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DRUG Development Consulting

LSK Global PS

Drug Development Consulting

Our Consulting Expert

Successful product development is directly correlated to its development strategy. Setting up a flexible development strategy early in product development guarantees greater confidence in success and provides a clear guidance along the way for the whole organization.

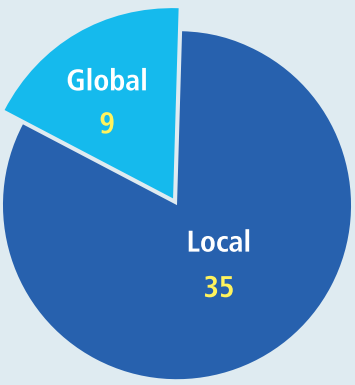
With 20 years of experience, LSK Global PS brings diverse expertise across therapeutic areas to provide consulting services throughout the product life cycle. There are also experts who have had long-term and diverse experiences in pharmaceutical industries.

Experience of Consulting Service

To date, LSK Global PS conducted total of 44 consultations (35 domestic and 9 global). Consulting for new drug development such as licensing and clinical development was conducted.

7 projects among 35 were from government projects from KoBIA (Korea Biomedicine Industry Association), KHIDI(Korea Health Industry Development Institute), and Ministry of SMEs and Startups.

In addition, LSK Global PS has been registered as a partner organization at Seoul Bio Hub and Korea Health Industry Development Institute, and consulting is ongoing for domestic bio-venture companies.



As of 2021.06.30

Our Experts are Your Experts
Expertise to optimize and accelerate development at every step

Our strategic advisory teams help you to create or update your development strategy from preclinical through post-approval or help you on more specific development tasks including TPP(Target Product Profile) establishment, regulatory intelligence, etc.

Specialized expertise

Our experts are established professionals in their field and truly dedicated to assigned projects. Our team brings valuable insights specific to your indication and in compliance with all regulatory requirements.

Real-time Communication & Fast Acting

We can define the project scope and provide our support immediately by real-time communication for all situation and issues.

Flexibility & High Efficiency

We work closely with you to develop customized plans that increase efficiency and reduce risk to help you realize your product's value.

Strategy Consulting Service Organization

Product Development Expert · · · · · · Medical Doctor · · · · · · Statistician · · · · · · Medical Writer

Strategy Consulting Director

- More than 30 years of experience in pharmaceutical industry
- License-in of new drugs / generics / drugs from natural sources for global/ multinational pharmaceutical companies : France, Germany, Austria, Switzerland, Japan, Unites States, Taiwan, India, and Greece.

Executive Medical Affairs Director

· Internal medicine doctor
· 10 years of clinical trials experience on many therapeutic areas (esp. oncology, immunology and metabolism) at multinational and Korean pharmaceutical company
· Experience of team leader for clinical strategy in Korean pharmaceutical company
· Management of advisory board meeting to reflect current unmet medical needs in global

Consulting Service

1. Integrated Development Planning Strategy

The development plan provides a road map for developing new product. A well-planned strategy is an essential element to improve efficiency, reduce overall costs, to shorten the timelines of clinical trials and to increase the probability of success in new drug development. It outlines essential development milestones and success criteria and also provides the bases for determining and managing the project priorities

- **Target product profile Establishment**

  Establishment of TPP analyzes therapeutic market assessment, disease prevalence and mortality surveys, approved or in development stage drug information (such as mode of action; MoA, dosage, route of administration) and clinical development status etc.

- **Medical unmet needs & Market forecast**

  Investigate limitations or problems of existing treatments
  Forecasting the marketability of new treatments based on the survey of future market growth rate of existing treatments

- **Timeline & Budget Planning**

  Plan and manage timelines and budgets to meet development goal as scheduled

2. Non-Clinical Development Plan

Non-clinical study is important part in drug development to assess the safety profile, pharmacokinetic and toxicokinetic (PK/TK) characteristics. Optimization of non-clinical development leads to successful clinical development.

Non-clinical development strategies vary depending on the specification of the candidate drug, and it should be planned with the purpose of the IND submission and the approval.

We will plan for non-clinical development optimized as the sponsor pursed its development direction and the characteristics of the drug to ensure the entry to the successful clinical trials.

- **Gap analysis for non-clinical study data**

  Provide evaluation and review non-clinical data. Provide assessment of additional non-clinical data/studies required, if any

- **GLP CRO selection & evaluation**

  Provide support in selection of the most adequate GLP CRO in terms of its competence and cost-effectiveness.
  Provide advice and support in reviewing GLP CRO proposals and selected sites management

3. Clinical Development Plan

As a full-service CRO encompassing all of the major areas of clinical research, we have conducted 1,185 clinical studies so far, including 662 registration trials and 134 global clinical studies. (Updated on March 2020)

We provide consulting for clinical development planning based on our experience achieved from clinical trial performances in various indications and development stage as a full service CRO.

· Clinical trial design Proposal & Strategy establishment

Propose a development strategy for the clinical trial design that complies with regulatory authorities requirements.

Provide optimized clinical design considering the specification of the drug candidate
Propose required patient number to enroll and endpoints for the demonstration of safety and efficacy according to clinical trial stage and purpose

Early phase

∴ PK-PD modeling simulation :
Initial and effective dose estimation, clinical trial design, PK/PD result prediction for specific dose and population, drug-drug interaction result prediction

∴ Study design concept for PK, BA/BE, FE, DDI, FIH study etc.
Target population, FIH dose estimation, dosage regimen, dose-escalation scheme, control group, eligibility criteria, duration of treatment, country selection etc.

Late phase

∴ Study design concept for Phase 2 & 3
Target population, sample size calculation, treatment dose and dosage regimen, control group, objectives and endpoints setting, eligibility criteria, duration of treatment etc.

∴ Clinical study analysis
Clinical trial design and clinical trial results review

∴ Clinical development planning & revision
Risk-Benefit Assessment with competitors

· Gap analysis for clinical study data

Review and evaluate clinical study data based on regulatory requirements relevant to each clinical phase

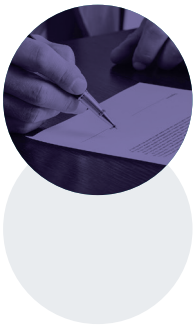
Consulting Service

4. CMC Development Plan

The development of CMC should consider not only the main features of drug supply and formulation strategies, but also the supply of placebo or comparative drugs.

We provide CMC development consulting services based on our expertise in CMC regulations achieved from many years of experience.

- **Gap analysis for CMC dossier for IND and NDA submission**
  Review and evaluate CMC dossiers compliant to regulatory requirements
- **Preparation of Specification and Analytical method**
  Support setting up in-house specifications, Review protocol and analytical method report
- **CMO Selection and Management**
  Provide support in selection of the most adequate CMO in terms of its competence and cost-effectiveness. Provide advice and support in reviewing of CMO proposals and selected sites management
- **GMP Audit**
  Support GMP audit and GMP Compliance check
- **Stability Test planning**
  Provide stability strategy such optimization and minimization of stability design. Provide study plan for DS/DP



5. Regulatory Preparation and Application Strategy (Local & Global)

The regulation varies by countries or regions, and can be more stringent or mitigated depending on the interests and circumstances of the authorities.

Since these variations can influence regulatory plan, it is crucial to plan a regulatory strategy with an expert with detailed understanding of the regulatory, requirements as well as the authorities' expectations.

- **Interpretation and evaluation of regulatory requirements and Trends**

  Understand and interpret the ever changing regulation circumstances (MFDS, FDA, EMA, PMDA etc.).

- **Gap analysis for IND/NDA dossier (Package review)**

  Evaluation and Review of IND package and CTD suitability for country-specific regulatory requirements

- **Bridging Study Strategy**

  Evaluate probability for Bridging study waiver

  Develop Bridging study strategy

- **Regulatory authority meeting plan and strategy**

  Plan for authority meeting and provide advice, support and manage critical issues for meeting

LSK Global PS

Start with LSK Global PS
97 Toegye-Ro, Coryo Daeyungak Tower 16th Fl,
Jung-Gu, Seoul 04535 Korea

Main : +82. 2. 546. 1008
Fax : +82. 2. 584. 9008
E-mail : bd@lskglobal.com (for Estimation)
information@lskglobal.com (for General inquiry)