

Equipping the Life Sciences Industry for the Next Generation of Pharmaceutical Breakthroughs

How companies are utilizing assisted reality technology to get medicine to patients in record time



COVID-19 set a new bar for what is possible in the world of drug development and production, and the industry is now poised to move beyond tradition and convention to solve some of the world's toughest challenges. In this white paper, we will examine why a historically risk-averse industry should change its processes for the long term and how it can replicate the success of the COVID-19 vaccine for other new therapies by integrating people and advanced technology and tools.

Over the last three years, life sciences companies have undergone transformation unlike anything seen before. The COVID-19 pandemic put the industry in a pressure cooker that has yet to release as companies race to manufacture increasingly complex drugs at even faster speeds. Many companies have risen to the challenge and delivered scientific breakthroughs, but others are hesitant to invest in the technology, equipment and training that will be required to remain competitive and innovative in the way the market demands. What has become clear is that for the industry to move toward long-term change, the integration of people with advanced technology and tools is required.

The Drug Development Race

The global life sciences industry is made up of companies operating in the research, development, and manufacturing of pharmaceuticals, medical devices, biomedical technologies, biotechnology-based food and medicines, cosmeceuticals, food processing, and other products that improve the lives of people and animals around the world. These companies are responsible for manufacturing the drugs that billions of people rely on every day as well as creating brand new medicines and therapies, which can be an incredibly expensive and risky process. The first stage in the drug lifecycle is research and development (R&D), where a new type of drug or molecule is discovered. The drug then moves into the development stages, which include pre-clinical, clinical and commercial. It can take 10 years and $2.6 billion before the average drug.[1]

Pre-pandemic, the life sciences industry was focused on commercializing a drug and manufacturing it consistently and with high quality. Today, speed across the drug lifecycle is becoming the main driver behind process improvement and is driving the adoption of new technology. Instead of spending 10 years to discover and produce a new drug, can it be done in five years? Or even faster, as in the case of the COVID-19 vaccine?

The Traditional Approach

While many companies within the life sciences industry have developed innovative and novel treatments throughout the years, manufacturers of highly regulated pharma products have traditionally been slow to adopt the latest technological advances.[2]

Prior to 2020, there had been a slow push within the pharmaceutical industry toward what is known as Pharma 4.0, or the integration of trends such as big data, interconnectivity, artificial intelligence and distributed cloud-based architectures to help develop next-generation therapies.[3] But at that time, the effort toward more integrated and automated processes was focused almost exclusively on technologies such as enterprise resource planning (ERP) and laboratory information management (LIM) systems and business intelligence, which was just beginning to help bring digital data into the drug production process.



> *The average drug takes 10 years and 2.6 millions dollars to develop before it ever gets to a patient.*
>
> ***- Forbes***

Industry 4.0 and Pharma 4.0

Industry 4.0 is a concept of digital transformation that includes the adoption of such innovative technologies and processes as cloud computing, the Internet of Things, big data analysis and AI.

Pharma 4.0 refers to the specific application of digital capabilities to advance pharma manufacturing and deliver next-generation therapies through innovative processes and techniques.



Even companies that had made the investment in LIMS or ERP systems prior to 2020 generally shied away from bringing new technology into the early stages of the drug production process due to heavy regulations and the need to ensure high-quality medicine. These companies often opted instead for the traditional method of sharing handwritten binders full of information between siloed internal teams - a method that would consistently lead to errors, breakdowns in communication, and millions of dollars lost due to quality deviations in drug batches. At this time, other technologies like virtual reality and assisted reality, were considered "nice-to-have" options, not essential to day-to-day operations.

> *Batch-processing costs the pharmaceutical manufacturing industry about $50 billion each year due to inefficiencies, losses, contamination and expenses that come along with product recalls.*
>
> ***- Pharmaceutical Processing World***

A New World

The industry's more risk-averse attitude toward technological transformation changed overnight when COVID-19 hit in March of 2020. The pandemic touched every industry across the world, but few felt the pressure to innovate more than the one attempting to develop and manufacture a life-saving vaccine for millions of people. That pressure mobilized the entire pharmaceutical ecosystem—including regulatory agencies—to speed up the drug development process in the interest of patients and brought unprecedented collaboration across life sciences and with stakeholders.

> *Forward-looking companies who want to compete beyond 2022 will to need adopt a think-digital-to-be-digital mindset and consider how these technologies can augment human capabilities and update the execution of processes.*
>
> ***- Deloitte 2022 Global Life Sciences Outlook***



realwear

With the COVID-19 vaccine now readily available across the U.S. and most of the world, there is an expectation for pharmaceutical manufacturers to sustain the same accelerated level of speed and innovation for all drugs with even fewer resources. With mRNA vaccines - a relatively new type of cell therapy - the COVID-19 inoculation was the first large-scale production of its type. It was a radical change for pharma manufacturing to not only create a drug that had never been made before but also do so on a timeline that was previously inconceivable. Companies were forced to figure out how to transition facilities, teams, and technology to make this new kind of cell therapy-and that has had a direct impact on how many of them view technology transformation for 2022 and beyond.

> *Pharma is a highly regulated industry: approximately 30 percent of staff time is spent on documentation-related activities, including product dossiers, machine logs, batch records, and more.*
>
> ***- McKinsey***



> *The global pharmaceutical manufacturing market size was estimated at $509.45 billion in 2022 and is projected to grow at a compound annual growth rate (CAGR) of 12.38% to reach $914.90 billion by 2027.*
>
> ***- Research and Markets***

The Time for Change

The current efforts to strengthen the drug manufacturing process are more important than ever as the therapies being developed increase in complexity. The industry is in the middle of a shift from legacy modalities such as small molecule drugs into advanced cell and gene therapies, such as the COVID-19 mRNA vaccine.

The process of manufacturing small molecule drugs is radically different than that of cell and gene therapies, and many companies are realizing that legacy systems and processes are not working in this new the environment isn't personalized - the drug and the mfg process is fast-paced environment. As part of their larger technology platforms, many companies have turned to assisted reality wearables to strengthen the manufacturing process throughout the drug lifecycle, stay competitive in an increasingly crowded field, and enable lasting change in unstable times.



Purpose-built Tools for a Highly Regulated Industry

Increasing drug complexity naturally means operators are tasked with more complicated steps and instructions to make that drug, which inevitably needs more requirements? Once COVID-19 arrived, it became clear that assisted reality (aR) technology—a part of the broader extended reality (XR) universe that includes augmented reality (AR), mixed reality (MR), and virtual reality (VR)—and remote collaboration tools were going to be vital for the rapid scale-up in manufacturing that was required.

Unlike other industries moving toward new technology platforms, pharmaceutical manufacturers are limited by the FDA and other international regulatory bodies in the kinds of software and hardware they can deploy. These companies are held to a higher set of regulatory standards and cybersecurity protocols, which makes it necessary for them to invest in software platforms and hardware that are purpose-built for the industry.

A wearable appropriate for the life sciences industry is a clean-room-ready industrial strength aR device that connects frontline workers within labs, factories and throughout entire companies with the data and collaboration tools needed to successfully complete job tasks safely and efficiently. Intrinsically safe aR wearables such as RealWear Navigator® 500 head-mounted device (HMD) allow users to interact and capture data while keeping hands-free, instead using vision, voice and head gestures. This is a game-changer for those working in highly regulated environments where limited tools are allowed.



RealWear Navigator® 500

RealWear Navigator® 500 head-mounted device is the leading assisted reality solution custom-built for the modern frontline worker. It allows users to:

- Connect and collaborate with remote experts in real-time
- Work completely hands-free
- Easily access and follow digital workflows and visualize IoT data
- Safely reduce downtime and improve quality and employee productivity while realizing a significant ROI



What is an HMD?

Head-mounted devices (HMDs) safely bring together the real and the digital worlds to create new kinds of interactivity and perception while allowing frontline workers to maintain full situational awareness. HMDs allow a user to view a screen within their immediate field of vision, hands-free, and access necessary information when they need it.



Let's look at a few areas where the adoption of assisted reality wearables has had the largest impact:

1. Accurate Execution and Data Collection

The industry is currently shifting from legacy modalities such as small molecule drugs into biologics and advanced cell and gene therapies. These new modalities have a different set of conditions that the old technologies simply weren't built for. Cell and gene therapies offer huge potential as treatments for a wide range of diseases, including cancer, neurological, and genetic diseases, making it essential for pharmaceutical companies to integrate processes and workflows with industry-specific hardware and software solutions.

RealWear industry solution partner Apprentice.io is one company leading the pharmaceutical industry toward technology transformation and helping manufacturers adopt the latest tools. The company has developed a manufacturing execution system (MES) that is natively integrated with the RealWear Navigator® 500 and that incorporates aR capabilities into mobile and head-mounted devices. Apprentice's MES is part of the Tempo Manufacturing Cloud, which also includes a Laboratory Execution System and virtual collaboration product.

All manufacturing processes in the pharma industry need to be documented in a well-defined and structured format that is transparent and adheres to regulatory guidelines. Together with Tempo, RealWear Navigator® 500 helps companies execute increasingly complex batch recipes by providing voice-navigated audio instructions and assisted reality overlays, keeping them completely hands-free.

RealWear Navigator® 500 also captures the live process and operational data while employees work, empowering them to focus on the process instead of the manual collection of information that may or may not be accurate. In this way, attention can shift from a tedious and error-filled method to one in which accurate and up-to-date data is shared, transferred and made available to stakeholders worldwide.

"Making cutting-edge medicine like cell and gene therapies widely available is dependent on making a complex production process repeatable at scale," says Angelo Stracquatanio, CEO and co-founder of Apprentice. "To do that, you

> *"Together with the power of the RealWear Navigator® 500, Tempo empowers operators to bring instructions with them wherever they go in the suite, which is a game-changer for batch execution. It enhances those instructions with assisted reality overlays for greater clarity and then automatically captures step completion, equipment readouts and usage logging."*
>
> ***- Angelo Stracquatanio, CEO and co-founder of Apprentice.io***



need technology that helps human operators follow batch procedure and document process data faster and more reliably. Integration of RealWear headsets into our Tempo MES helps those operators make complex therapies consistently and with the highest quality, ultimately getting medicine to patients faster."

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2. Team Collaboration

Even if a company has already made the investment in an ERP, LIMS or MES system, its pre-clinical, clinical, and commercialization teams are still traditionally very siloed, and there is often little communication between the groups throughout the drug development process.

Similar to working in clean rooms in semiconductor facilities, operators are often in head-to-toe gowns, head coverings, face masks and three layers of gowning, which makes it very difficult to both work through their individual process and collaborate with other team members. If the technology is not in place to accurately transfer knowledge between teams and across locations, the process can be extremely slow and painful. The use of wearables not only allows users to capture large amounts of data hands-free while working alone, but also drives global collaboration with team members at any time.

The production and lab systems both hold critical data that is far more valuable as a complete piece. Pharmaceutical customers of Apprentice utilize RealWear devices combined with its virtual collaboration software, Tandem, to connect team members in real time around the world; providing all of the relevant people in an organization with access to that data enables fast, informed decision-making.

3. Equipping a Modern Workforce

The increased use of and reliance on digital technologies by various industries is clear: Our lives, our homes, our work, and science are continuing to change rapidly as a result of technological advancements.

As in other industries, including consumer manufacturing and hospitality, the Great Resignation has resulted in a shortage of skilled labor in the pharmaceutical industry. Tech and healthcare experienced some of the highest resignation rates, which directly affected the life sciences industry due to its close ties with both. Pharmaceutical manufacturing and production roles saw the most talent loss, especially when it came to positions such as manufacturing technicians, process and validation engineers, data scientists, analysts and production technicians.[4] In tandem with this great loss of talent, new life sciences jobs were being created to meet the growing demands of the pandemic, making talent retention and hiring in life sciences seem nearly impossible.

Due to this large workforce gap, companies across the life sciences industry have struggled to keep up with and out-compete one another in a war for today's best technical talent. Younger workers, many of whom



> *"Combining process capabilities with collaboration is a powerful value proposition for any pharmaceutical company. Doing that all hands-free while interacting with equipment and drug product makes an assisted reality wearable a very valuable tool."*
>
> ***- Angelo Stracquatanio, Apprentice.io.***

are entering the industry for the first time, are adept at using technology and are accustomed to integrating it closely into their lives and work. They expect employers to provide modern tools and support to help them meet the everyday pressures that come with working in this kind of fast-paced environment. Offering the latest software and assisted reality tools such as wearables helps companies demonstrate their commitment to Pharma 4.0 and attract and retain qualified talent in a limited labor pool, while helping employees do their jobs more accurately and efficiently.

4. Forming a Technology Strategy

According to Apprentice, implementing new technology such as an MES system can take big pharma companies with armies of IT people 12 to 24 months. Small startups don't have that kind of time or capital, but they still need to invest in technology that helps them improve processes while remaining compliant. Apprentice is showing companies of all sizes what is possible with technology when it's customized for the industry, easily adoptable and built to support team members across the drug development lifecycle, from preclinical development to full-scale commercialization.

Based on the company's experience with customers across the life sciences industry, RealWear has identified three best practices that are key to a successful implementation strategy for modern manufacturing execution system:

- Step one: Find a valuable use case with a team that has an obvious pain point. Is the team looking to stop operator error and prevent batch deviations? Is it looking for enhanced communication across global teams?
- Step two: Once the value of that use case has been measured and the potential ROI has been identified, companies can move to step two by either continuing to improve the processes within the same team, or they can move on to a different team with similar pain points and implement a use case there.
- Step three: The final phase involves scaling out and scaling up for full company implementation, with a rollout of the technology and tools throughout the development lifecycle. This includes providing the same technology to teams and sites around the world, ensuring seamless integration of technology and easy sharing of real-time data.

Consider one Apprentice customer that happens to be the world's third-largest biotech company:

- The challenge: The biotech company, which specializes in rare and serious diseases and influenza prevention, was using pilot plants to test manufacturing processes on a small scale. The company was looking to upgrade its technology after decades of using manual methods to track data in its labs.
- The solution: The company kicked off a six-month pilot program with Apprentice to explore alternatives to paper-based batch records, standard operating procedures and work instructions. When integrated with lab facilities, Apprentice's software development platform and RealWear's integrated HMD provided on-the-spot



feedback, process directives and problem-solving techniques in real time. The company was able to replace paper records and calculations that would otherwise have been cross-checked manually by multiple employees with automated formulas, ranges and barcoding. If results didn't match, the Tempo system flagged it to the operator, saving time and ensuring compliance.

- The future: Colleagues at different sites are now also able to share data and see what's happening in real-time. The company plans to expand the software system to other facilities in Australia and the United States.

Scientific breakthroughs such as cell and gene therapies have many potential use cases for the future, and the adoption of new technologies will only continue to grow as bold pharmaceutical leaders take advantage of the many opportunities the pandemic uncovered. The new processes developed to expedite COVID-19 vaccines and therapeutic products are now also being applied to speed up the development of other drugs and treatments—and companies cannot revert to old ways if they want to compete. The technology to keep drug development safe, efficient and reliable is here in aR technology and assisted reality devices, but the technology must be easy to use, well-integrated with existing systems and meet the strict standards required in the drug production world to be successful.

1. "Drug Prices and Innovation." Forbes, June 20, 2019.
2. "Adopting Industry 4.0 Technologies: Challenges and Opportunities For Pharma Manufacturing." Forbes, Jan. 14, 2022.
3. "What is Industry 4.0? Here's A Super Easy Explanation For Anyone." Forbes, Sept. 2018.
4. "A Record 4.5 Million Workers Quit or Changed Jobs in November." Washington Post, Jan. 7, 2022.

Photography courtesy of Apprentice.io

