



From classroom to cleanroom: building a skilled cell and gene therapy workforce

Ali Shokoohmand^{1,*}, Eddie H.P. Tan², Arwa Z. Al-Riyami^{3,4}, Anna Koptina⁵, Colleen Richards⁶, Mariana Morato-Marques⁷, Piriya Yoganathan⁸, Nouf Al-Rasheed⁹, Gemma Moir-Meyer¹⁰, Nikita M. Patel¹¹, Alicia Didsbury¹², Jennifer L. Quizi⁸, Michael J. Medlyn¹³, Timothy D. Wiltshire¹³, Dominic Fernandez¹⁴, Laura Garcia-Gerique¹⁵, Janet Macpherson¹⁶, Rachel A. Burga¹⁷, Matthew Hewitt^{18,19}, Patrick J. Hanley²⁰, Zlatibor Velickovic^{21,22}

¹ School of Chemical Engineering, Faculty of Engineering, Architecture and Information Technology, The University of Queensland, Queensland, Australia

² Centre of Regulatory Excellence, Duke-NUS Medical School, National University of Singapore, Singapore

³ Department of Hematology, Sultan Qaboos University Hospital, University Medical City, Seeb, Oman

⁴ College of Medicine and Health Sciences, Sultan Qaboos University, Muscat, Oman

⁵ Exellierium AB, Stockholm, Sweden

⁶ Patheon Pharmaceuticals Services Inc, Waltham, Massachusetts, USA

⁷ Hospital Israelita Albert Einstein, São Paulo, Brazil

⁸ Center for Innovative Cancer Therapeutics, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada

⁹ Pathology and Laboratory Medicine Division, Hematopathology and Transfusion Medicine Department, King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia

¹⁰ Department of Medicine, Christchurch Heart Institute, University of Otago, Christchurch, New Zealand

¹¹ INmune Bio International, Royal Free Hospital, London, UK

¹² Faculty of Science, Biological Sciences, University of Auckland, Auckland, New Zealand

¹³ Department of Lab Medicine and Pathology, Division of Transfusion Medicine, Mayo Clinic, Rochester, Minnesota, USA

¹⁴ Epworth Centre for Immunotherapies and Snowdome Laboratories, Epworth Healthcare, Melbourne, Victoria, Australia

¹⁵ Center for Cellular Immunotherapies, Perelman School of Medicine, University of Pennsylvania, Philadelphia, USA

¹⁶ NSW Health Pathology, Cell Therapy Program, Royal Prince Alfred Hospital, Sydney, New South Wales, Australia

¹⁷ Obsidian Therapeutics, Cambridge, Massachusetts, USA

¹⁸ Charles River Laboratories, Wilmington, Massachusetts, USA

¹⁹ Technical Officer CGT & Biologics, Hanover, Maryland, USA

²⁰ Center for Cancer and Immunology Research, Children's National Hospital and George Washington University, Washington, DC, USA

²¹ Cell & Tissue Therapies WA, Royal Perth Hospital, Perth, Western Australia, Australia

²² University of Western Australia, Perth, Western Australia, Australia

*Correspondence: Ali Shokoohmand, PhD, School of Chemical Engineering, Faculty of Engineering, Architecture and Information Technology, The University of Queensland, Queensland 4072, Australia. E-mail address: a.shokoohmand@gmail.com (A. Shokoohmand).

ABSTRACT

The demand for the CGT workforce exceeds the capacity of current training programs to produce professionals ready for Good Manufacturing Practice (GMP) operations and associated quality and regulatory requirements. Most academic programs build strong scientific foundations but do not consistently prepare learners for process development and disciplined practice within regulated quality systems, resulting in prolonged onboarding and variable early performance. This gap reflects not only the specialized operational demands of CGT, but also the fact that most universities are designed to provide broad scientific education rather than role-specific preparation for a single employment sector. We synthesized a literature- and stakeholder-informed CGT Education Framework comprising five mutually reinforcing pillars: (i) curriculum innovation that embeds quality and GMP principles, (ii) interdisciplinary integration across science, engineering, and regulation, (iii) inclusive and scalable delivery approaches, (iv) structured experiential learning in GMP-aligned settings, and (v) competency-based credentialing. An accompanying implementation roadmap defines role-specific actions, timelines, and measurable workforce readiness outcomes, while case studies and short-format training exemplars illustrate practical application. Together, these recommendations provide a pathway to align academic preparation with the technical, regulatory, and quality-compliance demands of CGT, improve time-to-productivity, and support global workforce mobility. They move the field from ad hoc initiatives to a coherent, outcomes-driven approach that builds a pipeline of resilient, industry-ready talent.

<https://doi.org/10.1016/j.jcyt.2026.102899>

1465-3249/© 2026 International Society for Cell & Gene Therapy. Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>)

Key Words: Biomanufacturing, Cell and gene therapy (CGT), CGT education, Competency-based education, Good manufacturing practice (GMP), GMP training, Regenerative medicine, Workforce development.

Introduction

Cell and gene therapy (CGT) is reshaping modern medicine, offering curative potential across genetic, oncologic, and degenerative diseases. First-in-class regulatory approvals, including *in vivo* gene therapy (Luxturna) [1], chimeric antigen receptor (CAR) T-cell therapy (Kymriah) [2], and mesenchymal stromal cell (MSC)–based therapy (Ryoncil) [3], illustrate the translation of decades of research into clinical and commercial reality. The field is expanding rapidly; the American Society of Gene & Cell Therapy (ASGCT) and Citeline's Gene, Cell & RNA Therapy Landscape Report (Q3 2025) reports 3243 ongoing clinical trials worldwide across gene, cell, and RNA therapies, reflecting the sector's shift from niche innovation to a global enterprise [4]. Yet, despite scientific and commercial progress, the educational infrastructure that supports this growth has not advanced at the same pace.

Employers across the CGT ecosystem consistently report difficulty recruiting professionals with competencies in Good Manufacturing Practice (GMP), process development, quality systems, and regulatory requirements [5,6]. These applied skills remain under-represented in traditional academic curricula, which are often designed to provide broad conceptual and scientific training rather than sector-specific preparation for regulated manufacturing settings. Sector-level data further underscore the magnitude of this gap. The UK Cell and Gene Therapy Catapult's Skills Demand Report projects a 63% increase in CGT roles by 2028, with over half of new positions concentrated in manufacturing, highlighting the accelerating need for production-capable talent [7]. Recent analyses similarly show that roles requiring manufacturing and process-development experience remain among the most challenging to fill [8]. In an assessment of more than 250 job openings, How *et al.* reported consistent global demand for cell-manufacturing expertise across high-income countries [9]. Consequently, graduates often enter industry with strong scientific foundations but limited readiness for regulated manufacturing practice. This mismatch can prolong onboarding and slow time-to-productivity, while increasing the quality and compliance burden for employers, trends highlighted in sector-wide gap

analyses and workforce surveys in cell and gene therapy [6–8]. Although this disconnect between academic preparation and workplace readiness is not unique to CGT, it is especially consequential in this field because graduates enter highly regulated environments where documentation discipline, process control, and deviation management directly influence quality and compliance.

The complexity of GMP manufacturing for CGTs, shaped by product variability and limited precedent, further compounds these challenges. It requires expertise in manufacturing operations and contamination control; process development and analytics; quality systems and regulatory compliance; and engineering, equipment, and automation, as well as the ability to manage deviations and implement change control within a highly regulated environment [10–13]. Although some academic GMP facilities and translational centres offer valuable exposure, these competencies are not embedded in most university curricula, which still prioritize discovery-based experimentation over regulated, production-aligned training. As automation, digital bioprocessing, and electronic quality management systems expand, the gap between academic training and operational expectations within the CGT sector continues to widen. This misalignment limits sector-wide scalability, increasing regulatory risk, and delays patient access to emerging therapies [5,10,14–16], a pattern consistently reflected in workforce and manufacturing analyses that identify persistent skill gaps in process development, GMP capability, quality systems, and regulatory alignment [13,17–19].

These trends underscore the urgent need to realign academic and vocational training with the operational and regulatory demands of the CGT sector [15]. Beyond technical expertise, professionals must develop interdisciplinary fluency, regulatory literacy, and problem-solving skills through experiential, team-based learning, alongside essential soft skills such as attention to detail, a quality mindset, critical thinking, and accurate record-keeping [19–21]. They must also transition from an academic environment to an outcome-oriented mindset focused on defined tasks and milestone-based deliverables. While promising initiatives, such as modular GMP education, micro-credentials, and university–industry partnerships are emerging [7,22], their long-term impact will depend on stronger co-design

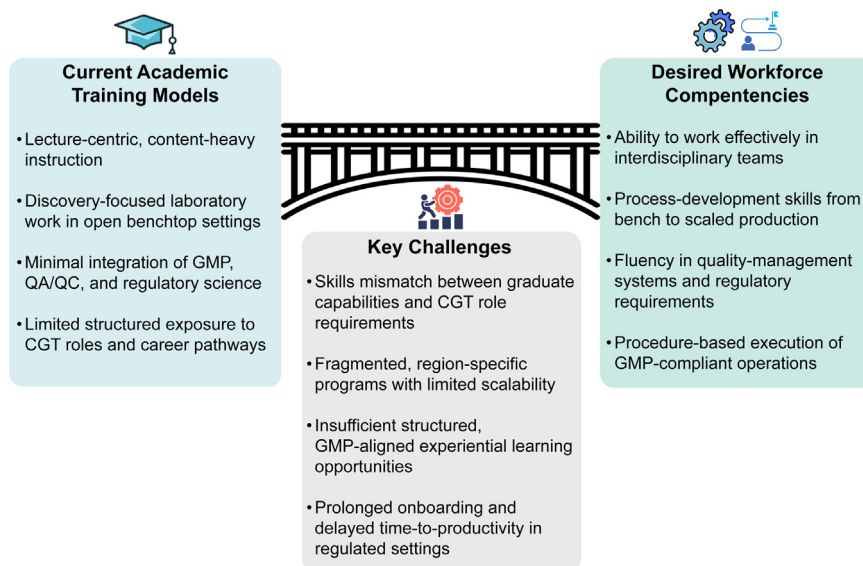


Fig. 1. Misalignment between academic training and CGT workforce competencies. Schematic overview illustrating how current academic training models fall short of the competencies required for CGT roles. The central bridge highlights key challenges that must be overcome to align curricula, practical exposure, and career pathways with workforce needs. CGT, cell and gene therapy; QA/QC, quality assurance/quality control.

across academia, industry, professional societies, and government rather than expecting universities alone to close the workforce gap effectively [23]. Figure 1 illustrates the misalignment between current academic training models and the competencies required of the CGT workforce, and the challenges the framework is designed to address.

To address these challenges, this perspective introduces the CGT Education Framework, an evidence-informed model comprising five interdependent pillars that link academic rigor with operational relevance and define sector-specific actions required to accelerate workforce readiness. The framework and its implementation roadmap provide a cohesive pathway to align education with CGT's technical and compliance complexity while reinforcing core workforce competencies across the career continuum. Together, they offer a strategic blueprint for transforming CGT education into an integrated, outcomes-driven approach supported by coordinated action across the sector.

Where Training Falls Short: A Concise Diagnostic

The CGT sector requires practitioners who can operate in regulated, team-based environments where GMP-aligned operations, quality systems, documentation discipline, and process control are essential. Yet, despite producing scientifically strong graduates, many academic programs do not prepare learners fully for these operational realities. As a result, workforce shortages persist, particularly in manufacturing, analytical development and quality roles [6,8,17–19,22], and employers frequently report difficulty translating academic training into reproducible GMP workflows [13,24]. Regulatory data reinforce this gap: U.S. Food and Drug Administration (FDA)'s current good manufacturing practice (cGMP) regulations require manufacturers to ensure personnel are appropriately trained for their assigned functions, while inspection findings (e.g., Form FDA 483 observations and warning letters) commonly cite deficiencies in training and documentation practices [25,26]. The International Society for Cell & Gene Therapy (ISCT) Early Stage Professionals (ESP)

committee surveys and National Academies workforce discussions indicate that early-career professionals are often least prepared for documentation-heavy, GMP-driven, and highly coordinated work settings [8,21,27]. Together, these findings underscore a persistent misalignment between science and research-oriented training and the operational, regulatory, and commercial demands of CGT [5,10,14–18], a gap further widened by limited opportunities for applied learning and the limited integration of CGT manufacturing into mainstream biotechnology and engineering curricula.

Importantly, these gaps should not be interpreted as simple institutional failure. Universities are generally designed to prepare students for diverse scientific and professional pathways, which can limit the extent to which highly specialized CGT training is built into core curricula. In many settings, this is compounded by practical constraints, including difficulty recruiting educators with relevant industrial and regulatory expertise and the challenge of designing programs that remain broadly valuable while still offering sufficient CGT-specific depth. These realities reinforce the need for coordinated training models that combines complementary contributions from academia, industry, professional societies, and policy actors.

These gaps consistently cluster into three interrelated domains: regulatory knowledge, technical capabilities, and commercial/translational readiness. These domains and their associated competencies are mapped in Table 1, linking industry-aligned expectations to typical gaps in academic preparation and exemplar learning outcomes and assessments. In practice, regulatory knowledge deficits reflect limited exposure to applied GMP, good documentation practice (GDP), internal auditing, root cause investigation, corrective and preventive action (CAPA) execution, and chemistry, manufacturing, and controls (CMC) documentation aligned with guidance from the FDA, European Medicines Agency (EMA), and International Council for Harmonisation (ICH) [20,28–30]. Technical capabilities remain constrained by reliance on discovery-scale workflows rather than GMP-grade facilities, automation, process analytical technology (PAT) tools, and validated analytical pipelines, leaving graduates underprepared for aseptic processing, process validation, and structured

Table 1
Core workforce competencies for CGT and representative gaps in current academic training programs.

Competency area	Industry-aligned competencies	Typical gaps in academic training	Example: learning outcome / assessment
Regulatory knowledge	Ability to interpret and apply GMP, GLP, and GCP; working familiarity with FDA, EMA guidance, and ICH guidelines and local regulations; conduct internal audits; execute CAPA processes; implement QA/QC systems; integrate CMC expectations into CGT development pipelines [20,28–30,34].	Minimal exposure to applied regulatory frameworks and risk-based quality systems; limited understanding of GDP, internal auditing, and CAPA implementation; lack of applied competence to interpret and implement regulatory principles in dynamic, real-world settings where audits, deviations, and expectations evolve.	Complete a deviation report to GMP standard; perform a mock internal audit and present findings aligned with risk-based priorities ($\geq 90\%$ items met); draft a CAPA plan addressing root cause and preventive steps; compile a mock clinical trial authorization dossier (CMC section; e.g., IMPD/IND-style) demonstrating documentation quality, traceability, and regulatory rationale.
Technical capabilities	Competence in aseptic processing under environmental monitoring; operation of single-use and automated bioreactor systems; viral-vector and cell-based production workflows; downstream purification; validated analytical assays (e.g., qPCR, flow cytometry, potency testing); and use of PAT tools and digital quality systems (eQMS/LIMS), to support traceability and data integrity [14,17–19,31].	Little or no access to GMP-grade facilities, automation technologies, and validated analytical systems; reliance on research-scale workflows; and minimal exposure to structured process validation, in-process controls, or digital documentation environments.	Execute an aseptic media-fill (pass/fail); qualify assays to predefined acceptance criteria; apply in-process control checkpoints during a mock manufacturing run; record results in an eQMS or LIMS to ensure traceability and data integrity.
Commercial/translational readiness	Ability to integrate technical, regulatory, and business perspectives to support technology transfer, scale-up, and lifecycle management; COGs analysis and risk-based decision-making; evaluate supply-chain and cold-chain logistics; and communicate process changes across manufacturing, quality, and regulatory teams [6,15,19,31,33].	Limited training in technology transfer, supply-chain logistics, or cost modeling; minimal exposure to product lifecycle management frameworks or cross-functional decision-making that links regulatory, manufacturing, and business operations.	Draft a technology-transfer plan integrating CMC and QMS touchpoints; develop a simplified COGs model for a manufacturing step; present a lifecycle risk–benefit analysis for a scale-up decision.

CAPA, corrective and preventive action; CMC, chemistry, manufacturing, and controls; COGs, cost of goods; eQMS, electronic quality management system; EMA, European Medicines Agency; FDA, U.S. Food and Drug Administration; GCP, good clinical practice; GDP, Good documentation practice; GLP, good laboratory practice; GMP, good manufacturing practice; ICH, International Council for Harmonisation; LIMS, laboratory information management system; IMPD, investigational medicinal product dossier; IND, investigational new drug; PAT, process analytical technology; QA/QC, quality assurance/quality control; QMS, quality management system.

in-process control [14,17–19,31]. Exposure to quality-by-design (QbD) frameworks and digital quality infrastructures such as electronic quality-management systems (eQMS) and laboratory information-management systems (LIMS) is likewise limited, further distancing academic training from contemporary CGT manufacturing environments [10,18,29,31,32]. Commercial and translational readiness is similarly under-developed, including limited exposure to value and evidence framing (e.g., health technology assessment), alongside minimal training in technology transfer, cost-of-goods (COGs) analysis, supply-chain logistics, and lifecycle management that integrates regulatory, manufacturing, and business constraints [6,15,19,28,29,31,33]. Together, these under-developed domains help explain why scientifically strong graduates often arrive without the operational, regulatory, and translational fluency required to contribute efficiently to CGT roles [6,8,13,19,24,27].

Despite growing recognition of these competency gaps, deeply entrenched university frameworks structural factors within universities continue to delay alignment between academic training and workforce needs. Indeed, most academic programs remain organized around science- and research-centric incentives and fragmented curricula, with limited integration of regulatory science, clinical operations, or regulatory submissions practice, thereby prioritizing discovery-focused outputs over manufacturing pedagogies [35–39]. Access to appropriate infrastructure is similarly constrained: GMP-like cleanrooms designed for single-use systems and realistic manufacturing simulations are expensive to establish and maintain [19], leading many institutions to rely on benchtop-scale training models that do not reflect the real-world environmental controls, monitoring, or documentation scope in regulated production facilities [13]. As a result, employers often need to provide substantial site-specific training in standard operating procedures (SOPs), quality documentation, and facility-specific workflows before graduates can contribute with confidence and consistency [13,40]. A further challenge is the pace of technological change: manufacturing innovation, automation, PAT, digital bioprocessing, and QbD are advancing faster than curricula, creating a widening technological gap between education and industrial reality [10,18,29,32]. Although the adoption of eQMS in academic GMP units demonstrates feasibility, such implementations remain the exception rather than the norm [32].

These constraints are magnified in low- and middle-income countries (LMICs), where limited digital infrastructure, language barriers, and the predominance of high-income–context educational materials restrict access to CGT-relevant training, credentialing, and sovereign manufacturing capacity [41,42]. Similar bottlenecks are also evident in some high-income settings with rapidly scaling CGT capability. Even here, shortages in GMP manufacturing, quality assurance, and regulatory expertise persist despite stronger fiscal capacity. Implementation studies similarly show that gaps in local workforce capability can delay or restrict the introduction of advanced therapies, underscoring the need for long-term investment in education and training as part of broader capacity-building strategies [43]. Programs that do succeed in narrowing the academic–industry divide make GMP literacy, documentation discipline, and process thinking explicitly visible, measurable, and assessable through SOP-anchored practicals, audit-style evaluations, and stackable, role-aligned credentials recognized by employers [20,28,29,31,33,34,36,37,44–46]. In this context, [Table 1](#) functions not only as a diagnostic of current gaps, but as a template for defining and assessing what “success” should look like in CGT education, linking clearly articulated competencies to concrete, assessable learning outcomes and assessments that signal genuine workforce readiness.

Bridging the Divide: Emerging Global Efforts

Bridging educational gaps requires better coordination across academia, industry, and government. No single stakeholder controls all

of the educational, regulatory, and workplace conditions needed to produce CGT-ready talent at scale. A growing number of initiatives, including curriculum reform, experiential learning, and policy-driven capacity building, are beginning to address these challenges. However, efforts remain uneven in scale, sustainability, and global reach, and many operate without shared competency definitions or portable credentials. Taken together, system-level policy initiatives, institutional curriculum reforms, and practice-focused partnerships are narrowing, but have not yet closed, the CGT workforce gap.

At the system and policy level, international and national agencies and institutions are increasingly investing in infrastructure, funding, and regulatory frameworks to support scalable and equitable CGT education. Strategic priorities include expanding training infrastructures, developing accessible and multilingual learning resources, incentivizing academic–industry partnerships, and integrating regulatory expectations into curricula. Programs such as the US National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)'s workforce development roadmap [33,47], the World Health Organization (WHO) biomanufacturing workforce training initiative [41], and the Advanced Research Projects Agency for Health (ARPA-H) translational programs [48] exemplify coordinated approaches to strengthen domestic and regional biomanufacturing capability and workforce capacity. However, sustained investment that spans geographic boundaries, especially in LMICs, remains limited but is essential to ensure global equity and participation. Representative initiatives across the United States, United Kingdom, Canada, Australia, Brazil, and key international organizations, including the ISCT-affiliated national science foundation (NSF)'s Engineering Research Center for Cell Manufacturing Technologies (CMA^T), which focuses on enabling technologies and translational workforce development rather than GMP training, are listed in [Supplementary S1](#).

At the institutional level, curricular integration is a critical next step in addressing the gap between academic training and workforce needs, with growing consensus that CGT-specific instruction must be embedded within biomedical and engineering programs to provide early exposure of students to GMP principles, quality systems, and regulatory science [9,23,31]. At the same time, the scope of this integration must be realistic. Few institutions can build fully specialized CGT pathways on their own, and many will need to rely on modular teaching, external partnerships, and shared infrastructure rather than standalone in-house programs. These efforts begin to move CGT education from purely conceptual coverage toward explicit preparation for regulated practice. This can be achieved through degree programs that integrate sustained GMP exposure and assessed practicals. Examples include Northeastern University's Master of Science in CGT [49] and the European Master's Degree in Manufacturing of Advanced Therapy Medicinal Products (ATMPs), developed under the Andalusian Network for the Design and Translation of Advanced Therapies in partnership with ISCT, both of which integrate structured GMP-aligned training and assessed work-integrated learning placements [50].

Building on these system- and institution-level reforms, sustained academic–industry collaboration remains pivotal in closing operational gaps and translating curricula into workplace-ready skills [19]. Initiatives such as NIIMBL, CMA^T, and the Canadian Alliance for Skills and Training in Life Sciences (CASTL) have developed workforce frameworks defining technician-level competencies and connecting academic research with commercialization pipelines [33,51]. Representative models include rotation-based, work-integrated training programs for highly qualified personnel (e.g., the Canadian Partnership for Research in Immunotherapy Manufacturing Excellence [Can-PRIME]) [52], and postgraduate fellowships such as the Mayo Clinic Cellular Therapy Fellowship. These models build workforce-ready capability for regulated operations, including supervised practice, documentation discipline, and cross-functional teamwork in cGMP

environments [53,54]. This is the direction the field should pursue more deliberately: not a transfer of responsibility from industry to universities, but a more deliberate partnership in which employers help shape, host, and assess training that reflects operational reality.

Similar programs at the Children's Hospital of Philadelphia, the University of Pennsylvania, and the University of Minnesota further demonstrate the role of structured rotations and mentorship in accelerating workforce proficiency [45] (Supplementary S2). In parallel, public-private and technology-enhanced learning hubs now link universities, start-ups, and translational centres to deliver modular, stackable credentials. Virtual and augmented-reality cleanroom simulations extend access to GMP-aligned training in resource-limited regions, providing safe, low-cost alternatives without compromising instructional fidelity [19,34,46]. However, geographic concentration in high-income regions and major biomanufacturing hubs restricts scalability, leaving mainstream curricula integration and access out of reach for many learners.

Professional societies and short-format training play a key role in harmonization and capacity building. ISCT, through its education and training portfolio [16,55], supports competency-based learning and mentorship. In Australia and New Zealand, ISCT ANZ region delivered a local regional CGT manufacturing workshop with experts from manufacturing facilities and contract research organizations (CROs), providing practical, locally relevant exposure to GMP-aligned manufacturing and quality practices [56,57]. Short-format programs, such as the ISCT-American Society for Transplantation and Cellular Therapy (ASTCT) Cell Therapy Training Course (CTTC), focus primarily on clinical implementation of cell therapies, protocol-driven care, and clinical trial conduct, thereby strengthening regulatory and quality literacy in clinical settings rather than manufacturing per se [24,40]. Complementary manufacturing-focused models, such as hands-on adeno-associated virus (AAV) manufacturing courses, provide structured training in unit operations, process control, and GMP-aligned analytics to address production-specific skills gaps [46]. However, credentialing remains fragmented and cost-intensive, particularly for early-career professionals and participants in LMICs. Supplementary S3 summarizes representative certificate-based and modular CGT programs offered globally through academic, industry, and regulatory organizations, illustrating scalable pathways for both entry-level and continuing professional education. Taken together, these efforts demonstrate substantial momentum but also persistent fragmentation in global CGT education, reinforcing the need for a cohesive CGT Education Framework to connect initiatives through shared competencies, assessable outcomes, and more portable credentialing pathways for scalable, equitable workforce development.

Strategic Enhancements for CGT Education: A Scalable Framework for Transformation

Building on national and international efforts, the next phase of CGT education reform requires a pragmatic, systems-based approach that unites academic rigor with real-world application. This reform must be developed with the realities of higher education in mind, including broad degree requirements, limited specialist faculty, uneven access to GMP-like infrastructure, and the need to prepare students for more than one employment pathway. Investing in scalable and inclusive training frameworks co-designed with industry is essential to cultivate a resilient workforce that supports safe, consistent, high-quality, and scalable CGT development and delivery, while broadening equitable access over time.

Here we present an evidence-informed framework for scalable and sustainable workforce development, conceptualized as a CGT Education Framework (Figure 2). The framework comprises five interdependent pillars: Curriculum Innovation, Interdisciplinary Integration, Scalable and Inclusive Delivery Models, Structured

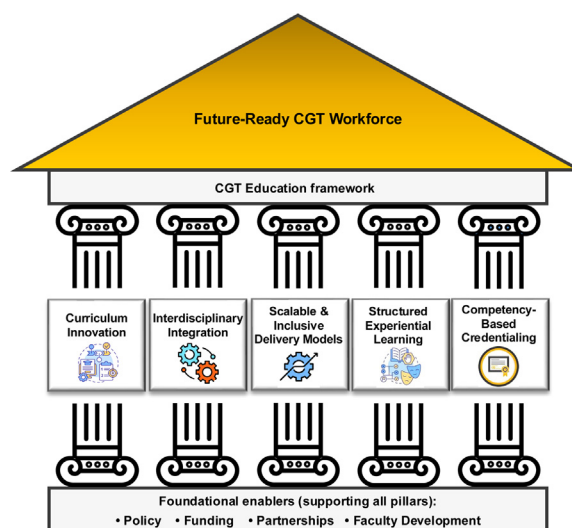


Fig. 2. Education framework for building a future-ready CGT workforce. Five pillars: Curriculum Innovation, Interdisciplinary Integration, Scalable and Inclusive Delivery Models, Structured Experiential Learning, and Competency-Based Credentialing, collectively support the development of a globally competent CGT workforce. Foundational enablers (policy, funding, partnerships, and faculty development) provide the structural base for sustainable implementation.

Experiential Learning (SEL), and Competency-Based Credentialing, each addressing a specific educational gap. Together, these pillars provide a strategic blueprint for aligning academic preparation with the technical, regulatory, and quality system demands of CGT development and delivery through shared, multistakeholder implementation rather than isolated institution-level redesign.

1. Curriculum Innovation

Strengthening CGT education begins with selectively embedding the core components of analytical development, manufacturing, and regulation into biomedical science, biotechnology, and engineering programs [16,17]. This integration bridges foundational science with real-world operational and compliance contexts, equipping graduates with the interdisciplinary understanding needed for modern biomanufacturing roles. Modular instruction on GMP principles, risk-based quality management, and key regulatory frameworks, such as FDA Chemistry, Manufacturing, and Controls (CMC) guidance [28], EMA QbD principles [29], and International Council for Harmonisation (ICH) pharmaceutical quality guidelines (e.g. ICH Q10) [30], can provide earlier exposure to regulatory requirements for product development. Institutions should adopt competency-based frameworks that define explicit learning outcomes across CGT-relevant competency areas (Table 1). For example, Warnock *et al.* describe a collaboratively designed cell-manufacturing competency model [36], while NIIMBL's Workforce Expansion in Biomanufacturing Emerging Technologies (WE-BET) and workforce roadmap demonstrate how modular, outcome-driven instruction can be implemented via academic-industry partnerships [37,58]. Where internal expertise or infrastructure is limited, shared facilities, co-taught modules, external placements, and society-supported short courses may offer more feasible pathways than expecting each institution to develop a fully specialized CGT curriculum on its own.

2. Interdisciplinary Integration

Building on this foundation, CGT programs should foster learning environments that unite foundational science with engineering, regulatory, and translational perspectives [19]. Team-taught courses, interdisciplinary degree tracks, and capstone projects can simulate cross-functional decision-making typical of CGT

development. Modules on supply chains, automation, intellectual property, and health economics expose students to the end-to-end product lifecycle, cultivating the ability to balance quality, cost, and feasibility in collaborative settings [59,60].

3. Scalable and Inclusive Delivery Models

Digital platforms can expand the reach of CGT education and improve affordability by offering multilingual materials, region-specific regulatory content, and culturally adapted pedagogy. Hybrid and blended formats, combining asynchronous online modules with in-person or simulated practicals, maintain engagement while reducing resource intensity [61]. Evidence from hybrid and online teaching suggests that tailoring course design to regional contexts is essential to maintain local relevance and sustainability [61–63]. However, persistent digital access inequalities, especially in LMICs, remain a barrier to equitable participation [41,62].

4. Structured Experiential Learning (SEL)

Expanding SEL co-operative opportunities, rotations in clinical-grade manufacturing settings, and industry-embedded project placements can markedly improve graduate readiness when co-designed with employers and aligned to operational standards. These experiences should immerse learners in process development, quality systems, and regulated manufacturing environments [46]. Because these settings sit largely outside the conventional university laboratory model, industry participation is not supplementary here; it is central. Government-funded workforce programs can scale such partnerships and address critical skills gaps [19,37]. In parallel, longitudinal mentorship strengthens professional identity, provides continuous competency feedback, and supports integration into regulated work cultures [64,65].

5. Competency-Based Credentialing

Competency-based micro-credentialing offers flexible mechanisms to certify specialized skills in regulated settings and can facilitate mobility across roles and regions [66–68]. Professional societies and regulators should collaborate with academic institutions to harmonize credentialing frameworks with international cGMP expectations (FDA, EMA, PIC/S) to support recognition and transferability [20,28,29]. Stackable credentials and digital badges can verify discrete competencies, such as regulatory literacy, cleanroom practice, or QC workflows, thereby reducing onboarding time and enabling targeted upskilling for mid-career professionals. By contrast, professional credentials, such as Association for the Advancement of Blood and Biotherapies (AABB)'s Certified Advanced Biotherapies Professional (CABP) and the modular certificate programs offered by ISCT, CATTI and CASTL, represent cross-functional professional qualifications [69–71]. Micro-credential examples include focused cell counting and quality-control courses offered by national blood services and regional CGT training providers which illustrate how focused, skill-based certifications can complement broader credentials [66–68]. [Supplementary S3](#) summarises representative certificate-based and modular CGT programs offered globally through academic, industry, and regulatory organizations, illustrating scalable pathways for both entry-level and continuing professional education.

Collectively, the five pillars provide an adaptable foundation for transforming CGT education into a coherent and sustainable system. Translating this framework into measurable impact requires coordinated, stakeholder-specific action. The next section operationalizes these pillars with concrete steps, responsible sectors, timelines, and outcome metrics.

Strategic Recommendations for Future Educational Models

The expanding CGT sector requires more than isolated training programs; it needs coordinated, repeatable mechanisms that

translate education into workplace-ready capability for regulated environments, including GMP-aligned practice, quality systems, and documentation. To operationalize the CGT Education Framework, implementation should be stakeholder-owned, sequenced, and measurable, with agreed indicators that enable evaluation across cohorts rather than relying on anecdotal success. Successful implementation will also depend on shared ownership of costs, infrastructure, mentorship capacity, and assessment standards, rather than expecting universities to absorb these responsibilities on their own. Building on the gaps and opportunities identified above, we outline actionable recommendations and an implementation roadmap to support a resilient, globally adaptive CGT workforce. Credential portability will require alignment not only of competency definitions, but of employer acceptance and jurisdictional expectations.

[Table 2](#) presents a conceptual implementation roadmap describing possible actions by universities, industry, professional societies, and regulators. Each action includes a deliverable, an indicative timeline, and an outcome metric to guide planning and evaluation. Timelines reflect anticipated initiation or achievement windows based on feasibility and urgency: near-term (≤ 12 months), mid-term (12–24 months), and long-term (24–36 months).

Domains of Workforce Development Across the Career Continuum

Sustaining a high-performing CGT workforce requires education and professional development that extend beyond entry-level preparation. A career-spanning approach supports progression from early practitioners to senior leaders, enabling continuity of expertise, adaptability to evolving technologies and regulations, and the development of leadership capacity across the sector. The 2023 workforce report by ARM highlighted the need for harmonized curricula and scalable, standardized training models that support reskilling and upskilling across workforce levels, from technical specialists to executive leadership [6]. Professional societies, including ISCT and AABB, are responding by expanding educational resources and competency frameworks that address skill gaps across this continuum.

[Figure 3](#) presents a career continuum model for CGT workforce development, organized around four interconnected domains that evolve across career stages: Structured Education, Mentorship and Fellowships, Community Building, and Continuous Learning. Together, these domains integrate formal qualifications with experiential training and professional engagement to support long-term capability and sector growth.

Structured education provides the foundational knowledge and practical skills necessary to enter and advance within the CGT workforce. Across the continuum, structured education typically progresses from foundation knowledge to practical skills training, and then to advanced degrees and professional certifications aligned with specialized roles. Programs include degree pathways, certificate courses, and micro-credentials offered by universities, specialized training providers, and professional societies. To maintain alignment with workforce needs, curricula should reinforce the competency domains introduced earlier, technical capability, regulatory knowledge, and translational awareness through authentic assessment (e.g., laboratory/manufacturing practice, GMP and QA/QC systems, and exposure to development pipelines). ISCT, for example, offers on-demand and in-person courses spanning laboratory and manufacturing practices, clinical CGT, and regulatory standards [69]. To remain workforce-relevant, these offerings should be co-designed with industry and regulators and evaluated using clearly defined, role-aligned competency outcomes rather than attendance-based completion alone.

Formal qualification pathways also vary by role. While bachelor's degrees commonly underpin entry-level scientific roles, associate degrees and technical diplomas remain important routes for

Table 2
Conceptual implementation roadmap for CGT workforce development.

Owner	Action	Example deliverable	Timeline	Outcome metric (measurable)
University (Undergrad/Postgrad)	Embed assessed GMP/QA/QC practical in final-year laboratories	SOP-anchored practical + audit-style rubric (documentation, deviations, traceability)	Near-term (≤12 months)	% students meeting audit threshold; inter-rater reliability; graduate self-efficacy on regulated tasks [31,36,68]
University + Industry (CDMO/biotech)	Make structured placements in regulated settings a defined pathway	MoU + placement handbook + competency checklist signed by supervisor	Near-term (≤12 months)	Placement completion rate; % achieving defined competencies; time to independent execution of specified tasks (weeks) [19,49,50]
University + Professional society	Map curriculum to role-based competencies	Curriculum-to-competency map + gap closure plan + external advisory review	Mid-term (12–24 months)	% competencies covered at assessed level; external review score/pass [31,36]
Professional society/Consortium	Launch stackable micro-credentials with proctored assessment	badge framework + assessment standards + recertification rules	Near-term (≤12 months)	Completions; assessment pass rates; employer uptake (recognition in job ads / HR frameworks) [41,66]
Government/Funder	Seed regional training hubs (simulation + shared infrastructure)	Shared-access facility + national course calendar + subsidized seats	Mid-term (12–24 months)	Trainees/year; utilization rate; cost per trainee; geographic access [41,72]
Industry (CDMO/biotech)	Co-design SOP-anchored assessments + “capstone-in-residence” projects	Assessment bank + capstone briefs tied to real deliverables	Near-term (≤12 months)	Offer rate from capstone cohort; 12-month retention; supervisor-rated readiness [19]
University (Global access)	Deliver low-cost digital modules with region-specific regulatory pathways	Multilingual LMS modules + regulatory add-ons + local mentor network	Mid-term (12–24 months)	Enrolment by region; completion rates; equity indicators (completion gap by region/language) [41,61–63]
Regulators/Accreditation bodies	Support credential portability via competency crosswalks	Competency crosswalk + guidance notes + pilot mutual recognition	Long-term (24–36 months)	Number of pilot recognition agreements; reduction in redundant retraining requirements [20,28,29]
Regulators / Professional societies	Standardized workforce outcomes reporting	Agreed KPI set + annual reporting template	Near-term (≤12 months)	% participating programs reporting KPIs; year-on-year changes in placement/readiness indicators [33,51]

CDMO, Contract Development and Manufacturing Organization; GMP, Good Manufacturing Practice; HIC, High-Income Countries; MoU, Memorandum of Understanding; QA/QC, Quality Assurance/Quality Control; SOP, Standard Operating Procedure; VR, Virtual Reality.

developing technicians and manufacturing specialists. Advanced qualifications (master's, doctoral, or medical degrees) are often expected for supervisory and regulatory leadership roles. In parallel, credentialing frameworks and accreditation requirements can formalize competence and support progression in laboratory and biotherapies settings [70,73–75].

Mentorships and Fellowships bridge the gap between formal training and real-world responsibility, supporting the transition into complex technical and leadership roles. Beyond early-career mentorship, structured leadership development and fellowship-based training support progression toward decision-making autonomy and leadership roles in regulated environments. As CGT matures, models that combine didactic learning with supervised experiential training are increasingly important to build both operational competence and

decision-making autonomy [8,19,53]. Structured programs such as the ISCT Cell Therapy Leadership Training Program and the ASTCT fellowship pathways provide mentored experiences for early- and mid-career professionals [76,77]. Mentorship programs, including the ISCT ESP mentoring initiative, further strengthen career planning, skill development, and leadership readiness through structured mentor–mentee engagement [78].

Community Building sustains workforce development by creating networks that share practice, build consensus, and develop future leaders. Committees and working groups within organizations such as ISCT and AABB convene stakeholders across academia, industry, and healthcare to exchange knowledge, advance standards, and coordinate best practices [14,79]. Structured participation, particularly for early-career professionals, can accelerate leadership development



Fig. 3. Career continuum model for CGT workforce development from entry to leadership. The horizontal axis depicts career progression (early-, mid-, and senior/leadership levels), and the vertical axis maps four domains that support workforce capability over time: Structured Education, Mentorships and Fellowships, Community Building, and Continuous Learning. The model illustrates how educational content and professional supports evolve across stages, spanning technical and leadership pathways through online and in-person learning, society engagement, and mentored development. ESP, Early Stage Professionals.

through contribution to society initiatives, collaboration with senior experts, and sustained professional identity formation [80].

Continuous Learning enables a resilient workforce as manufacturing platforms, analytical tools, and regulatory expectations evolve. Accessible learning formats, including conferences, webinars, workshops, and digital platforms, support ongoing upskilling and reskilling across career stages while maintaining alignment with emerging standards and best practices [55,69,79]. Together, these domains provide a practical, lifelong learning architecture that supports individual progression and strengthens sector-wide capability over time (Figure 3).

Conclusion

The CGT field is advancing rapidly and placing new demands on workforce capability in regulated environments. Sustaining this momentum requires innovation in how we educate, train, and support the global CGT workforce. We have identified persistent educational gaps, examined current training limitations, and proposed evidence-informed strategies to bridge them. Interdisciplinary and modular curricula, scalable and inclusive delivery models, structured academic–industry partnerships, and competency-based credentialing frameworks together provide a coherent pathway to strengthen workforce readiness across career stages. Collectively, these strategies aim not only to strengthen technical proficiency but also to foster cross-sector fluency, professional identity, and adaptability in regulated settings shaped by GMP-aligned practices.

A coordinated, systems-level response is now imperative. Academic institutions must modernize curricula to integrate emerging technologies and regulatory expectations; industry partners should co-design experiential learning programs that mirror operational realities; and governments and professional societies must invest in accessible, standardized, and sustainable training infrastructure to enable workforce mobility and consistent competence across regions. Progress will depend on training ecosystems that are rigorous, realistic, and scalable, and that draw on the complementary strengths of educators, employers, professional societies, and policy actors. Ultimately, CGT's success will rest not only on discovery, but on our collective ability to sustain quality, documentation discipline, and reproducibility as platforms and standards evolve.

Declaration of competing interest

AK is the Founder and Chief Executive Officer of Exellerium AB, a regulatory affairs consultancy. Through Exellerium AB, she provides regulatory advisory services and acts in Head of Regulatory Affairs roles for multiple biotechnology companies developing advanced therapies. MH receives compensation and holds stock in his employer, Charles River Laboratories. PJH has been an advisor to or on the advisory board of: Autolomous, CarTx, Cellenkos, Cipla, March Biosciences, MFX, and Y Innovations. All other authors declare no conflicts of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.jcyt.2026.102899.

Article History:

Received 8 February 2026

Accepted 20 April 2026

References

- [1] Biotechnology N. FDA approves hereditary blindness gene therapy. 2018;36:6.
- [2] U.S. Food and Drug Administration. FDA approves tisagenlecleucel for B-cell ALL and tocilizumab for cytokine release syndrome. 2017. Available from: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-tisagenlecleucel-b-cell-all-and-tocilizumab-cytokine-release-syndrome>. Accessed February 8, 2026.
- [3] Mahat U, Przepiorka D, Fashoyin-Aje LA. Remestemcel-L-rknd for steroid-refractory acute graft-vs-host disease in pediatric patients. JAMA 2025.
- [4] American Society of Gene & Cell Therapy (ASGCT). Gene, Cell, & RNA Therapy Landscape Report: Q3 2025 Quarterly Data Report. 2025. Available from: <https://www.asgct.org/uploads/files/general/Landscape-Report-2025-Q3.pdf>. Accessed December 10, 2025.
- [5] Levine BL, Miskin J, Wonnacott K, Keir C. Global manufacturing of CAR T cell therapy. Mol Ther Methods Clin Dev 2017;4:92–101.
- [6] Alliance for Regenerative Medicine (ARM). Workforce Report: Gap Analysis for the Cell and Gene Therapy Sector Washington, DC. 2023. Available from: <https://alliancerm.org/wp-content/uploads/2025/09/ARM-Workforce-Gap-Analysis.pdf>. Accessed October 25, 2025.
- [7] Cell and Gene Therapy Catapult. Cell and Gene Therapy UK Skills Demand Report London, UK. 2023. Available from: <https://www.atkskillstrainingnetwork.org.uk/app/uploads/2024/05/Skills-demand-report-2023-digital-1.pdf>. Accessed September 17, 2025.
- [8] Mamo T, Al-Riyami AZ, Couto PS, Weil B. Navigating workforce needs in the field of cell and gene therapy: results of workforce survey performed by the ISCT early-stage professionals committee. Cytotherapy 2025;4:417–21.
- [9] How A, Ta MT, Phan DTT, Tay A. Universities can do more to prepare the biomedical workforce for the cell-, tissue- and gene-manufacturing industry. Cytotherapy 2025;27:1375–83.
- [10] Nikita S, Mishra S, Gupta K, Runkana V, Gomes J, Rathore AS. Advances in bioreactor control for production of biotherapeutic products. Biotechnol Bioeng 2023;120:1189–214.
- [11] Moutsatsou P, Ochs J, Schmitt R, Hewitt C, Hanga MP. Automation in cell and gene therapy manufacturing: from past to future. Biotechnol Lett 2019;41:1245–53.
- [12] van den Bos C, Keefe R, Keville M, McCaman M. Manufacturing and quality of advanced therapeutics: cellular therapies, CAR-T and gene therapies. Biopharmaceutical Manufacturing: Progress, Trends and Challenges. Cham: Springer; 2024. p. 453–88.
- [13] Fury B, Bauer G. GMP manufacturing of cell and gene therapy products: Challenges, opportunities, and pathways forward. Mol Ther 2025;33:1886–8.
- [14] Vives J, Sanchez-Guijo F, Gnechi M, Zwaginga JJ. Cell and gene therapy workforce development: the role of the International Society for Cell & Gene Therapy (ISCT) in the creation of a sustainable and skilled workforce in Europe. Cytotherapy 2023;25:1033–6.
- [15] Myles L, Church TD. An industry survey of implementation strategies for clinical supply chain management of cell and gene therapies. Cytotherapy 2022;24:344–55.
- [16] Mount NM, Ward SJ, Kefalas P, Hyllner J. Cell-based therapy technology classifications and translational challenges. Philos Trans R Soc B: Biol Sci 2015;370:20150017.
- [17] Heathman TR, Nienow AW, McCall MJ, Coopman K, Kara B, Hewitt CJ. The translation of cell-based therapies: clinical landscape and manufacturing challenges. Regen Med 2015;10:49–64.
- [18] Lipsitz YY, Timmins NE, Zandstra PW. Quality cell therapy manufacturing by design. Nat biotechnol 2016;34:393–400.
- [19] Hopewell E, Pike NR, Lembong J, Hewitt M, Fekete N. Filling the gap: the workforce of tomorrow for CGT manufacturing as the sector advances. Cytotherapy 2024;26:540–5.
- [20] European Medicines Agency (EMA). Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells. 2020. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-quality-non-clinical-and-clinical-aspects-medicinal-products-containing-genetically-modified-cells-revision-1_en.pdf. Accessed August 13, 2025.
- [21] Hanley PJ, Ting AE, Tsokas K, Bates J, McFarland R, Salzman R, et al. Advanced therapies require soft skills: Insights from a National Academies Working Group. Cytotherapy 2026;28:102063.
- [22] ADC Consulting. Uncovering Workforce Shortages and Skills Gaps in Regenerative Medicine. 2024. Available from: <https://adc-consulting.com/wp-content/uploads/2024/10/Uncovering-Workforce-Shortages-and-Skills-Gaps-in-Regenerative-Medicine.pdf>. Accessed January 24, 2026.
- [23] Maryamchik E, Krull A, Tanhecho YC, Askar M, Cox C, Cui W, et al. Shaping the future of cell and gene therapy workforce development: training of cell therapy processing personnel-perspectives from the international society for cell & gene therapy lab practices committee. Cytotherapy 2025;27:1060–71.
- [24] Booth GS, Savani BN, Adkins BD, Woo JS, Bertram R, Trushinski J, et al. Cellular therapy processing laboratory: a workforce hiring nightmare. Bone Marrow Transplant 2023;58:735–7.
- [25] The Food and Drug Administration (FDA) Group. 21 CFR 211.25 & quality personnel: a guide to GMP compliance: national archives. 2022. Available from: <https://www.thefdagroup.com/blog/21-cfr-211-25-quality-personnel-a-guide-to-gmp-compliance>. Accessed January 6, 2026.
- [26] U.S. Food and Drug Administration. Samchundang Pharm Co., Ltd. Warning letter Available from: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/samchundang-pharm-co-ltd-599255-05132020>; 2020 Accessed January 6, 2026.

- [27] Mamo T, Couto PS, Al-Riyami A, Weil B. Career Development gaps and opportunities: results of the 2023 workforce survey performed by the ISCT early-stage professionals (ESP) committee. *Cytotherapy* 2024;26:e21–e2.
- [28] U.S. Food and Drug Administration (FDA). Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs). Center for Biologics Evaluation and Research (CBER), FDA. 2020. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/chemistry-manufacturing-and-control-cmc-information-human-gene-therapy-investigational-new-drug?utm_source=chatgpt.com. Accessed January 12, 2026.
- [29] European Medicines Agency (EMA). Quality: Quality by Design (QbD). 2020. Available from: <https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/quality-guidelines/quality-quality-design-qbd>. Accessed July 25, 2025.
- [30] International Council for Harmonisation (ICH). ICH harmonised tripartite guideline Q10: pharmaceutical quality system. 2008. Available from: <https://database.ich.org/sites/default/files/Q10%20Guideline.pdf>. Accessed October 16, 2025.
- [31] Bryans M., DeKloe J., Carrese J. Skill Standards and Curriculum Guidelines for Cell and Gene Therapy Technicians. National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). 2022. Available from: <https://biomanufacturing.org/uploads/files/162181136761177190-cgt-technician-skill-standards-2022-on-line-booklet-optimized.pdf>. Accessed November 11, 2025.
- [32] Wu X, Cadinanos-Garai A, Quach V, Jurado E, Vaissie A, Abou-el-Enein M. Redefining quality in cell and gene therapies: Lessons from implementing electronic QMS in academic cGMP facility. *Mol Ther* 2025;33:2091–103.
- [33] National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). Workforce development Available from: <https://www.niimbl.org/workforce/>. Accessed August 16, 2025.
- [34] National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). Training Programs for Biopharmaceutical Manufacturing 2020. Available from: <https://niimbl.force.com/s/article/Training-Programs-for-Biopharmaceutical-Manufacturing>. Accessed June 17, 2025.
- [35] Lewis P.A. How to create skills for an emerging industry: The case of technician skills and training in cell therapy. King's College London. SSRN. 2017. Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2903909. Accessed November 22, 2025
- [36] Warnock JN. Creating a competency model for the next generation workforce in cell manufacturing. In: 34th Australasian Association for Engineering Education Conference (AAEE2023), Gold Coast, Australia: Griffith University; 2023.
- [37] National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). Workforce expansion in biomanufacturing emerging technologies (WE-BET). 2023. Available from: <https://niimbl.org/projects/workforce-expansion-in-biomanufacturing-emerging-technologies>. Accessed July 18, 2025.
- [38] National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). Innovation of the Biopharmaceutical Manufacturing Talent Pipeline. NIIMBL. 2022. Available from: https://www.niimbl.org/wp-content/uploads/2024/01/Downloads/Innovation_of_the_Biopharmaceutical_Manufacturing_Talent_Pipeline_Oct2022.pdf?utm_source. Accessed December 18, 2025.
- [39] National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). Workforce strategy and leadership Available from: <https://www.niimbl.org/workforce/strategy/>; 2023 Accessed August 10, 2025.
- [40] Montgomery S., Schulze M. Financial incentives needed to attract next generation of laboratory professionals. 2023. Available from: <https://criticalvalues.org/news/all/2023/02/14/financial-incentives-needed-to-attract-next-generation-of-laboratory-professionals>. Accessed December 18, 2026.
- [41] World Health Organization (WHO). Biomanufacturing Workforce Training Initiative. WHO. 2024. Available from: <https://www.who.int/initiatives/biomanufacturing-workforce-training-initiative>. Accessed November 18, 2025.
- [42] Chejor P, Dorji T, Dema N, Stafford A. Good manufacturing practice in low-and middle-income countries: challenges and solutions for compliance. *Public Health* 2024;3:e158.
- [43] Horgan C, Serroukh Y, Gærde LK, Gagelmann N. Recognising inequalities in haematopoietic stem-cell transplantation and cellular therapy training. *Lancet Haematol* 2022;9:e323–4.
- [44] Al-Riyami AZ, Richard S. Educational intersections between transfusion medicine and biotherapies. *Global transfusion education: informatics, biotherapies, research, and ethics*. Bethesda, MD: AABB; 2025. p. 53–67.
- [45] University of Pennsylvania. Cellular therapy fellowship program. Available from: <https://pathology.med.upenn.edu/education/fellowships/programs/cellular-therapy-fellowship>. Accessed August 12, 2025.
- [46] Overton L, Boi C, Shastri S, Smith-Moore C, Balchunas J, Sambandan D, et al. Development and delivery of a hands-on short course in adeno-associated virus manufacturing to support growing workforce needs in gene therapy. *Hum Gene Ther* 2023;34:259–72.
- [47] National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). NIIMBL action plans & roadmaps Available from: <https://www.niimbl.org/industry-solutions/roadmaps/>. Accessed September 11, 2025.
- [48] Advanced Research Projects Agency for Health (ARPA-H). BIOGAMI: Rewriting protein “grammar” to stop neurodegenerative disease before it starts. 2026 Available from: <https://arpa-h.gov/news-and-events/rewriting-protein-grammar-stop-neurodegenerative-disease-it-starts>. Accessed February 8, 2026.
- [49] Northeastern University. Master of science in cell and gene therapies. Available from: <https://graduate.northeastern.edu/programs/ms-cell-and-gene-therapies/master-of-science-in-cell-and-gene-therapies/>. Accessed August 10, 2025.
- [50] International Society for Cell & Gene Therapy (ISCT). Master's degree in manufacturing of advanced therapy medicinal products (ATMPs). Available from: <https://www.isctglobal.org/workforce-development/master-in-european-atmp-manufacturing>. Accessed August 10, 2025.
- [51] NSF Engineering Research Center for Cell Manufacturing Technologies (CMA-T). Workforce development: national science foundation (NSF) center for cell manufacturing technologies. 2021. Available from: <https://cellmanufacturingusa.org/workforce-development>. Accessed September 14, 2025.
- [52] Ottawa Hospital Research Institute (OHRI). Ottawa researchers lead new global initiative to advance cell therapy manufacturing. Ottawa Hospital Research Institute. 2024. Available from: <https://www.ohri.ca/newsroom/story/view/1515?l=en>. Accessed October 20, 2025.
- [53] Krull AA, DiGuardo MA, Deeds MC, Skaer CA, Soiney KA, Wadewitz M, et al. Fellowship training for cellular therapy laboratory directors. *Cytotherapy* 2025;27:642–8.
- [54] DiGuardo M, Krull A, Dietz A, Soiney K, Chicos A, Wayne J, et al. The mayo clinic cellular therapy fellowship: training the next generation of cellular therapy leaders. *Cytotherapy* 2020;22:S202.
- [55] International Society for Cell and Gene Therapy (ISCT). ISCT training and development. Available from: <https://www.isctglobal.org>; 2025.
- [56] International Society for Cell & Gene Therapy (ISCT) ANZ. ISCT ANZ 2024 gene therapy manufacturing workshop: a review. 2025. Available from: <https://www.isctglobal.org/telegraphhub/blogs/lauren-reville/2024/09/10/the-isct-anz-2024-cgt-manufacturing-training-cours>. Accessed January 6, 2026.
- [57] Suttrave G.D., Alicia Shokooahmand, Ali Moir-Meyer, Gemma Sue Jessica ISCT ANZ 2025 Regional Meeting Recap: ISCT Telegraf Hub (News Hub). 2025. Available from: [https://www.isctglobal.org/telegraphhub/blogs/isct-head-office1/2025/09/11/isct-anz-annual-meeting-recap#:~:text=Simon%20Cool%20\(University%20of%20Queensland,integrating%20computational%20models%20into%20biomanufacturing](https://www.isctglobal.org/telegraphhub/blogs/isct-head-office1/2025/09/11/isct-anz-annual-meeting-recap#:~:text=Simon%20Cool%20(University%20of%20Queensland,integrating%20computational%20models%20into%20biomanufacturing). Accessed January 10, 2026.
- [58] National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). Workforce impact assessment framework. Available from: <https://www.niimbl.org/workforce/workforce-impact-assessment-framework/>. Accessed November 17, 2025.
- [59] Kools FR, Fox CM, Prakken BJ, van Rijen HV. A mixed method study investigating the key translational competencies acquired during a challenge-based course. *BMC Med Educ* 2024;24:1439.
- [60] Neuhauser L, Pohl C. Integrating transdisciplinarity and translational concepts and methods into graduate education. *Transdisciplinary professional learning and practice*. Cham: Springer; 2015. p. 99–120.
- [61] Wang X, Liu J, Jia S, Hou C, Jiao R, Yan Y, et al. Hybrid teaching after COVID-19: advantages, challenges and optimization strategies. *BMC Med Educ* 2024;24:753.
- [62] Reddy BA, Jose S, Vaidehi R. Of access and inclusivity digital divide in online education. *Econ Politic Weekly* 2020;55:23–6.
- [63] Lambert L, Wade A. Pedagogies of hybridity in the post-pandemic university. *Project Report*. Society for Educational Studies; 2023.
- [64] Teo MYK, Ibrahim H, Lin CKR, Hamid NABA, Govindasamy R, Somasundaram N, et al. Mentoring as a complex adaptive system—a systematic scoping review of prevailing mentoring theories in medical education. *BMC Med Educ* 2024;24:726.
- [65] Krishna LKR, Ravindran N, Kwok HYF, Tan XY, Soh J, Leong EYM, et al. The impact of mentoring relationships on professional identity formation in medical education: a systematic review. *BMC Med Educ* 2025;25:1–13.
- [66] Zdunek K, Dobrowolska B, Dziurka M, Galazzi A, Chiappinotto S, Palese A, et al. Challenges and opportunities of micro-credentials as a new form of certification in health science education—a discussion paper. *BMC Med Educ* 2024;24:1169.
- [67] Varadarajan S, Koh JHL, Daniel BK. A systematic review of the opportunities and challenges of micro-credentials for multiple stakeholders: learners, employers, higher education institutions and government. *Int J Educ Technol High Educ* 2023;20:13.
- [68] Tamoliune G, Greenspon R, Tereseviciene M, Volungeviciene A, Trepule E, Dauksiene E. Exploring the potential of micro-credentials: a systematic literature review. *Frontiers in Education* 2023;7:1006811.
- [69] International Society for Cell and Gene Therapy (ISCT). ISCT institute of training and development. Available from: <https://www.isctglobal.org/workforce-development/courses>. Accessed July 12, 2025.
- [70] Biotherapies AftAoB. Certified advanced biotherapies professional (CABP) credential. Available from: <https://www.aabb.org/education-career/career/certified-advanced-biotherapies-professional-credential>. Accessed August 11, 2025.
- [71] Canadian Advanced Therapies Training Institute (CATTI). Delivering industry-aligned training to accelerate individual careers and empower companies to build skilled, GMP-ready teams. Available from: <https://catti.ca>. Accessed June 13, 2025.
- [72] Cell and Gene Therapy Catapult. Advanced therapies skills training network. 2025. Available from: <https://ct.catapult.org.uk>. Accessed September 29, 2025.
- [73] Foundation for the Accreditation of Cellular Therapy (FACT). Cellular therapy accreditation eligibility requirements. Available from: <https://www.factglobal.org/accreditation-process/ct-accreditation-eligibility/>. Accessed October 10, 2025.
- [74] The Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee ISCT-Europe & EBMT (JACIE). International

- Standards for Hematopoietic Cellular Therapy Products Collection, Processing, and Administration. 9th Edition EBMT /FACT & JACIE. 2024. Available from: <https://www.ebmt.org/ebmt/news/fact-and-jacie-publish-9th-edition-hematopoietic-cellular-therapy-and-3rd-edition-immune>. Accessed December 22, 2025.
- [75] American Society for Clinical Pathology (ASCP). Earn a credential. Available from: <https://www.ascp.org/content/board-of-certification/get-credentialed#ct>. Accessed October 29, 2025.
- [76] International Society for Cell and Gene Therapy (ISCT). Cell therapy leadership training program. Available from: <https://www.isctglobal.org/workforce-development/cttc>. Accessed November 18, 2025.
- [77] American Society for Transplantation and Cellular Therapy (ASTCT). Fellowship programs directory. Available from: <https://www.astct.org/Careers/Fellowship-Programs>. Accessed August 15, 2025.
- [78] International Society for Cell and Gene Therapy (ISCT). ESP mentoring program 2024-2025. Available from: <https://www.isctglobal.org/resources/training-programs/esp-mentoring-program>. Accessed November 14, 2025.
- [79] Stem Cell Network (SCN). Training opportunities 2025. Available from: <https://stemcellnetwork.ca>. Accessed July 30, 2025.
- [80] International Society for Cell and Gene Therapy (ISCT). ISCT early stage professionals (ESP) committee. Available from: <https://www.isctglobal.org/about/isct-committees/esp>. Accessed October 25, 2025.