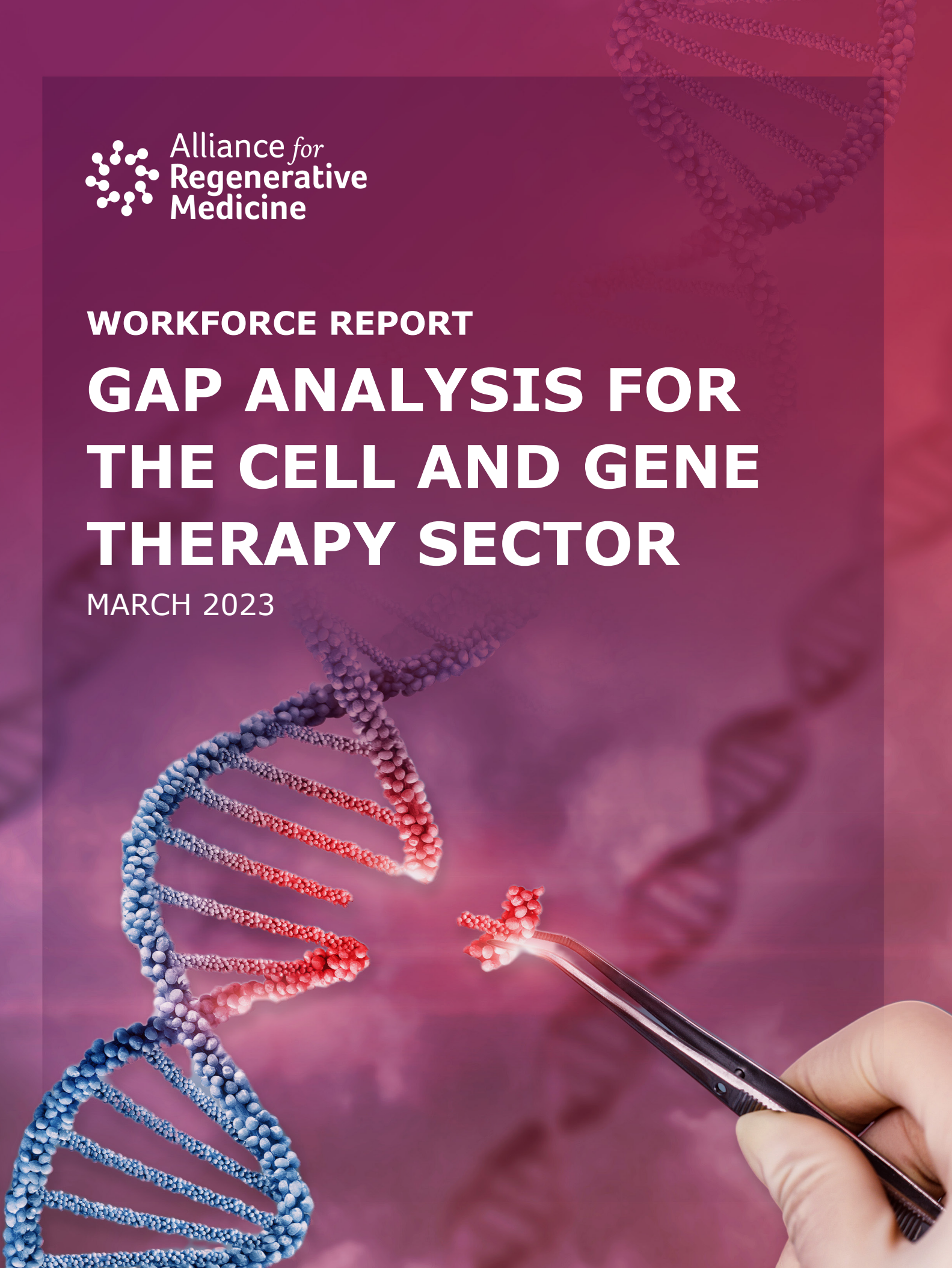




**WORKFORCE REPORT**

# **GAP ANALYSIS FOR THE CELL AND GENE THERAPY SECTOR**

**MARCH 2023**





# TABLE OF CONTENTS

Highlights .....	2
Introduction .....	5
Quantifying the Workforce Gap in the CGT Sector .....	8
US Landscape of CGT Hubs .....	13
Successful Models for Collaboration .....	18
Key Strategies for CGT Workforce Development .....	26
New Avenues for Workforce Training .....	34
The Role of FDA in the CGT Sector .....	40
Conclusion .....	41
Appendix .....	42

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# HIGHLIGHTS

This report provides a landscape overview and gap analysis of the workforce needed for sustainable biomanufacturing of cell and gene therapies (CGTs) in the United States. Recent transformative advances in fundamental biotechnology, including gene editing, CAR-T and other cell therapies, synthetic biology, and RNA vaccines—many of which were pioneered in the U.S.—are creating new business opportunities and jobs at all educational levels in regenerative medicine. With the rapidly evolving landscape in this sector comes great opportunity: desirable new careers for skilled workers, inclusion of underserved minorities in the public workforce, and expansion of centers of excellence throughout the United States.

To gather quantitative data and qualitative feedback on the state of the workforce in the CGT sector, the Alliance for Regenerative Medicine (ARM) commissioned a primary research study by Citeline, formerly Pharma Intelligence, which complements this report. Together, the team conducted a series of one-on-one interviews with stakeholders from therapy developers and contract development and manufacturing organizations (CDMOs) (n=11), as well as training providers, which are academic and non-profit institutions (n=10). The data shown herein are a result of these qualitative interviews and a quantitative survey sent to CGT experts in industry (n=15).



## Highlights in this report:

### 1 United States Leading the CGT Sector

- More than 2,000 clinical trials are active worldwide, of which 43% have sites in North America. Up to 13 new approvals are expected in the U.S. in 2023.
- As the field matures, the indications for treatment shift from rare diseases towards more prevalent disorders with larger patient populations.

### 2 Quantifying the Workforce Gap in the CGT Sector

- Workforce gaps are currently seen in manufacturing, analytical development and testing, as well as quality control. The gap in manufacturing is expected to widen the most.
- CDMOs perceive the gap as slightly larger than therapeutics developers, owing to the larger number of personnel required to support multiple clients.



**Has difficulty in finding the right talent negatively impacted manufacturing or clinical development timelines?**



**YES**

**(40% of respondents)**

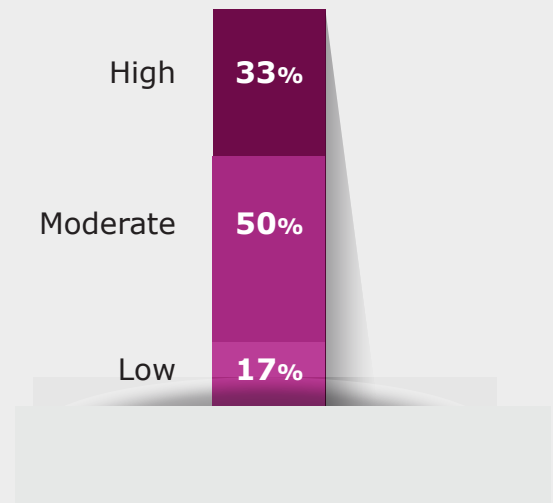


**NO**

**(60% of respondents)**



**Extent to which talent gap impacted manufacturing or clinical timelines (% of responses)**



### **3 Landscape of CGT Hubs Has Evolved Across United States**

- Traditional geographic biotech hotspots in Boston and California remain attractive for top talent.
- Local collaborations of academic institutions, hospitals, and industry partners form centers of excellence. These local partnerships are visible as discrete hubs across the U.S.
- Smaller CGT pockets such as Houston, TX, and Columbus, OH have gained traction in recent years as a result of purposeful local investments and the need for CDMOs to expand their talent pools.

### **4 Successful Models for Collaboration**

- Modularized training and stackable credentials create flexibility to upskill or re-skill workforce as needed. Vocational schools have identified regenerative medicine as new focus area requiring continuous supply of talent and are building curricula to meet the demand.
- Academic institutions are looking not only to expand what they offer, but also adapt to new ways of delivery. Virtual reality tools can augment hands-on training but will require the building of mock manufacturing suites.
- Apprenticeship programs pave the way in the U.S. and U.K. Trainees can obtain qualification while working for an employer.



## 5 The Role of the U.S. Food and Drug Administration (FDA) in the Sector

- FDA expects 10-20 new approvals per year by 2025. For context, the FDA has approved a total of 27 CGT products since 2017. To meet the current and anticipated demand in regulatory reviews and audits, the FDA is hiring 132 new staff in FY 2023 and an additional 96 in FY 2024-27.
- This creates an opportunity for the sharing of best practices and latest advances in technologies that can foster deeper understanding of advanced technologies emerging in CGT.

## 6 Key Strategies for CGT Workforce Development

- Incentives and apprenticeships are essential for attracting a diverse demographic of talent, and improve inclusion and opportunities for minorities.
- Cost for training can be prohibitive to candidates and educators alike. Lab hands-on training is considered essential to success and represents a major bottleneck.
- Regenerative medicine, including CGT, should be included in national STEM education and outreach activities at all levels of education and training.



# INTRODUCTION

The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organization championing the benefits of engineered cell therapies and genetic medicines for patients, healthcare systems, and society. As a community, ARM builds the future of medicine by convening the sector, facilitating influential exchanges on policies and practices, and advancing the narrative with data and analysis. We actively engage key stakeholders to enable the development of advanced therapies and to modernize healthcare systems so that patients benefit from durable, potentially curative treatments.

As the global voice of the sector, we represent more than 475 members across 25 countries, including emerging and established biotechnology companies, academic and medical research institutions, and patient organizations.

The CGT sector relies on a skilled workforce to produce, test, and transport a growing number of living drugs across the country to the patient's bedside. In addition, experienced

staff are essential for continued development and adaption of novel technologies to improve efficacy and accessibility. Finally, efficient scale-up and scale-out of manufacturing processes will need a growing number of trained technicians that understand the rules and requirements for working with biological products in a cleanroom environment. This growing demand has already created distinct employment opportunities across the United States<sup>1</sup> that require significant technical skills in traditional STEM areas such as bioprocessing, cell and molecular biology, and biomedical engineering.

Investment into developing a skilled workforce for the sector is key in enabling patient access to these advanced therapeutics across the U.S., especially as many of the patient-specific, potentially life-saving therapies need to be manufactured closer to the point of care to ensure timely delivery. A larger workforce is also vital for centralized manufacturing of off-the-shelf therapies. As the sector advances, both hard and soft infrastructure are required.



<sup>1</sup>2022 ESI Report: Greater Philadelphia Cell and Gene Therapy Update

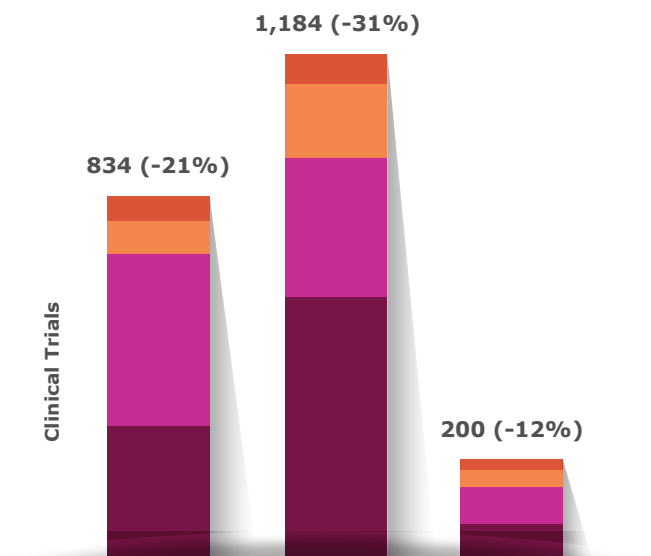
Importantly, this gap also opens an opportunity to include members of the workforce from underserved communities and demographics, by providing them with new career opportunities and the motivation to participate in the labor force and to generate potentially life-altering therapies. Establishing a sustainable and resilient biomanufacturing environment will enable drug developers to provide access to novel, highly tailored, and sophisticated products for patients suffering from rare diseases and prevalent pathologies, including cancer, autoimmune disorders, degenerative conditions, and cardiovascular disease. Support for this sector will expand U.S. leadership in innovation and manufacturing and enhance our ability to serve patients with products that can significantly improve quality of life or even have curative potential.



## State of the CGT Sector

ARM’s data show a robust pipeline of clinical trials in the U.S., with the majority of trials in phase II and close to 100 trials in phase III.<sup>2</sup> At the time of this writing, we forecast 13 cell or gene therapies that could be approved for use in the U.S., Europe, or both by the end of 2023. We are in reach of the FDA’s often-cited 2019 prediction that it would approve 10-20 new cell and gene therapies a year by 2025, which it based on an assessment of the current pipeline and the clinical success rates of these products.<sup>3</sup>

### Ongoing Clinical Trials by Phase and Region



**Region**  
■ North America ■ Asia Pacific ■ Europe ■ Other Regions

	Phase 1	Phase 2	Phase 3
Total	834	1,184	202
Other Regions	48	56	35
Europe	77	251	75
Asia Pacific	337	431	80
North America	339	526	99

Source: ARM data via GlobalData. Shown are total numbers of trials in phases and across regions. Please note that trials can take place in multiple locations. Percentages shown indicate change vs. previous year (2022).

<sup>2</sup>Preliminary data from Annual Report 2023 to be published in Q1 by Alliance for Regenerative Medicine  
<sup>3</sup><https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics>



Importantly, as the science advances and the sector continues to mature, the era of reaching larger patient populations has arrived. Of the currently active clinical trials, 58% have potential applications in a prevalent disorder and 60% of trials focus on oncology applications, with a near equal representation of solid and liquid tumors. With this shift, the number of patients and the amount of drugs needed per trial will increase. This in turn, will require hiring of more technical staff to manufacture these products quickly following approval and commercialization.

## Anticipated regulatory decisions in 2023

<b>Afami-cel (Cell Therapy)</b> <i>Adaptimmune Therapeutics</i> Advanced synovial sarcoma	<b>bb1111 (Gene Therapy)</b> <i>bluebird bio</i> Sickle cell disease	<b>B-VEC (Gene Therapy)</b> <i>Krystal Bio</i> Dystrophic epidermolysis bullosa	<b>CT-053 (CAR-T Therapy)</b> <i>CARsgen Therapeutics</i> R/R multiple myeloma
<b>CTX001 (Gene Editing Therapy)</b> <i>CRISPR Therapeutics &amp; Vertex Pharmaceuticals</i> Sickle cell disease, $\beta$ -thalassemia	<b>fidanacogene elaparovvec (Gene Therapy)</b> <i>Pfizer (formerly Spark Therapeutics)</i> Hemophilia B	<b>HPC cord blood (Cell Therapy)</b> <i>StemCyte</i> Unrelated Donor hematopoietic progenitor cell transplantation	<b>Libmeldy (Gene Therapy)</b> <i>Orchard Therapeutics</i> Metachromatic leukodystrophy (MLD)
<b>Lifileucel (TIL Therapy)</b> <i>Iovance</i> Metastatic melanoma	<b>Omidubicel (Cell Therapy)</b> <i>Gamida Cell</i> Hematological malignancies	<b>Remestemcel-L (Cell Therapy)</b> <i>Mesoblast</i> Steroid-Refractory Acute Graft Versus Host Disease	<b>Roctavian (Gene Therapy)</b> <i>BioMarin</i> Hemophilia
<b>SRP-9001 (Gene Therapy)</b> <i>Sarepta Therapeutics</i> Duchenne muscular dystrophy	<b>Tab-cel (Cell Therapy)</b> <i>Atara Biotherapeutics Inc</i> Epstein-Bar virus-associated post transplant lymphoproliferative disorder (EBV-PTLD)	<b>Upstaza (Gene Therapy)</b> <i>PTC Therapeutics</i> Aromatic L-amino acid decarboxylase (AADC) deficiency	<b>B-VEC (Gene Therapy)</b> <i>Krystal Bio</i> Dystrophic epidermolysis bullosa
<b>CTX001 (Gene Editing Therapy)</b> <i>CRISPR Therapeutics &amp; Vertex Pharmaceuticals</i> Sickle cell disease, $\beta$ -thalassemia	<b>Lumevoq (Gene Therapy)</b> <i>GenSight Biologics SA</i> Leber hereditary optic neuropathy (LHON)		

Source: ARM's State of the Industry Briefing (Jan 2023).<sup>4</sup>

■ United States ■ Europe

In line with this pipeline of anticipated approvals and future expansion of the CGT sector, the U.S. Food and Drug Administration (FDA) has elevated and reorganized its Office of Tissues and Advanced Therapies (OTAT) to a "Super Office" within the Center of Biologics Research and Evaluation (CBER) to meet its growing workload and new commitments under the Prescription Drug User Fee Act (PDUFA VII) agreement for FY2023-2027. This law provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products. The office will be renamed Office of Therapeutic Products (OTP).

<sup>4</sup>Cell & Gene State of the Industry Briefing - Alliance for Regenerative Medicine ([alliancerm.org](http://alliancerm.org))

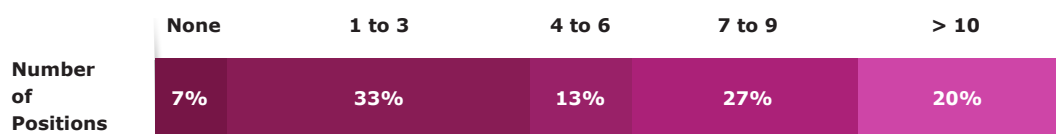


“With the current and anticipated increase in workloads, the proposed structural changes will improve functional alignment, increase review capabilities, and enhance expertise on new cell and gene therapies. Additional supervisory positions will not only help to address this increased workload but will also provide advancement opportunities to facilitate recruitment and retention of highly qualified staff,” FDA announced in September 2022.<sup>5</sup>

## QUANTIFYING THE WORKFORCE GAP IN THE CGT SECTOR

According to a study by The Manufacturing Institute and Deloitte, a manufacturing skills gap in the United States could result in 2.4 million unfilled jobs by 2028.<sup>6</sup> Finding workers with the right skill sets has been one of the biggest challenges in the manufacturing sector for a long time and was exaggerated during the COVID-19 pandemic.<sup>7</sup> Econsult Solutions, Inc. (ESI) projected the U.S. cell and gene therapy sector could potentially employ more than 32,000 workers in commercialization and R&D by 2025.<sup>8</sup>

### Range of open positions currently in workforce (% of response)



### Average amount of time to fill an open position in workforce (% of response)



Source: Citeline primary market research

<sup>5</sup><https://www.federalregister.gov/documents/2022/09/28/2022-20997/statement-of-organization-functions-and-delegations-of-authority>

<sup>6</sup>Deloitte: 2018 skills gap in manufacturing study. <https://www2.deloitte.com/us/en/pages/manufacturing/articles/future-of-manufacturing-skills-gap-study.html>

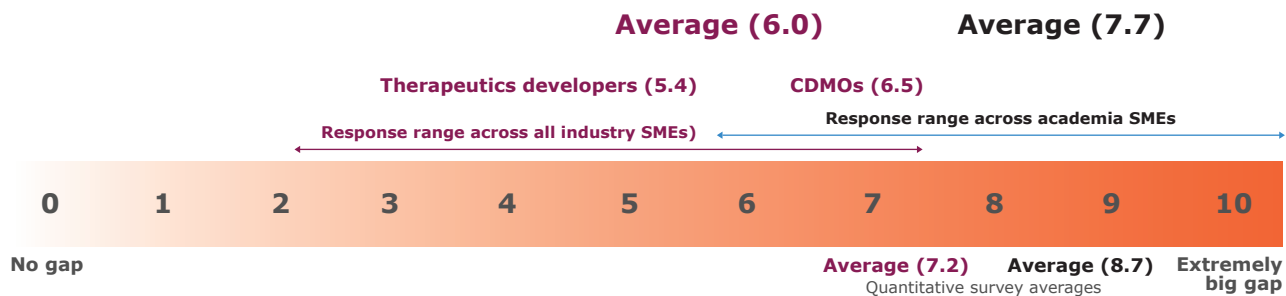
<sup>7</sup>The STEM Labor Force of Today: Scientists, Engineers, and Skilled Technical Workers

<sup>8</sup>ESI: The State of Cell and Gene Therapy in the Greater Philadelphia Region, A Comparative Analysis. [PowerPoint Presentation \(ceocouncilforgrowth.com\)](https://ceocouncilforgrowth.com) – September 2022

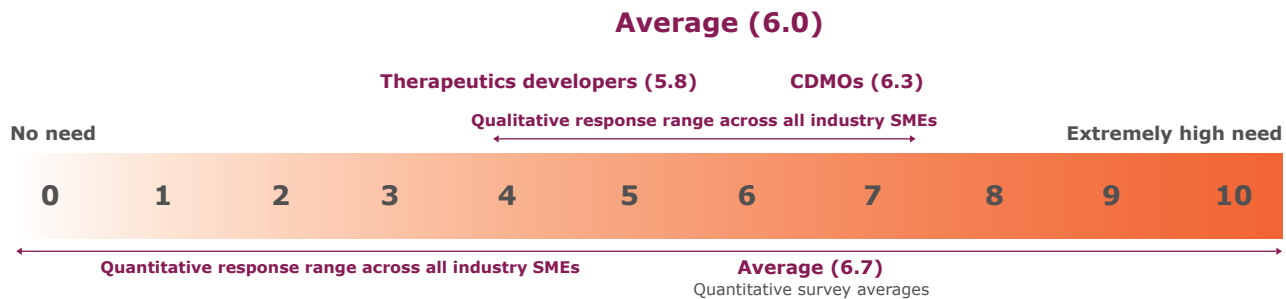
Currently, about half of industry respondents indicated in their survey to have  $\leq 6$  open positions in the workforce, and the other half to have greater than 7. For two thirds of our respondents, it takes an average 2-3 months (8-12 weeks) to fill an open position. This is a bottleneck in their current staffing regime and will likely be exacerbated in the future with increasing demand for drug manufacturing as the CGT sector scales and matures with approved commercialized products. Notably, this time frame does not include the training period needed for the new hire to meet expectations in executing procedures according to internal quality guidelines.

Scaling up of manufacturing activities will become especially important as 58% of current clinical trials have potential applications in a prevalent disorder. To date, all FDA approved therapies are for the treatment of rare diseases with smaller patient populations and thus require a lower number of products to be produced per year.

Size of gap between supply and demand for skilled workforce personnel in industry



“How big of a gap is there between the supply and demand for skilled workforce personnel **in the regenerative medicine sector?**”



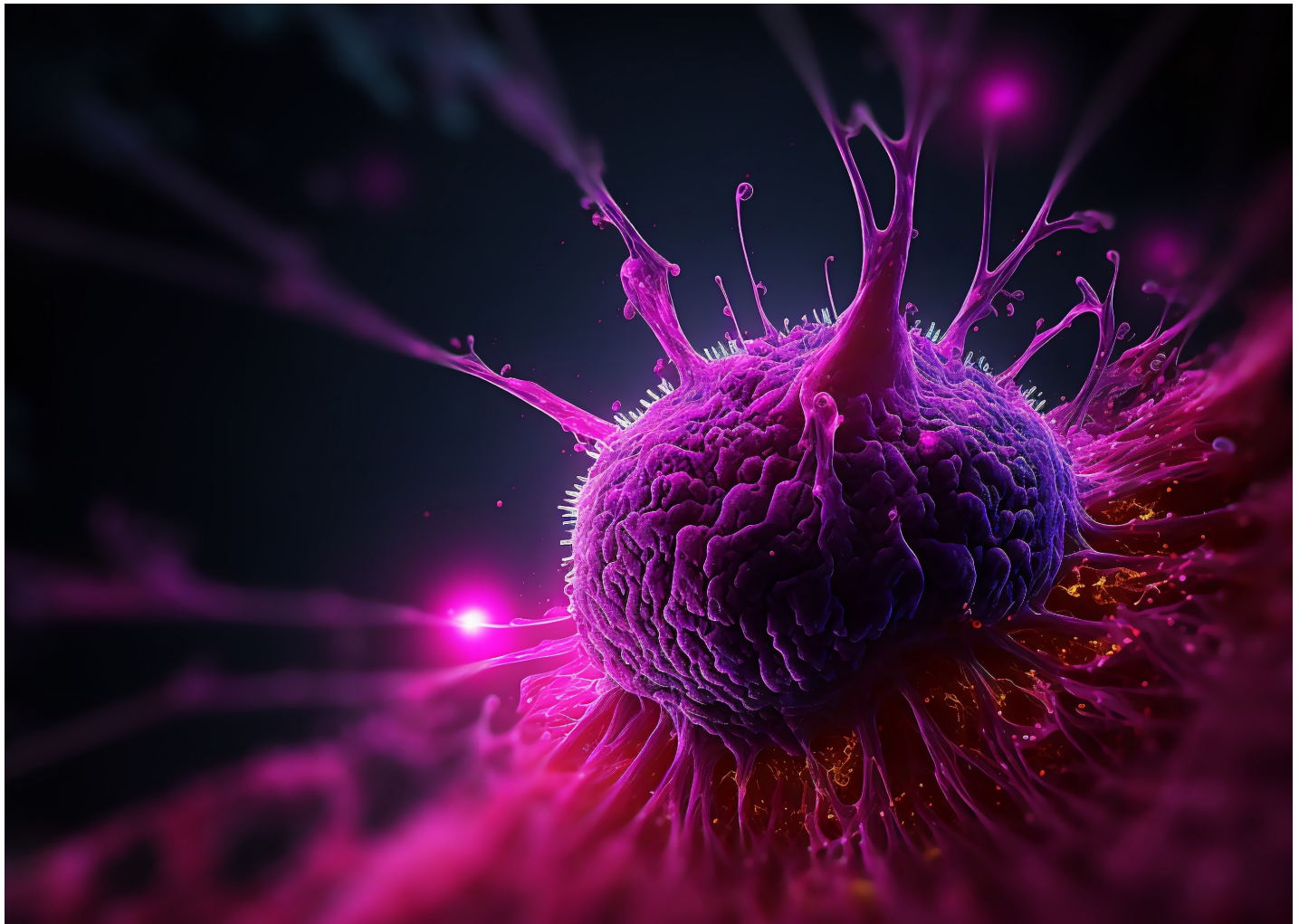
“To what extent does **your organization** currently need qualified, skilled workforce personnel?”



Lack in skilled personnel is one of the biggest challenges for developers to manufacture safe and efficacious products in a timely manner. Per our survey, difficulties in hiring are most pronounced in quality control, analytical development, and manufacturing, but also extend to process development and biostatistics. The gap in positions for manufacturing is expected to widen the most. Consequently, representatives from CDMOs perceive the gap as slightly larger than therapeutics developers, owing to the larger amounts of personnel required to support multiple clients. For CDMOs, there also exists a particular urgency to hire workforce personnel with baseline training, as staff needs to be in place as soon as clients sign contracts. Currently, the lack of experienced

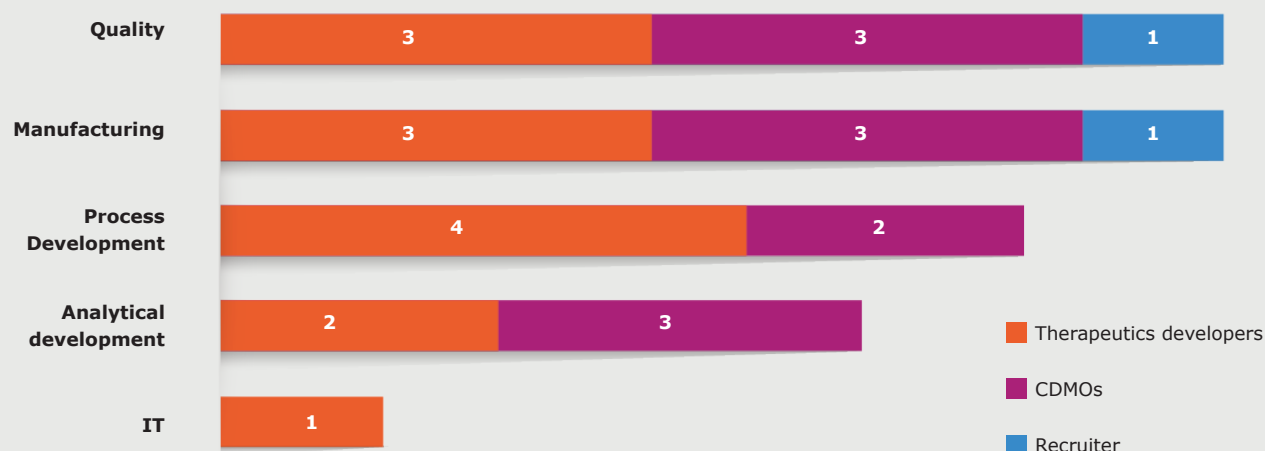
workers results in additional ramp-up time required for training new hires that is associated with financial and resource costs affecting production timelines.

Cell therapy products are often referred to as living therapies to highlight the difference between them and traditional biologics such as monoclonal antibodies, vaccines etc. Special attention is needed during biomanufacturing of cell therapies to ensure that a viable product can be administered to the patient. Likewise, quality control and analytical strategies have been adapted to reflect the nature of these drugs, and require dedicated training on the regulatory framework.



## Quantifying the gap according to functions

Most challenging workforce functions to recruit (number of mentions by industry SMEs)



### Industry (therapeutics developer) SME

“We’re still learning about quality control requirements... so this is a completely different way of manufacturing and doing quality control as compared to small and large molecules. So we are still somewhat reliant on a more qualified workforce.”

### Industry (therapeutics developer) SME

“The greatest need was both in direct manufacturing and QC. The main driver for that is as we were scaling up to do more clinical trials the manufacturing for the numbers of patients that we had had a direct correlation to how many people we needed, so it’s a very manual intensive process.”

### Industry (recruiter) SME

“Take manufacturing at a lower level, you would think those would be relatively quick and easy to fill. But some of those positions just never have enough of low level manufacturing people. They’ve got constant openings in that space.”

Source: Citeline primary market research

Abbreviations: Mnfg = Manufacturing; PD = Process Development; IT = Information Technology

This gap is especially significant for early-stage developers that grow from initial clinical trials in phase I to later stages (phases II and III) towards commercialization, as each step is accompanied by an increasing number in products required and patients served, as well as regulatory complexity.



### **Layoffs in the CGT Sector due to Economic Uncertainty in 2022/2023**

Like the biotech sector, some companies in the CGT space have been reducing their workforce along with adjusting their outlook for 2023 and beyond. The reductions in personnel are documented on Fierce Biotech's Layoff Tracker, which has recorded a total of 119 total layoffs among biotech companies in 2022.<sup>9</sup>

These layoffs have led to a temporarily high supply of workforce personnel, but demand still exists for certain roles, such as those that are highly specialized or entry-level manufacturing, due to the rapid growth seen in the CGT sector. The SMEs we interviewed believe high demand will return when financial markets recover and investor confidence returns to biotech industry overall.

In the current economic climate, CDMOs can spread the risk among multiple clients: If one client deprioritizes program(s) due to a difficult financial environment, CDMOs still have other clients to support and hire staff for, whereas therapeutics developers are inherently dependent on funding to continue work on their pipelines and hire personnel. Still, CDMOs may eventually feel the pressure of industry layoffs by therapeutic developers, if it starts affecting a critical mass of their client base.

Training is often provided by companies in internal formats. This allows new staff members to learn IP-protected know-how and unique bioprocesses related to the developer's pipeline. However, these trainings are time and resource-intensive, as this needs to happen on the job. Ideally, external training can be leveraged to make the hired worker proficient in aseptic technique and routine workflows in a cleanroom environment. Current education and workforce systems are lagging for many areas in biomanufacturing, with outdated curricula, lack of connections with industry, and hybridization of traditional skills demanded by the rapidly advancing technologies.<sup>10</sup> The gap is especially apparent in the highly dynamic CGT sector, where technological advances outpace school curriculums.

<sup>9</sup><https://www.fiercebiotech.com/biotech/fierce-biotech-layoff-tracker-2022>

<sup>10</sup>U.S. Department of Education: Advanced Manufacturing: Jobs of the Future (PDF) (July 28, 2021)



# U.S. LANDSCAPE OF CGT HUBS

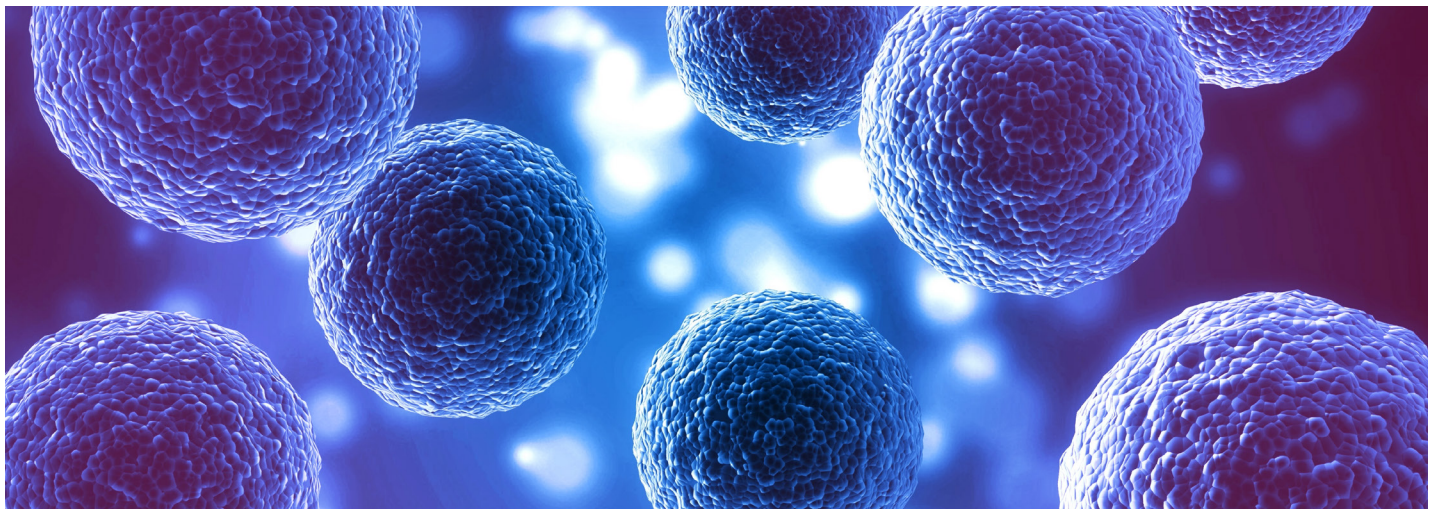
The current existing hubs in the CGT infrastructure across the United States are the result of private-public partnerships that engaged with industry to form locally integrated networks across various regions of the country. This is based on advantageous bioeconomic drivers, such as real estate, venture capital or state funding, and availability of a trainable workforce. The hubs also often engage local universities, startup companies, and other nearby clinical research institutes or medical schools to accelerate R&D and effectively translate new discoveries to new therapeutic modalities.

This section intends to provide an overview of CGT hubs in the U.S. and to highlight two emerging areas as examples for local efforts resulting in visible growth and success. The following map and area descriptions are a result of our interview series conducted with 30+ representatives from industry and academia.

## U.S. Landscape of CGT Hubs



According to our interviews, the two major CGT hubs include the **Greater Boston, MA**, and the **San Francisco Bay, CA**, areas. The main reasons for success include historic investments in the life sciences sector, proximity to universities and colleges, and talent. Space is at a premium, but generally available.



**Philadelphia** Become a major CGT hub since receiving the “spark” from Spark Therapeutics and experienced further growth as companies and founders settled into the area. The pioneering CAR-T cell therapy developed at the University of Pennsylvania (UPenn) by Carl June has made this region highly visible across all media platforms and is attracting start-ups and large companies alike. In addition, the area has benefitted from support by the Chamber of Commerce for Greater Philadelphia and real estate investors, e.g., Colliers Life Sciences. A notable organization in the area is the Wistar Institute, which offers dedicated apprenticeship programs and interfaces with local industry partners.

**North Carolina's Research Triangle Park (RTP)** The nation's fourth leading hub for biotechnology activity, trailing only Boston, San Francisco, and San Diego, according to Fierce Biotech<sup>11</sup>. The greater Research Triangle region, which includes Raleigh, Durham, and Chapel Hill, has about 10.6 million square feet of commercial bioscience lab space, is ranked No. 3 in research funding from the National Institutes of Health, and is a leader in biologics manufacturing, the article notes. 2022 was a record year for life sciences investment in North Carolina, with more than \$2.1 billion in investment and more than 2,700 new jobs created<sup>12</sup>. This is a result of continued investment into local infrastructure and dedicated workforce development programs organized by Wake Tech Community College and the BioNetwork Capstone Center. In 2021, FUJIFILM Diosynth announced its plans to invest \$2 billion to develop the largest cell culture CDMO in North America with eight 20,000-liter bioreactors and plans for an additional 24 bioreactors of the same size. This makes the Research Triangle a hotbed of manufacturing activity, with companies such as Catalent, Fujifilm, Eli Lilly, and Astellas starting or capping off multimillion-dollar projects in the area<sup>13</sup>.

<sup>11</sup><https://www.fiercebiotech.com/special-reports/top-biotech-hubs>

<sup>12</sup><https://www.ncbiotech.org/news/nc-books-21b-new-life-sciences-facilities-2700-jobs-2022-wins-accolades-overall-investments>

<sup>13</sup>Eli Lilly invests \$450M to expand its North Carolina Research Triangle manufacturing site – Endpoints News ([endpts.com](https://endpts.com))

In addition to these main hubs, smaller pockets have emerged across the U.S. that support and supplement the CGT hubs. These include Houston, TX, which has seen steady growth in response to Lonza and major hospitals in the area, Denver and Boulder in CO, Chicago, IL, as well as Columbus, OH.

The regions also showcase the distribution of CGT talent and organizations across the east and west coast, where renowned universities help drive R&D activities, but not necessarily

manufacturing. Manufacturing hubs are typically located in areas with lower costs for real estate and salary expectations. The desired skillset in workers differs from that trained at universities and employees are often hourly workers. Capex incentives can help attract organizations to these areas. Established companies like Amgen and Pfizer can draw talent almost anywhere, but small and early-stage companies rely on these hubs for talent access.

## Spotlight Columbus, Ohio:



### What works:

- “Our story” matters to talent, is motivating employees to receive training and apply for a job
- Flexibility in work schedule to allow employees to take time off for childcare, etc.
- Competition with other big and small biotech and pharma companies is a benefit—people who relocate can find a job elsewhere if first choice does not pan out
- Cost of living is low, land is cheap
- Strong education system
- International airport, good infrastructure, and four seasons climate



### Needs:

- Government support in STEM education has largely been neglected and needs initiatives at middle school, high school levels
- Incentives for relocation to Ohio, subsidized housing, moving costs or rebates, scholarships, support for non-profit organizations and low wage workers
- Bootcamp program needs funding to be sustainable; 1st cohort sponsored by industry, but will need funding in the future
- Skilled trade programs for CGT, technician-type roles are needed that don’t need advanced degree



**Maryland** An existing health care hub with Frederick County and Baltimore having a share of industry. In the field of CGT, Montgomery County has taken on a leading role in the state, owing to the proximity to the National Institutes of Health (NIH), FDA, NIST (National Institute of Standards and Technology), and other academic and medical research faculties that provide a rich environment of talent, science, and regulatory resources. One of Montgomery County's successful CGT companies is REGENXBIO, a biotechnology company that specializes in gene therapy. In the past year, the company opened a new 132,000-square-foot headquarters in Rockville that includes a state-of-the-art Manufacturing Innovation Center.

## Spotlight Houston, TX:



### What works:

- Texas Medical Center (TMC Houston) is the world's largest medical center
- Baylor University, MD Anderson, Children's Hospital are strong clinical drivers
- Lonza production facility: world's largest (300,000 square foot) dedicated cell and gene therapy facility
- Affordable homes and living



### Needs:

- Lack of trained, skilled personnel—high demand, low supply
- Retention an issue, poaching is common
- Salary range: lower wages vs Boston and other high-income areas; difficult to attract from high-margin areas or industries
- GMP training suites, mock facility, mock operation process—training model similar to that for electricians, HVAC engineers
- Analytical training and flow cytometry: very difficult to find people with experience and know-how

## The Los Angeles, CA, area

Has experienced rapid growth in recent years because of the presence of large successful companies, such as Amgen and Kite Pharma (Gilead). In the context of CGT, Atara Biotherapeutics has a large footprint in Thousand Oaks. In 2022, the company announced that the 90,000-square-foot facility was purchased by Fujifilm Diosynth to manufacture "a broader portfolio of cell therapies," according to the

Atara news release. Forming one end of “biotech beach” that runs up to Los Angeles, **San Diego** features 18.8 million square feet of lab and R&D space. One of its major CGT occupants is Bristol Myers Squibb, which signed off on a new 427,000 sq. ft. R&D campus in the University Town Center near La Jolla. The area is known for its technology development pioneers, such as Illumina, and recognized for its excellence in bioinformatics and digitalization of biopharma procedures.

## Seattle

Ranked as the fastest growing life sciences hub in a 2021 study by JLL. In terms of wage positioning—a metric comparing relative wages between biotech hubs—the Seattle area ranked fourth just behind Los Angeles, the Twin Cities, and the North Carolina triangle of Raleigh-Durham-Chapel Hill. Two of the major CGT companies located in the Seattle area are Sana Biotechnology and Juno Therapeutics (Bristol Myers Squibb). In addition, CGT pioneer Fred Hutchinson Cancer Center is based in Seattle, providing patients access to life-saving therapies.



Real estate investors have highlighted the need of companies for turnkey, move-in-ready facilities. Buildouts are deemed too capex-intensive and therefore cost-prohibitive to early-stage companies. Prefabricated GMP cleanrooms are in high demand. General-purpose lab space is available, but dedicated GMP space is not as easy to find, which can also present a hurdle in speed to market.

To prevent offshoring of biomanufacturing and loss of thought leadership into lower cost countries, these existing hubs will need to be nurtured and their appeal strengthened to continue attracting creative minds as well as technical staff on the manufacturing floors. The combination of innovation and execution of manufacturing processes will be key to enabling longevity and driving a successful bioeconomy.

<sup>14</sup><https://investors.atarabio.com/news-events/press-releases/detail/262/atara-biotherapeutics-enters-strategic-manufacturing>

<sup>15</sup><https://www.fiercebiotech.com/special-reports/top-biotech-hubs>

<sup>16</sup><https://www.us.jll.com/en/trends-and-insights/research/life-sciences-emerging-markets-index>

<sup>17</sup><https://endpts.com/move-over-boston-and-san-francisco-seattle-tops-list-of-fastest-growing-biotech-hubs-for-job-opportunities-report/>

# SUCCESSFUL MODELS FOR COLLABORATION AND TRAINING

At this time, there is a paucity of programs in the regenerative medicine space that provide certified training for the specific skills needed across the United States. Cell and gene therapies are related to, but differ markedly from, traditional biologics in many aspects of their manufacturing. This convolutes the skills gap. The following section provides an overview of major industry-recognized initiatives in the sector to provide dedicated training to the CGT workforce. It is not ranked or exhaustive, but rather intends to highlight successful models for collaboration at the national and community level.

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is a public-private partnership that has created a comprehensive education directory and searchable database of known trainings that exist within their member community. NIIMBL-funded projects have launched new curriculums and updated skill standards focused on cell and gene therapies, including the world's first hands-on gene therapy short course. This has paved the way for increased partnership between universities and community colleges and for pilot programs leveraging new modalities (e.g., AR/VR, digital twin, app-based training) for training. The National Science Foundation (NSF) Engineering Research Center for Cell



Manufacturing Technologies (CMA<sup>18</sup>T), led by the Georgia Institute of Technology, has created renowned training programs for workforce development in the CGT sector, including training programs for high school, undergraduate, and technical college levels. Recently, CMA<sup>19</sup>T and the International Society for Cell & Gene Therapy (ISCT) launched the joint-training program “Workforce Development in Biomanufacturing” to broaden the audience and outreach of their individual organizations. Developed by field experts from academia, regulatory, clinical, and commercial domains, this program provides training to up-skill key personnel for roles within companies and clinical manufacturing centers across the CGT sector.

<sup>18</sup><https://niimbl.force.com/s/education-and-training>

<sup>19</sup><https://cellmanufacturingusa.org/vital-training-opportunity-cgt-manufacturing-global-partnership-isct-cmat>



## ISCT – ASTCT Cell Therapy Training Course

The biennial ISCT – ASTCT Cell Therapy Training Course (CTTC) aims to address the need for in depth training in the development and translation of cellular therapies and expose scholars to topics that are not part of their formal education. The course covers all aspects of translation from pre-clinical research to cell manufacturing and clinical trials in cellular therapy, including regulatory components.

### Program Format



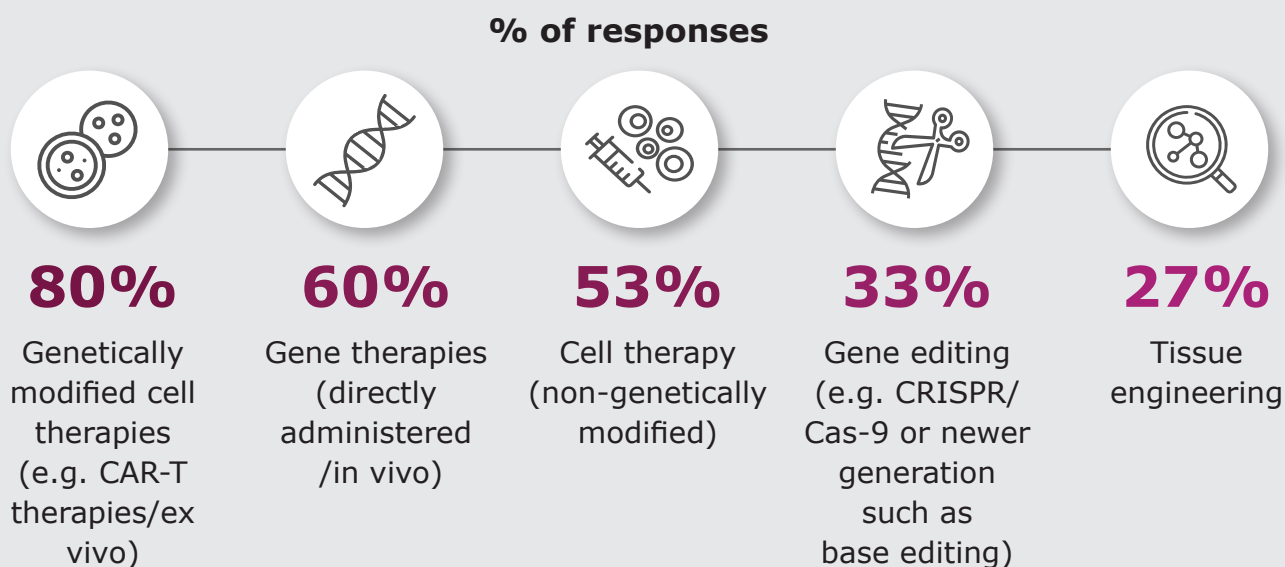
Many of the interviewees contacted for this report provided positive feedback on the available formats, but also highlighted the critical role for hands-on training, especially with a focus on Good Manufacturing Practice (GMP) required for manufacturing therapeutic products. In addition, the low frequency of these trainings and limited number of available seats per course were listed as an impediment to growing the biomanufacturing workforce needed to scale complex bioprocesses quickly and execute according to the documentation standards expected by regulatory authorities. Many interviewees thus asked for an “industry stamp of approval” to be established by a national organization or agency.

### Challenges in Delivering Effective Training Programs

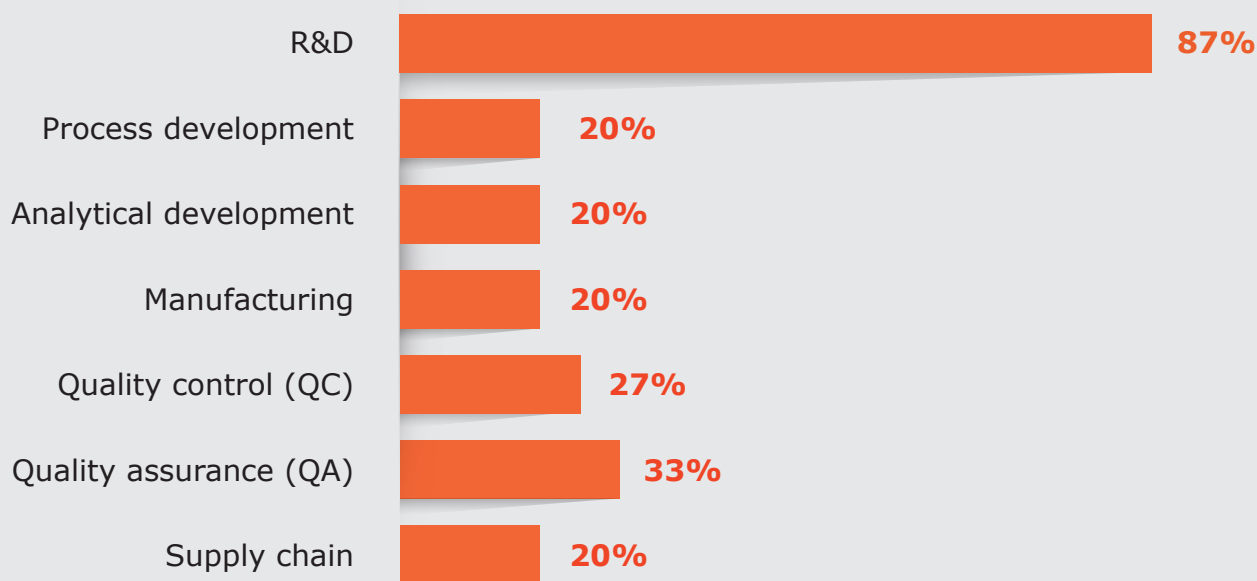
At this time, only a small number of universities and non-profit organizations have launched CGT manufacturing-focused programs that provide instruction on how to process living cell therapies. Examples include use of bioreactors, closed and automated equipment/instruments, aseptic connections, and scale up technologies as well as regulatory training for CGTs. Currently, most teaching institutes provide hands-on GMP-level manufacturing training only in the context of traditional biopharma or biologics manufacturing, for example for monoclonal antibodies or proteins.



## Regenerative medicine areas covered in academic training programs



## Workforce functions covered in academic training programs (% of responses)



Source: Citeline primary market research

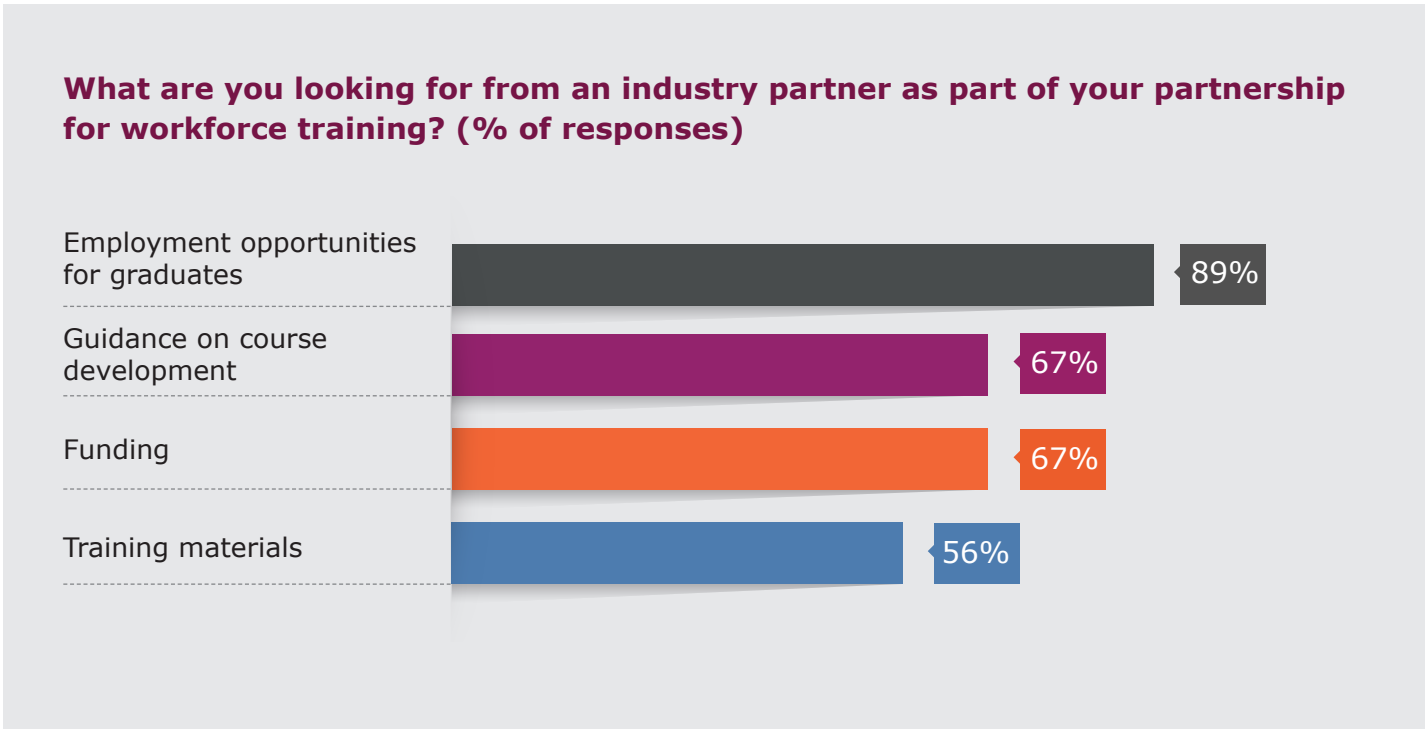
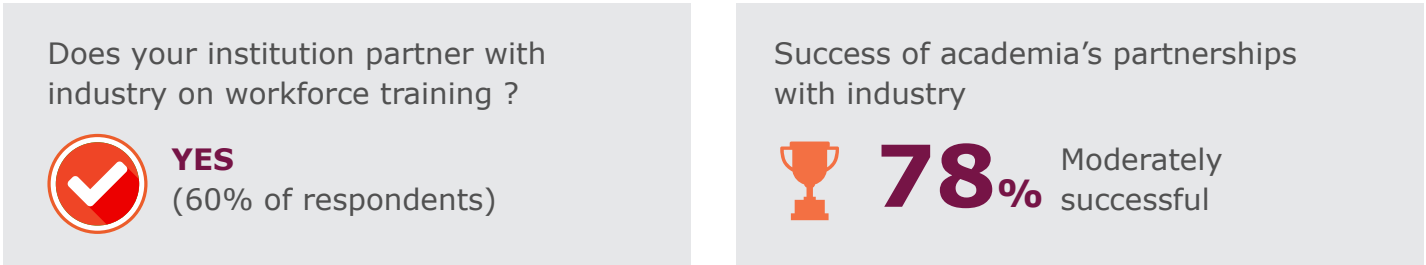
As a result, there is a shortage of workers who have the deep knowledge and experience in cell culture processing, viral vector production and GMP-compliant workflows that are necessary to develop and execute new manufacturing processes. In addition, an increasingly wide range of bioproducts currently in development use fully closed, automated systems and other sophisticated, expensive equipment for bioprocessing and quality analytics.

Incentives provided by the government could be helpful to the industry for providing expensive equipment, single-use technologies and other reagents at reduced or no cost for training purposes. Demo units or over-produced, non-qualified samples could be utilized in training centers for hands-on experience with the actual products and instruments.

Finally, our general level of understanding of technologies needs to improve, so that employees can better define and improve processes and related analytics.

### Training Providers Rely on Support from Industry

Academic training providers that were interviewed for this report recognized the need for training a skilled workforce and acknowledge that they often “can’t graduate students quickly enough” to fill the gap. Trainers emphasized the need to locally engage talent via outreach programs and offering tailored courses to align with an industry partner and specific roles. Enrollment of employees by local industry and contribution to content building of, e.g., a syllabus, was cited to be as important as funding for training.



Notably, the implementation of good training is an expensive undertaking: a typical spend has been priced at \$50-100k by a training provider for development of a high-quality online course with pedagogic, interactive modules. This does not include the cost for hands-on training in a lab setting, which entails cost for space, equipment, and single-use components and reagents for the cohort. This is a major factor limiting the number of students that can join hands-on sessions and lowering the frequency of trainings as providers need to be able to make ends meet with existing resources. There is currently no incentive for drug developers or CDMOs to provide dedicated space for training purposes since the same space utilized for drug manufacturing will yield higher rewards.



### **The Northeast Biomanufacturing Center and Collaborative (NBC2)**

NBC2 is a National Science Foundation Advanced Technology Education regional center established in 2005. Initially located at Great Bay Community College in Portsmouth, New Hampshire, the center has been housed at Montgomery County Community College (MCCC) in Blue Bell, PA, since 2009. In addition to the Pennsylvania hub, NBC2 has four additional strategically placed hubs in

New York, North Carolina, Indiana, and California.

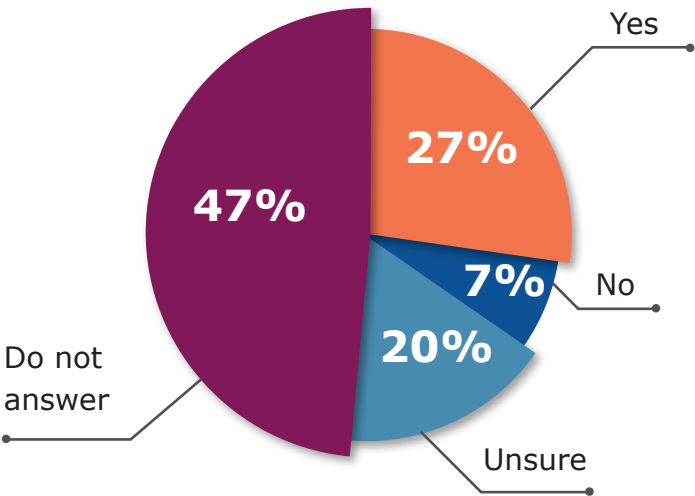
Over the past ten years NBC2 has worked with industry subject matter experts to develop a suite of curricular materials, including a biomanufacturing lab manual, and developed hands-on experiences in the areas of biofuels, industrial biotechnology, and stem cell technology.

Finally, cost of training is also an issue for companies facing high turnover. Skilled staff in the CGT industry is in high demand, which increases turnover rates. Many industry members are thus loath to invest in expensive training programs if they experience low retention rates due to job hopping and poaching of employees by higher paying companies. Strategies for talent retention need to provide skilled workers with a career path and opportunities for growth inside the organization. As an example, a GMP operator may be offered a role outside of the physically taxing cleanroom environment to join the MSAT or the process development team. Long-term career pathways and opportunities for advancement are also critical in recruiting talent to take the offered training for upskilling.

## Opportunities for Funding and Incentives

Funding is needed and could be provided as in-kind contributions as well as monetary help and/or donation of equipment and single-use components and reagents. An industry-consortium could likely provide joint funding to support a nationwide training program.

Does your organization receive government support for regenerative medicine projects? (% of responses)



### Range of government funding in 2022 for regenerative medicine projects

 ~ \$ 1.5m - 100m

### Challenges in securing government support for regenerative medicine projects

- "Paper and bureaucracy"  
**Academic SME**
- "The availability of governmental funding related to regenerative medicine"  
**Academic SME**
- "Demand is higher than the opportunities for funding. Regenerative medicine therapies require partnering with physicians and broad infrastructure to support clinical trials"  
**Academic SME**



Governmental funding could be leveraged to expand existing programs, such as NIIMBL and NIST-funded activities. One related example is the workforce activity funded by BARDA, the Biomedical Advanced Research and Development Authority, part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services. BARDA supported the Certificate

in Biopharmaceutical Manufacturing (ACBM) program delivered with the National Center for Therapeutics Manufacturing (NCTM), located at the Texas A&M Engineering Experiment Station at College Station. A national certification program for technicians in GMP-manufacturing and CGT-specific quality control could certainly accelerate harmonization of training programs and concerted roll-out in major hubs with qualified partners.



## The Wistar Institute

### Wistar Institute's Biomedical Technician Training (BTT) Program

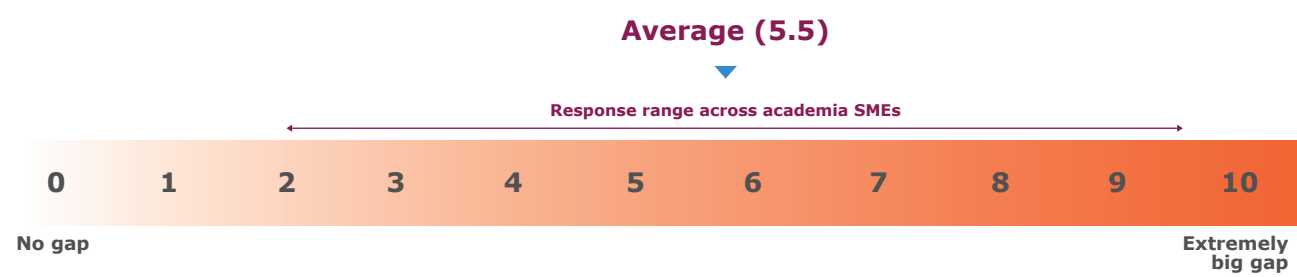
- Created in partnership with Community College of Philadelphia (CCP) in 2000. BTT Program is a registered pre-apprenticeship that can lead into Wistar's Fox Biomedical Research Technician (BRT) Apprenticeship.
- Students are paid during the laboratory training. Funding is from a National Science Foundation (NSF) Advanced Technological Education (ATE) grant.
- Accelerated model for the BTT Program allows students at different stages of their education and career to prepare for positions as laboratory technicians and research assistants in both academic and industry labs. After completion of the BTT Program, trainees can obtain positions that are traditionally held by graduates of four-year baccalaureate programs.

### Quality Science Pathway Apprenticeship

- Program starting spring 2023; Curriculum licensed from collaborator Pathway for Patient Health
- Free admission: Requires 3-5 hours per , offered as an online, synchronous class scheduled in the evening
- Upon completion of the program, QSP apprentices receive certification as a Certified Quality Science Professional (CQSP)
- Network and access to mentorship network and employer portal for internship and career opportunities
- Employment and on-the-job training with biotechnology companies

An industry’s stamp of approval to recognize the offered training as per the desired standards and compliant with regulatory expectations was suggested by interviewees in advancing local training initiatives and in providing clarity on the usefulness of existing courses to meet the need. This is especially important in the highly dynamic CGT sector, which necessitates re-development of resources and training curricula every 1-2 years to keep up with changes in advancing technologies.

**Size of gap between supply and demand for skilled workforce personnel in industry**



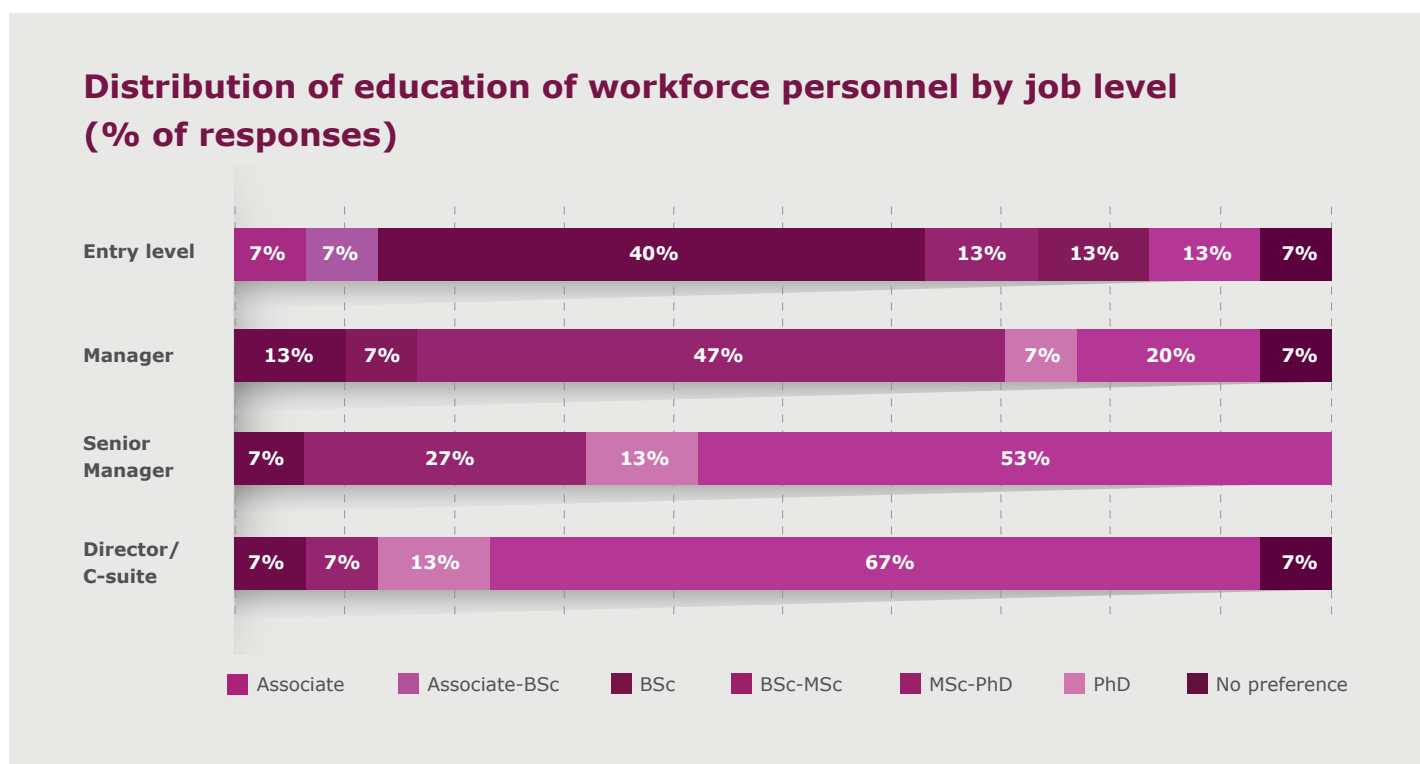
Finally, there is a clear need to train the trainers. Our interview series showed a paucity in skilled trainers—our interviewees often cited one or two staff per organization that have the relevant experience to provide meaningful training. Low salaries and insufficient resources in academic institutions have resulted in faculty attrition and retention. As a consequence, many experienced educators are retiring out of the workforce without replacement.

In a positive development, the excitement around CGT and emerging technologies has resulted in the establishment of training organizations led by dynamic and highly dedicated staff.



# KEY STRATEGIES FOR CGT WORKFORCE DEVELOPMENT

In our interview series conducted to inform this report, participants distinguished between academic education at universities and vocational training at community colleges as two separate pathways for addressing the labor shortage. Workforce development encompasses both areas—academic education that also links to STEM activities starting at an early age, and vocational training aimed at re- and upskilling early-stage as well as experienced workers.



In order to train technicians in manufacturing, there is a need to re-balance the entry-level workforce and shift to employing candidates with shorter, e.g., 2-year, degrees or high school graduates, in addition to the traditional labor pool with Bachelor's and PhD degrees. A dedicated certification program, e.g., for technicians in biomanufacturing, technicians in quality control, etc., could provide standardization to the field, which would accelerate and harmonize training efforts across the U.S. A standard curriculum implemented in all training centers across the U.S. can be instrumental in facilitating a national, scalable training program. The need for a harmonized curriculum was highlighted by several interviewees.

## Modernizing STEM Education to Include Regenerative Medicine

In the traditional academic trajectory, students will embark on a lengthy educational path towards obtaining a degree, i.e., Bachelor's, Master's, and PhD, that indicates their specialization in a certain subject matter and deep understanding of complex scientific or engineering principles. Their academic work usually culminates in a thesis documenting their hypothesis, experimental results, and relevance for advancing the field. This type of teaching is focused on producing creative thinkers and scientists, and fostering innovation through research and development (R&D). Academic curricula are generating highly skilled workers that will add to the intellectual property portfolio of organizations and thought leadership in the U.S. This depth of knowledge is essential in research for early-stage development. For later stages in the process, breadth of knowledge

becomes a key component in a worker's ability to problem-solve and follow operational principles.

As the field of CGT and regenerative medicine is still nascent and rapidly developing, knowledge about this field, including a working understanding of cell biology, cell and gene therapy, and processes to manufacture these living therapies is still lacking in traditional high school curricula or at vocational schools. As a consequence, the existing and future workforce is unaware of potential career opportunities in this field. ARM advocates to include CGT into STEM education programs and curricula at all levels to inform teachers and students alike of career opportunities in this emerging and highly dynamic discipline.





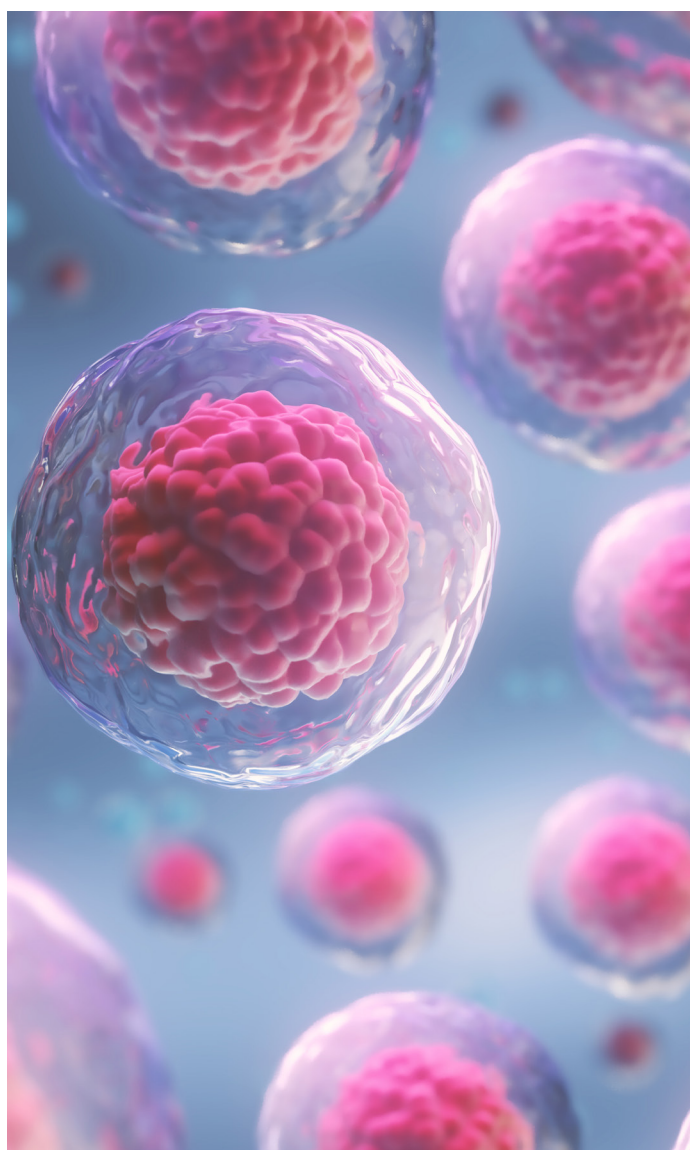
## Building Equitable Pathways for Entry-level Skillset

Vocational schools and community colleges provide programs and courses that have the goal to up- and re-skill a highly manual and technical workforce. Talent includes high school graduates and adult learners with previous careers in adjacent industries. For the new roles created in the CGT sector, such as technicians needed in cleanrooms, process development scientists, and quality control and analytics staff, our interviewees highlighted that many applicants have tangential skills that they could apply, but they lack knowledge of CGT specifics and hands-on experience with dedicated equipment.

Skilled technicians are needed to perform routine tasks in cleanrooms, using standardized SOPs and manual, semi-automated or fully automated equipment for manufacturing cell and gene therapies according to GMP requirements. This type of work requires attention to detail and execution of standardized protocols without deviation, as well as the ability to document processes according to regulatory expectations. In 2022, industry subject matter experts (SMEs) generated a Skill Standards for Cell and Gene Therapy Technicians describing the roles for CGT technicians as a common resource for training providers.<sup>21</sup>

Many manufacturing processes in CGT still require paper documentation. While electronic systems are on the rise, most of the work still requires specialized personnel with experience. GMP-compliant manufacturing of CGT products involves executing repetitive

tasks at a high level of accuracy and repetition. This skillset differs from that of an R&D scientist, which currently often supervises or executes these processes. As the tools and techniques change, so do the demands on teams. Now common on biotech job boards are positions like cloud engineer, data scientist, automation engineer, software engineer, machine learning engineer, and computational biologist.<sup>22</sup>

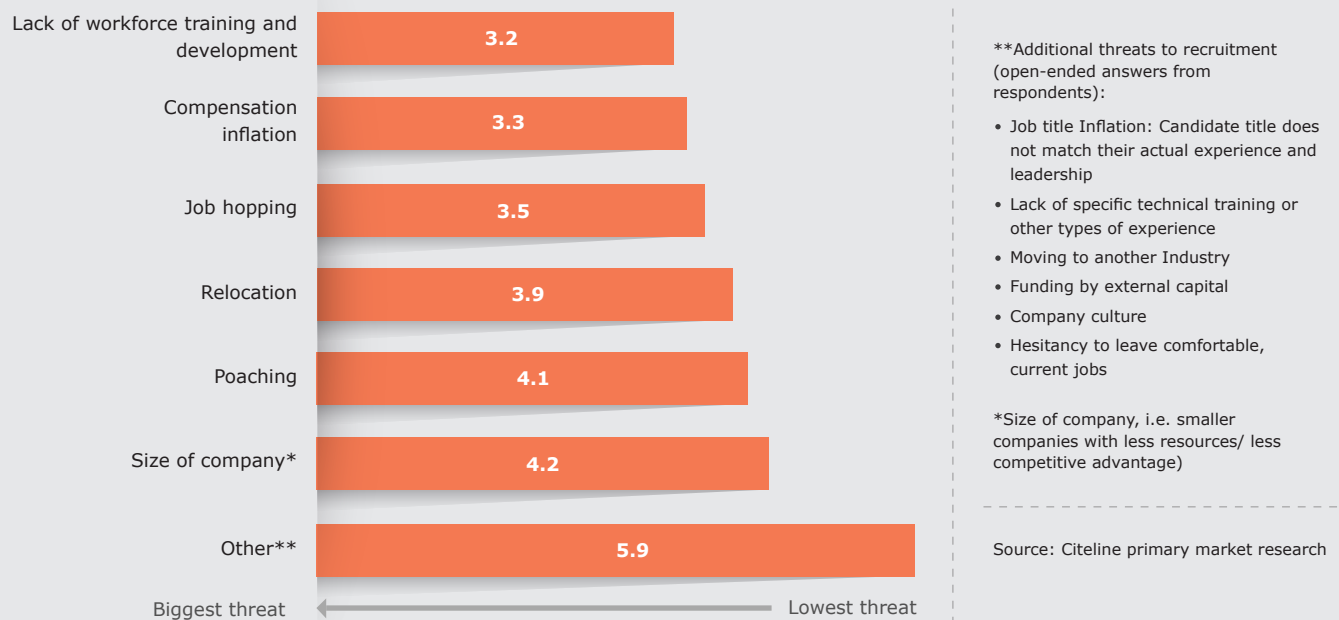


<sup>21</sup>Skill Standards for Cell and Gene Therapy Technicians: <https://biomanufacturing.org/uploads/files/162181136761177190-cgt-technician-skill-standards-2022-on-line-booklet-optimized.pdf>

<sup>22</sup>[How biopharma companies can recruit more data scientists, engineers \(statnews.com\)](https://www.statnews.com/2022/08/01/how-biopharma-companies-can-recruit-more-data-scientists-engineers/)

# Challenges to industry workforce recruitment or retention

## Mean ranking of biggest threats to workforce recruitment



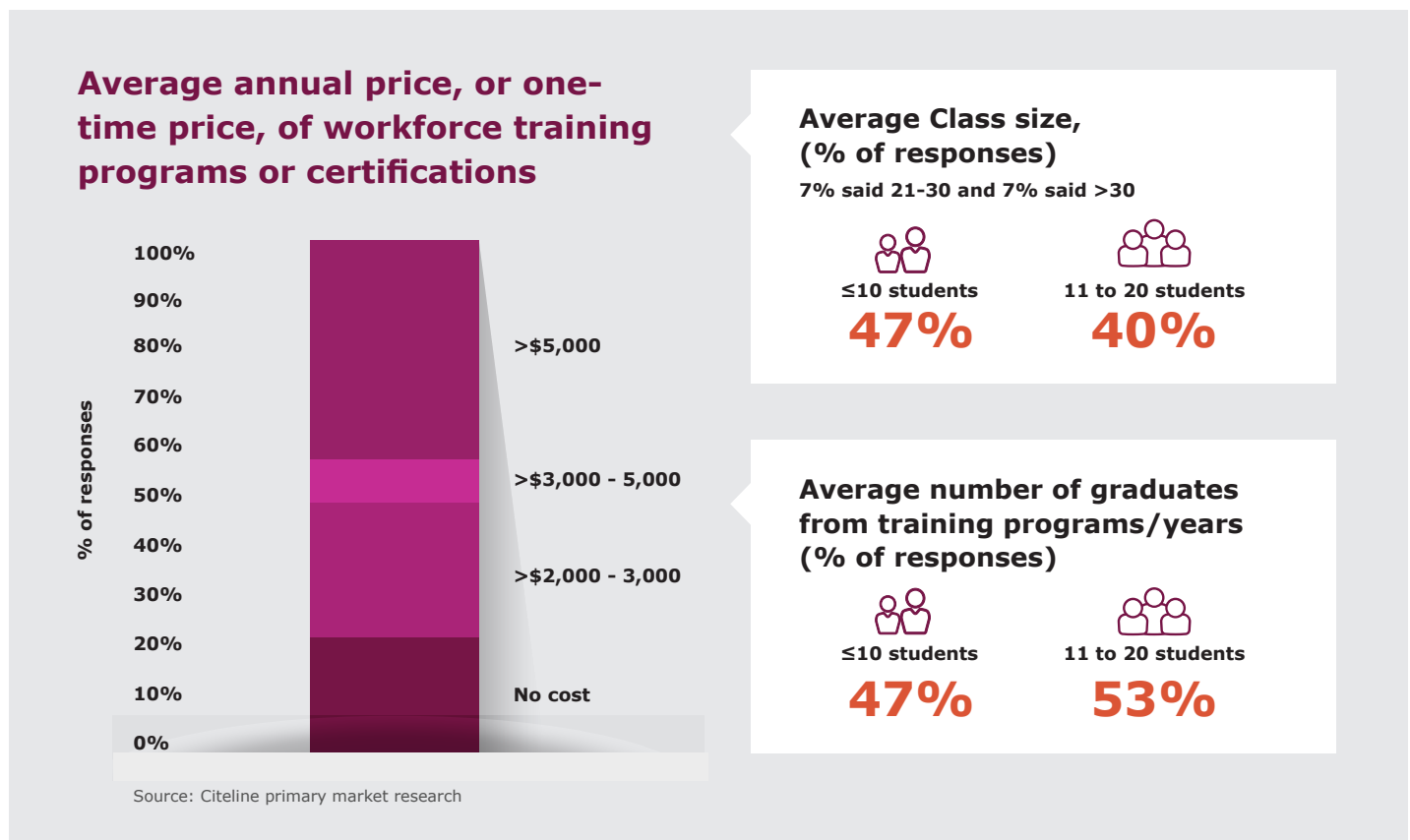
The rapid pace and diversity of processes run in CGT manufacturing organizations require a range of talent to fill positions in quality control, analytics, and manufacturing that are hired from different backgrounds. This is challenging in areas of high competition (poaching of employees is common in higher-tier positions) and where wages/living costs are high. A large new pool of talent is needed to supplement the current workforce and to achieve the numbers in employees needed to manufacture CGTs for commercial scale and application in centers across the U.S.

One proposed solution to standardize technical training programs is modular certificates that can be accumulated in sequence to promote to a higher-level position ("career laddering"). Modular training can also be used to retrain existing staff and contingency staff and satisfy competency requirements. The goal of training centers is to create a better environment for upward mobility. This results in higher rates of retention and job satisfaction, and motivation for candidates to continue on a career path that can challenge them towards the highest level of execution they wish to attain.

## Awareness Programs and Incentives to Attract Talent

Enrolling students is typically not an issue for providers once students understand the impact of their work towards making a difference in patients' lives. Still, incentives and paid training programs are key to recruiting local talent, which would otherwise not be financially able to attend the training. Awareness programs to showcase roles and career pathways in the field of regenerative medicine and CGT are needed at the national and state level to help foster an understanding of the opportunities that await potential candidates.

Hurdles in attracting talent into training courses can also include the distance needed for travel, time off work to attend training, and costs for taking the course. Reducing the "sticker shock" for training registration and supplies via scholarships, subsidies or "pay for success" models can help lower the barrier to access.



## Expanding the Talent Pool by Building a Diverse and Inclusive Workforce

This existing gap between demand and supply also presents an opportunity to expand the existing talent acquisition pool and attracting a diverse workforce with transferrable skills from adjacent industries. In our interview series, participants shared that they are recruiting workers from non-traditional fields, including military veterans, workers in the automotive and electronics industries, and even baristas.



## Veterans

A new career in CGT is being offered to veterans bridging out of their military service by Wake Tech Community College.<sup>23</sup> “The goal is to provide veterans with a new employment path and training plan that they can embark on during their 6 months exit plan from the service,” according to an academic training provider.

Veterans have been welcomed into CGT manufacturing and facilities roles, valuing the service members’ dedication to executing standard operation procedures (SOPs) with high levels of accuracy and precision for ensuring the safety and quality of therapeutic products.

In addition to underserved and underrepresented communities, there exists a generational gap between the five generations currently in the workspace, which now includes Gen Z workers. Their motivation and approach towards their work/profession differs markedly, with younger generations valuing the need to make a positive impact on society and quality of life through their work. Gen Z workers view diversity and inclusion as a ‘norm’ and 77% say a company’s diversity would be a deciding factor when choosing their work environment.

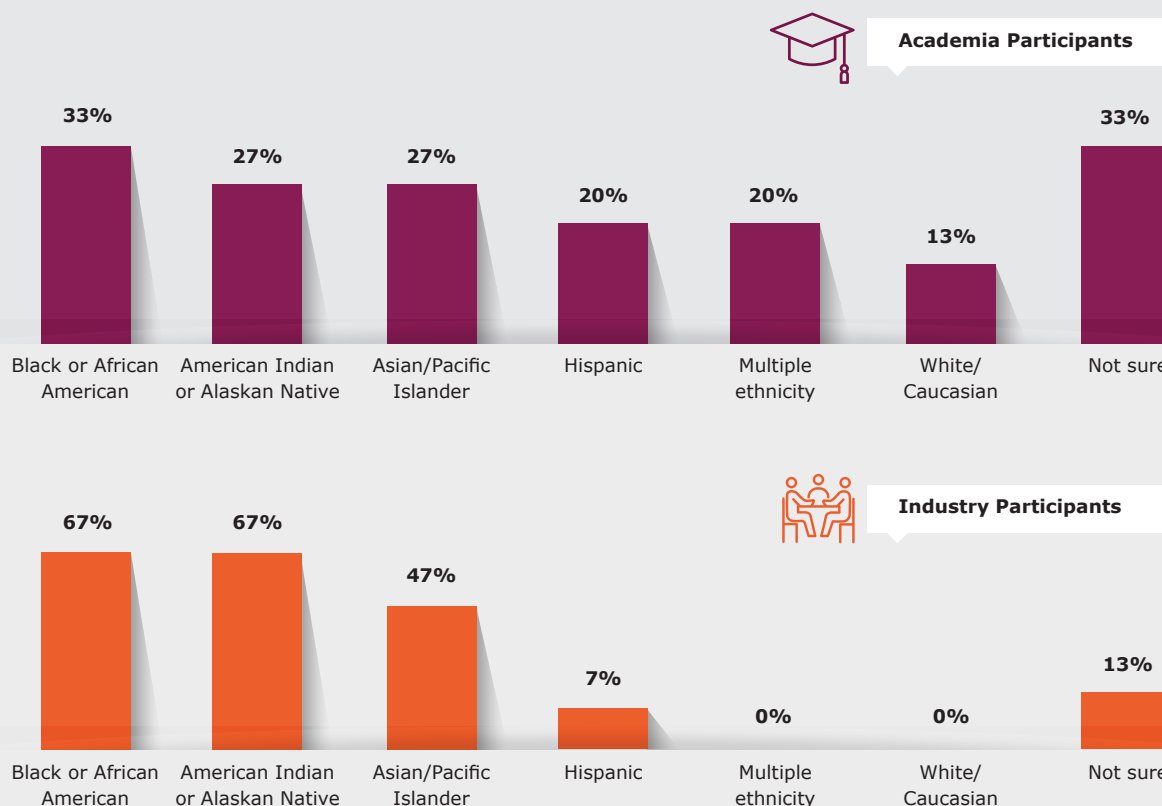


<sup>23</sup><https://www.waketech.edu/help-center/military-veteran>

<sup>24</sup>Gen Z: What to expect from the next workforce - Harvard



## Races or ethnicities that are under-represented in enrollment in workforce training (% of responses)



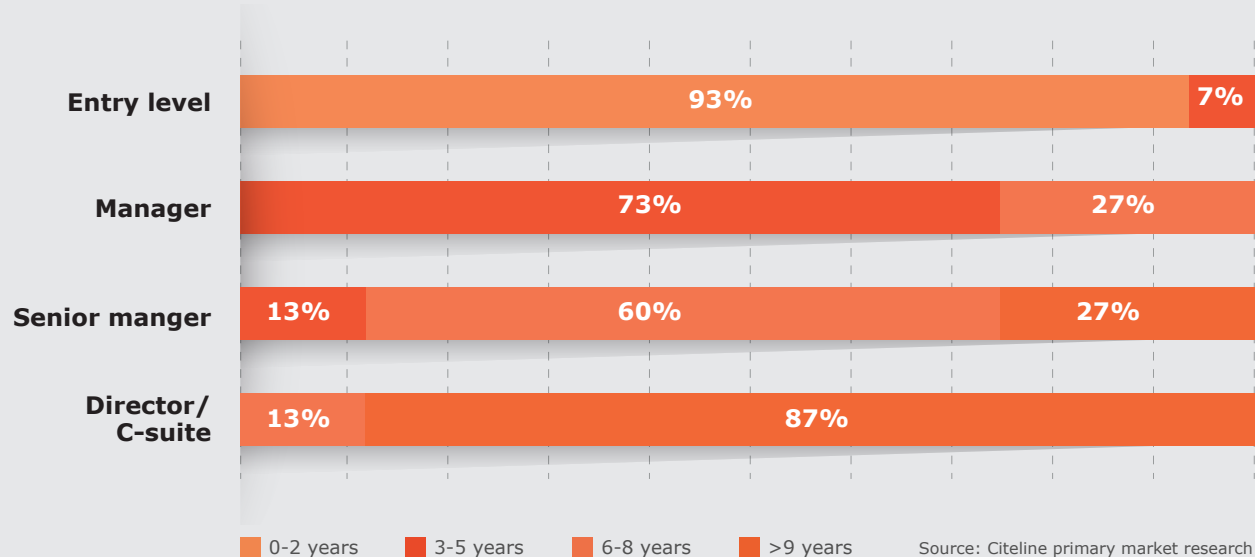
Source: Citeline primary market research

Many U.S. organizations are engaged in building an inclusive biomanufacturing workforce. A study conducted by BIO in 2022 was dedicated to diversity, equity, and inclusion (DEI) in the workplace<sup>25</sup> and highlights the efforts undertaken by both small and large companies. Some of these efforts include creating programs that encourage and enable more women to acquire leadership roles such as CEO and other executive roles. With the rapid increase of companies in the CGT sector, there is a greater need to fill the executive roles. The C-suite level workforce also requires a good working knowledge of CGT specifics, especially regarding CMC (chemistry, manufacturing, and controls) issues in manufacturing, which have been the most frequent cause for delays during the FDA review process.<sup>26</sup> This advancement will be critical, as our leaders shape the policies and initiatives that sustain our workforce and ultimately drive change and innovation across our industry.

<sup>25</sup> BIO International Convention: Measuring Diversity in the Biotech Industry.  
[https://www.bio.org/sites/default/files/2022-06/261734\\_BIO\\_22\\_DEI\\_Report\\_P4.pdf](https://www.bio.org/sites/default/files/2022-06/261734_BIO_22_DEI_Report_P4.pdf)

<sup>26</sup><https://www.genengnews.com/topics/bioprocessing/cell-and-gene-therapy-sector-needs-cmc-clarity/>

## Distribution of years of experience of workforce personnel by job level (% of responses)



In sum, awareness and outreach programs are needed to diversify the workforce talent pool at all levels. Building equitable pathways, highlighting career paths, and showcasing successful leaders in this sector are essential. Engagement in community labs, making connections with the scientific community and having meaningful conversations with scientists can build bridges with local talent. Scientists and technical and non-technical staff can encourage young people from all socio-economic backgrounds to consider a career in the biomanufacturing sector by sharing their experiences. As a community, we will need to continuously engage and support activities for developing a diverse and highly skilled workforce.

Mentorship programs can facilitate advancement at all stages and prepare the next generation for future positions. The Meyerhoff Scholars Program<sup>27</sup> is at the forefront of efforts to increase diversity among future leaders in science, technology, engineering, and related fields. Nearly 300 graduates are currently pursuing graduate and professional degrees in STEM fields. Each scholar is paired with a mentor, recruited from among Baltimore- and Washington-area professionals in science, engineering, and health. In addition, scholars have faculty mentors in research labs both on and off campus, across the nation, and in other countries.

Currently, many of these local successful collaborations receive braided funding, with many programs relying on support by state and local philanthropic donations. Continued and expanded governmental support through, e.g., NIH, Innovation Funds, or similar entities, will be instrumental for sustainable continuation of these pioneering programs.

<sup>27</sup>UMBC Meyerhoff Scholars Program: <https://www2.umbc.edu/Programs/Meyerhoff/>

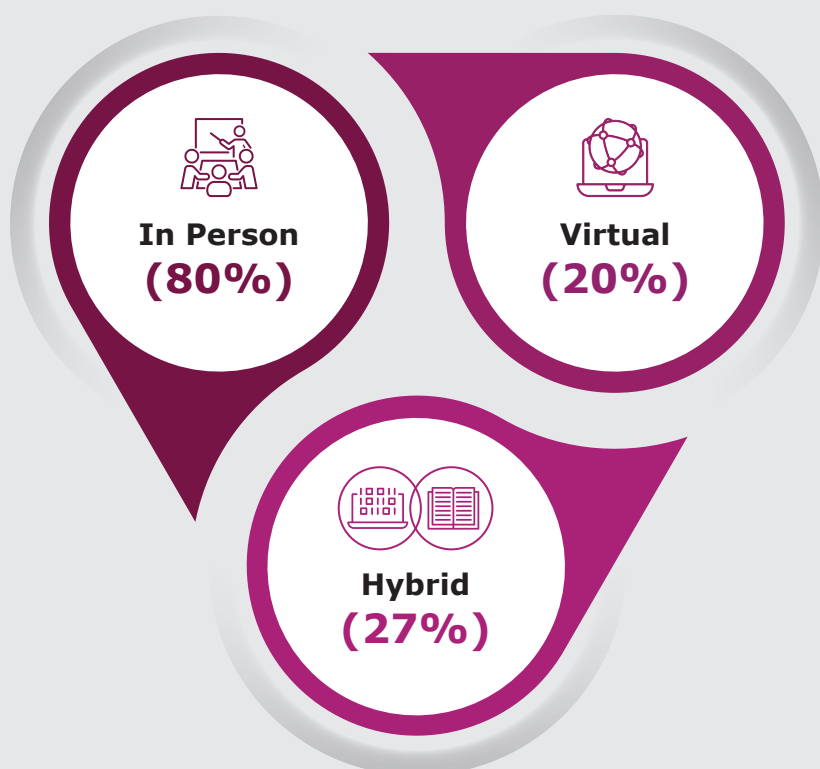
# NEW AVENUES FOR WORKFORCE TRAINING

## Virtual and Augmented Reality

Virtual and augmented reality (VR and AR) tools can be used to make training more accessible to candidates from all socioeconomic backgrounds and across a broad range of geographic locations. AR and VR have become mainstream since the COVID-19 pandemic and dedicated resources are now starting to be leveraged by therapeutic developers in-house and by training providers in their programs. These tools offer a distinctive advantage to potential employees by allowing them to visualize their workplace and offer familiarity to the otherwise inaccessible cleanroom environment. With this, VR and AR can be helpful in scaling standardized training programs across the U.S. At this time, however, existing solutions cannot fully replace hands-on training and the experience of manual operations, ranging from handling a micropipette to using complex and sophisticated automated instruments and equipment. This in turn provides an opportunity for dedicated content development by leaders in the VR/AR industry, e.g., Microsoft, Google, Meta, and others.

### Training formats

(% of survey responders who selected each option)



### Sufficiency of online training (% of responses)

Among n=6 respondents who selected virtual or hybrid:

17%	Moderately sufficient
50%	Neutral
33%	Moderately insufficient

### Participants in VR

☒ **Yes**  
(33% of respondents)

☐ **No**  
(67% of respondents)

n=1 said VR was **extremely effective**

n=1 said VR was **moderately effective**

In current curricula, mixed reality is the most favored type of teaching style. Many respondents commented on the use of a video camera mounted on an instructor's head to follow the exact steps performed by an employee working in a cleanroom facility, and executing a typical process. In addition, instrument providers, such as Beckman Coulter,<sup>28</sup> have started producing immersive, instructor-led VR training content for their devices, recognizing the need and opportunity. We expect to see an increase in expert-led virtual trainings to augment in-person lab courses.

## Apprenticeship Programs

Apprenticeships are an alternative route for providing experiential training opportunities. MassBio, Ohio Life Sciences, and similar state-funded organizations have created programs focused on training educators, exposing students to college and career opportunities within the life sciences sector, and advancing the discussion between community colleges, universities, and employers to better align training with industry needs. These organizations mirror an example set by the United Kingdom's Catapult, which has received widespread recognition for accelerating the CGT sector by, among others, providing dedicated workforce development resources to talent across the U.K.

MassBioEd, a non-profit organization launched by MassBio in 2021 has designed two apprenticeships—one for Biomanufacturing Technicians and one for Clinical Trial Associates. Selected candidates are joining a one-year apprenticeship at biopharmaceutical companies in Massachusetts at no cost to the apprentice. These apprenticeships offer a pathway to full-time permanent employment and they have been applauded by training providers in other states during our interviews for paving the way to success.



<sup>28</sup>Beckman Coulter VR Training: [https://pages.beckman.com/cmna-serv-biomek-training-vr-22-11-na\\_lp-register.html](https://pages.beckman.com/cmna-serv-biomek-training-vr-22-11-na_lp-register.html)





## Example from U.K.: Cell and Gene Therapy Catapult

- Companies can use the UK's apprenticeship levy to connect industry and talent to train and upskill talent.
- Renowned is the ATAC program.<sup>29</sup>
  - In this program, trainees work in industry and complete a degree in ~2-3 years. Degrees can be completed in 1 year or 5 years, depending on type of apprenticeship.
  - Apprenticeship in U.K. is intended for workforce that is not entering university following high-school graduation. Degrees include Master's programs and technician education.
  - Notably, trainees in this apprenticeship are fully employed while receiving additional training at a local college or academic institution.
  - Catapult found 92% retention rate for apprentices vs industry average of 52%.
- Three training areas established in the UK: Scotland, Midland, and Northeast. The site in Stevenage is the CGT cluster for hands-on training. The goal is to incentivize the trainees by bringing the training to them and making it more accessible.
- Career converter: have an established "CV algorithm" to scan a resume and suggest potential roles in CGT areas depending on background of the candidate.

Scholarships and governmental subsidies to fund these programs can be instrumental in helping candidates gain access to higher income jobs and opportunities in regenerative medicine. Similarly, internships can pave the way for interested candidates to gain experience in industry or hospital settings and potentially enter employment following their assignment. A recent report showed that 56% of interns were able to obtain a full-time job from internships in 2020 and that the retention rate for hires with internal internship experience was 71.4%.<sup>30</sup> Internship conversion into full-time employees is a key element in many companies' hiring strategies, but requires resources to pay the intern and host them at the organization. This is where subsidies and incentives can help bridge the gap.


Paid early-stage opportunities are also important in facilitating access to underrepresented minorities. A report released by BIO in June 2021 found that Black Americans comprise only 7% of biotechnology company workforces while making up more than 13% of the U.S. population.<sup>31</sup> Social media movements such as #BlackInSTEM brought attention to discrimination faced by Black students and professionals throughout the science, technology, engineering, and mathematics pipelines. U.S. black residents studying and working in STEM

<sup>29</sup><https://advancedtherapiesapprenticeships.co.uk/>

<sup>30</sup>98 Internship Statistics: 2020/2021 Data, Trends & Predictions | CompareCamp.com

<sup>31</sup>BIO International Convention: Measuring Diversity in the Biotech Industry. [https://www.bio.org/sites/default/files/2022-06/261734\\_BIO\\_22\\_DEI\\_Report\\_P4.pdf](https://www.bio.org/sites/default/files/2022-06/261734_BIO_22_DEI_Report_P4.pdf)

fields are underrepresented at every level, from undergraduate degree programs to the workforce.<sup>32</sup> To help close the gap, dedicated minority-focused apprenticeships have been established that facilitate access for students to organizations developing and manufacturing advanced therapies. Two examples of paid immersion programs are highlighted below: NIIMBL’s eXperience and ARM’s GROW RegenMed Program.



### The NIIMBL eXperience

- The NIIMBL eXperience<sup>33</sup> is an exclusive in-person, all expenses paid immersion program that offers candidates real-world insight into biopharmaceutical industry careers through hands-on activities and direct interactions with industry professionals.
  - The program targets African American/Black, Latinx, and Native American students completing their freshman or sophomore year of college. It is open to students enrolled in any STEM-based major living in the United States.
  - Each NIIMBL eXperience student will receive a \$500 stipend, plus, all travel costs are covered by NIIMBL eXperience partners.
  - In 2023, three unique NIIMBL eXperience programs are being offered in conjunction with Albany College of Pharmacy and Health Sciences in New York, BioKansas in the Kansas and Missouri Region, and Raritan Valley Community College in New Jersey.

## Successes

NIIMBL eXperience program	has proven to be a successful model for inspiring Black, Latinx, and Native American community college and university students to consider careers in biopharma		
	39 Total eXperience Fellows (30 institutions including 14 HBCUs)	25 Industry federal partner host org	13 Internships in NIIMBL member companies secured by 11 students
NIIMBL talent initiatives	include virtual job fairs and networking events to better connect students, job seekers, recruiters, and academic career service professionals		
	3100+ 1 on 1 meetings held	140+ Academic institutions represented	

<sup>32</sup>These 6 graphs show that Black scientists are underrepresented at every level (sciencenews.org)

<sup>33</sup><https://niimbl.force.com/s/niimbl-experience>

The GROW RegenMed Internship Program provides early career opportunities for Black undergraduate and graduate students and creates a pipeline for the regenerative medicine workforce sector. ARM has close to 500 member companies nationwide. Interns can be placed at these companies for both in-person and virtual internships during the 12-week summer period. “Black STEM students often do not consider a career in CGT because they have not been exposed to the vast career opportunities available to them in this industry,” says Rosie Walker, director of the GROW Program.



### **ARM's GROW Internship Program**

ARM established the Action for Equality (AFE) Task Force to determine concrete steps ARM and its members could take to ally with the movement for racial equality and address the underrepresentation of Black employees within the regenerative medicine workforce. The AFE Task Force recognized that the representation of minority populations, in particular the Black population, is significantly below those populations' representation in broader society.

ARM launched the GROW Internship Program in 2021 to provide crucial, early-career paid opportunities in the regenerative medicine sector, initially to Black students and over time to a broader minority population.

- In 2021 to 2023, all GROW internships were placed in the United States.
- Earning while learning: Interns will be paid, with some employers offering housing, relocation, and travel support.
- Build community: Interns will be part of an intern class and given a chance to connect with their peers at several points throughout the internship.
- Professional development: Interns will participate in an ARM-organized kick-off session, a two day in-person professional development event, and a closing session with their class. Post-internship, interns will be given the chance to reconnect with their class and engage with industry leaders at the annual Cell & Gene Meeting on the Mesa the October following their internship, free of charge.

In summary, there exists a general deficit in hands-on training resources and specifically in-person training to obtain CGT-relevant skillsets. This is due to a paucity in skilled, experienced trainers, a shortage of GMP-grade lab space for teaching purposes and minimal resources to purchase expensive, state-of-the-art equipment and reagents used for CGT manufacturing processes. Cost of goods for CGTs is a major bottleneck in the industry and affects product development as well as training of new staff.



## Practical solutions for advancing workforce development in CGT:

1. Merit-based internship and apprenticeship programs to offer opportunities for students from small communities towards building a strong technical know-how foundation.
2. Community programs for middle school and high school students that lend awareness and build excitement about biomanufacturing careers. Inviting speakers from large and small companies in the biomanufacturing sector to share their journey can create excitement and may lead to young students choosing a career in the biomanufacturing sector. Field trips to small and large companies will provide exposure and garner interest.
3. Mentorship programs to guide mentees on their career paths, to connect them with a larger network of peers and potential opportunities.





# THE ROLE OF FDA IN THE CGT SECTOR

PDUFA VII was signed into law on September 30, 2022. This ensures that FDA will continue to receive a source of stable and consistent funding during fiscal years 2023-2027 and allow the agency to fulfill its mission to protect and promote public health by helping to bring to market critical new medicines for patients.<sup>34</sup>

As outlined in the commitment letter, FDA will build on the success of the Cell and Gene Therapy Program (CGTP) in CBER to further support and advance a balanced approach to product development and regulation. To this end, FDA will substantially strengthen staff capacity and capability in order to meet the increasing challenges and demands in this growing field. This will entail the hiring of 132 new staff into CBER in FY 2023 and an additional 96 full-time employees planned for FY 2024-27.

Staff will be hired for direct review activities, indirect activities (e.g., policy, external outreach, post market safety), and supporting activities in the CGTP. CBER recognizes the importance of integration of new staff into the CGTP and will focus on hiring staff with technical, scientific, clinical, or other specialized expertise necessary to understand and advance cell and gene therapies.<sup>35</sup>

As many of these new employees are expected to be experts with relevant industry experience, this creates an opportunity to facilitate exchange of best practices and newest technologies employed in the CGT sector to support the onboarding and continued training of FDA staff and stakeholders alike.



**ARM supports and regularly facilitates such outreach programs (e.g., webinars and workshops) to promote industry and stakeholder education and interaction for staying informed about regulatory changes, and the latest scientific, manufacturing, and clinical advancements. ARM will continue to provide industry-recommended best practices, as showcased in the A-Cell and A-Gene documents.**

<sup>34</sup><https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027>

<sup>35</sup><https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027>

# CONCLUSION

The field of regenerative medicine and advanced therapies has made significant progress in recent years. Cell and gene therapies continue to transform medicine and human health as they offer solutions for the treatment of diseases where traditional pharmaceutical drugs have failed. The remarkable success enjoyed by this sector has propelled manufacturing organizations and resulted in significant capital investments. This significant acceleration in manufacturing efforts has led to an increasing shortage of skilled workforce in the sector.

To maintain U.S. competitiveness in this rapidly evolving field, coordinated partnerships between government, industry, and scientific and educational institutions will be essential to achieve goals that are too difficult for any single organization. The existing CGT hub network across the U.S. requires increased funding for sustaining current efforts and supporting future expansion as the CGT sector scales with expected FDA approvals. Support for programs across the spectrum of post-secondary training opportunities in this area will be essential to train and further develop the workforce needed to fill the increasing gap between supply and demand. In summary, this report highlights the need in workforce gap and provides opportunity for improvement via the following activities:

**01**

Awareness campaign to include CGT in STEM programs. High schools and colleges are opportunities for recruitment of talent into a career in the emerging regenerative medicine and CGT sector.

**02**

Workforce training to attract an inclusive and diverse talent pool. Years of experience matter, existing skills are often transferrable. Training certificates can help demonstrate quality of training and industry stamp of approval.

**03**

Centers of excellence are hubs of education and hands-on training in CGT. They are critical to sustainable workforce development and core areas for innovation.

**04**

Sustainable workforce: need incentives to retain talent (train the trainer) in academia and industry for future generations.

There is a potential role for ARM in convening workforce initiatives on a U.S. national level. ARM's biggest annual meeting, the Meeting on the Mesa would present an excellent forum for discussing workforce needs and opportunities for collaboration, as this meeting is attended by a large membership of the 475+ member organizations and external participants. Representatives from FDA and other agencies have been invited as plenary speakers in the past and provided valuable feedback on common challenges and the path forward.

# APPENDIX

## Additional examples of national workforce programs and courses:

### **Manufacturing USA® network**

The Manufacturing USA® network has successfully accelerated technology and scale-up, and supported small and medium-sized manufacturers to gain access to opportunities, and built out unique advanced manufacturing ecosystems. The network's large-scale public-private collaboration is being employed in scores of projects to expose students of all ages to STEM careers and equip workers with the necessary skills in advanced manufacturing in robotics, automation, and AI.

Each of the 16 institutes in the network has significant STEM-related workforce development initiatives. The unique breadth and diversity involving the institutes and their stakeholders make it possible for the Manufacturing USA network to understand and frame future work requirements. They are empowering the next generation to become the STEM workforce needed to strengthen United States' global economic competitiveness.

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### **Biomanufacturing Training and Education Center (BTEC)**

In 2018, NIIMBL funded two projects at North Carolina State University's Golden LEAF Biomanufacturing Training and Education Center (BTEC).

BTEC has been offering industry-recognized courses to health professionals, industry, and the FDA. The BTEC facility is located on NC State University's Centennial Campus in Raleigh and has a gross 82,500 ft<sup>2</sup> of laboratory, classroom and administrative space and is the largest such training center in the United States.

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### **The Advanced Regenerative Manufacturing Institute (ARMI)**

The Advanced Regenerative Manufacturing Institute (ARMI) is a member-based, nonprofit organization whose mission is to advance the bioeconomy of the United States. The institute's work will positively impact not only manufacturing but also healthcare and education and workforce development for the nation.

BioFabUSA, a program of ARMI, is a public-private partnership with more than 170 members, including companies, academic institutions, and not-for-profit organizations. The mission of BioFabUSA is to bring together the fundamental tenets of good manufacturing processes and the science of regenerative medicine to create regenerative manufacturing and the trained and ready workforce necessary for that manufacturing.

## BioMADE

BioMADE's mission is to enable domestic bioindustrial manufacturing at all scales, develop technologies to enhance U.S. bioindustrial competitiveness, de-risk investment in relevant infrastructure, and expand the biomanufacturing workforce to realize the economic promise of industrial biotechnology. The Department of Defense awarded BioMADE as the Bioindustrial Manufacturing Innovation Institute in October 2020. BioMADE officially opened its first project call in April 2021, funding Technology and Innovation Research and Education and Workforce Development projects.

BioMADE has more than a half dozen projects focused on STEM talent, including an afterschool program in Worcester, Mass., which could serve as a template for nationwide implementation. Another program focuses on college freshmen at the University of Texas in Austin and Austin Community College. This program leverages local biotechnology certification in partnership with local biomanufacturing companies to expose students to relevant topics, develop needed skills, and build pathways to internships as they sort through career options.

## Description of Common Roles in Cell and Gene Therapy

### Manufacturing

**roles:** GMP Operator/  
Manager/Supervisor

GMP Operator carries out the manufacturing of final product in compliance with Good Manufacturing Practices (GMP) and Master Batch Records (MBR). He/She prepares equipment and raw materials for manufacturing, executes manufacturing operations in cleanroom, following cGMP requirements and wearing sterile gowning, prepares for production (engineering batch, clinical), and executes all steps outlined in the master batch records and conducts all manufacturing activities in compliance with company safety policies.

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### Process Development (PD)

**roles:** PD Technician/  
Scientist

Process Development scientist is responsible for development and/or optimization of the cell product manufacturing process in line with phase-appropriate regulatory expectations. PD scientists support the technology transfer activities to GMP manufacturing, provide training support to the Manufacturing and QC teams and interact with the MS&T team with the goal of ensuring that the manufacturing process can be executed with success and minimal deviations.

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**Manufacturing  
Science and  
Technology (MS&T  
or MSAT) roles:**  
MS&T Scientist

The MS&T team occupies a pivotal position between the partner and/or process development (PD), and the manufacturing team. The MS&T scientist is responsible for ensuring a smooth technology transfer and the identification of process optimization needs such as scalability and the closing of unit operations. MS&T scientist develops and refines all process-related documents including Standard Operating Procedures (SOPs) and Master Batch Records (MBRs). He/She also conducts risk assessments, process verifications, and aseptic process verifications prior to initiation of cGMP manufacturing.



**Analytical Assay Development (ADA) roles:** ADA technician/scientist

The Analytical Development team works closely with the Process Development (PD) and Manufacturing Science & Technology (MS&T) teams during technology transfer to support the transfer and establishment of analytical methods. Analytical Development allows for the determination of Critical Quality Attributes (CQAs) that are essential in monitoring the product from early process development to clinical and commercial manufacturing.

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**Quality Control (QC) roles:** QC Technician

A quality control technician/scientist working in the biomanufacturing industry, including CGT, conducts tests to determine the quality of raw materials, intermediate cellular products, and finished or final products to ensure that they meet quality and safety standards. He/She also carries out routine maintenance activities for QC systems, instruments, and equipment used in the QC lab.

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**Quality Assurance roles:** QA Technician

A Quality Assurance technician/scientist checks the implementation of the quality system and conducts quality assurance audits. He/She creates and implements well-defined standards, procedures, and methods that reduce variation to ensure reproducibility in the manufacturing process. QA roles are responsible for eliminating all process variation by creating, revising, and strictly implementing a set of tightly and precisely defined processes and procedures that when exactly followed, ensure the final quality of the product.

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**Procurement/Supply Chain roles:** Procurement Manager

Procurement personnel are responsible for purchasing goods or services that meet the quantity and quality expectations of the organization. He/She evaluates and negotiates contracts with vendors, tracks inventory, restocks goods when needed, tracks and records orders, receives orders, and document arrivals and manages the supply base



# Abbreviations

Abbreviation	Meaning
<b>AAV</b>	adeno-associated virus
<b>ARM</b>	Alliance for Regenerative Medicine
<b>BLA</b>	biologics license application
<b>CAR-T</b>	chimeric antigen receptor T-cell
<b>CCRM</b>	Centre for Commercialization of Regenerative Medicine
<b>CDMO</b>	contract development and manufacturing organization
<b>CGMP</b>	current good manufacturing practice
<b>CGT</b>	cell and gene therapy
<b>CIRM</b>	California Institute for Regenerative Medicine
<b>CMC</b>	chemistry, manufacturing, and controls
<b>CRISPR</b>	clustered regularly interspaced short palindromic repeats
<b>FDA</b>	Food and Drug Administration
<b>GMP</b>	good manufacturing practice
<b>HR</b>	human resources
<b>IND</b>	investigational new drug
<b>ISCT</b>	International Society for Cell and Gene Therapy
<b>MIT</b>	Massachusetts Institute of Technology
<b>Mnfg</b>	manufacturing
<b>MSAT</b>	manufacturing, science and technologies
<b>n/a</b>	not applicable or not available
<b>NCSU BTEC</b>	North Carolina State University Biomanufacturing Training and Education Center
<b>NIIMBL</b>	National Institute for Innovation in Manufacturing Biopharmaceuticals
<b>NSF ERC for CMaT</b>	National Science Foundation Engineering Research Center for Cell Manufacturing Technologies
<b>PD</b>	process development
<b>PPQ</b>	process performance qualification
<b>QA</b>	quality assurance
<b>QC</b>	quality control
<b>R&amp;D</b>	research & development
<b>RA</b>	research associate
<b>REU</b>	research experience for undergraduates
<b>RUO</b>	research use only
<b>SME</b>	subject matter expert
<b>STEM</b>	science, technology, engineering, and math
<b>VR</b>	virtual reality
<b>WPI BETC</b>	Worcester Polytechnic Institute Biomanufacturing & Training Center

