WHITEPAPER

Building a Sustainable Workforce for Decentralized Manufacturing: Perspectives from The Industry

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Abstract

This whitepaper explores both the challenges and opportunities associated with workforce development within the context of the Decentralized Manufacturing Model (DMM) for producing Advanced Therapeutic Medicinal Products (ATMPs). The ATMP manufacturing sector is currently facing a significant workforce deficit, emphasizing the urgent need for innovative and adaptive training models [1]. To gain deeper insights, we consulted with experts working to develop training and education within their respective countries. Our focus is on overcoming existing challenges, exploring alternative education pathways, and capitalizing on technological advancements such as Virtual Reality (VR) and Augmented Reality (AR) in training. The insights gathered are instrumental in addressing the immediate workforce shortage and laying the groundwork for a sustainable, inclusive, and efficient workforce development strategy for a DMM.

Introduction

As the DMM for ATMPs grows to meet increasing industry demands, smaller communities are presented with opportunities to become significant contributors in this evolving sector. However, this comes with inherent challenges. In the United States, there's a significant 500% deficit in ATMP manufacturing, with many states ill-equipped in infrastructure, as depicted by the service disparities in Figure 1 [1].

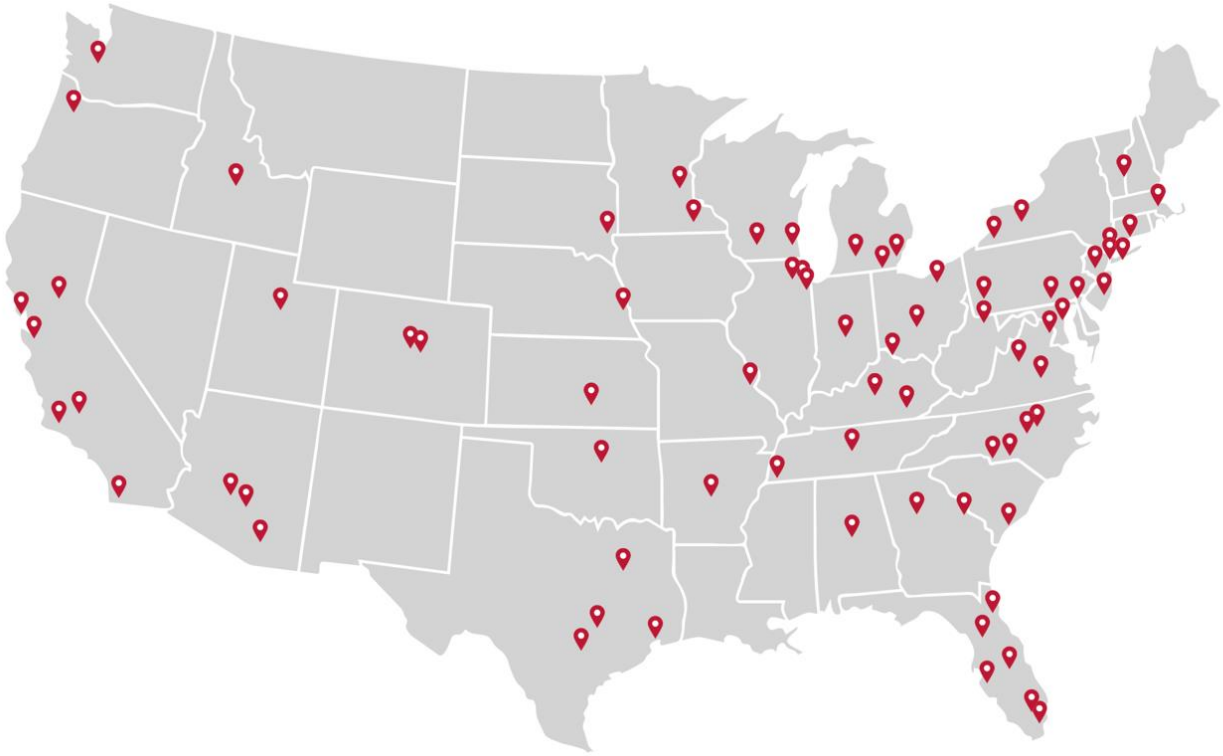

Figure 1. 110 Approved Treatment Centers for ATMPs like CAR-T in the U.S. [Kite Pharmaceuticals].

This deficit is exacerbated by the acute shortage of Highly Qualified Personnel (HQPs) in the field, and the situation is further complicated by non-standardized clinical trial designs and ATMP manufacturing protocols, posing considerable challenges to efficiency, cost-effectiveness, and regulatory adherence [2]. Nonetheless, this landscape provides a huge opportunity for the integration of innovative training models, specially designed for individuals aspiring to join the pharmaceutical and biotech sectors without the barrier of extensive post-secondary education.

In this paper, insights from interviews with three distinguished experts in ATMP training and workforce development are shared. Each expert offers a unique viewpoint, growing our understanding of potential solutions to support a DMM. We explore varied educational pathways, the incorporation of innovative learning tools like VR/AR, and the initiation of dedicated certification programs to globalize, standardize, and streamline training initiatives. Our objective is to establish a resilient, sustainable workforce in even the smallest communities,

adeptly navigating the DMM landscape while promoting inclusivity and diversity within this up-and-coming industry.

Expert Insights

To address the pressing issues and potential innovations in workforce development for the DMM of ATMPs, we interviewed three experts in the field, representing Canada, the United States, and the United Kingdom. They bring unique, valuable insights rooted in their extensive experience and regional contexts.

- Craig Hasilo (CH), Chief Scientific Officer at the Canadian Advanced Therapies Training Institute (CATTI) and CellCAN, Canada.
- Jenny Ligon (JL), Senior Associate Director of Training and Education at the National Center for Therapeutics Manufacturing (NCTM), United States.
- Stephen Stewart (SS), Head of Skills & Apprenticeships at Cell and Gene Therapy Catapult (CGTC), United Kingdom.

Q1. Can you tell us a little about your organization and how you are contributing to the training of the next generation of ATMP HQPs?

CH: CATTI is an evolution of CellCAN which is an organization focused on knowledge mobilization and fostering collaboration within the Canadian cell and gene therapy field with training being one the services that was offered. CATTI was founded in 2021 with the mission to deliver specialized best-in-class training for advanced therapies biomanufacturing under GMP. To date CATTI has trained over 50 HQP and we are rolling out our first hands-on training this Fall 2023 at the University of Guelph, northwest of Toronto.

JL: With 20 years of experience in workforce development and 11 years in the pharma/biotech sector, I'm currently involved in a government-funded, non-academic training center for biologics and vaccines, with plans to expand into gene therapies. In terms of training HQPs, a

major challenge is retention due to high demand and competition. However, to lessen the burden on manufacturing in the U.S., we are focusing on building a global workforce by working with companies around the world to help set up sites and to train their future trainers.

SS: CGT Catapult has been developing skill initiatives based on industry demand surveys from 2019, 2021, and 2023. From those surveys, we've created an apprenticeship program to train and upskill employees within organizations and bridge skills gaps. We are also looking to recruit HQPs from other sectors into pharma/biotech that have similarly transferrable skills using our program.

Q2. The recent ARM Report suggested hiring and training individuals with 2-year degrees and high school diplomas to bridge the ATMP Workforce Gap. Could you share your thoughts about this vs. a 4-year degree?

CH: Historically in Canada, university students can commit to 1 year working in industry, on a co-op program, and then come back to school for the 4th year, which allows them opportunities to develop skills that make them attractive candidates for hiring. A 2-year degree program, which should have been introduced a decade ago, is effective for preparing and finding candidates, but the challenge lies in advertising to potential students. There's a general lack of awareness about what cell therapy manufacturing involves due to limited exposure. Re-examining traditional educational requirements would allow more individuals to enter the pool of candidates for manufacturing roles which is greatly needed, and with robust specialized training the quality of HQP would not be impacted. Biomanufacturing is an attractive industry, there are so many incentives for pay increases and professional growth with many varied roles that individuals can explore.

JL: This industry is protocol driven, so with the right training and exposure to the industry, training and hiring people without 2 or 4-year degrees has huge potential to make up a large percentage of the workforce.

SS: Shorter degree programs and apprenticeship programs can bridge the gap in practical skill and theoretical knowledge. In the UK there are 3-year degrees as a
Bachelor's as standard. It is common for other 3-year degree programs in different sectors to have 1 year of work experience halfway through the degree, but that does not exist in the CGT sector yet because of the nascence of the industry.

Q3. With the increasing demand for more HQP, what are your perspectives on where the industry could potentially source appropriate candidates outside the conventional pool of university and college graduates?

CH: In terms of sourcing candidates, flex manufacturing has been a wave of revolution in the industry by enabling the workforce to quickly pivot between projects. A big part of hiring HQPs is not just screening, but also seeking individuals with a strong work ethic. The people who I've found to excel in the industry are often among those who favor manual work. The work environment is very structured, and military personnel are particularly good at it.

JL: Military veterans could be ideal candidates due to military training and conditioning that would serve well in the protocol driven industry. Development of a pilot curriculum for neurodivergent and/or military veterans who would thrive in the predictability and repetitive environment could be a fruitful pathway of sourcing new successful candidates for the industry. I also think neurodivergent populations should be considered for this industry if they enjoy work environments with day-to-day predictability and repetition.

SS: In the UK, there are strong apprenticeship programs to help students enter the biomanufacturing industry. Apprenticeship programs also facilitate career conversion to help people from diverse academic backgrounds enter the sector and develop opportunities for social mobility. Developing the workforce has shown the need for open-mindedness in transferable skills and capabilities going into life sciences.

Q4. As we project growth in the ATMP industry over the next decade, do you believe that there should be greater onus on secondary or post-secondary institutions to enhance student readiness in ATMP production skills, or do you view this advanced training as a responsibility that lies primarily with the industry and specialized training bodies?

CH: I feel the onus should be on specialized training bodies. Specialized training bodies are bridging the gap between universities and industries. Traditional universities themselves lack the infrastructure and practicums to properly prepare students for industry. Further collaboration between industry, specialized training bodies, and universities will go a long way to better preparing students to enter industry. For the present, specialized training bodies such as CATTI provide the best avenue to prepare students to become successful HQPs.

JL: The responsibility lies with the industry because the schools do not have the funds to keep up with the pace and startup cost to keep up with the fast-paced industry. Most of manufacturing happens in-house where the infrastructure already exists, and that currently does not require building out educational institutions for it.

SS: Both academia and industry have the opportunity right now to work together to share knowledge and learning. The degree apprenticeship has been merging academia and industry to help students gain strong practical skills - from collaboration between the two entities. I believe growing deep partnerships with universities will be beneficial to the students, industry, and academia.

Q5. Considering the substantial time and financial commitment involved in proper training due to factors such as high equipment, materials, clean spaces, and industry expertise costs, do you envision the potential for cost mitigation through the incorporation of e-learning and mixed reality (VR and AR) methods?

CH: CATTI are already delivering e-learning modules on GMP and biomanufacturing which are very popular. In terms of AR/VR, there is the potential for huge cost mitigation in its use as a transition between the real thing and the hypotheticals. The change in environment and expectations of a cleanroom cannot be replaced, but the VR can front load information and help recruit HQP and identify who should be advanced through training. The technology still has some way to advance before it can be used as a tool that could replace, partly or entirely, the real thing but there is no doubt it will become a larger part of HQP training as the industry continues to grow.

JL: We will have to - it is too expensive to train people without it across the board. VR (ideal) and AR might significantly cut cost and provide exposure to background knowledge and expectations before entering hands on training, but hands on training is still critical.

SS: I believe time, finances, and the environmental agenda to reduce single-use plastics will be improved with VR and AR. The U.K. government is investing in the development of these technologies for companies to use to customize and improve training potentials. It will also open accessibility to those who want to gauge interest in the industry without needing to commit to being in a lab. For example, bringing VR to schools so students can practice before committing to the industry.

Q6. When contemplating the implementation of a Decentralized Manufacturing Model, with smaller-scale manufacturing dispersed over several centers and regions, how do you propose training could be structured to maintain consistency, regulatory compliance, and foster growth in local bio economies?

CH: Training, codeveloping, and co-testing each other's best practices is the best form of training development. That way you make sure that SOPs are consistent across sites regardless of jurisdiction and equipment. How you monitor the product and perform the testing is also important for competency-based training. If every job role can identify and outline required competencies, then this hierarchy template can be shared and distributed. This will allow for robust standardized training which can be implemented with the same quality and consistency regardless of where you are. Another important tool is to build case studies around what goes wrong because this type of career path requires building skills and doing it quickly. It takes about 3.5 years holding a job role to be able to be competent and autonomous, and training takes about 18 months - so you want to minimize that as best as possible.

JL: If you establish a DMM, the training to maintain consistency and applicability with regulatory bodies may require going to the companies themselves and have them share knowledge via consortium (find a sponsor to cover the cost of the training). There is a lot of content that exists, but getting everyone on the same page is critical and that is high effort to coordinate. The knowledge is there, so use the resources that are out there.

SS: Finding one common language of training is challenging and requires co-working across facets of the industry. Online training platforms to have a prescribed method of learning, using VR/AR, and working closely with regulators to help promote new training methods and assure compliance will help bring accessibility and trust quality of content. Cross jurisdiction agreement on job roles/codes to base training off could be an effective way of ensuring standardization with more creative curriculum. Also, adding recommended training opportunities to develop personnel specializations.

Discussion

Our discussions with experts uncovered key themes and potential progressions. A unanimous belief is held in the DMM's capacity to bridge the ATMP production shortfall and enhance local bioeconomies. Each expert identified a direct correlation between robust workforce training and anticipated economic growth. They emphasized the opportunity to diversify the ATMP sector by integrating individuals from various educational backgrounds, especially the significance of 2-year degree programs and alternative education paths. Additionally, they advocate for the incorporation of technologies like VR and AR, highlighting their role in improving the quality and accessibility of training, especially within the DMM framework.

With these perspectives in mind, the DMM becomes more than a strategic shift in manufacturing; it will have significant influence on bioeconomic development. This approach, with its adaptability and inclusivity, fosters a workforce that is not only growing, but is also diverse and skilled, equipped to navigate the ever-changing landscape of ATMP development.

In conclusion, the on-going collaboration between specialized training, technological integration, and strategic collaborations among industry stakeholders promises a future of resilience and innovation for the ATMP sector within the DMM framework. The pathway ahead, though challenging, has many opportunities for transformation and growth. The collective insights of our contributors map out a future where workforce development is not a hurdle, but a new opportunity for innovation, inclusivity, and economic vitality in the local and global ATMP landscape.

Acknowledgments

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You can find more information about the training services they provide at:

www.catti.ca

www.ct.catapult.org.uk/capabilities/skills-and-training-laboratories

www.nctm.tamu.edu/training/

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