Miltenyi Biotec

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Location:

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Manufacturing facilities footprint & capacity:
San Jose, CA - This completely renovated facility was commissioned in 2020 and builds on the experience gained during four years of operating at Miltenyi's previous CDMO facility, based in nearby Sunnyvale, as well as experience from operating the Cell Factory GMP facility in Germany. Miltenyi's San Jose facility is ~52,000 ft2 with three state-of-the art, cleanroom suites providing manufacturing capacity from Phase I through commercialization. Significant space is available in the building to add additional suites to expand capacity, as needed.

Gaithersburg, MD - Miltenyi's Gaithersburg facility, operated by wholly-owned subsidiary Lentigen Technology, Inc. (LTI), is a ~150,000 ft² (~14,000 m²) site supporting both lentiviral vector (LV) and cell therapy manufacturing, with segregated cGMP manufacturing, Quality Control, process development, and R&D laboratories. The LV manufacturing portion was designed specifically to support clinical development and commercial manufacturing of cGMP LV using LTI's manufacturing platform; the first two suites commenced GMP operations in Q2 2022, and the facility comprises four independent and identical ISO 7/Grade C LV production rooms, each capable of manufacturing up to 40 lots per year at either 50L or 200L scale (180 GMP batch annual capacity total). Pairs of LV production rooms are connected to a dedicated cell culture room, and the facility provides dedicated areas for column packing, materials weigh and

dispense, buffer and media prep, and final product fill. Aseptic fill rooms are ISO 6/Grade B with segregated air handlers and terminal ULPA filters. The site also includes dedicated CGT manufacturing space, 8,940 ft² of classified production space and 3,367 ft² of QC laboratory space, housing multiple CliniMACS Prodigy-based cell therapy suites for clinical and commercial cell therapy supply. Pressure cascades prevent cross-contamination and are monitored with a validated building monitoring system (BMS).

Modalities/tech platforms supported:

San Jose, CA - As a center of excellence for the CliniMACS Prodigy, Miltenyi excels in leveraging this cutting-edge instrument for clinical manufacturing purposes. Our production team focuses on utilizing the Prodigy platform to deliver exceptional results in mission-critical clinical manufacturing.

Being the manufacturer of the CliniMACS Prodigy, our team possesses extensive experience and expertise in operating troubleshooting, and developing on this device. We are intimately familiar with the intricacies of the Prodigy system and have in-depth knowledge of its capabilities, allowing us to optimize its performance for efficient and reliable clinical manufacturing processes. We are backed by the global Technical Support arm of Miltenyi, including dedicated Service and unparalleled application support. In addition to CliniMACS platforms, the team has experience with a variety of non-Miltenyi equipment and is able to implement other platforms as needed.

Gaithersburg, MD - The Gaithersburg site supports both lentiviral vector (LV) and cell therapy manufacturing. For LV, Miltenyi's well-established LV process platform (a 3rd generation (4-plasmid) transient transfection, serum-free, chemically-defined suspension upstream process launched in 2017) has produced over 400 GMP and thousands of research and preclinical batches. Both 50L and 200L production scales are supported with equivalent unit operations adjusted only for scale, with Cryobag and AT Vialing fill options available. For cell therapy, the site runs the

CliniMACS Prodigy platform, the same closed, automated, end-to-end cell manufacturing platform used at San Jose, for clinical and commercial manufacturing of gene-modified HSCs, CAR-T, and other cell therapy modalities from fresh or frozen apheresis starting material. Single-use, disposable items are used where feasible.

Process & analytical development capabilities:
San Jose, CA - We have a dedicated PD/AD team for development studies and optimization and MSAT/ASAT groups focused on translation to GMP. We have full capability and capacity to support development studies, including, but not limited to, media formulation, culture duration, scale-up, and automation of final formulation and cryopreservation, depending on future needs of program. PD is experienced with performing investigative runs to troubleshoot or otherwise support clinical MFG. Members of the PD team are experts on Miltenyi clinical platforms, specifically the CliniMACS Prodigy, including capability to develop and optimize custom applications.

Gaithersburg, MD - The Gaithersburg site has dedicated development and manufacturing teams for the design, construction, and manufacture of LVs, as well as cell therapy process development capabilities. For LVV, a two-tier pilot phase (molecular feasibility and process feasibility) takes client constructs from Research Grade transfer plasmid through a 4L Purified Vector Demonstration Batch (predictive of successful GMP outcomes) and on to 50L or 200L preclinical, engineering, and GMP batches. Client projects can move directly to GMP manufacturing from small scale feasibility runs, eliminating the time and expense associated with typical process development. For cell therapy, dedicated PD space supports process optimization on the CliniMACS Prodigy platform. LTI's Analytical Method Qualification and Validation process supports product maturity through commercial readiness, aligned with ICH, FDA, and EMA expectations. Analytical Develeopment Capabilities include, but are not limited to, Assay Design, Deelopment, Qualification, validation, Robustness Streamlined process characterization and PPQ workflows leverage historical platform data.

GMP manufacturing capabilities:
San Jose, CA - The GMP production team includes Manufacturing, QC, QA and all supporting functions such as facilities, warehousing, regulatory and project management. The highly skilled team has over eight years of experience manufacutring cell therapy products, with a particular emphasis on using the CliniMACS Prodigy platform. The team operates multiple shifts to ensure coverage and flexibility for client processes.

Gaithersburg, MD - The GMP production team includes Manufacturing, MSAT, QC, QA, and all supporting functions such as facilities, warehousing, regulatory, and project management, with extensive and experienced staffing across all functions. Manufacturing is supported by ISO 6/Grade B aseptic fill suites (Cryobag and AT Vialing fill options), dedicated cell culture rooms, column packing, materials weigh and dispense, and buffer/media prep areas. The site is approved for commercial production (TECELRA® / afamitresgene autoleucel) following FDA pre-license inspection in May 2024.

Analytical capabilities:
San Jose, CA - The QC team performs in process and release testing on a variety of products using many different methods. Flow cytometry is performed using the MACSQuant instrument. Safety testing, potency and functional assays are performed using other commercially available platforms. All method development follows ICH Q2 R2 and ICH14 Guidelines, and all method qualification follows USP <1220>.

Gaithersburg, MD - The Gaithersburg Site operates five segregated, controlled-access QC laboratories at the Gaithersburg site supporting LV release and characterization testing, including DNA extraction, qPCR preparation, tissue culture, QC molecular, and EM laboratories. These labs are equipped with PCR workstations, incubators, flow cytometers, plate readers, qPCR machines, and -20°C/4°C storage units. All method

development follows ICH Q2 R2 and ICH14 Guidelines, and all method qualification follows USP <1220>.

Track record:
San Jose, CA - The team has manufactured over 650 GMP batches and supported over eighteen successful U.S. IND submissions since 2020. Clients are currently in various stages as the organization can support from development through commercial manufacturing. The team specializes in T-Cell, NK, HSC and Monocytes, and has worked with many others including CAR B, CAR Macrophages, TCR-T, TILs, TRTs, VSTs, Tregs, TCRγ/δ+, MoDCs, PSCs and more!

Gaithersburg, MD - LTI has manufactured LVs in support of investigational studies for a variety of clients across a broad range of therapeutic applications, with over 400 GMP LV batches and thousands of research and preclinical batches produced. The team supported the first-in-human clinical trial utilizing LVs (Dropulic OBA/RAC Meeting, June 2004; Levine et al., PNAS 2006) and has supported clinical trial submissions in over 25 countries (e.g., US, EU, Canada, Korea, Japan, Singapore, Brazil, Australia). LTI is currently working on multiple commercial readiness programs, and its first client commercial license received regulatory approval in Q3 2024 (TECELRA® / afamitresgene autoleucel). The site also performs clinical and commercial cell therapy manufacturing on the CliniMACS Prodigy platform, leveraging Miltenyi's global experience of over 650 clinical CGT batches and a common QM system across San Jose, Gaithersburg, and Bergisch Gladbach. Programs span Phase I through commercial manufacturing across LV vectors and gene-modified cell therapies including CAR-T, gene-modified HSCs, TCR-T, and other modalities.

Facility certifications:
San Jose, CA - The facility is registered with the US FDA for HCT/P processing and is licensed by Canada for drug manufacturing for clinical trials.

Gaithersburg, MD - The Gaithersburg site holds Biologics Master Files with the US FDA and Health Canada and has supported multiple European submissions including Investigational Medicinal Product Dossier (IMPD), Environmental Risk Assessments (ERA), Genetically Modified Organism (GMO) applications, and import licenses for multiple jurisdictions. LTI and Miltenyi have also supported Client IND submissions in countries that do not utilize a Biologics Master File for microbial vectors (e.g., Japan's PMDA). Quality systems comply with 21 CFR Parts 11, 210, 211, and 600; ICH Q7, Q8, Q9, Q10, and E6; Eudralex Vol 4 (Part II and the ATMP Annex); CHMP/BWP/2458/03 (Guideline on development and manufacture of lentiviral vectors); and the FDA Guidance for Human Somatic Cell Therapy and Gene Therapy. Computer systems and electronic data storage are validated to 21 CFR Part 11.

Regulatory inspections & corrective actions:
San Jose, CA - To date, the site has not undergone a regulatory audit, however the team has performed mock PLI inspections and is routinely audited by clients. Additionally, the site shares quality systems with the Gaithersburg facility, which recently passed an audit by the FDA for commercial Lentiviral Vector Manufacturing.

Gaithersburg, MD - In May 2024, the Gaithersburg site successfully hosted a US Food and Drug Administration (FDA) pre-license inspection and is approved for the commercial production of TECELRA® (afamitresgene autoleucel). The site has also been audited successfully by multiple pharma and biotech clients.

Value proposition:
San Jose, CA - At Miltenyi Bioindustry, we combine unparalleled expertise with deep platform know-how to accelerate cell therapy programs from development to clinic. By leveraging optimized Miltenyi platforms and proven manufacturing experience, we help partners reduce development

risk, shorten timelines, and achieve a faster, more cost-effective path to clinical manufacturing.

Gaithersburg, MD - Gaithersburg combines nearly 20 years of lentiviral vector experience with clinical and commercial cell therapy manufacturing capability — anchored by a commercially approved LV platform, an FDA pre-license-inspected (May 2024) commercial-ready facility, and the CliniMACS Prodigy end-to-end cell manufacturing platform shared with San Jose. The site offers integrated LVV plus cell therapy programs under one organization and one global QMS spanning San Jose, Gaithersburg, and Bergisch Gladbach (Germany). Vertical integration with Miltenyi provides in-house plasmid design and manufacturing, production materials and QC reagents, standardized release assays, and global regulatory support including Biologics Master Files (FDA, Health Canada) and Regulatory Support Files in over 25 countries — accelerating client programs from preclinical through commercial supply.