Facility Name
UC Davis GMP Facility

Facility Contact
Brian Fury

Contact Email
bfury@ucdavis.edu

Facility Location
2921 Stockton Blvd, Sacramento, CA 95817

The UC Davis GMP Facility located at 2921 Stockton Blvd, Suite 1345, Sacramento, CA 95817, within the UC Davis Institute for Regenerative Cures on the UC Davis Health System campus, is a multi-suite cleanroom complex operating according to cGMP guidance under state licensure for the manufacture of cell, gene, and small molecule products.

The facility includes cleanroom suites and support infrastructure for GMP manufacturing of cell, gene, and drug products for clinical research and early-phase trials.

Manufacturing facilities footprint & capacity:
The UC Davis GMP Facility features:

- 6,000 sq ft of classified manufacturing space, including 3,500 sq ft of classified cleanroom space which are ISO 7/8 cleanroom suites, ISO 5 BSCs, and dedicated gowning and airlock areas.
- Modular room design supporting parallel campaigns and phase-appropriate customization.
- Closed and semi-closed system processing for autologous and allogeneic workflows.
- Daily operational capacity supports 6 concurrent manufacturing runs across (6) ISO 7 suites.
- Support infrastructure includes QC sample staging, cryogenic storage, temperature-controlled warehousing, and GMP document control systems.
- Scalable personnel and scheduling systems to meet Phase I–III and compassionate use manufacturing demands.

Flexible room design supports parallel campaigns and phase-appropriate customization. Closed and semi-closed system processing is supported for autologous and allogeneic workflows.

Daily operational capacity supports 2–4 concurrent manufacturing runs across multiple suites. Support infrastructure includes QC sample staging, cryogenic storage,

temperature-controlled warehousing, and GMP document control systems.

Scalable personnel and scheduling systems meet Phase I–III and compassionate use manufacturing demands.

Modalities/tech platforms supported:
The UC Davis GMP Facility in Sacramento is equipped to support a wide range of advanced therapeutic manufacturing platforms for clinical-stage products. Our capabilities include:

- Autologous and Allogeneic Cell Therapy: Manufacturing support for T cells, NK cells, dendritic cells, MSCs, and other somatic cell products. We offer isolation, activation, expansion, gene modification, and cryopreservation under GMP conditions.
- Gene-Modified Cell Therapy: Full support for CAR-T processes, including lentiviral or retroviral transduction and in-process QC testing. We also accommodate non-viral gene transfer technologies, with closed-system compatibility and scalable formats.
- Viral Vector Integration: Use of prequalified viral vectors with integration into manufacturing workflows. Our systems support optimized vector handling, transduction, and safety protocols across multiple suites.
- Small Molecule & Fill-Finish: Manual and semi-automated fill/finish capabilities for clinical drug products, including sterile vial filling, compounding, stoppering, crimping, and labeling in ISO 5 environments.

The facility supports closed and semi-closed manufacturing workflows using a broad range of industry-leading instrumentation. Our team has experience with automated cell processing platforms, sterile welding/sealing systems, and tubing sets designed for aseptic function and reduced contamination risk. This allows us to support flexible, scalable manufacturing for both autologous and allogeneic products across multiple modalities.

Quality Support: Onsite electronic documentation systems, QA/QC support, stability testing, and certificate generation are available for release of both cell and drug products.

This flexible platform supports Phase I-III clinical trials, investigator-initiated INDs, and collaborative academic/industry programs.

Process & analytical development capabilities:
The UC Davis GMP Facility provides early-stage process and analytical development support to enable GMP readiness and technology transfer. Capabilities include:

- Development and phase-appropriate optimization of upstream and downstream processes
- Scalability assessments and transition from research protocols to GMP-compliant methods
- Support for tech transfer documentation and training
- Analytical method qualification for identity, purity, viability, and vector copy number
- Stability-indicating assays and in-process control strategies
- Collaboration with external testing labs for assay validation as needed

These services are designed to streamline the path from preclinical innovation to clinical-grade production.

GMP manufacturing capabilities:
The UC Davis GMP Facility is a fully State licensed, academic manufacturing center located in the Institute for Regenerative Cures on the UC Davis Health Campus in Sacramento, CA. The Facility supports early- and late-phase clinical production of advanced therapies.

Our infrastructure and operational design enable flexibility, regulatory compliance, and scalability across a range of product types.

- The facility includes ISO 7 and ISO 8 classified cleanroom suites, ISO 5 workstations for critical operations, and controlled-access support areas for material handling, cryostorage, and staging.
- Environmental monitoring, validated cleaning procedures, and quality oversight are integrated into all operations.

We support clinical manufacturing for a range of modalities including:

- Cell-Based Therapies: Autologous and allogeneic T cells, stem cells, and other somatic cell types
- Gene-Modified Therapies: CAR-T and other engineered immune cells using viral (lentiviral/retroviral), AAV and AD vectors as therapeutics
- Small Molecule Fill-Finish: GMP compounding and manual vial filling, stoppering, crimping, and labeling of sterile drug products in ISO 5 environments
- Cryopreservation & Storage: Controlled-rate freezing, LN_2 vapor storage, temperature monitoring, and controlled cold-chain logistics

Manufacturing is supported by comprehensive QA oversight, GMP documentation systems, trained production staff, and release protocols that include batch record review, Certificate of Analysis (CoA) issuance, and chain-of-custody tracking.

The facility has demonstrated the ability to handle complex, multi-step production

protocols under accelerated timelines. Our cleanroom suites can support up to 6 concurrent manufacturing campaigns, with adaptable scheduling for Phase I-III clinical studies and compassionate-use manufacturing. We also support lot matching, randomization, and blinded product packaging when required for clinical protocols.

Analytical capabilities:
The UC Davis GMP Facility offers a range of analytical capabilities to support GMP-compliant product characterization, in-process monitoring, and final release testing. These capabilities are essential for ensuring product quality, identity, safety, and regulatory readiness.

Key analytical services include:

- Identity & Purity Testing: Flow cytometry-based immunophenotyping, cell viability assays, and assessment of cell surface markers
- Potency Testing: Custom assay development and qualified surrogate potency methods for cell function or viability
- Sterility & Safety Testing: Mycoplasma, endotoxin (LAL), sterility, and rapid microbial testing (outsourced to qualified vendors or partner labs)
- Vector Copy Number & Transduction Efficiency: Quantitative PCR-based methods for vector copy number (VCN) and CAR expression level analysis
- Viability & Enumeration: Trypan blue exclusion, AO/PI, and automated cell counting systems
- Stability Testing: Support for real-time and accelerated stability studies with sampling coordination, storage, and data collection
- In-Process Controls: Sample collection and trending during manufacturing to ensure compliance with critical process parameters (CPPs)

Analytical testing is performed in alignment with phase-appropriate GMP standards, with documentation, chain of custody, and CoA generation included. When needed, we coordinate with external laboratories for method validation, adventitious agent testing, and product-specific assay development.

Track record:
The UC Davis GMP Facility has a strong history of supporting early- and mid-phase clinical trials through high-quality manufacturing, regulatory alignment, and academic–industry collaboration.

Since its inception, the facility has successfully supported over 40 Phase I-III IND-enabling studies involving cell, gene, and small molecule therapies across multiple indications, including oncology, rare diseases, regenerative medicine, and infectious diseases.

- Our team has manufactured products for both investigator-initiated trials and externally sponsored studies funded by NIH, CIRM, and other major agencies.
- We have experience preparing and releasing CAR-T therapies, genetically engineered stem cell products, cell vaccines, and sterile liquid drug products under full GMP conditions.
- We have also supported pivotal process development projects and novel technology integration to advance therapeutic readiness.
- The facility has partnered with leading academic investigators, hospital systems, biotech startups, and established pharmaceutical companies to advance complex clinical programs under compressed timelines and evolving regulatory expectations.
- Several of these programs have progressed to multi-site clinical trials and/or licensing discussions.
- We maintain strong internal QA/QC processes and work collaboratively with institutional and federal oversight bodies to ensure audit readiness.
- Our team has supported successful regulatory submissions, including INDs, IDEs, and FDA pre-IND meeting packages, and we routinely contribute to CMC documentation and batch record authoring.
- With a flexible cleanroom footprint and a deeply experienced technical staff, the UC Davis GMP Facility continues to serve as a trusted hub for translational science and advanced therapy manufacturing in California and beyond.

Facility certifications:
The UC Davis GMP Facility operates under a comprehensive quality management system and holds the following certifications and regulatory authorizations:

- California Department of Public Health (CDPH) Drug Manufacturing License
- Controlled Substance Use Authorization for handling Scheduled materials under institutional oversight
- Institutional Biosafety Committee (IBC) Approval for gene-modified products and use of viral vectors
- Environmental Monitoring & Cleanroom Certification conducted semi-annually by certified third-party vendors
- GMP Documentation System including controlled batch records, SOPs, equipment logs, and training records
- Qualified Equipment & Facility Validation in compliance with phase-appropriate GMP standards (USP, where applicable)

All facility operations follow established procedures suitable for early-phase manufacturing and ensure consistent, high-quality execution of production activities.

Regulatory inspections & corrective actions:
The UC Davis GMP Facility has undergone sponsor and institutional inspections and maintains a strong compliance record.

The facility has been inspected by the California Department of Public Health (CDPH) and reviewed by the UC Davis Human Gene and Cell Therapy Facility Oversight Committee, Institutional Biosafety Committee (IBC), and Environmental Health & Safety (EH&S) programs.

Our CAPA program includes root cause analysis, effectiveness checks, and full documentation per GMP expectations. All issues are tracked through controlled logs and reviewed by QA for resolution before closure.
We remain ready and responsive to sponsored regulatory inquiries and operate under phase-appropriate compliance frameworks aligned with FDA guidance, ICH, and USP standards for clinical manufacturing.

Value proposition:
The UC Davis GMP Facility provides academic sponsors and industry partners with a uniquely agile, regulatory-compliant environment for translating early-stage therapeutic innovations into clinical-grade products.

As a university-based manufacturing site with CDPH licensure, we offer phase-appropriate GMP support tailored to the evolving needs of advanced therapy programs.

Our integrated model combines scientific rigor, operational flexibility, and cost-conscious execution, enabling efficient production of complex cell, gene, and drug products.

We specialize in first-in-human manufacturing, rapid tech transfer, and IND-enabling activities for high-impact clinical trials, with personalized QA oversight and full documentation support.

By leveraging UC Davis' scientific ecosystem and collaborative ethos, we serve as a critical bridge between discovery and patient access, delivering both technical excellence and mission-driven partnership.