Atheln inc.
Propelling life science innovations

Chemistry, Manufacturing, and Controls

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 provides a depth and breadth of CMC services, including:

- Technical due diligence & strategic planning

- Design and lead the execution of Integrated CMC (Chemistry, Manufacturing & Controls) development plans for an IND submission, including:

  - Evaluation of manufacturing process development data and analytical data for bulk drug substance (BDS) at different scales to establish Phase appropriate specifications and in-process controls requirements
  - Evaluation of existing analytical characterization data for molecule and identification of additional testing and testing sites as needed
  - Design of molecular characterization studies
  - Assist contractors with planning, execution and reporting of analytical method development and validation programs to optimize time and cost
  - Evaluation of formulation and fill & finish development data for drug product (DP) and assist on their optimization
  - Design of Phase appropriate stability studies and plan to support filing timeline
  - 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
  - Set up of Phase-appropriate specifications for BDS & DP
  - Design of stability studies for BDS & DP
  - Design of analytical comparability studies

- Design of analytical strategies for all stages of product development, including:

  - Design and setup of analytical laboratories, including equipment evaluation Analytical method troubleshooting & optimization / design of validation protocols
  - Data evaluation, analysis and writing of reports / opinions
  - Design and interpretation of protein and glycosylation analysis
  - Design and interpretation of carbohydrate analysis

- Selection, auditing and management of CMOs, contract laboratories and critical suppliers, including:
    - Writing and negotiation of Quality Agreements
    - Vendor qualification
    - Management of project execution
- Set up of stage-appropriate Quality Systems
    - Build the necessary components of a Phase appropriate Quality Policy, including SOPs, document archiving and control, qualification of contract organizations, implementation and training. For more details see our Quality Section.
- Writing of CMC sections, Technical Reports & Opinions / Participate in meeting with Regulatory Agencies
- Technical Investigations / Troubleshooting / Optimization & Problem Solving