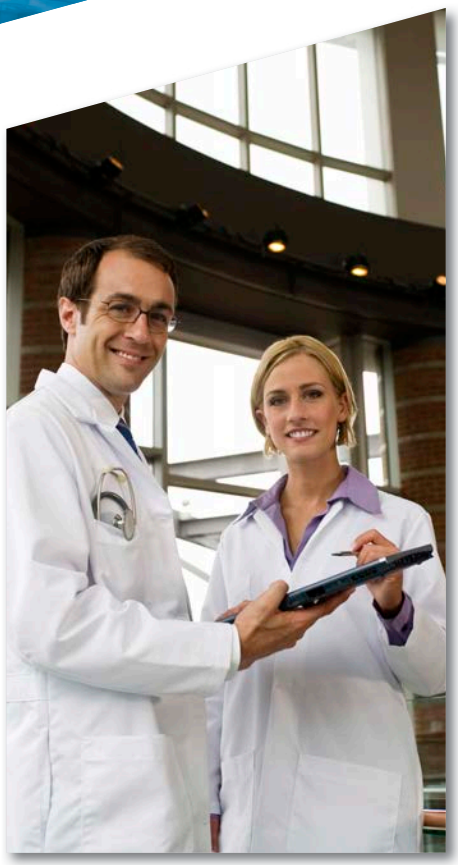
BIOLOGICS & BIOTECH

Lachman CONSULTANTS
Experience. Excellence.™

Experience excellence in technical, regulatory consultation and guidance services for biologics and biotechnology.



CONSULTATION, SERVICES & SUPPORT FROM A TRUSTED PARTNER

Lachman Consultants brings both experience and excellence to its Biologics and Biotechnology Consultation Services. Through a dedicated single point of contact, multi-disciplinary groups of accomplished FDA and industry experts are assembled from our Compliance, Regulatory, and Science and Technology Practice Groups. These comprehensive teams are selected and assigned based on each client's unique set of objectives, needs and circumstances.

Our expertise and knowledge, gained through decades of experience, is evident throughout our extensive quality systems, protocols and procedures. Lachman Consultants is well-prepared to serve the needs of companies developing biological products, as well as those whose products are transitioning from NDAs to BLAs. We are ready to serve clients with required reporting, documentation, and pre- & post-approval changes.

Lachman Consultants Biologics & Biotechnology Services and Features:

- Support for CDER-, CBER-, and CDRH-Regulated Products, including:
  - Monoclonal Antibodies
  - Growth Factors
  - Replacement Enzyme Therapies
  - Peptides
  - In-vitro Diagnostics
  - Cellular and Tissue-based Therapies
- GMP Audits
- Regulatory Transitions of HCT/P's to Drug Products
- Manufacturing Technology Transfers
- FDA Meeting Preparation
- FDA Document Preparation
- Testing Assessment and Guidance
- cGmp Facility Audits
- FDA Inspection Preparation
- Due Diligence Assessments

LACHMAN CONSULTANTS ADVANTAGES AND BENEFITS:

- Optimum Regulatory Compliance
- Increase Operational Efficiencies
- Reduce Costs & Process Complexity
- Minimize Compliance Risks
- Accelerate Business Outcomes

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