Lachman CONSULTANTS

CELL & GENE MEETING ON THE MESA | OCT 5–7, 2026 | ARIZONA BILTMORE, PHOENIX

You trust your science.
Are you CGMP ready?



Phase-appropriate quality, CMC, and inspection readiness for cell & gene therapies — from IND to BLA/MAA and beyond.

QUALITY SYSTEMS

Assess, design, and implement

INSPECTION READINESS & RESPONSE

PLI / PAI readiness led by former FDA and industry experts.

SUPPLY CHAIN ASSESSMENT & QUALIFICATION

Qualify, audit, and remediate your potential supply chain partners.

Meet us at Mesa.

Visit our exhibit table or book time in the Lachman private meeting room.
Request a 1x1 through partneringONE: Lachman Consultants

SCAN: ADVANCED THERAPIES

ADVANCE. CONFIDENTLY.

How Lachman supports advanced therapies

FDA and EMA expertise | strategy and hands-on execution.

Regulatory Strategy

IND, BLA, CTA and MAA strategy; RMAT, Breakthrough and PRIME pathways; INTERACT, pre-IND and pre-BLA meeting prep.

Phase-Appropriate Quality Systems

Design and implement QMS that fit your stage and scale to commercial.

CMC Guidance

CMC support from development through commercialization.

GMP & Inspection Readiness

GMP readiness assessments and inspection preparedness for all stages of the product lifecycle.

Contamination Control

Risk assessments aligned with EU GMP Annex 1 and ATMP-specific guidelines.

CMO / Supplier Qualification

Evaluate and qualify CDMOs, suppliers and technology platforms.

Data Governance & Integrity

Data integrity and documentation for complex biologics.

483 & Warning Letter Response

Response strategy, authoring and remediation when findings land.

WHO WE SERVE

Autologous & allogeneic CGT developers • ATMP sponsors • Viral vector & plasmid producers
CDMOs supporting advanced therapies • Biotech startups & academic spinouts

SINCE 1978

Former regulators. Industry veterans. One integrated team.

+1-516-222-6222 | LCS@lachmanconsultants.com | lachmanconsultants.com

Westbury, NY • Bethesda, MD • Dublin, IE

LEARN MORE