CELL & GENE THERAPY

Lachman CONSULTANTS
Experience. Excellence.™

Experience excellence with a full range of consultative services and support for Cell & Gene Therapy.

A TRUSTED RESOURCE FOR CONSULTATION AND SUPPORT

Lachman Consulting Services, Inc. is your partner for taking a proactive, solutions-focused approach to Cell & Gene Therapy (CGT). We provide advice and guidance to CGT clients in the early phases, moving towards GMP manufacturing as well as more advanced programs, preparing for later phase and registration.

We work closely with you to help avoid common missteps and potential delays due to inadequate or poor Quality and Compliance planning and execution. Lachman Consultants also enables clients to resolve and remediate health authority observations.

Lachman Consultants' CGT Consulting Services Include:

- GMP Readiness
  - Early stage – GMP Readiness for FTIH / Phase II
  - Phase III / Commercialization planning
  - Regulatory submission
  - Inspection readiness assessment/preparation
- Quality System Development for CGT
  - Phase appropriate elements and approach to Quality System for CGT
  - Quality System assessment, development and deployment
- Regulatory Inspection Response
  - Observation response
  - Remediation program
- Regular review and insights on CGT compliance, CGT trends and topics
  - Inspection trends
  - Responding to new and emerging regulations (Annex 1)
- Data Governance and Integrity
  - Guidance on current trends and expectations
  - Data Integrity Assessment and recommedation
- Third Party CMO evaluation & selection
  - Third Party audits
  - Process / capability fit
  - Robustness & capacity confirmation
  - Third Party Quality Performance monitoring
- Operations
  - Quality Issue Support
  - Quality Performance 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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