team Tranquil

Pharmaceutical

Regulatory Services

eCTD and SPL Preparation and Submission
Draft and Final Container Labels and Package Insert Preparation
Pharmacovigilance Services including PADER and ICSR Submissions

Professional Partner of
EXTEDO
eRegulatory Affairs

Regulatory Services

- Filing of NDA / ANDAs in US and ASMFs in EU.
- Preparation of Generic Applications such as Paragraph II , III and IV
- Post approval maintenance and submissions of PAS, CBE 30/CBE, Annual Reports in US and EU.
- Help with creation of customized FDA regulatory/development strategies.
- Help with writing all submission documents.
- Design Final Printed Labeling and Container Labels
- Help with responding to FDA questions during the approval process.
- Help with eCTD process and provide eCTD Preparation Services
- Help with filling annual reports, adverse reactions, and ongoing CMC updates.
- Manage Good Manufacturing Practice (GMP) and clinical site audits.
- SPL Preparation for Establishment Registrations, Labeler Code Requests, Drug Listings, GDUFA Self-ID Submissions
- Duns and establishment registration, self-identification for all sites for drugs.
- Provide Pharmacovigilance Services including PADER and ICSR Submissions
- Act as a U.S. Agent for non-U.S. companies.
- We are Professional partners and resellers of eXtedo's eCTDmanager software
- Provide first level support for eCTDmanager software in NA and ASIA markets.