PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

INTEGRATED PRODUCT DEVELOPMENT

"If you don't know where you are going... you might end up someplace else."

Mark Lane

Vice President, Principal Consultant
Development Consulting & Scientific Affairs

Drug development requires the integration of many different, yet interrelated activities. Without a clear destination and roadmap your journey to the market will cost more and take longer than expected. An integrated development approach reduces cost and complexity while helping to ensure commercial success.

TARGET PRODUCT PROFILE: THE DESTINATION

A Target Product Profile (TPP) is critical to defining your ultimate destination, how your drug will fit into clinical practice and the market landscape, resulting in commercial success. The TPP also forms the basis of the overall development strategy.

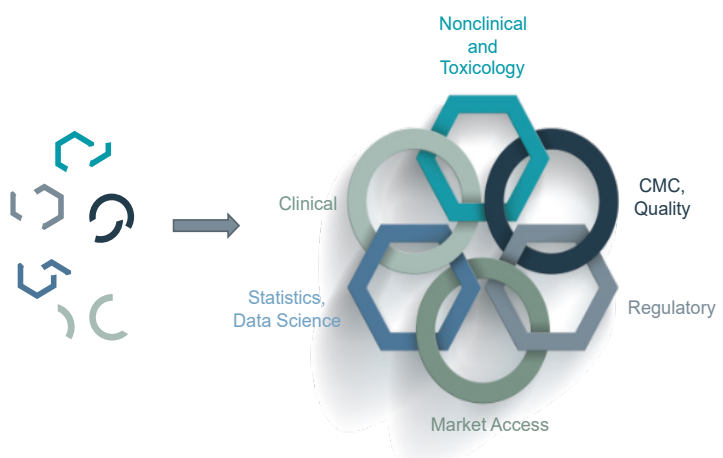
A TPP should address the following questions:

- ✓ What unmet medical need does your product address?
- ✓ What are the targeted indications and patient population?
- ✓ What doses will be developed including route of administration and frequency of dosing?
- ✓ Are there key safety and efficacy claims needed for success?
- ✓ How will your product differentiate from existing therapies or those in development?
- ✓ What key scientific and clinical questions must the development program address?

WHAT IS INTEGRATED PRODUCT DEVELOPMENT (IPD) ?

Once a TPP has been established, an integrated product development (IPD) strategy ensures the various functional activities come together to progress development efficiently while improving the probability of regulatory and commercial success. Why is this important?

- Drug formulation and supply strategies must account for design and timing of both animal and human studies
- Regulatory guidance and precedence along with region or country specific medical practice impact the design of the global clinical program
- Early clinical studies not only establish safety and proof of concept, but also influence the design of future studies
- Patient, physician and payer considerations may differ from regulatory requirements for approval



Failure to consider these and other cross-functional considerations ultimately leads to cost overruns, delays in product development and launch, and ultimately impact commercial success. At Pharmalex we understand how the various pieces must come together to deliver new products to the market and ensure commercial success.

PHARMALEX OFFERS A HOLISTIC FRAMEWORK OF DEVELOPMENT SOLUTIONS

CMC Development

- CMC product services: All types of active pharmaceutical ingredients, including complex biologics and advanced therapies
- Strategic CMC consultancy such as comparability exercises
- CMC technical writing
- CMC compliance services

Nonclinical Development

- Nonclinical development and IND-enabling program design and gap analysis
- Scientific due diligence
- Target product profile
- Pre-IND meeting and scientific advice
- Special designations such as orphan and fast track
- Pediatric investigation plan

Clinical Development

- Global clinical development strategy, including regulatory road map
- Gap analyses
- Agency and regulators interactions
- Scientific, medical, technical, and regulatory writing: IND, clinical trial authorization, including investigator's brochure, protocol, and other supportive clinical trial documentation)
- Program and project management

File Preparation and CTD-Module Authoring

- CTD-module writing
- All types of regulatory pathways
- Presubmission meeting support
- Label development

Our Global Center for Integrated Development (GCID) is comprised of IPD Leaders, Program Mangers, and Subject Matter Experts who help craft and execute your asset development strategy.

CONTACT US
Email: contact@pharmalex.com