



**Optimal
Business Solutions & Service
Providers
to the
R & D, Manufacturing,
Life Sciences IT and ITES
Industry**

Over four hundred preclinical, clinical trial (Phase I to IV) approvals, product registrations, marketing authorisations, covering a large number of therapeutic and product categories.

- **Drug Development**
- **Medical Device & Diagnostics Development**
- **Business Solutions**

Optimus
Pharma Consulting

www.optimuspharmaconsulting.com

Knowledge & Expertise @ work for you.....

TO DELIVER YOUR PROJECTS ON TIME AND WITHIN BUDGET.....



FOR RESEARCH, DEVELOPMENT & MANUFACTURING CUSTOMERS

BUSINESS SOLUTIONS

- **Preclinical, Clinical Development** Strategy
- **Regulatory** Strategy
- **Project / Program management** (Preclinical; Clinical Development & Implementation)
- **Service Provider Auditing** (GLP; GCP; GCDMP)
- **Outsourcing** – Opportunity identification, Business Case, RFP Process, Deployment, Transition, As-is to To-be process mapping
- **Quality Management System** – Drug and Device Development
- **Process** Auditing & Process Re-engineering

AUDITING (INDEPENDENT)

- Due diligence & gap analysis (Drug & Device Development Quality Management Systems)
- Standard Operating Procedures
- Clinical and Pre Clinical Sites & Study Audits (Phase I to IV; BA/BE EMEA; FDA; WHO, ICH GCP and Indian GCP)

CALL OPTIMUS..... DURING

- Project overloads; Special requirements; Quick turnarounds, Rescue projects etc.,

SERVICES

- **Regulatory** (Study Approvals; Import / Export / Market Authorisations; IND/NDA/e-CTD/ MAA)
- **Clinical Analytics** CRF, CDASH, SDTM, ADaM
- **Biostatistics**
- **Medical Writing**
- Drug Safety
- **Dossier Management** (Essential Documents, Drug Safety, Regulatory)
- **Stem Cells** (Regulatory, Development, Manufacturing, Market Authorisations)

BUSINESS BENEFITS

- Projects tracked in real time, delivered on schedule within service levels agreed upon – reducing development costs
- Providing localized strategic and process expertise to attain business competitiveness – delivering approvable projects faster
- Faster design, planning and implementation processes – leading to increased ROI
- Improved regulatory compliance
- Improved drug development productivity, risk mitigation, increased revenue.

MANUFACTURERS & DEVELOPERS OF

Biologicals, Vaccines, rDNA products; Pharmaceuticals, Biotechnology products; Medical devices; Diagnostics

INDUSTRIES FOCUSING ON

Life Sciences IT Products; Life Sciences IT Services; Life Sciences ITES;

THERAPEUTIC EXPERTISE

Oncology; Immunology; Endocrine disorders; Cardiovascular; Central nervous system; Anti-infective; Gastrointestinal; Ophthalmology; Genitourinary; Ophthalmology; Respiratory; Blood disorders; Nutraceuticals etc.,

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