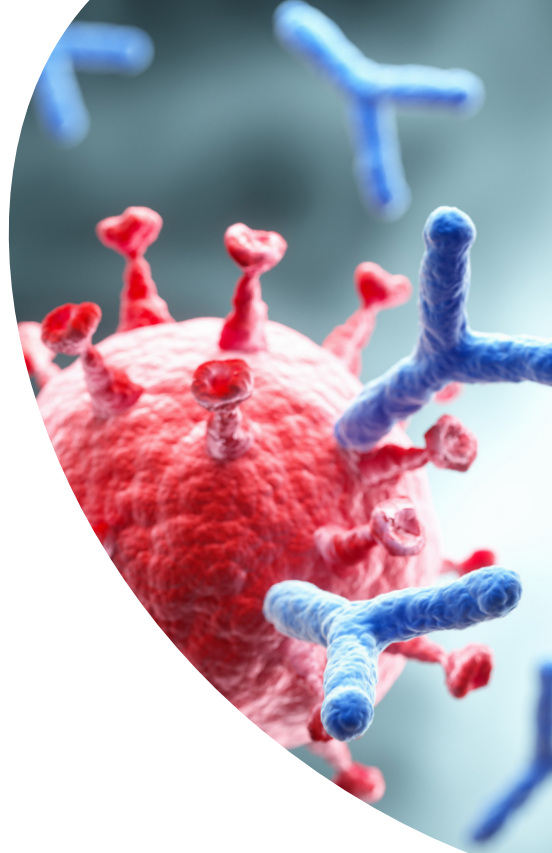


Building a Phase-Ready CMC Organization for a Clinical-Stage CAR-T Cell Therapy Company



The Challenge

A three-employee biotechnology company was advancing an autologous CAR-T program toward first-in-human development, but lacked the internal CMC organization needed to coordinate manufacturing, analytical development, regulatory strategy, and IND preparation.

The company required experienced leadership and specialized expertise without the time and fixed cost of building a large permanent team.

The Operating Model

Syner-G embedded senior CMC leadership and added specialized SMEs as development needs evolved, providing flexibility and capital efficiency.

Program at a Glance

- ✓ **3**
CLIENT EMPLOYEES
- ✓ **CMC**
EMBEDDED LEADERSHIP
- ✓ **INTERACT**
MEETING SUPPORT
- ✓ **PRE-IND**
MEETING STRATEGY
- ✓ **IND**
CMC AUTHORIZING

The Syner-G Solution

Syner-G served as an embedded extension of the company, combining a senior CMC program lead with specialists across process development, analytical development, manufacturing, quality, supply chain, Regulatory CMC, preclinical development, and nonclinical strategy.

CDMO SELECTION & MANUFACTURING STRATEGY

- Established technical and quality criteria for prospective cell therapy CDMOs.
- Led capability assessments, due diligence, selection, onboarding, and governance planning.
- Developed an early-clinical manufacturing and technology-transfer strategy.

PROCESS & ANALYTICAL DEVELOPMENT

- Led phase-appropriate process development and manufacturing control strategy planning.
- Defined the analytical roadmap for identity, potency, characterization, safety, release, and stability.
- Integrated technical risks and mitigation actions into the development plan.

PRECLINICAL & NONCLINICAL PROGRAM GUIDANCE

- Embedded preclinical and nonclinical SMEs to guide study strategy, program planning, and execution.
- Aligned preclinical and nonclinical activities with CMC priorities, regulatory interactions, and the integrated development plan.

REGULATORY CMC & AGENCY ENGAGEMENT

- Built the high-level Regulatory CMC strategy and integrated CMC development plan.
- Led CMC preparation for FDA INTERACT and pre-IND meetings, including briefing content, key questions, and follow-up actions.
- Aligned agency feedback with manufacturing, analytical, and documentation priorities.

IND GENERATION

- Authored and coordinated IND CMC content across process, analytical, manufacturing, and quality disciplines.
- Established a structured, submission-ready documentation framework.

Business Impact

Syner-G enabled the lean company to operate with the capabilities of an experienced cross-functional development organization, including CMC, preclinical, and nonclinical expertise, without extensive internal hiring.

01

Coordinated CMC development roadmap

02

Qualified external manufacturing strategy

03

Integrated CMC, preclinical, and nonclinical development programs

04

Clear path through FDA interactions

05

Integrated IND CMC package

A scalable CMC foundation for clinical advancement

Integrated strategy, technical execution, and regulatory readiness from CDMO selection through IND generation.