



## **Preclinical Stage Support Services**

**Atheln, Inc.** is a **multi-disciplinary** life science consulting firm with a broad range of execution capabilities. We cost-effectively tailor the integrated, cross-functional approach to product development and commercialization, practiced by successful life science companies, to the needs of our clients. Our team's hands-on involvement ensures effective planning, execution and management of deliverables. We can work closely with your internal staff, or serve as your **development team**.

The Atheln team will propel your preclinical stage, early development company toward the clinic by assisting in multiple areas, including:

- Gap Analysis of all aspects of a program
- Intellectual Property:
  - Evaluate current intellectual property and relationship to business strategy
  - Provide recommendations to strengthen intellectual property and bring IP protection into alignment with business strategy
  - Coordinate with IP counsel to achieve IP goals
- Regulatory:
  - Plan and develop questions for a Pre-IND meeting with FDA
  - Plan and execute pre-IND briefing document
  - Evaluate regulatory strategies (Orphan Drug, Fast Track, etc.)
- CMC
  - Identify, evaluate, and manage a CMO for production of Phase 1 material
  - Advise on formulation development and stability program
  - Develop preliminary release criteria and specifications
- Non-clinical
  - Interface with scientists and capture primary data in IND ready reports
  - Plan IND-enabling Pharmacology/ Toxicology Program
  - Evaluate and advise on appropriate animal models and CRO selection
  - Study protocol writing and execution
  - Advise on biological activity/ potency assay development
  - Review final study reports



- Quality
  - Develop phase appropriate SOPs and documentation systems
  - Develop Quality Agreements with potential CMOs
  - Conduct audits of potential CMOs
  
- Clinical
  - Develop a full Phase 1 Clinical Protocol
  - Develop an Informed Consent Form
  - Interface with company clinician or clinical advisor
  
- Business Development and Licensing
  - Licensing strategy
  - Business Development support
  - Finance strategy and planning
  - Investor package
  - Due diligence support
  
- Commercial Support
  - Initial business plan/ product strategy
  - Due diligence/ portfolio analysis
  - Identification of business models and value propositions
  - Commercial technology assessment and validation (Key Opinion Leader & Strategic Partnerability Assessment™)
  - Identification of market requirements for FIH trials
  - Development of initial product profile
  - Market assessment and forecasting
  - Fundraising support

Contact us at: [info@athelnbiomed.com](mailto:info@athelnbiomed.com)