Practice supply chain control system policy.

Ongoing pilot support for Traceability Project. Responsibilities include:

- Support serialization pilots which determined a baseline for Cold Chain processing in the Distribution Center.
- Integration of serialization software into the distribution and manufacturing centers.
- Provide validation services for packaging lines.
- Perform detailed mapping of the DC process flows, both as-is and future state under ePedigree laws. Evaluated requirements for packaging line conversions to meet serialization and traceability compliance regulations and provided related cost estimates, timelines and risk assessments.
- Execute business process mapping across organizations (IT, Operations, Supplier, Distribution), General pharmaceuticals, Cold Chain, Controlled Drugs, Returns, Receiving, Pharmagistics (Third Party Logistics), Destructions, and Inventory Management.
- Performed process mapping of Chicago Distribution Center and Third-Party Logistics providers and completed a gap analysis of the impact of Track and Trace legislation on the Distribution Center.

Ongoing GS1 Consulting. Responsibilities include:

- Provided Project Management and expertise on GS1 Standards.

Ongoing compliance consulting to support the Traceability pilot programs. Responsibilities include:

- Review business process flows and standard operating procedures (SOPs) relating to workflow and product segregation, starting from labeling operations through eventual product release and shipment.
- Perform gap assessments between the current business process flows and product segregation requirements of the FDA Predicate Rule.
- Perform historical reviews of warehouse operations, including personnel interviews and a review of audit observations, to gain perspective on the underlying principles governing current product segregation and movement practices.

- Summarize findings in an Executive Report for management, including recommendations assessing risk and reward relating to the use of RFID and traceability technology.
- Developed and conducted a survey of the customer base for purposes of determining the path forward in creating a compliant distribution network for products.
- Provide validation support for packaging line conversions on traceability pilot programs in domestic and global locations.

Provided quality consulting and validation services for a major Medical Medical Device company.**Responsibilities include:**

- Developed site SOPs, Training, and Examples for implementing sites quality systems requirements into the validation methodology.
- Developed SOP's and templates for automated equipment line. Documentation was implemented on 40 machine types.
- Managed the execution of the equipment and software validation on three production lines totaling 150 pieces of equipment.
- Developed a site specific quality plan remediating identified issues per FDA observations. Provided significant resources to execute the plan, documenting installation and specification requirements.
- Performed 21 CFR Part 11 assessments.
- Provided resources to address test method validation in a Design Assurance lab area.
- Developed and executed the following:
 - Spreadsheet validations
 - Database validations
 - Software validations
 - Production Equipment validation
 - Lab Equipment validation
- Actively providing Software Quality Assurance resources for PD production lines and Database validations.

Design and validation of a Complaint Tracking Notebook for a major medical device manufacturer. Responsibilities include:

- Validation of system data retrieval from SAP along with validation of spreadsheet functionality.
- Created and executed design specifications and test protocols.
- Provided software support by developing custom functions to replace complicated and resource consuming formulas.
- Re-design of application to optimize reporting function performance. Took current application of over 100MB and created new application of 1MB. New application involved creating a dynamic report generator and placing functionality that was performed repeatedly through formulas in VBA code.

Assisted with the transfer and move qualification for Microbiology Lab equipment for a pharmaceutical manufacturer. Responsibilities included:

- Development and execution of equipment qualifications for systems required for use. Systems include Autoclaves, Mini-Retorts, Lyophilizers, Dry Heat Ovens, Ampule Fillers, Flammable Freezers, Glassware washers, Ultrasonic Pipette Cleaners, Bar Code Printers, HPLC, Spectrophotometers, centrifuges, Microbial samplers, laminar flow hoods, biosafety cabinets, incubators and clean utilities (purified water).

On-going Complaint Handling support for major medical device manufacturer. Responsibilities include:

- Provide resources to assist with complaint handling, disposition and MDR reporting.
- Supported and developed applications that facilitated disposition of the MDR reporting function.

Validation of a new offshore biological facility for a rheumatoid arthritis drug. Responsibilities include:

- Development of equipment qualifications for systems required for use. Systems include clean utilities (water for injection, purified water, clean steam, oil-free compressed air), ancillary utilities (nitrogen, oxygen, carbon dioxide, helium), bioreactors, buffer hold, capture, harvest, media prep, and purification tanks, incubators, freezers, refrigerators, biosafety cabinets, autoclaves, glassware washers, ultra filtration, chromatography, and CIP skids, glove boxes, hepa carts, HVAC, and classified clean rooms.
- Development of on-site commissioning documents and off-site FATs for the equipment systems listed above.
- Design, configuration, and implementation of an automated solution that allows for collaborative protocol development with the client and all parties involved in the validation effort, and offers a repository to track detailed document version control and audit history.

Retrovalidation for a parenteral diagnostics manufacturer. Responsibilities include:

- Project management for the process validation of more than ten aseptic diagnostic product lines. Project included development of process validation documents, related equipment qualifications and final reports for lyophilized products at the plant. Equipment includes isolators, lyophilizers, and autoclaves.
- Review of design documentation, specifications, and IQ, OQ, and PQ documents.

Validated a biological manufacturing facility renovation for a blood-clotting agent.**Responsibilities included:**

- Development and execution of equipment IQs and OQs for systems required for use. Systems included temperature-controlled reactors, buffer, mix, harvest, and hold tanks, heat exchangers, centrifuges, chromatography skids, an ultra filtration skid, autoclaves, glassware washers, biosafety cabinets, environmental chambers, waterbaths, cold rooms, cryomed freezers, CIP skids, refrigerators, nitrogen, compressed air, HVAC, and classified clean rooms.
- Development and execution of uniformity studies for mix tanks and shakers.
- Validated to aseptic conditions for biosafety cabinets and facilities.
- Final summary reports on cleaning validation for sNDA submittal.

Master Planning for bulk chemical manufacturing unit. Responsibilities include:

- Annual system performance reviews of purified water and water for injection systems.
- Evaluations for revalidation of reactor systems and clean room facilities.
- Qualification of HVAC systems.

Computer Validation of an API manufacturing facility project. Responsibilities include:

- Development and execution of IQs for the API Electronic Control system. IQ sections include HMI screen navigation, layout and tag properties, I/O checks to and from the PLC registers, and I/O labeling.
- Development and execution of OQs for the API Electronic Control system. OQ sections include transition, sequence of operation, parameters and instructions.
- Development of trace matrices that link user requirements and design specifications to protocol test procedures.

Validated a dionized and purified water facility of a major pharmaceutical manufacturer.**Responsibilities included**

- Developed documentation of system Installation Qualification, Operational Qualification and Performance Qualification.
- Performed dry-run of qualifications.
- Executed Installation Qualification, Operational Qualification and Performance Qualification

Ongoing validation efforts to support bulk manufacturing and fermentation operations of major pharmaceutical manufacturers. Projects include:

- LOTO (lock-out-tag-out) procedure-writing and related P & ID walkdown verifications.
- Facility-wide CIP upgrade qualifications.
- Cleaning validation for chemical unit.
- Equipment qualification for capital projects. Equipment/systems include reactors, crystallizers, fluid bed dryers, tray dryers, heat exchangers, centrifuges, fermentors, blenders, mixers bulk solvent tanks, supporting utilities, HVAC, and classified clean rooms.
- Development of commissioning documents for process start-up.

Validated new facility for a powder inhalation therapy product. Responsibilities included:

- Gap analyses of vendor design documentation, user requirements and specifications, and validation protocols.
- Modifications to vendor protocols to comply with client policies and CFR Part 11 based on gap analyses.
- Development and execution of installation, operational, and performance qualifications (IQ/OQ/PQ) for systems required for use. Systems included compressed air, nitrogen, purified water, HVAC, classified clean rooms, micronizers, mixers, conditioning and drying chambers.

Validated final packaging equipment for a major OTC drug manufacturer. Responsibilities included:

- Development and execution of equipment and PLC control protocols for capper and sealer systems.

Validated an automated assembly machine for a medical device assembly manufacturer. Responsibilities include:

- Development of Design, Functional, Hardware Specifications.
- Development and execution of Installation and Operational qualifications.
- Quality System implementation - Providing reviews of existing templates and feedback regarding changes towards industry standard practices.
- Assisting with standardizing the validation processes and tools to facilitate the validation life cycle.

Ongoing compliance consulting to support the Point of Care Facility, East Windsor, New Jersey

Responsibilities include:

- In an effort to bring the site into a current evaluated state, PharmTech is performing plant wide equipment and software system assessment.
- Develop and approve intended use and revalidation summary documents.
- Develop and execute summary documents for equipment, facility and utility systems at the site.

Clients include:

Abbott Laboratories, Pfizer, Tyco Healthcare - Mallinckrodt Division, Eli Lilly, Boston Scientific, Bayer, DSM Pharma Chemicals, GE Healthcare, Cardinal Health, Perrigo Company, Pfanstiehl, APP, Abraxis Bioscience, Aventis-Behring, Jacobs Engineering, Merial, sortimat, Hospira, Guidant, Minntech, Medtronic