QUICK REFERENCE GUIDE

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.

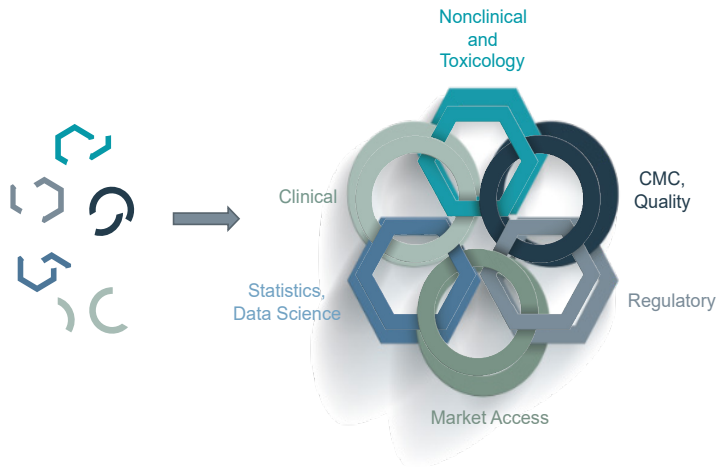
A TPP should address the following questions:

- ✓ 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 BENCH-TO-BEDSIDE DEVELOPMENT SOLUTIONS

Pre-clinical

- * Non-clinical Development and IND-enabling Program Design and Gap Analysis
- * Scientific Due Diligence
- * Target Product Profile
- Computational Biology. Data Sciences, & Bioinformatics
- CMC Consulting
- Statistical Services
- * Toxicology Assessments
- * Pre-IND meeting, Scientific Advice
- * Special Designations (Orphan, Fast Track, etc.)
- * Pediatric Investigation Plan (PIP)
- Environmental Risk Assessment
- CMC services and support.

Clinical Development

- * Global Development Strategy (incl. clinical / regulatory)
- * Gap Analyses
- * Health Authority and Agency interactions (SPA, Sci Advice, EOP, other)
- * Scientific, Medical, Technical and Regulatory writing (IND / CTA incl. IB, Protocol and other supportive CT documentation)
- Clinical Trial Safety Support, including Safety writing (annual reports), PV Systems / Signal Management
- IMP management
- Risk Management Support
- QMS Development / Implementation, incl. audits and Inspection readiness
- * Study design (e.g. adaptive trials); statistical analysis, digital biomarkers
- Program and Project Management.

Submission, Review & Approval

- * NDA, BLA, MAA submissions
- * All types Regulatory Pathways
- * Submission sequencing
- * Pre-Submission Meeting Support
- * Label Development
- * Market Access strategy
- PAI and Commercialization Readiness
- Tech Transfer and Scaleup
- Promotional Material Review

Life Cycle Management

- * Geographic Expansion
- * New Uses, Indications, Populations
- * Pre-Submission Meeting Support
- Case processing and safety literature review
- Ad promo
- Post-Approval Commitment Strategy
- Health Economic Modeling
- * Pricing and reimbursement.

* Example IPD solutions requiring cross-functional integration

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