TLI Development

A PHARMACEUTICAL SUPPORT SERVICE COMPANY

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Regulatory Affairs:

- IND/ NDA/ ANDA/ BLA/ PLA/ ELA/ DMF/ CTX/ MAA Preparation & Review
- Analytical Methods & Validation Report Review
- Specifications Development & Review
- Product Development Reports
- Stability Testing Protocols & Stability Summaries
- Prescribing Information/ Labelling Preparation & Review/ Advertising

Medical Writing:

- Preclinical Reports - Compilation & Review
- Clinical Protocols
- Informed Consents
- Study Reports
- External Publications
- Investigator Brochures

Quality Assurance:

- cGMP Audits
- Mock Pre-Approval Inspections (PAI)
- SOP Reviews/ SOP Writing
- Product/ Process Reviews
- DEA/ Controlled Substances Audits & Compliance

Regulatory Support - Overview

TLI Development has prepared over 100 IND filings and at least a dozen market applications. Although our expertise is in CMC, we have prepared entire NDAs, as well as clinical and nonclinical portions of several others. A portion of the projects is listed below, broken out by type of submission and product indication.

IND (Investigational New Drug)

· a recombinant human parathyroid hormone (indicated for osteoporosis)
· a recombinant human pulmonary surfactant protein (indicated for ARDS/ ALI)
· an anti-inflammatory drug (metered dose inhaler (MDI) indicated for asthma)
· a purified, unconjugated, monovalent vaccine (for plasma donor immunization)
· a bivalent, conjugated vaccine (for both active and passive immunization)
· a leukotriene antagonist drug (indicated for asthma)
· a polyvalent, conjugated vaccine (indicated for sepsis)
· a nebulized tartaric acid solution (indicated as a diagnostic aid in stress urinary incontinence)
· a anti-retroviral vaginal gel (indicated for HIV prevention in 3rd world countries)
· an anti-inflammatory suppository (indicated for IBS)
· a lyophilized drug (indicated for sepsis)
· a specified intravenous gamma globulin (indicated for cystic fibrosis)
· a specified gamma globulin (indicated for infection in renal dialysis patients)
· an anti-retroviral solid oral dosage form drug (indicated for HIV+/ AIDS)
· emergency use of plasma derivative in West Nile Virus (WNV)
· a calcium channel blocker (indicated for use in glioblastoma multiforme)
· a dopamine antagonist (indicated for use in self-injurious behavior)

NDA (New Drug Application)

· Entire 505(b)(2) for a dopamine antagonist (indicated for anti-emetic & increased GI motility)
· NDA CMC section for a nucleoside analog (indicated for pediatric chemotherapy)
· NDA CMC section for a solid oral dosage form drug (indicated for erectile dysfunction)
· NDA CMC section for a solid oral dosage form drug (indicated for Alzheimer's disease)
· NDA CMC section for a nucleoside analog (indicated for pediatric chemotherapy)

SNDA (Supplemental NDA)

· SUPAC NDA amendments for technology transfers (change of manufacturing sites)
· SNDA for a solid oral dosage form drug (indicated for arthritis)

BLA (Biologics License Application)

· BLA CMC section for a plasma derivative (IGIV)
· BLA CMC section for a blood derivative

CTA (Clinical Trial Authorizations)/IMPD (Investigational Medicinal Product Dossier)

· IMP sections for several chemotherapeutic agents
· Simplified IMP section for an anti-inflammatory suppository (indicated for IBS)

ANDA (Abbreviated New Drug Application)

· ANDA for an injectable controlled substance (Schedule II)
· ANDA for an ophthalmic solution (indicated for reducing IOP)
· ANDA for a topical anti-fungal cream

PLA (Product License Application)/ELA (Establishment License Application)

· PLA for a hepatitis vaccine