



Identifying and Addressing Workforce Skill Gaps in ATMP Manufacturing

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1. Introduction

Advanced Therapy Medicinal Products (ATMPs) or Cell and Gene Therapies (CGTs), represent one of the most innovative and fast-growing fields of modern biopharmaceutical science. These therapies promise transformative treatments for previously incurable diseases, but their complexity requires a workforce equipped with both specialised technical expertise and adaptive soft skills. The sector is currently facing a significant talent gap. According to Cytiva's *Global Biopharma Resilience Index 2025*, despite a modest improvement in the talent pool pillar since 2023, the biopharma industry continues to face significant workforce challenges. Talent remains one of the weakest areas in the index, with the pipeline under serious pressure. Persistent skill shortages particularly in advanced modalities such as ATMPs, mRNA, and antibody-drug conjugates (ADCs), are hindering progress. Executives report critical gaps in staffing across key areas: 38% in novel therapeutics, 34% in sustainability, 29% in digital and AI, and 27% in manufacturing.

The report underscores that access to specialised talent is one of the strongest predictors of commercial success in biopharma. However, efforts to build a capable workforce are lagging. This is largely due to the long-term nature of workforce development and the rapid pace of innovation, which makes it difficult to align skills with emerging needs in time to realise immediate returns. Moreover, in Ireland, the Expert Group on Future Skills Needs (EGFSN) has projected that approximately 21,000 new biopharmaceutical roles will be created by 2027, many within the ATMP field. However, the report also highlights serious challenges in meeting this demand, citing critical shortages in digital manufacturing technologies, quality assurance and control (QA/QC), regulatory affairs, and research and development. Additionally, the growing complexity of ATMP manufacturing demands that employees possess cross-functional abilities in communication, teamwork, and project management.

2. Industry Survey of ATMP Workforce Needs

2.1. Method and Participants

To better understand these ongoing workforce challenges, Shada Warreth, working within NIBRT and as part of her PhD studies, conducted a comprehensive survey between June 2023 and January 2024, engaging professionals from across the ATMP value chain. Participants included members of the NIBRT CGT Forum, the Parenteral Drug Association (PDA) Ireland Chapter, and other industry professionals reached through LinkedIn networks. The survey gathered both quantitative and qualitative data, ensuring participant anonymity to encourage candid feedback. In total, forty responses were collected from individuals representing regulation, education, manufacturing, supply chain management, clinical trials, and technology sectors.

3. Survey Results

3.1. Shortage of Skilled Personnel in ATMP

The results revealed near-unanimous agreement that there is a shortage of skilled personnel within ATMP manufacturing. Ninety percent of respondents confirmed the existence of a significant talent gap, while only one respondent disagreed. The main barriers to recruitment and retention included difficulties identifying experienced candidates, limited access to training and professional development opportunities, uncompetitive salaries, and inadequate recognition of transferable skills from adjacent industries. Participants also noted that many job descriptions contained unrealistic qualification requirements, such as PhD level credentials for roles that could be filled by experienced practitioners. Others observed that short-term contracts, lack of structured graduate schemes, and limited awareness of the ATMP sector within universities contributed further to recruitment challenges.

3.2. Critical Areas of Shortage in ATMP Manufacturing

When considering the most critical areas of shortage, respondents highlighted QA/QC, manufacturing and process development, and regulatory affairs. Additional gaps were identified in contamination control, sterility assurance, and quality risk management. Many participants agreed that ATMP manufacturing could benefit from a more diverse talent pipeline, drawing from graduates, apprenticeships, and experienced professionals in related industries such as aseptic processing and biologics production. Almost half of the respondents felt that a combination of all these pathways would be most effective in building a sustainable workforce.

3.3. Required Skillsets in Evolving ATMP Landscape

The study also explored which specific skills are most needed in the evolving ATMP landscape. The findings revealed three broad categories: theoretical knowledge, technical expertise, and soft or transversal skills. Theoretical understanding of cell biology, bioprocess design, and regulatory compliance formed the foundation for technical skills such as aseptic processing, GMP compliance, bioprocess engineering, contamination control, and the use of analytical instrumentation. At the same time, respondents emphasised the importance of soft skills particularly teamwork, problem-solving, critical thinking, and adaptability as equally essential to effective manufacturing performance. Many participants noted that these interpersonal and cognitive abilities are vital for supporting innovation and ensuring quality in a highly regulated environment.

Aseptic processing emerged as the area with the greatest combined deficiency in both skill availability and competency. This was closely followed by digitalisation and automation capabilities, bioinformatics, and mathematical analysis. Respondents stressed that while digital transformation is rapidly progressing, the sector lacks sufficient personnel who can integrate robotics, data analytics, and automated systems into compliant manufacturing processes. This suggests that the challenge lies not only in attracting talent but also in enhancing the depth and quality of expertise among existing professionals.

3.4. Preferred Training Methods in ATMP Manufacturing

When asked about preferred training methods, most respondents favoured practical learning approaches such as on-the-job training and hands-on laboratory experience. There was also widespread support for the integration of digital training tools, including augmented reality (AR) and virtual reality (VR). These immersive technologies were seen as particularly useful for simulating cleanroom environments and other high-stakes manufacturing settings, though participants agreed that they should complement rather than replace real-world experience.

To organise and visualise these findings, Warreth developed a skills heatmap, categorising responses into theoretical, technical, and soft skills (See Figure 1). Each skill was scored based on frequency of mention and color-coded to indicate urgency: red for high-priority gaps, yellow for moderate needs, and green for lower-priority areas. The heatmap showed that aseptic techniques, automation, analytical testing, regulatory compliance, teamwork, and leadership represent the most urgent development areas. The model could be integrated with risk-assessment frameworks such as ICH Q9 or Failure Mode and Effects Analysis (FMEA), allowing organizations to prioritize training based on the level of operational risk associated with each skill gap.

Theoretical Knowledge	Score	Technical Skills	Score	Quality Shortage	Score	Quantity Shortage	Score	Soft Skills	Score
Manufacturing and process knowledge	11	Cell culture and bioprocessing	9	Aseptic processing	29	Aseptic processing	23	Teamwork	37
Biology and cell biology	10	Analytical techniques and methodologies	7	Digital and automation technologies	25	Digital and automation technologies	18	Critical thinking	36
Technical skills and awareness	8	Aseptic processing and contamination control	6	Bioinformatics	22	Bioinformatics	12	Communication	36
Regulatory and quality compliance	6	Regulatory compliance and documentation	4	Mathematics	15	Mathematics	10	Problem-solving	34
Interdisciplinary skills	3	Interdisciplinary skills and cross-training	4	Contamination control	1	Contamination control	1	Emotional intelligence	24
		Hand-on/practical laboratory experience	4	Flow cytometry	1	Safety expertise (e.g., cellular toxicology)	1	Leadership capability	21
		Risk assessment	1	Current good manufacturing practice (CGMP) and quality functions	1	CGMP and quality functions	1	Digital capability	20
		Time management	1	Microbiology	1	Microbiology	1	Honesty	1
								Dedication and work ethic	1
								Friendliness and professionalism	1

Figure 1. Skills Heatmap - Skill areas with the lowest demand (score <5) are marked in green, those with moderate need (score 5–10) appear in yellow, and the most critically needed skills (score >10) are highlighted in red.

4. Research Implications

One of the most significant outcomes of the research was the creation of a new micro credential program designed to address these high-priority needs. Developed through collaboration between the NIBRT Global Qualifications (NGQ) project, and Atlantic Technological University (ATU) Sligo, the Certificate in Advanced Therapy Medicinal Products Development and Manufacturing provides targeted education and training aligned directly with the heatmap's findings. The program integrates theoretical learning with practical applications in cell and gene therapy production, digital manufacturing, and regulatory compliance. It also emphasises the development of transversal skills such as teamwork, communication, and critical thinking. Delivered flexibly and designed for working professionals, the micro credential bridges the gap between industry demand and formal qualifications, ensuring that learners can apply their new skills immediately within the biopharmaceutical environment.

Ultimately, the ATMP industry stands at a pivotal moment. The convergence of biotechnology, digitalisation, and automation presents extraordinary opportunities for growth, but only if supported by a well-trained and adaptable workforce. The collaboration between NIBRT and ATU Sligo exemplifies how education providers can work together to design targeted learning solutions. By adopting data driven approaches such as the skills heatmap and implementing focused programs like the NGQs, the sector can strengthen its human capital and ensure that it remains capable of delivering the next generation of life-changing therapies safely and effectively.

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