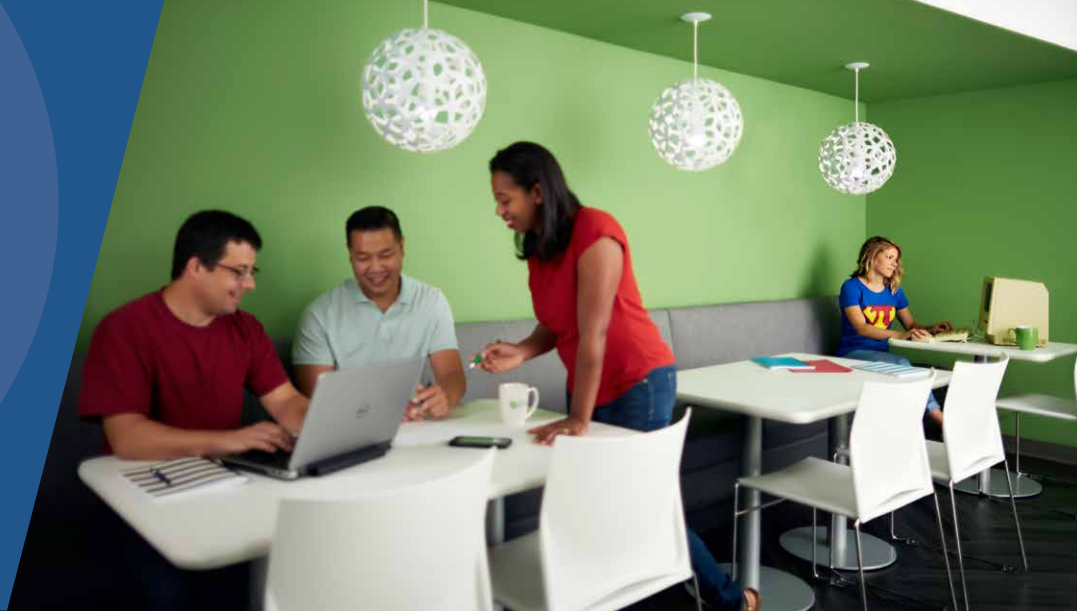
Integrated Product Development



Strategically chart an efficient, integrated path for your product from beginning to end.

From preclinical proof-of-concept candidates to approved products primed for post-marketing label extension, our Integrated Product Development experts provide intelligent guidance to catalyze development of your products.

Choose from our scalable biopharmaceutical services to meet your specific product developmental and life-cycle goals:

- Brief discipline-targeted consulting
- Longer-term discipline-specific oversight and guidance
- Integrated, multidisciplinary product planning and support

Rho's Integrated Product Development experts plan and coordinate each clinical, non-clinical, CMC/Quality, and regulatory activity for your product, balancing risk against accelerated timelines by optimizing regulatory interactions and strategically running the right studies at the right time to achieve milestones with maximal efficiency. We allow you to focus your resources more effectively and get your products to patients faster while preventing costly development missteps.

Intelligent, Integrated Product Development. *Catalyzed.*

SERVICES AND CONSULTING

- Targeted consulting engagements in any discipline, including Regulatory, Nonclinical, CMC, Clinical, Data Management, and Biostatistics
- End-to-end development guidance and support
  - Creation and implementation of a strategic Integrated Product Development Plan
  - Development of the Target Product Profile
  - Product management through full life cycle
  - Coordination of concurrent activities to accelerate development timelines
  - Design, implementation, and conduct of clinical studies (Phase I-IV)
  - Proactive risk management/mitigation
  - Maximization of portfolio value by leveraging current technologies

INTEGRATED PRODUCT DEVELOPMENT

Dedicated cross-functional advisors serve as a cost-effective extension of your team

- Target product profile development to set nonclinical, clinical, CMC, regulatory, and commercial goals to achieve key milestones
- Gap analyses and integrated product development planning
- Coordination of all nonclinical, CMC, phase I-IV clinical studies, and regulatory activities
- Orchestration of concurrent activities to maximize efficiency and reduce costs
- Establishment and maintenance of excellent communication and collaboration to keep your program moving forward

REGULATORY	NONCLINICAL	CMC	CLINICAL	ANALYTICAL DATA SCIENCES
• Regulatory strategy and agency communication to obtain first-cycle approvals • IND, CTA(N), NDA, BLA, MAA, briefing packages, and full life-cycle management • Submission technical writing and regulatory dossier preparation • Compliance audits (mock/formal)	• Nonclinical safety assessment and strategy/gap analysis • Pharmacology/ toxicology/ pharmacokinetic study design and oversight • Regulatory authority representation and negotiation • Complete outsourcing services, study monitoring, and CRO management	• Pre-formulation/ formulation development • Due diligence and regulatory compliance audits • Regulatory authority representation and negotiation • Drug substance and drug product planning, coordination, and oversight • Contractor evaluation • CTM packaging and labeling oversight	• Design and execution of global Phase I-IV clinical studies • Protocol and clinical study report development • Study feasibility assessments • Site selection, management, training, and clinical monitoring • Global safety and reporting services with Argus Safety including E2B interchange	• Complex study design and analysis, including Adaptive Design • Leaders in development and implementation of CDISC data standards • State of the art electronic data capture (in-house Medidata/ RAVE) • End-to-end integration of data standards from protocol to CSR • Submissions and integrated analysis (ISS/ISE)

FOR 30+ YEARS, Rho has been a trusted partner to leading pharmaceutical, biotechnology, and medical device companies as well as academic and government organizations Our commitment to excellence, innovative technologies,and therapeutic expertise accelerate time to market and lead to an exceptional customer experience.

WHAT OUR CUSTOMERS ARE SAYING...

"[Rho is a] completely different kind of company – you deal with people to build a solution to your needs, not a rigid set of policies and timelines. Clearly tuned to addressing their clients' needs. Organized, thorough and FAST. A pleasure to work with, and will definitely use them again."