Atheln inc.
Propelling life science innovations

Quality Systems 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****.*

Quality Systems must be tailored to your current stage of product development. The Atheln team brings a depth and breadth of expertise to all aspects of Quality. We can set up your initial Quality systems framework, as well as serving many Quality Assurance functions, as detailed below.

Quality support services include:

- Gap Assessment to ensure compliance with regulatory agency requirements, including cGMP/ GLP/ GCP/ ISO 9001 compliance

- Development of Phase appropriate Quality Systems
  - SOP preparation
  - Serve as Quality Assurance Department

- Development of Quality Agreements with CMOs and critical suppliers

- Conduct audits of manufacturing and testing facilities in the U.S. and worldwide, including
  - review of laboratory and manufacturing process controls
  - stability programs
  - environmental monitoring
  - equipment qualifications and process validation
  - CAPA systems
  - complaint and product recall handling
  - material controls and non-conforming product
  - equipment/utilities/calibration & maintenance
  - personnel training

- Assist in quality investigations:
  - Deviations
  - OOS
  - Complaints
  - non-conforming materials, etc.

- Documentation review:
  - batch/device records
  - raw material and finished product specifications
  - validation protocols
  - clinical data review
  - deviation analysis/reporting
  - critical system changes
  - product complaint analysis,
  - annual product reviews

- Training in all aspects of quality and compliance

- Pre-Approval Inspection preparation and response to FDA observations or Warning Letters

- Assured compliance with FDA requirements when corrective actions are implemented.

Contact us at: *info@athelnbiomed.com*