PHARMALEX

STRATEGIC REGULATORY OPERATIONS

PharmaLex offers full lifecycle management for the submission process with flexible options for report-level publishing, compilation of major applications (IND, NDA, BLA) and lifecycle maintenance. Our regulatory affairs professionals are experienced in an array of electronic formats, including electronic Common Technical Documents (eCTD), and Structured Product Labeling (SPL).

Our teams bring together knowledge, skill and expertise ensuring accuracy, accountability and responsivness for the successful preparation, compilation and delivery of regulatory submissions.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- **Submission Planning & Tracking with Regulatory Project Management**
  - End-to-end planning, coordination and execution of major applications worldwide
  - Timeline development / management, meeting facilitation, communication planning / management, deliverable acceleration, risk assessment, mitigation and plan execution
  - Simultaneous submissions to multiple regions with minimal document re-work
- **Electronic submissions processing/publishing and submission**
  - Electonically publish high-quality regulatory submissions utilizing eCTD software
  - Submission to global health authorities
  - Adhere to assigned timelines for global regulatory submissions
- **Operational and technology consulting**
  - Efficient processes and authoring of Regulatory Operations work practices and guidelines
  - Technical guidance across all aspects of regulatory operatons to ensure generation of the highest quality regulatory submissions

9 out of 10 top pharma companies are our valued clients

Over 1000 eCTD submissions annually

Regular interactions with all major global health agencies

Proven track record with 6,000 successfully completed projects

InnoPHLEX

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

APPROVAL / AUTHORIZATION

PRODUCT MAINTENANCE

SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

PHARMALEX IS A LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

Stay **one step ahead** of essential requirements needed by health agencies. Our knowledge accelerates your business success...

Knowledge. Accelerated.

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

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