



Pharmaceutical eSubmissions and Validations

Reseller of EXTEDO eCTDmanager and Professional Partner
eCTD and SPL Preparation and Submission
Draft and Final Container Labels and Package Insert Preparation
Laboratory Systems Qualification
Computer Systems Validation

Professional Partner of



Our Services

Filing of NDA / ANDAs in US and ASMFs in EU in eCTD format

Sell, Install and Provide Training for eCTDmanager from EXTEDO in USA and ASIA markets.

Provide optional extended support services and validation services for eCTDmanager

Help with eCTD process and provide eCTD Preparation Services

SPL preparation and submission for Drug Listing

DUNS and establishment registration, self-identification for all sites for drugs.

Act as a U.S. Agent for non-U.S. companies.