ARE YOU READY?

ELEVATEBIO, WALTHAM, MA

ELEVATEBIO BASECAMP CLEANROOM EXPANSION

CASE STUDY: BUILDING COMMISSIONING

BaseCamp Cleanroom Expansion

PROJECT OVERVIEW

ElevateBio BaseCamp in Waltham, Massachusetts is a flagship cell and gene therapy development and cGMP manufacturing facility, with roughly 140,000 square feet of cleanrooms, laboratories, process development space and support areas. The site supports cell therapy suites, viral vector and mRNA suites, quality control laboratories and warehouse functions in a continuously operating cGMP environment.

To meet growing demand from internal programs and external biopharma partners, ElevateBio retro-fitted existing support areas with additional cleanroom suites and supporting mechanical, electrical and HVAC infrastructure to expand GMP capability. The expansion was designed to increase manufacturing capacity and strengthen environmental control while keeping existing GMP operations running without interruption.

CLIENT:
ElevateBio

LOCATION:
Waltham, MA

TIME FRAME:
16 Months

CONTRACT SIZE:
$262,000

OBJECTIVE

The CAI Mission Critical team was engaged to provide full MEP Building Commissioning services from early planning through final reporting. The objective was clear: bring the new cleanrooms and MEP systems online with verified performance, complete documentation and a smooth handoff into qualification, with minimal disturbance to live operations next door.

CLIENT CHALLENGES

EXPANSION INSIDE AN ACTIVE CGMP ENVIRONMENT

Construction, starting and testing had to take place adjacent to live cell and gene therapy operations. Any disturbance to differential pressures, particulate counts, temperature or humidity in adjoining cleanrooms could disrupt ongoing batches and threaten product quality, schedule and patient commitments.

INTEGRATION OF NEW SYSTEMS WITH EXISTING INFRASTRUCTURE

New air handling units, terminal devices, exhaust, electrical distribution and building controls had to tie into existing site infrastructure that was already in daily use. Sequencing of tie-ins, temporary measures and cutovers needed careful planning to protect the operating areas of the building while enabling the expansion.

STRICT ENVIRONMENTAL PERFORMANCE REQUIREMENTS

Grade B and Grade C cleanroom spaces demand tight control of pressurization, air changes, temperature, humidity and recovery. Each system had to be proven against design intent and owner requirements before the spaces could move forward into qualification for GMP use.

AGGRESSIVE SCHEDULE TIED TO CAPACITY COMMITMENTS

The expansion was driven by capacity needs and external partner programs, so any slip in commissioning or startup would push back qualification, validation and revenue. The schedule left limited room for rework, sequencing surprises or unresolved field issues at turnover.

DOCUMENTATION BUILT FOR QUALIFICATION, NOT JUST STARTUP

Because the cleanrooms and supporting GMP systems were headed straight into a qualification process, commissioning documentation had to be clear, organized and defensible. Gaps or inconsistencies in test records would create rework downstream, slow qualification and erode confidence with quality and regulatory stakeholders.

MISSION CRITICAL SOLUTIONS

COMMISSIONING PLANNING ALIGNED TO OWNER AND QUALIFICATION NEEDS

The CAI team developed commissioning planning documentation aligned with User Requirements, design intent and owner expectations. Test plans and acceptance criteria were structured so that commissioning evidence could flow directly into the cleanroom and GMP qualification process, reducing duplication and surprises later.

Scope, responsibility, and document control were defined early with the owner, design engineering team and contractors, so every stakeholder understood what was being tested, by whom and to what standard.

RISK-BASED STRATEGY FOR A LIVE, REGULATED ENVIRONMENT

Building Commissioning in an active cGMP facility is a different challenge than a greenfield project. The mission critical building commissioning team applied risk-based thinking to prioritize systems and failure modes that posed the greatest exposure to adjacent operations and to long-term cleanroom performance, including pressurization cascades, exhaust, recovery times and controls behavior at limits.

High-risk activities were sequenced around live operations, with coordinated windows, temporary measures and clear hold points to protect product quality and personnel safety in the operating areas of the building.

INSTALLATION VERIFICATION AND QC OVERSIGHT

The CAI team performed installation verification to confirm that HVAC, electrical, building controls and supporting MEP scope were installed in line with design intent and ready for energization. The team witnessed construction QC testing and equipment startup across air handling units, terminal devices, electrical distribution and controls, setting a consistent expectation for documentation quality from the field forward.

Issues identified during installation and startup were tracked and resolved early, before they could compound into rework at functional testing or, worse, after turnover.

SOLUTIONS CONTINUED

FUNCTIONAL PERFORMANCE VERIFICATION AND SEASONAL TESTING

Detailed functional performance testing was executed for air handling units, terminal devices, building controls sequences and environmental systems. Tests covered normal operation, setpoint changes, alarm response and recovery, with particular focus on the behaviors that matter most for cleanroom integrity and downstream qualification.

Seasonal testing verified functional performance under varying outdoor conditions so that the cleanroom suites and supporting systems could be trusted to hold environmental targets year-round, not just on the day of startup.

DOCUMENTATION, TURNOVER AND QUALIFICATION READINESS

Final commissioning reports were delivered in a clear, organized package that supported facility operations, ongoing maintenance, plus the cleanroom and GMP qualification process to follow. Test records, issues, resolutions and as-tested performance were assembled so the owner could move into qualification with a strong, defensible foundation.

Basecamp Cleanroom Expansion

VALUE PROVIDED

The CAI Mission Critical team helped verify that all MEP systems supporting the cleanroom expansion met performance, reliability and environmental control requirements before the spaces moved into qualification. Air handling, terminal devices, controls sequences and environmental systems were proven against design intent and owner expectations across normal operation, failure modes and seasonal conditions.

By identifying and resolving issues during installation verification, QC witnessing and functional testing, the team reduced rework and supported schedule adherence on a program where every week mattered to capacity and partner commitments. Field issues were caught and closed out before they could turn into late surprises at turnover.

Clear, organized commissioning documentation gave the operations and quality teams a strong foundation for ongoing facility operations, maintenance and the qualification process for the cleanrooms and GMP systems. The owner moved from construction completion into a fully commissioned, operational state with confidence in system performance and a complete record to back it up.

ElevateBio has publicly described BaseCamp Waltham as a flagship cell and gene therapy facility with Grade B and Grade C cleanrooms, multiple cell therapy and viral vector suites and integrated process development and quality control capabilities. Verified, well-documented MEP performance protects the value of that footprint and the advanced therapy programs it supports.

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LESSONS LEARNED / WHAT THIS MEANS FOR SIMILAR FACILITIES

Several themes from this expansion translate directly to other cleanroom and cGMP capacity programs:

- Bringing commissioning leadership in early — through planning documentation, installation verification and QC witnessing — strengthens coverage and protects the construction schedule rather than competing with it.
- Risk-based testing focuses effort on the systems and failure modes that matter most for cleanroom integrity, environmental control and adjacent live operations, which builds confidence without bloating the schedule.
- Tight coordination among construction, operations, vendors and the commissioning team is essential when expansion work sits next to live GMP suites; sequencing, temporary measures and hold points need to be planned, not improvised.
- Commissioning documentation built with qualification in mind — clear, organized and traceable — converts turnover into a launchpad for cleanroom and GMP qualification instead of a recurring source of rework.

Summary

CAI Mission Critical helps owners and operators of cleanroom and cGMP facilities bring complex MEP scope online with verified performance, complete documentation and confidence on day one. To explore how building commissioning, digital tools and lifecycle services can support a similar expansion or capacity program, connect with the CAI team at caiready.com.

REFERENCES

ELEVATEBIO FACILITIES — CORPORATE HEADQUARTERS AND BASECAMP WALTHAM — HTTPS:ELEVATE.BIO/FACILITIES/

ELEVATEBIO – CELL AND GENE THERAPY GMP MANUFACTURING (BASECAMP) — HTTPS://ELEVATE.BIO/CELL-AND-GENE-THERAPY-GMP-MANUFACTURING/

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