

Facility and Program Brief

UT Tyler Center for Sterile Compounding and Advanced Therapeutics

Concept for discussion with Dean Pamela Ochoa | 9 October 2026

Purpose. This brief organizes an ambitious academic, research, and practice vision into a coherent program and facility concept. It proposes a Center that begins with sterile compounding and prepares the pharmacy workforce for advanced and increasingly personalized therapies.

Vision

The UT Tyler Center for Sterile Compounding and Advanced Therapeutics will prepare the pharmacy workforce and improve the systems that bring complex, personalized therapies safely to patients. Through immersive education, applied research, and partnerships across pharmacy, medicine, science, and engineering, the Center will advance sterile compounding, radiopharmacy, cell and gene therapy operations, and emerging forms of precision medicine.

Organizing principle

The Center focuses on the safe preparation, handling, verification, and delivery of complex therapies. This connects conventional sterile preparations, radiopharmaceuticals, cell and gene therapies, and future patient-specific medicines through shared concerns: product integrity, identity, dose, quality, process control, and patient care.

A connected learning and improvement cycle

Understand Apply standards and evidence	Practice Perform the process in a realistic environment	Decide Defend a patient-centered decision	Improve Strengthen the system and prevent recurrence
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Strategic distinction

The Center’s defining strength is the connection between hands-on practice, professional judgment, applied research, and real-world improvement. Advanced therapies broaden that mission while requiring distinct technical environments, partners, and quality systems. The Center can lead education and practice translation while collaborating with specialized manufacturers and clinical programs.

Program model

Five connected program areas give the Center a broad horizon and a practical center of gravity.

1. Sterile compounding education and workforce development

Build competency-based instruction in aseptic technique, microbiology, environmental monitoring, hazardous drug handling, documentation, and quality systems. Connect PharmD coursework with P2 and P4 experiential learning, professional development, certification preparation, and competency refreshers. Existing work provides a starting portfolio: sterile compounding curriculum, the Sterile Compounding Decision Lab, and the BCSCP Prep Hub.

2. Decision science and medication safety

Teach learners to recognize risk, assess uncertainty, investigate evidence, decide, defend the choice, and prevent recurrence. Use realistic cases, evidence rooms, structured debriefs, and AI-verification exercises. Learners remain responsible for evidence selection and professional judgment.

3. Advanced and personalized therapeutics

Prepare learners and practice partners for cell-based therapies, CAR-T, gene therapies, individualized RNA-based therapies, and emerging modalities. Study identity and custody, receipt, storage, preparation or thawing, traceability, handoffs, and coordination with clinical teams. FDA guidance treats CAR-T as a specialized gene therapy product with product-specific manufacturing and control considerations; the Center should build expertise through education, research, and qualified partners.

4. Radiopharmacy and theranostics

Develop education and research in radiopharmaceutical preparation, dose integrity, quality, logistics, radiation safety, and patient-specific therapy workflows. USP General Chapter <825> provides a dedicated framework for radiopharmaceutical preparation, compounding, dispensing, and repackaging. Begin through licensed radiopharmacy, imaging, and clinical partnerships.

5. Applied research and practice innovation

Conduct studies that connect the Center's teaching and facilities to practice needs: contamination control, aseptic process simulation, workflow and human factors, environmental monitoring, cleaning, competency assessment, stability and compatibility, traceability, and education outcomes. Use partners for specialized analytical capabilities as appropriate.

Facility concept

The facility should let learners observe work, practice it, study it, and improve it. Spaces should connect through shared teaching and data systems while meeting the distinct workflow and quality needs of each program.

Facility zone	Primary function	Planning considerations
Sterile compounding and simulation suite	Train and study routine, complex, hazardous-drug, and aseptic workflows.	Flexible mock cleanroom configurations; observation, video capture, competency checks, and debrief.
Advanced therapeutics suite	Study cell processing, cryogenic handling, closed systems, and product identity and custody.	Dedicated workflows, equipment, and quality framework; partner access for specialized methods.
Research and quality core	Study microbiology, environmental monitoring, process simulation, human factors, and quality.	Separate research use; define instrumentation and data needs with faculty and partners.
Radiopharmacy capability	Teach radiopharmacy and theranostics; study product quality, dose, and logistics.	Shielding, licensing, radiation safety, specialized staff, and clinical partners.
Classrooms and debrief rooms	Teach, run team cases and workshops, assess skills, and debrief.	Flexible layouts with access to demonstration and simulation spaces.
Digital and media studios	Create demonstrations, courses, cases, simulations, and remote training.	Video and audio capture, editing, simulation control, and digital learning systems.

Signature platform: From Patient Signal to Therapy

Learners and research teams follow a therapy through a realistic lifecycle: patient need, therapy selection, product source or manufacture, identity and quality checks, preparation or handling, handoff and administration, and follow-up. Cases can range from a complex sterile preparation to CAR-T logistics or radioligand therapy. The Decision Lab develops judgment; the practice suites make workflows tangible; the research core measures processes; and the studio extends learning beyond campus.

Cyclotron as a future option

A cyclotron could add local production of selected short-lived radionuclides and enable radiopharmaceutical research. It also creates a substantial capital and operating commitment involving facility design, production systems, quality and safety infrastructure, specialized staffing, licensing, and dependable utilization. Preserve it as a long-range option. Begin radiopharmacy education and research through partners, then commission a separate feasibility study based on clinical demand, research demand, potential partners, staffing, and a sustainable operating model.

Development path

Phase	Focus	Evidence to advance
1. Establish the academic core	Confirm mission and governance; integrate curriculum, Decision Lab, BCSCP Prep Hub, experiential learning, and media development; define facility requirements.	Defined leadership effort, faculty and partner commitments, learner outcomes, and an approved facility program.
2. Add partner-supported advanced therapies and theranostics	Develop cell and gene therapy operations education; radiopharmacy and theranostics projects; applied quality and workflow studies.	Sustained clinical and research partners, external learner interest, successful pilot projects, and a growing evidence base.
3. Evaluate local production infrastructure	Assess whether local radionuclide production, including a cyclotron, is justified.	Documented demand, capital and operating plan, licensing pathway, staffing, utilization, and a viable partner model.

Partnership and governance

The Center should be interprofessional and practice-connected, with pharmacy leadership and an advisory group representing relevant UT Tyler programs, health-system practice, advanced therapy and radiopharmacy expertise, and facility or quality specialists. The director's role should include authority and protected effort to align the academic program, facilities, research, and partnerships. Clinical manufacturing or patient-care functions should be developed with the applicable institutional and regulatory structures.

Measures of progress

- **Learner readiness.** Demonstrated competencies, sound decisions, and performance in realistic workflows.
- **Practice reach.** Participation by students and practicing professionals; active clinical and technical partnerships.
- **Applied scholarship.** Research outputs, grants, and projects that answer practical compounding or advanced-therapy questions.
- **Practice impact.** Evidence that Center-developed education, tools, or process changes improved a decision, workflow, or safety outcome.

Decisions for the next planning stage

Confirm the Center's name and institutional scope; identify initial facility and research priorities; define the director's authority, protected effort, staffing, and budget; identify potential partners; and commission a facility and cyclotron feasibility process that separates launch requirements from future options.

Selected sources

[FDA CAR-T guidance \(2024\)](#); [FDA individualized-therapy draft guidance \(2026\)](#); [NIH patient-specific gene-therapy report \(2025\)](#); [USP General Chapter <825>](#); [FDA Pluvicto update \(2026\)](#); [IAEA cyclotron resources](#)