Clinical 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****.*

As the development pathway continues and your company embarks in Phase 2 or 3 clinical trials, the Atheln team can assist you in multiple areas, including:

- Regulatory:
  - Plan and execute end of Phase 1 and end of Phase 2/ Pre-Phase 3 meetings
  - Plan, execute, and publish NDA or BLA submission

- Non-clinical
  - Advise on Pharmacology/ Toxicology Program needs

- CMC
  - Troubleshooting technical issues and manufacturing problems
  - Select and manage a CMO for production of Phase 2 and 3 material
  - Select and manage analytical testing labs and assist with planning, execution and reporting of Phase appropriate analytical validation programs
  - Advise on stability programs for BDS, DP, as well as shipping and point of use needs
  - Adapt release criteria and specifications based on historical results and Phase needs; review Certificates of Analysis
  - Assist on the selection, qualification and use of reference standards for BDS and DP at each stage, including set up of specifications and control program
  - Design analytical comparability studies, analyze the results and write the conclusions
  - CMC section for NDA, BLA or DMF
  - Set up or upgrade Quality System to be Phase appropriate

- Commercial Support
  - Go-to-market strategy (out license, co-market, launch)
  - Pre-launch strategy/roll-out
  - Finalize product profile and claims strategy
  - Strategic communications and advocacy strategies
  - Create or review payor plan
  - Constantly scan competitive assessment