CELL & GENE THERAPY

Advance.Confidently.

Lachman CONSULTANTS (IRELAND)

Experience. Excellence.™

A TRUSTED RESOURCE FOR CONSULTATION AND SUPPORT:

GMP Readiness

- Early stage – GMP Readiness for FTIH / Phase II
- Phase III / Commercialization planning
- Regulatory submission
- Inspection readiness assessment/preparation

Quality System Development

- Quality System assessment, development and deployment
- Phase appropriate elements and approach

Regulatory Inspection Response

- Observation response
- Remediation program

Compliance

- Inspection reviews - trends and topics
- New and Emerging regulations (Annex 1)

Data Governance and Integrity

- Guidance on current trends and expectations
- Data Integrity Assessments and recommendations

Data Governance Third Party CMO

- Evaluation and selection
- Third Party audits
- Process / capability fit
- Robustness & capacity confirmation
- Quality Performance monitoring

Operations

- Quality Issue Support
- Quality Performance Assessments

COMPREHENSIVE CAPABILITIES. PROVEN EXPERIENCE.

Optimise Regulatory Compliance | **Increase Operational Efficiencies** | **Reduce Costs and Process Complexity** | **Minimise Compliance Risks** | **Accelerate Business Outcomes**

CONTACT US TODAY

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