



## RedLotus Pharmtech Pvt. Ltd.

A Pharma Technical Services Company





## Introduction & Purpose :

In the last two years, import ban orders have been issued by the USFDA and Canada's Health Canada to more than 25 Indian API (active pharmaceutical ingredients) and formulations. GMP/ Quality non-compliance could be considered as a grave threat to trip-up the Indian pharmaceutical industry, growing at a steady trot of about 15 per cent in the last few years.

Findings of the two recent reports on compliance in the Indian pharmaceutical industry are not encouraging. While the regulatory action is not unusual to the Indian pharmaceutical companies and the companies have also demonstrated their capability of resolving the issues. However, in the subsequent inspections the same companies have found themselves in deeper trouble, this raises a serious question. Why do the pharmaceutical companies find it difficult to comply with the GMP/ Quality requirements when they know what is expected by the regulators? The simple yet complex answer to that question is, "the shortage of skilled manpower". Though this is not the only reason, it has been identified as a key reason in both these industry reports.

Leading pharmaceutical companies seek to achieve and maintain world-class excellence in all aspects of pharmaceutical quality from research and development through manufacturing. In pursuit of this goal, savvy companies continuously strive to upgrade and improve the development and manufacturing set-up to match the standing and business performance of the company and ensuring compliance with the dynamic regulations. Usually these efforts work for the companies up to a certain limit, drying research pipeline and constant market pressures of product cost reduction without compromising the product quality often results in a decision of making these highly specialized resources redundant. This is contradicting but true to the findings of these two industry reports.

This quality staffing and structures that support the full spectrum of various functions, including research & development, vendor qualification/ development, manufacturing process development, technology transfer, manufacturing facility & equipment design, qualification & validation, process validation, trouble-shooting, related computer systems validation, failure investigations, and continuous product/ process improvements is important for any company to develop & manufacture a quality product. As all of these are cross-functional, activities developing such skill set takes enormous time and usually this staff become liability for an organization after completion of a research/ development project(s).

With an intention to fill in this critical competence/ performance gaps RedLotus, "Pharma Technical Services" has been formed. Along with it's identified and qualified national as well as international associates and partners (including ex regulatory officials) it can help pharmaceutical companies in responding to resolve with guarantee any GMP/ Quality issue arising from a regulatory inspection, such as the USFDA warning letter and/ or prospectively work with the companies in developing, establishing and continuously improving each element/ system (Quality, Materials, Equipment & Facility, Production, Laboratory, Labeling & Packaging) that constitutes a reliable and robust GMP/ Quality compliance system.

According to a conservative estimates, about 25 percent of the costs of bringing a pharmaceutical product to market comes from manufacturing expenses. By adopting optimal structures and strategies for manufacturing technical services, companies can maximize resources while positioning the function as an improvement arm for processes across the supply chain. RedLotus, "Pharma Technical Services" can play a critical role in ensuring that safe and efficacious products reach the market by the most cost-effective methods possible and in guiding the companies at different stages:





# Mission

- (a) During the manufacturing process/ product development stage in designing and selection of right facility, equipment & technology, their qualification, process validations, data handling, computer system & critical support systems validation, and establishing robust quality assurance and management systems/ processes.
- (b) During the regulatory approval phase in preparing for the regulatory approval inspections by performing mock inspections, identification & resolution of GMP compliance risk/ gaps, staff training, resolution of regulatory inspectional findings/ observations.
- (c) During the commercial manufacturing phase in trouble-shooting, failure investigations, continuous process and quality systems performance verification and improvement.

All of the above – if done well – can avoid regulatory challenges, costly product recalls and facility shutdowns.

## About us:

Along with its identified and qualified, national as well as international associates and partners (including ex regulatory officials) RedLotus, "Pharma Technical Services" brings in years of collective experience in the areas of a drug substance as well as a drug product development, analytical method development & transfer, technology transfer, manufacturing, quality assurance & control, regulatory affairs, pharmaceutical engineering qualification and validation and supply chain.

**Our Vision:** To be the leader in the delivery of Pharma Technical Services.

**Our Mission:** To contribute to our customers' success by helping them develop deeper and better understanding of technical aspects necessary for achieving GMP/ Quality compliance and manufacture quality products.

## Our Services:

### QA & GMP Compliance:

- Quality Management System – Design & Effectiveness Reviews
- GMP Audits – Process Design, Review & Performing (Vendors, Suppliers, Service Providers, Mock Regulatory Inspections, Data Integrity, Sterility Assurance)
- GMP Risk/ Gap – Analysis & Mitigation Plans
- Training – GMP Compliance, QMS, Data Integrity, Special – Sterility Assurance

### Regulatory:

- Regulatory Filing Document – Preparation and Reviews
- Regulatory Compliance Issues – Response Strategy and Response Drafting/ Preparation/ Review, Issue Resolution & Remediation Plan





### Technical Due Diligence:

- Assessment of Client Identified Target – Organization, Facilities, Systems, Products, Processes and Resources for Capacities, Capabilities, Competence, Performance & Compliance with Current Regulations.
- Gap Analysis – Identification of deficiencies and gaps in compliance and provision of remediation plans
- Assessment of Systems & Controls – Management Controls and Management Personnel Capabilities

### Qualification and Validation:

- Development – Qualification Policies, Strategy, Validation Master Plan, Qualification & Validation Protocols & Reports, Sterility Assurance Plans, Cleaning Validation, Computer System Validation, Process Validation, Sterilization/ Biodecontamination Process, Media Fill, Analytical Methods (Chemistry & Microbiology).
- Reviews and Gap Analysis – Regulatory Compliance, Suitability & Adequacy, Sterility Assurance, Media Fills, Trend Analysis, Statistical Process Analysis, Annual Product Reviews.
- Guidance & Training – Qualification & Validation, Sterility Assurance, Media Fills, Aseptic Manufacturing
- Investigations – Failures Investigation, Guidance, Reporting, Review and CAPA (product testing, stability, environmental monitoring, market complaints, sterility, media fill etc.) and Position Papers
- Execution – Coming soon

### Training:

- General & Specific Training – GMP & Compliance, Qualification & Validation, Quality Management Systems, Continuous Process Improvement, Sterility Assurance, Sterilization Processes etc.
- Custom Training – Depending upon the specific customer need.

### Design & Engineering:

- Development – Conceptual Facility Design, User Requirement Specifications (Facility, Equipment & Critical Support Systems), Factory Acceptance Testing, Facility/ Equipment Maintenance Plan and Processes, Instrument Calibration Plan and Processes.
- Reviews and Gap Analysis – Facility Design, Equipment & Critical Support System Design and Specifications, Facility / Equipment Maintenance Plan and Processes, Instrument Calibration Plan and Processes.

### Mentoring & Advisory:

- Manufacturing Philosophy and Strategies.
- Strategic advisory and/ or mentor role
- Mentor teams/ chosen professionals to meet challenges of operations and business
- Consulting role in project overviews and management
- Providing strategies for setting-up pharmaceutical business right from concept to operation.
- Operational excellence

## PARTNERS



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