Atheln inc.
Propelling life science innovations

Phase 1 Entry 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 can assist your company in multiple areas as you advance your product into a first-in-human clinical trial. Services include:

- Gap Analysis of all aspects of a program
- Intellectual Property:
  - Provide recommendations to strengthen IP, including expansion of patent portfolio, such as adding protection of formulations and additional indications
  - Review proposed publications for consistency with IP strategy
- Regulatory:
  - Plan, execute, and publish IND submission
  - Assist in obtaining appropriate regulatory approvals (for example, Institutional Review Board, Institutional Biosafety Committee)
  - Correspond with FDA
  - File IND Amendments and Annual Reports
- CMC
  - Identify, evaluate, and manage a CMO for production of Phase 1 material
  - Prepare CMC section of the IND
  - Advise on formulation development and stability program
  - Develop preliminary release criteria and specifications; Review Certificates of Analysis
  - Evaluation of existing analytical characterization data for molecule and identification of additional testing and testing sites as needed
  - Manage analytical testing labs and support the planning, execution and reporting of analytical method development and validation programs to optimize time and cost

CMC *(continued)*

- Assist in the selection, qualification and use of reference standards for BDS and DP at each stage, including set up of specifications and control program
- Design and setup of analytical laboratories, including equipment evaluation and purchasing

- 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 design and interpretation
  - Advise on biological activity/ potency assay development
  - Review final study reports

- Quality
  - Develop phase appropriate SOPs and documentation systems
  - Develop Quality Agreements with CMOs
  - Conduct audits of CMOs
  - Conduct training

- Clinical
  - Develop Phase 1 Clinical Protocol
  - Develop Informed Consent Form
  - Identify and evaluate clinical CROs to assist in conducting the IND
  - Develop a Phase 2 Clinical plan

- Business Development and Licensing
  - Licensing strategy
  - Business Development support
  - Finance strategy and planning
  - Investor package
  - Due diligence support

- Commercial Support
  - KOL development and input
  - PR Strategy
  - Publication Plan
  - High level Commercial Validation
  - Market assessment and forecasting
  - Develop Product Profile
  - Commercial strategy for fundraising

Contact us: info@athelnbiomed.com