



PTS CONSULTING

Paul T, Sudhakar, Owner/President/CEO of PTS Consulting, LLC and PTS Pharma Labs, has over 30 years of experience in the pharmaceutical and related industries. Sudhakar has been actively involved in management and product development activities including development support activities including but not limited to, preclinical, clinical, bioequivalence studies, chemistry & manufacturing controls and filing/approval of drug applications. PTS is also involved in FDA review management of drug and biologic applications and approval/launch activities for numerous products some of which require circumventing of patents and exclusivities.

PTS is also experienced in design, establishment, qualification, and management of various pharmaceutical operations including sterile injectables and stem cell processing, finished drug products and bulk drug manufacturing operations in compliance with US FDA standards in USA and globally. Sudhakar has held various positions in FDA regulated operations for over 30 years including President/CEO for a multinational pharmaceutical operation for 14 years. PTS is also currently serving as management consultant for various Pharma and biotech operations. In these positions he has a leading role in quality, development, production, materials management, personnel management, regulatory compliance, management of supply chain, marketing and sales, and all other activities of full-fledged pharmaceutical operations. Also currently operates a stem cell operation with offices and operations in USA and designed and established clean room operations for such products for various organizations. PTS also serves as scientific and regulatory consultant for numerous pharmaceutical firms located in USA, Europe and Asia. Paul also is a consultant for Kansas University Medical Center and Midwest Stem Cell Treatment Center, in this function PTS has completely designed, installed and validated a clean room operation for GMP cell processing and other biotech products. Paul is also a consultant for device firms Biomedical Devices of Kansas, and Arctic Fox in Boston, firms involved in devices for laser treatment of breast cancer and collagen injection devices and American Screening Corporation of Louisiana involved in in vitro devices (IVD) and Cure Pharmaceuticals Inc in Oxnard, CA (www.curepharmaceutical.com). Paul is scientific director for OWP Pharmaceuticals (www.owppharma.com) which specializes in neurology products development, manufacture and marketing and Scientific Consultant various other companies globally and also has partnership interest in various US pharmaceutical firms. Paul is also a senior specialist for Lachman consulting services providing regulatory and compliance guidance in various aspects of the pharmaceutical industry.

PTS has owned and worked with numerous pharma operations in North America, Europe and Asia over the years and has successfully brought some of the firms in these regions into US FDA compliance and also assisted them in drug development and approval processes in USA. PTS also has filed a number of use and formulation patents.

Key fields of expertise range from preparation of drug, food and/or cosmetic facilities from inception to full FDA qualification and filing and managing the processes FDA drug applications especially Abbreviated New Drug Applications (ANDAs), PIND, INDs, NDA and PMAs, De Novo, 505(b)(2) and BLA applications. PTS has numerous clients for this work in USA and around the globe. PTS also has capabilities for FDA eCTD filing requirements for all types of FDA applications via its own ESG gateway. PTS can also provide end to end pharmacovigilance services, for INDs and post-approval reporting requirements for drug, biologicals, devices and combination products.

PTS also performs drug development for various dosage forms including sterile injectable products, liquid orals, topical solutions, solid dosage product, active ingredients from various pathways including

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fermentation technology and drug device combinations and GMP operations at its own 30000 square foot facility in Kansas City area or at the client's and/or third-party facilities. PTS can also assist in design, organization and management of clinical/bio-equivalence studies, in USA and abroad. PTS is also actively involved in assisting various firms in FDA compliance activities including functioning as the primary FDA agent for some manufacturing and API firms and as ANDA filing agent and as principal FDA contact. PTS is also well versed and with FDA compliance audits and review management of drug applications at US FDA. Performance of most of these activities economically and at fast pace is a key expertise. Sudhakar has detailed insight and understanding of the drug development and review process since he has also been in the forefront of new drugs including NCEs and generic drug business from 1984 year of Waxman Hatch through evolution of the Generic drug process and 505(b)2) NDAs and the reorganization and establishment of the current drug regulations and guidelines. Paul also has number of US patents related to formulation development and 505(b)(2) NDAs.

Contact:

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PTS Services provided as consultant:

Assist and/or manage in E-filing and understands the critical importance of complete and accurate regulatory submissions and collaborate on submission planning and preparation. We ensure consistency, scientific accuracy, completeness, and regulatory compliance of all processes and documents. PTS can aid in:

- CMC, nonclinical, clinical and submissions
- Compliance audits (all pharma operation including commercial warehousing and distribution)
- Life cycle management
- Pre-and post-launch strategies
- Regulatory and drug development guidance
- Regulatory liaison with FDA- Agent services
- Maintenance of Archives for regulatory authority correspondence, meeting minutes, dossiers, and documents
- Post-meeting analysis, response and dispute resolution
- Meeting preparation and rehearsals, correspondence, meeting minutes, dossiers, and documents meetings
- Compilation, preparation, submission and follow-up responses to Agency
- Health Authority requests for information and action letters
- Fast track and orphan applications
- Maintenance of Amendments, Periodic Safety and Annual Reports, post-submission updates
- Paper and/or eCTD formats
- Preparation of Regulatory Strategy Assessments
- Prepare CMC, nonclinical, clinical subsections and labeling
- Product Registration [NDA, ANDA, BLA, ETC]



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- Review Statistical Analysis Plans, CMC, nonclinical and clinical study reports
- Submission planning and management
- US Agent services
- End to End Pharmacovigilance services

PTS provides services to assist your company in compliance, design and installation of GMP facilities and mock regulatory audits, review of your quality systems including your CAPA plans, and/or any of the following services.

Site Quality Compliance Review and Advisement

- Evaluate Design and construction and qualification of GMP facilities
- GLP Audits
- GCP Audits
- CMC Reviews
- GMP Inspections
- QA Training

Can also provide Quality assurance audit services for:

- Manufacturing and Control sites
- Investigator sites
- Clinical and analytical laboratories
- Drug packaging and distributors
- Institutional Review Boards
- Supplier/Vendors
- GCP, GMP and GLP compliance
- Study Files (at a site and in-house)
- Conducting mock regulatory agency inspections
- Training to prepare investigator sites for actual regulatory inspections
- Assisting in the preparation of responses to FDA 483s and Warning Letters.
- Safety Management Plans (SMPs)
- SAE (Serious Adverse Effects) Reconciliation, Management & Reporting
- Medical Monitoring Plans

PTS current business description:

PTS' current business model involves formulation development, clinical trial production, regulatory services and analytical control laboratory based at 14130 Minnesota Avenue, Bonner Springs, KS 66012. Operations for PTS Labs include, tablets, capsules, granules, modified dosage forms, topical dosage form, suppositories, film products, liquid and suspension formulations and injectable products development for vial fill and autoclave sterilization, all housed in dedicated suites in the same building. The cGMP systems are common for all



units with the PTS Consulting SOPs and procedures applying to all units. PTS is also involved in active raw material clinical production by fermentation technology, with various size fermenters in dedicated operation.

PTS also offers various consulting services for pharmaceutical, devices, foods and other such regulated products in USA and Europe, as outlined in below. As senior advisor at Lachman Pharmaceutical Consulting and can offer any services required on a wider range via that relationship.

The current operation was established in 2003 by Paul Sudhakar who is also the sole owner of the firm.

SUMMARY OF RELEVANT SKILLS AND EXPERIENCE:

- Over 35 years of solid and comprehensive experience in the pharmaceutical sector (industrial, academic, and research and supply chain activities). Most recently managed a pharmaceutical business with development, manufacturing, distribution and sales and marketing capabilities-also involved in consulting in fields of product development, novel drug delivery systems, and other related activities.
- Previous ten years as a President/CEO of a Pharmaceutical firm located in Kansas City, a Branch of a large generic firm in Europe. Managed inception to commercialization (marketing and sales) of various products and filed numerous ANDA products and obtained approvals for a number of these products with significant brand sales in the US and European market.
- Recently managed numerous NDAs, ANDAs with CDER and the FDA (Office of Generic Drugs) for various clients, some of which are Extended Release drug application and one IR combination drug products and injectable drug products. All but one which is in patent litigation has been approved. Had intensive personal, email, telephone and letter interaction with all levels of OGD including the Director. Have numerous product approvals, including some difficult to formulate Extended-release products and first to file ANDAs. PTS has developed and is managing its own NDA, BLA, 510K and ANDA approval process for a product to be marketed in USA.
- Extensive knowledge of drug development process acquired through hands-on and didactic experience in all aspects of drug product development and problem solving, drug registration regulation and R&D activities. Developed about 15 products for some clients all of which are in technology transfer phase, will be filing and managing the entire filing and review of the drug application.
- Thorough knowledge of drug development process acquired through hands-on and didactic experience in all aspects of drug product development and problem solving, drug registration regulation and R&D activities.



- Extensive pharmaceutical experience combined with excellent entrepreneurial and administrative skills necessary for achieving organizational goals in a complex and competitive business environment.
- Extensive knowledge of pharmaceutical regulations in USA, Canada and European Union, Asia and other countries.
- Audited numerous pharmaceutical operations for compliance in USA, Europe, India, China and Canada
- Audited and setup procedures and guidelines and brought major Chinese, European and Indian pharmaceutical firms into full FDA compliance which were under an FDA compliance problems, was also involved in the successful follow-up FDA inspections resulting in products being shipped to USA. Assisted some new Indian and Chinese firms to bring into first time compliance with US FDA.
- Assisted and directed compliance activities in a large German firm and Swiss firm and had products approved in USA from these sites.
- Was involved in major patent litigation cases and successfully defended several patent infringement lawsuits.
- Was key individual in obtaining product licenses from various firms and for licensing products to various firms in USA.
- Organized, designed and directed many FDA acceptable **bioequivalence and clinical studies** in USA, Canada, Europe and India.
- Established and managed a full-service pharmaceutical, marketing and distribution operation including controlled substances in conformation with FDA regulations, including state licensing, formularies and other requirements in US for sales and marketing of approved drug products.
- Expertise acquired to direct all aspects of in-house formulation and product development licensing activities including- **A full-fledged state of art R & D laboratory with all processing and testing equipment and operations is in Kansas City area and a small volume parenteral and large scale oral solutions manufacturing operation and:**
 - Development and review of formulations with respect to patent infringement and compliance with FDA inactive ingredient lists
 - Filing and Review of Drug Master Files from Active Pharmaceutical Ingredients (API) vendors.
 - FDA agent for number of foreign pharmaceutical establishments
 - Supervision of the scale-up of formulations to pilot plant batch size
 - Direction of all aspects of process development



- Direction of the manufacturing of pre-exhibit, exhibit and validation batches
 - Initiation and conduct of stability programs
 - Development of protocol for phase 1 and Phase II studies
 - Supervision of the generation of CMC and clinical documentation for regulatory submission in various jurisdictions.
 - Directed and formulated responses to scientific issues from regulatory bodies
- Designed, installed, directed and managed two full-fledged start-up pharmaceutical firms with all activities including manufacturing, product development, ANDA (abbreviated New Drug Application) and IND approval processes, laboratory controls, regulatory activities, marketing and sales.

Other services:

- Writing, compiling, reviewing, and submitting drug product submissions electronically. Including responding to deficiencies to see product through approval
 - Experienced in generic (immediate release, modified release, locally acting, parenterals), and PINDs, INDs, NDA (including 505(b)(2)), BLAs, CTAs, DMFs.
 - Providing Regulatory input to R&D team in terms of product development including for products where FDA may not have requirements published
 - Reviewing bio study protocols for acceptability in terms of end points and FDA requirements
 - Periodic reporting (Annual Reports, Quarterly Reports)
 - Electronic drug and facility registration
 - Drug labeling including Structured Product Labeling and Physician Labeling Rule
 - Post approval product life cycle management (negotiate, develop and submit comparability protocols, supplements that seek to reduce cost or improve productivity through scale up, removal or redundant testing through lower reporting categories)
 - Convert paper application into electronic to lend operational efficiencies, including operating paperless with minimal investment into expensive software
 - Develop submissions for same product targeted at various regulatory agencies (like FDA, EMEA, Health Canada etc.)
- Also operate secure email exchange with the FDA and an Electronic Submission Gateway that ensure immediate delivery of submissions (especially critical in PIV or first to file submissions)
- Prepared responses to 483s, Warning letters, Field Alerts and routine interaction with District Offices
- Federal and State Licensing requirements (including those for distribution and marketing)
- Prepare and face FDA and Vendor Audits
 - Preparing and reviewing SOPs, Applying current FDA thinking into Change Management. Applying principles of Risk Assessment and Management
 - Headed efforts to make a previously R&D center cGMP capable
- Structure and conduct vendor quality agreements and audits
- Already implemented recent FDA initiatives like eCTD, eListing, and is prepared for future initiatives like eStability, PREDICT and ITACS etc
- Scout and liaison for bio study sites appropriate in terms of capabilities and cost



- Scout and liaison for Para IV providers appropriate in terms of capabilities and cost
- Scout and liaison for Sales and Marketing providers appropriate in terms of capabilities and cost (Able to bring these in-house if preferred)
- Scout and liaison for Distribution and Logistics providers appropriate in terms of capabilities and cost (Able to bring these in-house if preferred)

OTHER

Handled and direct all aspects of post-approval and post-marketing FDA regulatory activities, including but not limited to FDA field alerts, ADR reporting, periodic reporting, annual reports, and compliance reports and other.

Have been serving as FDA agent for foreign firms and have advised on product development activities, including product selection, procedures for development, reports, bioequivalence pilots as well as full studies conducted in US, Europe and India. Licensed various products into and outside USA, obtained some product approvals in EU and numerous in US, some of which are hard to develop and patented products. As list and details can be provided.

WORK EXPERIENCE / HISTORY:

Jan 2004- Present: PTS Consulting LLC and PTS Labs (A firm incorporated in October 2003, product development, regulatory compliance activities and other FDA related functions advising and consulting various pharmaceutical firms in USA and abroad. CEO of Lifecells, LLC, a global stem cell research and manufacturing operation. Well versed in pharma product development, electronic and regulatory services using its own organization based in Kansas City. Senior consultant special projects at Lachman Consulting, Scientific Officer for OWP Pharm, PBA and Regulatory officer/consultant for numerous forms globally.

2004 to 2008: Owner, President/CEO, Midland Pharmaceutical.

1998 to 2004: President/CEO, ratiopharm GmbH, US operations, now TEVA part of Pharmaceutical.

1995 to 1998: President, Founding group, Scientific Affairs & Product Development, Martec Scientific, Inc, Kansas City and New Jersey (Now Nostrum Lab, LLC)

1990 to 1995: Vice President, Scientific Affairs and Executive Vice President, Marketing and sales Martec Pharmaceutical, Inc.

1986 to 1990: Manager, Scientific Affairs, Harcos Chemicals and Felton Worldwide, Pilot Scale Operations in USA

1983 to 1984: Associate Professor, Pharmaceutical Technology Faculty of Pharmacy, in two universities, Bombay University and SNTD College of Pharmacy.



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1980 to 1983: Pharmaceutical Research Student, Indian Drugs and Pharmaceuticals, Ltd and Biological Evans International.

1976 to 1980: Pharmaceutical Student/Research Assistant- University Department of Chemical Technology, Bombay India, now Indian Institute of Chemical Technology.

1980 to 1982: Supervisor and Production Pharmacist, Indian Drugs and Pharmaceuticals, Ltd.

Educational Information:

Bachelor of Pharmacy (B. Pharm), University Department of Pharmaceutical Sciences, India.

Master of Pharmacy (M. S. Pharm), University Department of Chemical Technology (now Institute of chemical technology), Bombay, India.

Master of Business Administration (MBA), Andrews University, Michigan and Kansas State University, Kansas.

Holder of number of formulation development patents