



The ATMP Revolution: Global-Scale Bespoke Manufacturing

Are your teams
David or Goliath in
the battle for market
dominance?

Nicole Felice Lopez, M.S.Ed.

Facing Reality in High-Stakes Bespoke Manufacturing

We live in a customizable world. Whether it's a coffee order or your medical treatments, if your organization can't deliver a tailored and responsive experience, you fail. The challenges facing decision makers along the product innovation and staff retention roadmap are myriad. To gain competitive advantage in the war for talent, you must provide your advanced therapeutics and medicinal products teams with immersive learning experiences that add measurable, high-impact upskilling. These instructional platforms must be responsive, pliable, and scalable. They must be built by industry subject-matter experts who also understand not just the ins and outs of the content, but also how to uncover that information for synthesis and long-term retention. Got it? Great, let's keep moving because the list is long, friends.

Your organization must deliver, at scale and with a sense of immediacy, the fluid product innovation demands of Pharma 4.0. And don't forget, while you're executing strategies for product manufacturing improvement (you did stay ahead of these trends, right?), your teams must also:

- Engage standardized skill uplift methodologies for high-risk, advanced manufacturing techniques across all relevant teams
- Ensure that these learning and upskilling strategies take into consideration the needs of your teams operating across the globe
- Guarantee that the platform chosen suits the strategy to create profound reduction or elimination of human error while decreasing time to market

FDA's Facts About the Current Good Manufacturing Practices (CGMPs)

"Facilities that are in good condition, equipment that is properly maintained and calibrated, employees who are qualified and fully trained, and processes that are reliable and reproducible, are a few examples of how CGMP requirements help to assure the safety and efficacy of drug products."

Overwhelmed by this list? Too bad. The [major players](#) in the regulatory game are scoping your functionality, systems, and delivery; they have some opinions on how you do what you do.

Your mission now is to uncover a singular source for scalable, standardized, and multilingual CGMP-aligned learning and upskilling for your globally dispersed teams. It is imperative that the chosen solution measurably improves efficiency in high-risk operations without jeopardizing product, time, or money. This unicorn does exist; keep reading.

Surviving the Multiple Mission Vortex

To gain and maintain competitive advantage in the precision medicine marketplace, you need to see your staff as athletes training for the marathon of dominating market share. Your training plan includes:

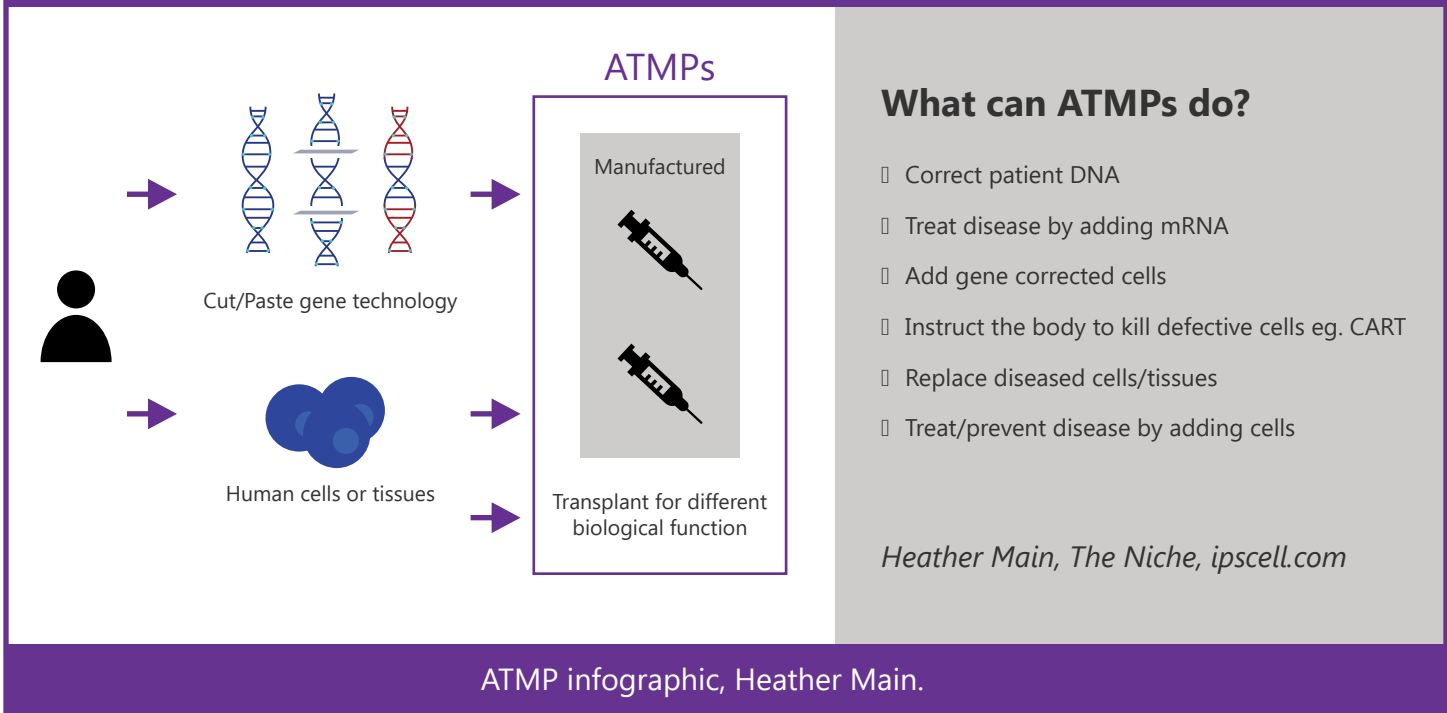
- Streamlining the on-boarding of new hires while prepping them for a shifting skills landscape
- Reducing time to skills competency for new hires and for existing staff on novel skill set acquisition
- Eliminating human error rates in your product manufacturing
- Guaranteeing scalability of your manufacturing process via an equally scalable platform for upskilling
- Creating standardization of learning and upskilling that aligns to CGMP and Industry 4.0 best practices

If your leadership teams aren't monitoring and analyzing organizational vulnerabilities in terms of staff time to competency and human error rates within your manufacturing processes, it's time to come to grips with it. If long-term success is the goal, your moment to minimize risk profiles rather than giving in to the comfort of short-term thinking has arrived.

Failure to embrace the training strategy previously outlined almost guarantees that your reputation won't bear up under regulatory scrutiny. Your organization will be outpaced by the sea of boutique upstarts who are speedier and nimbler than you. These new entrants to the market aren't hamstrung by self-inflicted bureaucratic bottlenecks resulting from years of trying to play it safe, clinging to penny wise but pound-foolish stances.

It's jarring to face the paradigm shift in which staying ahead of the competition is no longer about EBITA, projected revenue, and numerous outdated indicators of success. Being first to market with tech-enabled optimization and pliability of thought is quite literally what wins the race now. Take comfort in the fact that you're not alone on this road. [Virtuosi](#) is the singular industry leader for turnkey, multilingual, CGMP-aligned immersive learning and upskilling. Our platforms are tailored by adult learning, pharma, and biotech SMEs. We've been in your shoes and understand your needs for standardized delivery of curriculum and content for advanced, high-stakes advanced ATMP and pharmaceutical manufacturing. We have your back. Think of us as the supporters with cups of water along the marathon course!

ATMPs - new Pharmaceuticals using human cells and/or genes



ATMP infographic, Heather Main.

“And you may ask yourself: Well, how did I get here?”

- Talking Head

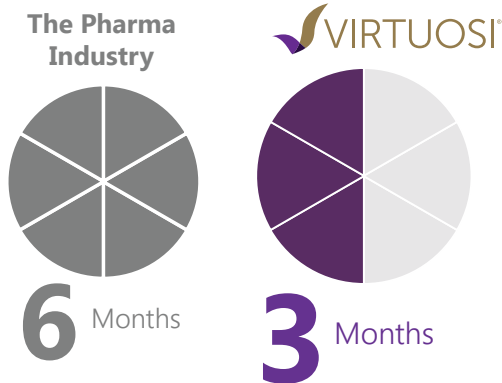
The Talking Heads song “Once in a Lifetime” outlined the very human tendency to sail through challenges with blinders on. Fear of the future and its inherent uncertainties can often give leadership an opening to lean into “This is how we’ve always done it”—good enough’isms. When pathways to organizational change are unclear, fear of exploring and still not understanding dominate and usher in the analysis paralysis cascade. Any lack of will related to facing down perceived risk amidst uncertain outcomes then becomes galvanized.

Buttressing the above is everyone’s least favorite race participant, sunk cost fallacy. It’s the point in the marathon when you’re hitting the wall and terrified of placing a foot wrong; but reinvesting in a different, better angle may be the move that takes you down the path to victory. Immersive and virtual learning platforms may be perceived as novel (particularly in pharma and biotech, where despite all the innovation in product offerings, the bias toward old-school regimentation models dominates); however, their responsive nature is a perfect complement to the transformations that Industry 4.0 is ushering in across multiple manufacturing ecosystems.

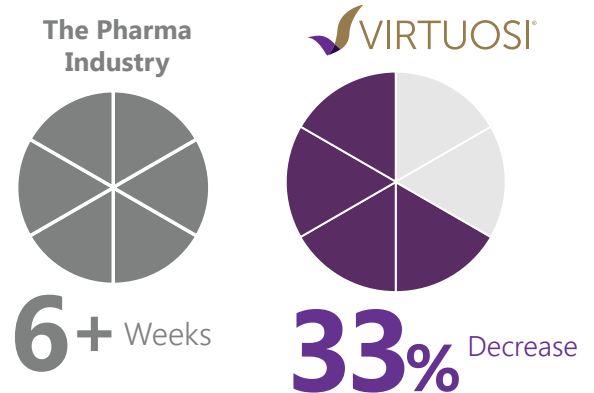
SOP (standard operating procedure)–based training, OJT (on-the-job training), and SME (subject-matter expert)–led training still have their place, but their roles are limited in the face of the synthesis, long-term retention, and cross-application that [Virtuosi’s](#) multi-modal and interactive platform can provide. Embracing immersive learning environments creates a marked reduction in SME overstretch while creating instructional standardization that is immediately deployable around the globe. Your teams, regardless of language variations, will understand how to engage CGMP-aligned best practices because our SMEs spent thousands of hours structuring the most effective approaches for learning acquisition and skills mastery.

Pharma and biotech are working hard to shake their reputations as slow-moving enterprises. The trick is balancing agile strategies with the discipline and meticulous execution still required in the manufacture of life-enhancing and lifesaving cell and gene therapies. This industry demands guaranteed outcomes, which are arduous to prove. It must embrace lightweight, adaptive, recently proven solutions for training new and existing talent to run the gamut of manufacturing skill sets requires not a leap of faith, but a solid analysis of the [evidence](#).

Time to Competency



Training Time



Error Time



In the brave new world of organizational interconnectedness, the possibilities for optimizing employee satisfaction and performance are expansive. Embracing a potent directive for [ongoing skills uplift](#) is a key decision that will yield an invaluable return on investment across multiple verticals—not least among them, staff loyalty. Securing a partner to get you across the finish line in record time, while setting up the blocks for the next race, is essential to building and maintaining staff with the specific skill sets that are at a premium in advanced manufacturing. Virtuosi is the singular source for meeting the needs of ATMP manufacturing because our teams have decades of experience in pharma, biotech, and L&D. We resolve your points without fail because we've already worked through them.

The Upskilling Imperative



Sources: 22nd Annual Global CEO Survey, PwC, 2019; *The Upskilling Crisis*, West Monroe Partners and the Human Capital Media Research and Advisory Group, 2019.

The myriad requirements by stockholders for maximizing profit—from ruthlessly reducing operational costs to decreasing spending on recruiting and retention—can drive executive teams to unnecessarily conservative decisions. They may feel outpaced by regulatory, customer, and stakeholder team scrutiny. Everything outside of familiar solutions can feel like a drag on their speed to the next short-term goal. The solution to meeting the scatter of needs and delivering measurable results for optimal outcomes lies in an all-out sprint—not to the finish, but to the future with [Virtuosi](#).

“If you want to win a race you have to go a little berserk.”

—Bill Rodgers
American runner and Olympian

We developed our foundational curriculum for microbiology and advanced manufacturing with your globally distributed teams at the center of our design process:

- The only multi-language immersive learning and upskilling platform for high-risk pharma and biotech manufacturers
- Content translation conducted by native Spanish, German, French, and Swedish speakers who are also pharma subject-matter experts
- VR-enabled modules to mirror lab environments and allow for zero-risk practice and no equipment downtime
- Haptic feedback and embedded responsive process checks give learners precise coaching that even the most skilled SMEs may not be capable of
- Digital learning modules to frame concept synthesis and prep for the kinesthetic engagement within VR experiences

Stop undercutting your effectiveness with outdated and unmeasurable check-the-box training.