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Bridging Cell & Gene Therapy's Critical Skills Void

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The cell and gene therapy (CGT) industry has witnessed major breakthroughs and is one of the most promising frontiers in modern medicine. Since the first CGT product received global regulatory approval in 2004, 76 therapies have been approved by the US FDA, based on data from the American Society of Gene & Cell Therapy and Citeline. The field is poised for continued momentum, with more than 200 treatments expected to receive FDA approval, according to Cardinal Healthâ??s 2025 Advanced Therapies Report.



According to Cytiva's 2025 Global Biopharma Index, more than one-third of the 1,250 industry leaders surveyed reported severe or critical workforce shortages to support emerging modalities such as cell and gene therapies. Key drivers straining the talent pipeline include increasing demands in sustainability, advanced manufacturing, and digital capabilities such as AI, areas that are simultaneously accelerating innovation while widening the skills gap.

The challenge is equally noticeable in Australia. According to an AusBiotech report, 83 per cent of respondents expect workforce shortages to negatively impact their organisation's strategy over the next five years. The findings highlight a lack of CGT-specific training pathways (61 per cent), an insufficient R&D workforce (42 per cent), and significant gaps in Good Manufacturing Practice (GMP) expertise (65 per cent), all of which pose substantial barriers to sector growth.

This challenge reflects a larger shift across the CGT industry, as it moves from pipeline expansion toward execution at scale. "Recent landscape data from the American Society of Cell and Gene Therapy's (ASCGT) Gene, Cell, & RNA Therapy Landscape Report for Q4 2025 show CGT has shifted from rapid pipeline expansion to execution at scale. The gaps we see today are no longer just about volume but about specialised knowledge and global execution capability. In looking at ASCGT's Q4 2025 report and Q1 2021 report, data also shows that while candidate growth has moderated since 2021, the Q4 2025 landscape still includes ~130 more candidates than in 2021, and a larger share are clinicalâ??stage (39 per cent in 2025 vs 31 per cent in 2020), increasing demand for clinical operations talent," said **Louise Kearney, MSc, PMP, Executive Director, Head of Rare Diseases, Pediatrics and Cell and Gene Therapy, Global Project Management at Fortrea.**

As CGT expands beyond oncology/rare disease into autoimmune and other prevalent indications, that requires broader therapeutic experience and stronger safety management, including physicians with immunology backgrounds, clinical scientists adept at translational medicine and regulatory strategists familiar with evolving CGT guidelines.

This increasing complexity is also reflected in how CGT programmes are executed globally. “The geographic footprint is also changing: Alliance for Regenerative Medicine’s (ARM’s) Q4 2025 snapshot shows APAC leads global CGT trials (44 per cent vs 41 per cent U.S.; 15 per cent Europe), requiring scalable, standardised CGTâ??capable delivery across regions. In addition, with more phase III studies, programmes increasingly require larger, more diverse populations and experienced CRAs, study managers and crossâ??regional teams; Fortrea is scaling recruitment and using highâ??touch earlyâ??phase monitoring for coâ??monitoring, shadowing and mentorship. Finally, site readiness remains a bottleneck: oncology centers are more CGTâ??mature, while nonâ??oncology departments often depend on oncology teams for administration and management—driving efforts to expand nonâ??oncology cell therapy site networks,” said Louise.

Talents Gaps

Across APAC and beyond, workforce capability is a key constraint for CGT growth. “Having driven cell therapy initiatives across the US and Asia Pacific, I see the same story unfold regardless of geography, company size or organisation type: the workforce is the universal bottleneck,” said **Wenyan Leong, Director for APAC Commercial and Global Strategic Partnerships, Terumo Blood and Cell Technologies.**

This is also because the field is highly specialised and relatively young, limiting the availability of experienced talent across the value chain. “While some expertise from other cell-based therapies is transferable, the broader cell therapy sector itself is still relatively young. This naturally constrains the availability of talent across research, development, and manufacturing. In addition, the slowdown in investor and strategic partner activity in cell therapies over recent years has further impacted the talent pipeline. Company closures and workforce reductions across the sector have discouraged many skilled professionals from committing long-term to the field, leading some to redirect their expertise toward more established therapeutic modalities,” said **Dr Ian Nisbet, CEO, Cartherics.**

This challenge is even more obvious in emerging subsegments of CGT. “It is not surprising that talent in this area remains limited. The therapy being developed by Cartherics (iPSC-derived CAR-NK cells) represents a highly specialised and emerging segment of the cell therapy field, and there are currently no approved products in this category. As a result, the industry has had only a short period of time to develop a deep pool of experienced professionals,” said Dr Nisbet.

As these challenges persist, the core issue lies not in early-stage science but in translating innovation into scalable therapies. “Cell and gene therapy is incredibly exciting, but it is also incredibly complex. The biggest gap I see today is in the talent needed to translate innovation into scalable therapies, particularly in areas like process development, manufacturing, quality, and regulatory expertise,” said **Tiffani Manolis, VP and general manager, cell biology, Thermo Fisher Scientific.**

She further said, “A lot of the breakthrough science begins in academic labs, which is fantastic. That is where foundational discoveries happen and where the next generation of scientists is trained. But as those discoveries move from early research toward clinical development and commercialisation, the industry needs more people who understand how to scale those therapies, ensure quality and consistency, and ultimately get them to patients. At the same time, the field is expanding rapidly, moving from oncology into areas like autoimmune disease and other conditions. As more therapies enter development, the need for talent that can bridge science, manufacturing, and regulatory pathways is only going to grow.”

Dr Nisbet agrees, “I can’t comment on the gene therapy side but for cell therapies Cartherics has not found it difficult to recruit excellent research scientists for earlier-stage R&D activities (gene editing, research-scale manufacturing, in vitro and in vivo efficacy, etc.). But, for later-stage development activities (GMP cell editing and selection, process scale-up, clinical manufacturing, regulatory guidance, etc.), it is much more difficult to find experienced people.”

This gap is most pronounced in technical and operational roles across the CGT value chain. “From a talent perspective, the biggest gaps in CGT are process development, GMP manufacturing, quality, and regulatory: basically, the people who know how to take something out of the lab and make it work under GMP. Everyone can do research, but far fewer people know tech transfer, scaleâ??up, comparability, and how regulators think in CGT. The shortage is driven by how fast the field has grown, how manual and complex CGT manufacturing still is, and the fact that most training hasn’t caught up. So real, hands-on experience is rare and heavily competed for as its niche to find,” said **Zenab Nessa, Vice President, EPMScientific, APAC.**

Experts feel that while the ecosystem has made progress in regulatory areas such as harmonisation, guidance documents, and accelerated approaches, workforce initiatives in manufacturing and quality control have yet to achieve the necessary scale and impact.

“The disconnect is clear: academic programmes prioritise creative thinkers and discovery over industrial operations; most established vocational training programmes are focused on traditional biologics rather than the unique complexity of cell

therapies; and company-led training remains siloed and extremely resource-intensive. Furthermore, we often rely on Ph.D. and Masters-level graduates to fill these gaps because they possess the advanced aseptic skills and troubleshooting the process requires; however, this is an expensive and unsustainable compromise and there is a fundamental difference between laboratory precision and the rigorous, repetitive compliance of a regulated manufacturing process," said Wenyan.

This points to a clear shift in the industry. For many, the core bottleneck is no longer science, but execution. "Over the last decade, we have mastered the 'proof of concept' phase and rapidly moved pipelines towards approvals and commercialisation. However, that success has led us to a wall- execution, not biology, is the bottleneck. I believe that manufacturing and quality control operations have now become the definitive barrier to patient access, and our inability to scale a specialised, GMP-ready workforce is the single, greatest threat to our field's long term success," added Wenyan.

Bridging the Talent Gap

Efforts to address capacity constraints in the CGT ecosystem across the Asia-Pacific region are being implemented through training programmes, infrastructure development, and regional collaboration.

One approach gaining traction is structured, organisation-led capability building. "Fortrea is addressing CGT talent gaps through deliberate capability building: adding CGTâ??focused regulatory strategists, physicians, a clinical scientist and operational staff; standardising delivery through training, an operational manual and specialised service models; and forming a Cell & Gene Therapy Delivery Group to share experience across programmes while staying aligned to therapeutic areas. As APAC activity accelerates, Fortrea is extending U.S./Europe training frameworks to the APAC region and medical oversight to build consistent capability in highâ??growth regions and expanding site networks and crossâ??departmental models to help hospitals adopt nonâ??oncology CGT workflows safely. More broadly, government and academia are scaling the pipeline via initiatives such as the UK Cell and Gene Therapy Catapult and their Advanced Therapy Treatment Centre Network (ATTC) and programmes like Alliance for Regenerative Medicine's (ARM's) GROW RegenMed Internship. With clinicalâ??stage CGT growth accelerating across geographies and indications, sustained progress will require coordinated investment in capability building, knowledge transfer, site readiness and earlyâ??career education," said Louise.

Companies are increasingly investing in building talent internally through hands-on training and development. "At Cartherics, our strategy has been to obtain advice from experienced advisors and consultants but to basically build our capabilities by training and developing our own people. This has been mostly via 'on the job' training. The scientists who developed our research-scale manufacturing process also did the scale-up work and were then trained in GMP to enable them to manufacture clinical trial products in our own clean rooms.

"Similarly, scientists who started on gene editing of iPSCs in our research labs were trained to conduct the same activities in accordance with GMP principles for preparing the cell banks that ultimately formed the basis for a GMP master cell bank. We've found our scientists are very motivated to work on these downstream development activities because they know the work they do can have a direct impact on patients," said Dr Nisbet.

Industry-led training, particularly through Contract Development and Manufacturing Organisations (CDMOs) and pharmaceutical companies, is also emerging as a practical solution to bridge immediate skill gaps. "What's working best is industryâ??led, hands-on training, with CDMOs and pharmaceutical companies building people internally through GMP academies, shadowing, and fast upskilling from biologics into CGT. The potential is there but it takes time and investment from the CDMOs and pharmaceutical companies to upskill these people. However when they do it means they have an advantage in the market and employees who value them in return. Academic–industry partnerships help, but only when they focus on real GMP. Exposure to learning in the classroom is very different to learning on a GMP floor. What's still missing is scaled, practical training at the midâ??career level and easier talent mobility. Until then, the same experienced CGT people will just keep getting recycled between companies, rather than developing internal employees," said Zenab.

One example is in October 2025, when Cell Therapies partnered with Teijin Limited, with a key focus on building long-term infrastructure and capability through joint training and workforce development initiatives. Another example is in December 2025, when Korea-based ENCell partnered with Australia-based Cell Therapies to co-develop training programmes aimed at strengthening the CGT talent pipeline and building long-term manufacturing and research capabilities across APAC.

Large firms such as Cytiva are also contributing to workforce development through structured training initiatives such as the Fast Trak programme, which provides hands-on bioprocessing training to build and retain industry talent.

Beyond individual organisations, collaboration between academia and industry is widely seen as critical to building a sustainable talent pipeline. Experts greatly emphasise the importance of integrating academic learning with real-world

application.

“The strategies that work best are the ones that bring academia, industry, and training programmes closer together. Academic institutions play a critical role because they generate the foundational discoveries and cultivate the next generation of scientists. But we also need more opportunities for people to see how those discoveries translate into real therapies, and how they move from the lab bench into development, manufacturing, and ultimately the clinic. That is where collaborative ecosystems are incredibly powerful. When researchers, startups, and industry experts can work side by side and share tools, expertise, and process development capabilities, we accelerate both innovation and workforce development,” said Tiffani.

These partnerships are increasingly being translated into structured training programmes and national initiatives. For example, in November 2025, Miltenyi Biotec, Translational Health Science and Technology Institute (THSTI), Biotechnology Industry Research Assistance Council (BIRAC) launched India’s first hands-on gene therapy training programme, providing end-to-end exposure to CGT manufacturing, from preclinical development to quality control, with a focus on CAR-T therapies.

“To complement our in-house training activities, we collaborate with academic groups working in related areas. In this way we add to the overall knowledge and experience in the field, which, over time, will build the pool of external talent that we can tap into. We also regularly participate in university (and other) internship programmes, offering on-site training and development in return for an extra pair of hands. We’ve found these programmes to be very useful and, sometimes, have led us to offer positions to talented individuals,” said Dr Nisbet.

At a broader level, coordinated action across industry, academia, and policy is seen as essential. “A collaborative ecosystem strategy across public, private and policy players is required and has the most potential to break down this wall. We must invest in sharing the burden of training. We need government-funded vocational hubs and academic institutions to provide dedicated cell therapy manufacturing programmes; for example, National Institute for Bioprocessing Research and Training (NIBRT), Korea and KBIOHealth rooted in biologics manufacturing have started offering cell therapy training programmes for regulatory and manufacturing professionals. Policy makers must understand the unique nature of these therapies to create standardised guidance and therefore provide a pathway towards recognised certification. Simultaneously, rather than spending six months on internal onboarding, industry players need to provide clear feedback and actively partner with the public sector to design and potentially co-execute ‘industry-ready’ courses so we can transfer their knowledge and expertise to the next generation of workforce. Furthermore, the industry needs to embrace digital tools and automation to de-skill the manufacturing process, reducing the workload and allowing access to a wider pool of talent,” said Wenyan.

Across APAC, several regional initiatives reflect this ecosystem approach. Advanced Cell Therapy and Research Institute, Singapore (ACTRIS) platform supports CGT process development, manufacturing, and workforce training through public–private partnerships. Similar cluster-based models are being developed in South Korea (Osong Bio Valley) and China (Shanghai Cell Therapy Cluster). In Australia, the Cell and Gene Catalyst, led by AusBiotech and Medicines Australia, focuses on accelerating the CGT sector, including workforce development. The International Society for Cell and Gene Therapy Asia-Pacific Industry Committee supports coordination across jurisdictions, including regulatory alignment and workforce initiatives.

There is a growing recognition that cell therapy must be treated as an industrial manufacturing product rather than a bespoke scientific process, requiring a workforce capable of delivering therapies at scale.

“Ultimately, closing the talent gap will require more hands-on training, stronger partnerships between academia and industry, and more pathways that expose scientists and engineers to the full development journey. At the end of the day, the goal is the same for all of us: turning scientific breakthroughs into therapies that can reach patients around the world,” said Tiffani.

The sector is expected to create thousands of jobs, including around 6,000 roles in Australia alone by 2035, making workforce development a critical priority for the continued growth of CGT across the region.

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