

## Accelerate Your Path to Clinic: Complimentary CMC Consultation Services for Cell Therapy Developers

**Introduction:** In today's competitive and capital-constrained cell and gene therapy environment, early decisions around Chemistry, Manufacturing, and Controls (CMC) can make or break a therapy's timeline, cost-efficiency, and eventual approval. Yet many emerging cell therapy companies struggle with CMC strategy until it becomes a bottleneck.

Excellos is offering a limited number of **complimentary 60-minute CMC consultations** designed to provide early-stage developers with strategic guidance before they engage a CDMO partner. This no-cost service is part of our commitment to scientific collaboration and building stronger foundations for future partnerships.

### Why CMC Strategy Matters Early:

- Regulatory agencies are increasingly scrutinizing CMC sections in IND filings, often leading to delays due to avoidable issues.
- Key decisions around donor material, process comparability, and scalability are best made early—not during tech transfer.
- A proactive CMC strategy reduces risk, compresses timelines, and improves regulatory confidence.

**What the Consultation Includes:** Each 60-minute session is led by a member of our QC/Regulatory leadership team, and may include:

- Review of high-level CMC strategy and current development phase
- Identification of potential gaps or misalignments in current plans
- Discussion around raw material sourcing, cleanroom compatibility (viral vs. non-viral), and regulatory expectations
- Recommendations for sequencing CMC activities in alignment with clinical milestones

### Who It's For:

- Emerging biotech companies in pre-IND or early clinical planning stages
- Scientific and operational leaders seeking clarity on CMC readiness
- Teams evaluating CDMO partnerships but unsure where to begin

**What It's Not:**

- This is not a substitute for formal regulatory consulting or tech transfer execution
- No proprietary data or NDAs are required for participation

**Why Excellos:** As a donor-to-dose CDMO with deep expertise in both upstream material and downstream manufacturing, Excellos brings a uniquely integrated perspective to early CMC planning. Our team understands the scientific, operational, and regulatory nuances that CGT developers face—and we're here to support your success.

**Get Started:** To schedule your complimentary consultation, reach out to our team at [info@excellos.com](mailto:info@excellos.com) or connect with us on LinkedIn.

**About Excellos:** Excellos is a purpose-built cell therapy CDMO based in San Diego, offering integrated services from high-quality starting material to GMP manufacturing. Our E360 platform enables deep cell characterization and optimized donor selection, supporting greater consistency and clinical impact across the cell therapy development lifecycle.

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