



Partners in Implementing
Optimal, Scientific
Business Solutions to the
Drug, Device &
Diagnostics
Development Industry

Overall experience includes over four hundred preclinical, clinical trial (Phase I to IV) approvals, product registrations, marketing authorisations, covering a large number of therapeutic and product

- 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.....



SERVICES AND BUSINESS SOLUTIONS

REGULATORY

- Regulatory strategy development
- Clinical Trial (Phase I to IV) approvals – pre & post study; Preclinical study approvals
- Marketing Authorizations (MAAs, NDAs, BLAs)
- Import and marketing (NEW DRUG)
- Manufacturing and marketing (NEW DRUG)
- INDS , NDA's; Drug, Site Master Files
- Electronic publishing (CTD's, eCTD's)
- Regulatory reporting (PSUR's)
- Export, Product Registration dossiers

AUDITING

- Due diligence & gap analysis
- Quality management system
- Standard Operating Procedures
- Clinical Study Audits (Phase I to IV; BA/BE EMEA; FDA; WHO, ICH GCP and Indian GCP)
- Essential Documents
- Vendor Audits; Risk Management Plan
- Process; GCDMP; PhV; Project Audits

DRUG SAFETY

- AE, SAE tracking, coding & case processing
- ICH E2B – Electronic Safety Reporting

CLINICAL ANALYTICS

- Case Report Form (CRF) design & review
- CDASH, SDTM, ADaM Services
- Terms coding (MedDRA, WHODD)
- Reporting

BIOSTATISTICS

- Statistical Analysis Plan
- Sample size calculation
- Statistical analysis & reporting (BA/BE/ Phase I to IV)
- Protocol & Study Reports

MEDICAL WRITING

- Protocols; Informed Consent; Investigators Brochure
- Clinical study reporting (ICH E3)
- Standard Operating Procedures
- Study / Trial documents, plans & Checklists
- Periodic Safety Update Reports

CONSULTING

- Pharma Process Outsourcing
- Project management
- Competitive intelligence
- Information Technology

INDUSTRY FOCUS

- Biologicals, Vaccines, rDNA products; Small molecules; Biotechnology products; NBE's, NCE's, MME's; Medical devices; Diagnostics; API's (Chemistry & Biotechnology); Generics and Formulations;
- 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; Genito-urinary; Ophthalmology; Respiratory; Blood disorders; Nutraceuticals

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