UC DAVIS HEALTH

Offerings to the Alpha Clinics Network

Good Manufacturing Practice

GMP Overview

The UC Davis GMP Facility, located in Sacramento, has supported early through late phase clinical trials since 2010. We specialize in manufacturing cell and gene therapy products according to cGMP regulatory standards.

Our cleanrooms, quality systems, and expert staff help academic and industry partners move products from “bench to bedside”.

Process & Analytical Development

- Early-phase optimization and scale-up
- Tech transfer documentation & training
- Analytical method qualification (identity, purity, viability, VCN)
- Stability-indicating assays & in-process controls

Manufacturing Modalities

- Cell Therapy (Autologous & Allogeneic): CAR T cells, MSCs, HSCs; isolation, expansion, gene modification, cryopreservation
- Gene-Modified Therapies: Viral vector gene transfer (LVV, RVV, AAV and AD)
- Viral Vector Integration: Prequalified vector handling, safety protocols, and GMP workflows
- Fill-Finish: Manual/semi-automated sterile vial filling, labeling, ISO 5 environments

Quality Control and Analysis

- Identity & Purity: Flow cytometry, viability, surface markers
- Potency Testing: Qualified assays, ELISAs, dPCR, Flow cytometry
- Sterility & Safety: Mycoplasma, endotoxin, sterility
- Vector Copy Number (VCN): qPCR for gene-modified products
- Stability & Enumeration: Real-time stability studies, automated cell counts

Facility & Certifications

- ISO 7 cleanrooms, ISO 5 workstations
- CDPH Drug Manufacturing License
- Institutional Biosafety Committee (IBC) & EH&S oversight
- Full GMP documentation systems (batch records, SOPs, equipment logs)
- Qualified equipment, validated cleaning, and controlled-access storage

Regulatory & Quality Assurance

- Aligned with ICH Q7 and FDA phase-appropriate GMP guidance
- Onsite QA/QC support, chain of custody, Certificates of Analysis (CoA)
- CMC section writing support and consultation

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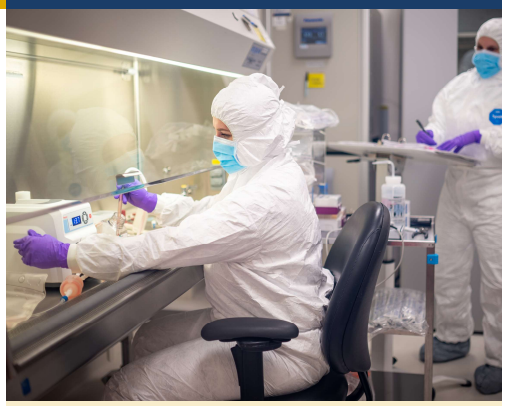

UC Davis Health Alpha Clinic

Member of

CIRM ALPHA CLINICS NETWORK

Experience Beyond the Bench

Institute staff have exceptional skills and experience with cell and gene therapy and gene-modified adult stem cells and their translation from pre-clinical phases to clinical investigations. Hourly consultation rates are available.

Believe in Better