

Space Program & Capital Planning Brief

Sterile Compounding Center of Excellence for Advanced Therapeutics

Planning basis: October 2026 | Prepared for leadership discussion

Planning recommendation: advance a flexible academic and applied-research core sized at approximately 12,000–16,500 net square feet (NSF), with a separately planned 2,500–4,000 NSF theranostics / radiopharmacy expansion and a distinct 3,500–6,000 NSF cyclotron production option. Treat these as space envelopes for programming, not architectural design or a construction estimate.

1. Executive planning direction

Create a high-visibility, hands-on center where students and practitioners learn, test, improve, and translate the preparation and handling of complex therapies. The facility should make sterile compounding the operating foundation, while enabling advanced therapy readiness, applied research, quality systems, and a credible path to radiopharmacy and theranostics.

- Design around three parallel uses: teaching and simulation; applied research and process development; and, only where authorized, regulated preparation or handling of products for patient care or clinical research.
- Build a strong core first. Make future cleanroom modules, analytical capacity, cryogenic infrastructure, and radiopharmacy systems possible without requiring the first phase to carry cyclotron-level cost and licensing complexity.
- Use modular, observable workflows as the signature: learners can follow a therapy from order and product receipt through preparation, independent verification, release, storage, administration readiness, and quality review.

The concept is deliberately ambitious in capability and staged in commitment. A university teaching and research center can build deep expertise in aseptic process design, quality, cell-therapy handling, radiopharmaceutical practice, and manufacturing science without assuming that every activity is initially a licensed clinical service or commercial manufacturing operation.

2. Planning assumptions and area envelope

The figures below are early net assignable area ranges. They are intended to frame test fits, not to prescribe room dimensions. “Core” covers the first buildable center; “Expansion” describes future rooms or dedicated suites. Program requirements, equipment selections, enrollment, research commitments, and facility location will change the final area.

Program zone	Core NSF range	Typical functions / rooms
Learning, simulation & collaboration	2,000–2,800	Flexible classroom; active learning / debrief; team room; observation and recording studio; public-facing demonstration zone.
Sterile compounding education suite	2,500–3,300	Separate teaching cleanroom environments; ante / garbing spaces; hazardous-drug simulation; device and workflow stations; wash / staging / equipment support.

Program zone	Core NSF range	Typical functions / rooms
Applied research & quality laboratories	2,000–2,800	Aseptic process development; analytical / microbiology support; method development; environmental monitoring; sample receipt and controlled storage.
Advanced therapeutics readiness	1,600–2,400	Cell-therapy receiving and identity checks; cryogenic storage / monitoring; controlled thaw and preparation simulation; chain-of-identity and handoff workflows.
Formulation and adjacent practice skills	800–1,200	Nonsterile formulation; hazardous-drug handling simulation; small-batch process and device development; packaging / labeling studies.
Operations, materials & facility support	1,800–2,500	Receiving / quarantine; released materials; equipment staging; waste holding; clean / dirty utility; gowning lockers; janitorial; mechanical / electrical allocation.
Leadership, offices, IT & meetings	1,000–1,500	Director / staff workpoints; quality office; conference / project room; secure records / IT; staff support.
Core subtotal	11,700–16,500	Target concept envelope: about 12,000–16,500 NSF.

A concept-level grossing factor of roughly 1.4–1.6 applied to the core program would imply about 16,400–26,400 gross square feet (GSF). This is only a placeholder: cleanroom corridors, mechanical space, structural constraints, circulation, egress, and institutional standards can move the gross area materially. The architect should establish the actual net-to-gross factor after a test fit.

3. Expansion options

Option	Incremental planning area	Scope and decision logic
Theranostics / radiopharmacy suite	2,500–4,000 NSF	Radiopharmacy education, shielded workstations / isolators, QC, controlled storage, dose preparation / dispensing simulation, radioactive-material support and waste. Define the permitted scope with radiation safety and regulators before design.
Cyclotron production module	3,500–6,000 NSF (initial allowance)	Cyclotron vault, service / control / power rooms, radiochemistry and aseptic production, hot cells, QC, material / personnel airlocks, shipping, decay / radioactive waste, radiation-safety support. The vendor, beam energy, isotope portfolio, self-shielding, building structure, licensing, and site logistics determine final scope.
Future cell / gene therapy scale-up	1,000–3,000 NSF beyond core (if justified)	Additional segregated process rooms, dedicated equipment, QC / release support, material flows, and cryogenic capacity. Build only against funded collaborations, defined product / process needs, and an approved quality and regulatory model.

IAEA’s cyclotron facility guidance illustrates why the cyclotron belongs in a separate feasibility study: even a representative cyclotron block includes a shielded vault, service room, power-supply room, and control room, while a production facility also needs aseptic production / hot-cell, QC, packing, access control, storage, and radioactive-waste functions. The guide provides example room areas but explicitly treats them as guidance to be adapted to the selected cyclotron and process.

4. Adjacencies and flow principles

Keep close	Separate / control	Why it matters
Classroom + simulation suite + observation studio	Public classroom traffic from controlled suite entrances	Allow instruction and debrief without compromising controlled spaces; capture practice for feedback and competency assessment.
Receiving / quarantine + material airlock + released storage	Incoming supplies from personnel entry; quarantined from released stock	Support status control, traceability, clean transfer, and efficient replenishment.
Research / process development + analytical / QC rooms	Research samples from teaching materials and any patient-care materials	Protect data integrity and avoid cross-contamination or confusion between simulation, research, and regulated operations.
Cell-therapy receipt + monitored cryostorage + preparation / handoff	Cryogenic handling from routine sterile compounding flow	Maintain identity, custody, temperature, alarms, backup power, and a controlled route for high-value patient-specific products.
Radiopharmacy production + shielded hot cells + QC + dispatch	Radioactive controlled areas from public learning spaces and ordinary waste routes	Integrate radiation protection, contamination control, aseptic product protection, and short-lived product logistics.

Keep close	Separate / control	Why it matters
Mechanical / HVAC / controls + cleanrooms	Maintenance access from aseptic core; avoid long or inaccessible service runs	Improve reliability, maintainability, balancing, monitoring, and future reconfiguration.

Plan distinct people, material, product, waste, and maintenance paths. Use a visible “glass line” or digital observation layer at the teaching suite so learners can see process steps without entering the cleanroom. For future radioactive production, locate and engineer that suite as a dedicated controlled zone; do not route public visitors or general classroom traffic through it.

5. Building systems and equipment allowances

The cleanroom and laboratory systems are major capital drivers, not finish upgrades. The design team should be selected for pharmaceutical cleanroom experience and should validate the concept with pharmacy operations, quality, facilities engineering, infection prevention / occupational safety, radiation safety, IT security, and the intended regulators.

System / package	Planning requirements
Cleanroom HVAC and controls	Dedicated air handling as needed; pressure cascade / containment strategy by room use; temperature / humidity control; HEPA filtration; room monitoring, alarms, trending, and validated control points; maintainable filter and sensor access.
Cleanroom envelope	Cleanable, durable surfaces; sealed penetrations; appropriate doors, pass-throughs, and access control; gowning / garbing workflow; surfaces and detailing suited to the cleaning agents and operating model.
Power, cooling, water and gases	Emergency / backup power for critical freezers, alarms, monitoring and data; capacity for biosafety cabinets, isolators, refrigerators, freezers, analytical instruments and future skids; point-of-use utilities designed with maintainability and safety.
Quality and digital infrastructure	Environmental monitoring; electronic training / competency records; batch / process documentation sandbox; equipment and calibration management; secure video capture; data integrity, access control and cybersecurity.
Cell-therapy support	Monitored cryogenic storage, continuous alarms, backup and response plans; identity / custody controls; safe thawing capability; validated shipping-receipt and temperature excursion workflows.
Radiopharmacy / cyclotron, if pursued	Radiation-shielded construction; equipment access / replacement path; hot cells and shielded transfer; specialized ventilation and exhaust; cooling and service penetrations; radiation monitoring; radioactive waste / decay storage; licensing, security and emergency systems.

6. Capital plan: scope, cost model, and gates

No defensible construction dollar figure is assigned at this stage. There is no confirmed site, building condition, delivery method, local cost benchmark, room data sheet, mechanical concept, equipment list, or cyclotron vendor definition. A single \$/GSF figure would conceal the very systems that drive this project. The next decision should authorize programming and a campus-validated estimate, not imply a construction commitment.

Capital model to use in the next estimate

Total project cost = site / enabling work + building construction + cleanroom / laboratory systems + specialist equipment + IT / security + design and project costs + commissioning / qualification + escalation + contingency

Cost the core and each expansion as independent packages, then show the cost and schedule effect of designing enabling infrastructure in Phase 1. Include both installed capital and the annual cost of operating, maintaining, monitoring, certifying, and staffing each suite.

Package	Include in estimate	Key question
Core building / renovation	Site work, demolition / shell, structural reinforcement, standard interiors, egress, fire protection, utilities and campus tie-ins.	New build, shell space, or renovation? What is the actual capacity of existing central plant and utilities?

Package	Include in estimate	Key question
Cleanroom / lab fit-out	HVAC, controls, HEPA systems, room envelope, pressure monitoring, exhaust, backup power, process utilities, commissioning / balancing.	Which rooms need classified environments now, and which are simulation / research labs designed for future conversion?
Specialist equipment	BSCs, isolators, pass-throughs, refrigerators / freezers, cryogenic storage, autoclaves, washers, analytical instruments, training devices, shielding / hot cells.	What is owner-furnished versus contractor-installed, and what requires vendor commissioning or qualification?
Technology and data	Environmental monitoring, alarms, access control, secure capture / AV, learning systems, equipment software, data storage / integration.	Which data are instructional, research, quality, or potentially regulated records?
Soft costs and readiness	Architecture / engineering, commissioning agent, cleanroom consultant, validation / qualification, permits, regulatory consultation, furniture, training, move / start-up.	Who owns the quality system and facility qualification before any regulated work begins?
Risk, escalation and lifecycle	Design contingency, construction contingency, market escalation, owner reserve, maintenance contracts, replacement and decommissioning provisions.	What is the estimate date and confidence range; what assumptions drive the high case?

Recommended capital gates

- Gate 0 — sponsor and program: confirm executive sponsor, director role, intended educational / research / service scope, partner commitments, and the governance of a center that spans pharmacy, facilities, research, and clinical partners.
- Gate 1 — feasibility: compare renovation, shell fit-out, and new-build scenarios; complete site / utility due diligence; confirm room program, adjacencies, enrollment and staffing assumptions; develop a concept test fit and risk register.
- Gate 2 — core estimate: obtain an independent estimator or campus facilities estimate with trade-level cleanroom / MEP allowances, owner-furnished equipment, soft costs, escalation, contingency, and operating-cost model. Report a range and estimate basis, not false precision.
- Gate 3 — advanced suite authorization: add a dedicated cell / gene therapy or radiopharmacy module only with a funded research / clinical partner, defined operating model, quality ownership, licensure path, staffing, and sustainable annual operating support.
- Gate 4 — cyclotron investment decision: proceed only after regional demand / supply analysis, isotope and market portfolio, vendor budget quote, site and shielding study, full licensing pathway, staffing / service plan, operating economics, distribution logistics, and decommissioning liabilities are reviewed.

7. Phasing strategy

Phase	Build / activate	Readiness test
0. Program and feasibility	User-group programming; campus and partner discovery; site, utility and regulatory screening; cost model.	A signed program of requirements, conceptual test fit, operating model, funding path and estimate range.
1. Core Center	Classroom / studio; sterile compounding teaching and simulation; research / quality labs; materials and support; core digital backbone.	Curriculum, staffing, cleaning / maintenance, competency assessment, and suite commissioning plans are approved.
2. Advanced therapeutics	Cell-therapy handling and cryogenic systems; modular advanced suite; radiopharmacy / theranostics capability only as scope and authorizations support.	Partner demand, quality governance, SOPs, training, equipment qualification and regulatory status are ready.
3. Cyclotron option	Dedicated accelerator / production module with licensed operations and linked QC / distribution capability.	Independent business case shows volume and partnerships justify capital, staffing, isotope production, service and lifecycle obligations.

8. What makes this facility distinctive

- A live learning environment: students can observe, record, replay, and improve aseptic workflows while keeping the instructional and controlled environments appropriately separated.
- A translation bridge: research, process development, quality analytics, human factors, medication-use systems, and patient-care partnerships share a planned pathway from simulation to evidence and implementation.
- A “patient-specific therapy readiness” platform: chain of identity and custody, time-critical receipt, cryogenic handling, workflow simulation, and decision support can be taught and studied now; future automation and individualized preparation research can be added under an approved quality and regulatory framework.
- A deliberately modular technical backbone: reserve shafts, electrical capacity, controls integration, mechanical plant space, equipment routes, and site placement for future cleanroom or cyclotron modules where the feasibility study supports it.

9. Decisions to take to the dean

- Endorse the Center as a staged academic and translational platform, not only a compounding lab.
- Authorize a cross-functional programming study and concept test fit for a 12,000–16,500 NSF core, with separate option studies for radiopharmacy and a cyclotron.
- Name an executive sponsor and a working group that includes pharmacy, facilities, research administration, quality, radiation safety, finance, IT, and clinical partners.
- Ask the planning team to return with two or three site / delivery scenarios, capital ranges with clear confidence levels, lifecycle operating costs, partner commitments, and a recommended phasing / funding strategy.

Selected planning references

These sources support early scope and compliance discovery. They do not replace project-specific regulatory consultation, current USP text, design criteria, or professional engineering.

- [U.S. FDA, Chemistry, Manufacturing, and Controls Flexibilities for Developing Human Cellular and Gene Therapy Products for a BLA \(May 2026\).](#)
- [USP General Chapter <797>, Pharmaceutical Compounding—Sterile Preparations \(official USP chapter page\).](#)
- [Texas State Board of Pharmacy, Rules and recent adopted changes \(including 2026 sterile compounding rule amendments\).](#)
- [Texas Department of State Health Services, Radioactive Material Licensing and Texas radiation-control rules.](#)
- [International Atomic Energy Agency, Cyclotron Produced Radionuclides: Guidance on Facility Design and Production of \[18F\]FDG, STI/PUB/1515 \(2012\).](#)