MOBILE MANUFACTURING IN PHARMA
Promise, Progress, and Practicalities

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Advancements in technology—such as process intensification, continuous manufacturing, and 3D printing—are enabling transportable and point-of-care (PoC) medicines manufacturing, especially with the rise of personalized medicine. Modular, small-scale production systems are particularly well-suited for cell and gene therapies and other advanced therapy medicinal products (ATMPs) designed for patient-specific treatments.

Even for small molecule oral solid dose medicines, supply chain constraints and access considerations may make modular and transportable production units a viable option. However, regulatory challenges persist—particularly in terms of demonstrating product comparability across modular units. Additionally, scaling innovative modular manufacturing remains difficult.

While technological advancements have significantly progressed, commercial adoption of transportable and point-of-care manufacturing remains limited, primarily due to persistent regulatory and economic barriers.

INTRODUCTION

The ISPE PQLI® Transportable Point-of-Care Manufacturing Technology Team has defined transportable or point-of-care manufacturing as: "a capability that can be readily deployed temporarily in closer proximity to the patient base" [1]. Expanding on this, transportable or point-of-care (PoC) medicines manufacturing refers to the concept of highly mobile manufacturing units that can be relocated within or across different locations, including geographies and regions. In the full extension of the concept, these units can even be deployed directly at the point-of-care, such as in a clinical or hospital setting. This approach naturally implies a diseconomy of scale while supporting greater patient segmentation, ultimately leading to customized medicines tailored to individual patients.

Several factors have driven this concept, including regulatory requirements to keep the latter stages of medicines manufacturing within a region, supply chain demands for responsiveness to unforeseen needs, the flexibility to leverage lower cost manufacturing regions, and the need to improve access to medicines in underserved poorer countries.

Coupled with these macro socio-economic drivers, technological advancements have made highly mobile manufacturing units a viable option. These include advances in process intensification—such as continuous manufacturing for both drug substance and drug product—as well as alternative formulation approaches, including 3-D printing of drug product [2].

Additionally, the rise of combination products and the ability to co-formulate specific combinations tailored to patient needs make transportable modular manufacturing a potentially more attractive option.

Finally, the emergence of novel modalities—such as cell and gene therapies—custom biologics and more recently, mRNA-based vaccines—has disrupted the traditional global manufacturing hub model.

This paper aims to review the current status and trends in transportable and point-of-care medicines manufacturing. It will reassess the key drivers behind the concept, examine industry progress in deploying this approach for both clinical and commercial manufacturing, and identify areas where the ideas remain largely theoretical. Additionally, it will explore how the regulatory environment is evolving to accommodate these advancements. Finally, we will consider potential future developments and their timelines, acknowledging the inherent uncertainties in making predictions.

Because there are varying transportable approaches to consider for future manufacturing platforms (eg. mobile truck/trailer, prefabricated modules, portable units), and there is no one size fits all solutions to accommodate varying manufacturing processes, the paper will not focus on the transportation aspect itself.

DRIVERS FOR TRANSPORTABLE AND POINT-OF-CARE MANUFACTURING

Drivers of transportable and point-of-care manufacturing vary by modality and whether it pertains to primary drug substance or secondary drug product manufacturing.

For small molecules, large molecule biopharmaceutics and protein-based antigen vaccines, drug substance manufacturing typically benefits from the economies of scale achieved through centralized high-volume production. While the COVID-19 pandemic and recent geopolitical uncertainties have tempered this to some degree, the response has largely been a shift toward re-shoring or regionalizing primary drug substance manufacturing to enhance supply chain security. However, even with regionalized production, drug substance manufacturing for these modalities remains centralized and a long way from being truly transportable or suitable for point-of-care deployment.

For secondary drug product manufacturing, in addition to supply security concerns, financial considerations and access to medicines also play a role in driving some companies to regionalize or localize drug product manufacturing. Certain countries, such as Brazil, are working to implement fiscal and regulatory policies that incentivize local drug product manufacturing. This typically begins with final-stage packaging but has the potential to expand further upstream as governments leverage medicine regulations to stimulate economic growth.

Additionally, some global pharmaceutical companies have embraced an access-to-medicines agenda aiming to deploy drug product manufacturing solutions into developing countries. This gave rise to the development of "factory-in-a-box" concepts, most notably by GSK in partnership with Bryden Wood [3]. This concept was developed as part of GSK's Africa 2020 strategy—an initiative that focused on designing a modular factory facility that was partially pre-assembled offsite and could be deployed and validated rapidly in challenging markets.

Another example of industry innovation in response to these challenges was the collaboration between Pfizer, GSK, GEA, and G-CON to develop a Portable Continuous Modular Manufacturing (PCMM) unit based on continuous direct compression tableting technology to enhance production flexibility and efficiency [4].

Over the past decade, there has been a significant emergence of new modalities including cell and gene therapies (also known as ATMPs, mRNA, and custom biologics). The emerging modalities are generally more suited to transportable and point-of-care manufacturing than traditional modalities, as they tend to be more patient-specific and produced in significantly lower volumes. Additionally, these new modalities often have challenging storage and transportation requirements, making centralized manufacturing and distribution via traditional pharmaceutical supply chains more difficult. A notable example was the Pfizer-BioNTech mRNA COVID-19 vaccine, which required -90°C to -60°C transit and storage conditions. While this posed logistical challenges even in developed markets, it created significant obstacles in regions lacking advanced cold chain distribution infrastructure.

TECHNOLOGICAL ADVANCES AND NEW MODALITIES

Historically, industrialized pharmaceutical manufacturing has relied on large, fixed factory installations that serve as global or regional supply hubs. To ensure supply, pharmaceutical companies typically maintain multiple production sites for revenue-generating or medically essential medicines. The dominant production model in these facilities—for both drug substance and drug product—has traditionally been batch manufacturing, and this remains largely the case today. However, technological advancements, cost pressures, and evolving quality and regulatory expectations have driven innovation in manufacturing operations.

Continuous Manufacturing

One such innovation is the gradual adoption of continuous manufacturing for both drug substances and drug products. This shift inherently leads to significant process intensification with a correspondingly much smaller physical footprint while maintaining the same product output. Implementing this approach allows drug manufacturers to achieve the necessary production capacity within a considerably smaller facility compared to traditional batch operations. This paradigm shift will be a critical factor driving the deployment of a decentralized or point-of-care manufacturing network.

Small Molecule Pharmaceuticals

Drug product manufacturing has also been shifting toward continuous operations. In oral solid dose (OSD) manufacturing, tableting is already a continuous process. However, operations such as wet granulation and drug powder blending have historically been batch processes. Recent advances with twin screw wet granulations systems, continuous driers and powder blending technologies now make fully continuous oral solid dose manufacturing possible [5].

Similar to drug substance manufacturing, continuous OSD technologies require significantly smaller physical footprints, making modular manufacturing units a more viable option. For example, GSK reported that the physical footprint of their drug substance manufacturing operations was reduced thereby improving capacity and reducing costs [6]. This reduction not only leads to significant savings in initial capital investment and ongoing operating costs but also enables the design of modular skids for drug substance synthesis that can be constructed offsite, shipped, and reassembled as needed, enabling a portable manufacturing paradigm.

However, widespread adoption of continuous manufacturing for drug substances is still constrained by the limitations of certain chemical transformations required to achieve the completed synthesis of the desired active ingredient. Not all chemical reactions are compatible with flow chemistry, but these challenges can be managed through mini-batch or fed-batch approaches.

Large Molecule Biologics

Continuous manufacturing is particularly valuable in biologics and can drive efficiency in production, which in turn can reduce the costs of biomanufacturing and provide more people with access to such therapies [7]. The development of transportable or modular facilities for manufacturing custom biologics is also advancing, driven by the need for flexibility, scalability, and speed. These

facilities, which rely on continuous and connected intensified processes, offer significant advantages— particularly in regions where traditional large-scale manufacturing is not viable.

Due to their smaller footprints and modular design, these platforms are inherently deployable and scalable, reducing time to market and capital expenditure for biologics manufacturers. They can be assembled more quickly than conventional facilities and are adaptable enough to accommodate various stages of biologics production, including both upstream and downstream processes. Additionally, they support the use of single-use technologies, which help to minimize contamination risks and are especially beneficial for smaller batches, such as those required for personalized medicines [8].

For those process steps, such as purification, which require significant volumes of buffer, strategies will need to be developed for local or regionalized buffer production—leveraging technologies such as in line dilution or through innovative supplier arrangements.

While continuous manufacturing of biologics has not yet reached the level of advancement seen in small molecule pharmaceuticals, significant investment and technological progress are driving its development. Many leading process technology providers continue to innovate, launching systems and platforms designed for intensified and continuous biologics manufacturing. In addition to larger biotech companies, a growing number of universities and start-up companies are focused on developing continuous platforms to enhance traditional mammalian and microbial-based processes as well as pioneering novel approaches for manufacturing mRNA vaccines and therapies.

Advanced Therapy Medicinal Products

Advanced therapy medicinal products (ATMPs) are particularly well-suited for point-of-care manufacturing. These therapies—which involve techniques such as gene editing, cell manipulation and tissue engineering—generally require immediate delivery to patients, making hospital-based manufacturing highly desirable. Currently, production is managed under regulatory exemptions granted by various authorities. However, as ATMPs become more widespread, new regulatory frameworks will likely need to emerge to better support point-of-care manufacturing.

One evolving concept in this area is point-of-care manufacturing readiness [9]. This framework outlines three key aspects of PoC manufacturing readiness: institutional procedures and staff training; material infrastructure and equipment; and relationships with providers and distributors. This concept has merit, given the need for drug manufacturers and healthcare providers to integrate their quality and operational management systems in an effective and efficient manner, ensuring the quality of the product and the health and safety of the patients.

As with any cGMP manufacturing site, the training of operators and staff within a PoC operation will be critical to ensure compliance with quality systems and regulatory licenses and authorizations. Standardization of procedures and systems across PoC sites, minimizing manual tasks through automation, and implementation of digital technologies wherever possible, will be critical to mitigate the risk of quality issues and deviations.

Autologous Therapies

Autologous cell therapies are a form of personalized medicine in which a patient's own cells are extracted, modified through a proprietary process, and then reintroduced for therapeutic use. Among these, CAR T cell therapies—an immunotherapy that enables the patient's immune system recognize and attack cancer cells—have gained significant attention over the past decade. As of June 2025, six US Food and Drug Administration (FDA)-approved CAR T therapies are on the market; however, several challenges remain. The centralized manufacturing model for CAR T therapies has, at least in part, been identified as a major supply chain bottleneck limiting patient access in the US [10].

Shifting toward distributed or point-of-care manufacturing could enhance capacity, streamline logistics, and reduce lead times. This approach could help mitigate risks associated with chain of custody, cold transport and storage, and the short treatment window following initial apheresis cell collection. In this context, manufacturing could be performed very close to where the patients are treated—e.g., in hospitals and clinics. Localized "production units" could be designed for mobility allowing for transport to different locations where patients require treatment.

However, this model presents its own set of unique quality and regulatory challenges, as it diverges from traditional and accepted drug manufacturing standards. For example, quality control (QC) testing requirements for cell therapies can be significant and will need to be addressed as a potential component of the localized facility if existing capability is not in close proximity. Despite these hurdles, the strongest driver for transportable and point-of-care medicines manufacturing will likely be the increasing demand for customized, patient-specific therapies like CAR T cell treatments.

Pharmacy Compounding and Formulation

Industry consolidation, drug shortages, and the increasing demand for customized drug products—such as co-formulations and patient-specific dosages—are driving innovation and investment in the capacity of both hospital-based and independent 503A and 503B compounding pharmacies. Consolidation has largely been fueled by heightened regulatory scrutiny and oversight following quality lapses, some of which have had serious consequences, including patient fatalities [11]. Companies that have remained in operation have focused on improving their processes and quality systems while attempting to increase their capacity to address the current drug shortage issues. Additionally, hospitals are exploring innovative solutions from companies like OnDemand Pharma (ODP), which offers transportable compounding pharmacy units that can be temporarily located at their site to compound the most critical drugs in shortage. ODP and other companies are developing new processes and technology platforms to support a distributed

manufacturing network, further enhancing the resilience and flexibility of pharmaceutical supply chains.

3D Printing

A significant advancement in oral solid dose formulations is the use of 3D printing. This takes various forms. One example is GSK's Liquid Dispensing Technology (LDT), which deposits a solution of the active ingredient onto a placebo tablet. This fully continuous process can be scaled up to produce two million tablets per day from a single modular, self-contained unit [12]. In 2016 Aprecia Pharmaceuticals became the first company to receive FDA approval for 3D-printed tablets, Spritam (levetiracetam) for the treatment of epilepsy [13]. 3D printing holds promise for personalized medicine, potentially enabling drug formulation in pharmacies, at home, or even at the patient's bedside. One of the leading innovators in the field is FabRx, which offers a range of 3D printing solutions employing a variety of techniques with a strong focus on developing the technologies for personalized medicines applications.

MODULAR MANUFACTURING FACILITIES

Modular manufacturing is the process of assembling individual prefabricated sub-assemblies in a controlled factory setting to create a substantially complete building product ready for transportation to a host site. In pharmaceutical and biopharmaceutical applications, over 85% of the assembly is completed in the factory, while the remaining work is completed at the host site. The approach is based on Design for Assembly (DfA) principles and practices.

Modular prefabricated facilities can vary in size, ranging from small 500 square-foot units to much larger multi-story structures. For distributed or point-of-care manufacturing, most facilities are expected to fall within the 500 to 5,000 square-foot range, depending on factors such as process requirements, output capacity, and the need for relocation. Installation locations can also vary, with some requiring the facilities to be housed within a shell structure, such as a warehouse, while others may be placed outdoors, such as in a parking lot adjacent to a hospital or treatment center.

For manufacturers deploying modular facilities across multiple sites, a standardized pre-engineered platform approach is preferred. This ensures that facilities can be easily replicated, yet also configurable to accommodate site-specific requirements or constraints. This approach can significantly reduce the time required to deliver a new facility and reduce the total cost of ownership of the manufacturer's network.

Successful Modular Manufacturing Models

Core elements of these models include:

- Factory assemblies follow a process flow moving efficiently through the factory footprint from beginning to end, utilizing factory standard operating procedures (SOPs) to organize and streamline each step of the build.
- Modules are designed and built on a structural product platform that supports both the factory environment and transportation.
- Build process primarily relies on pre-engineered sub-components and assemblies that are well-established and familiar to the assembly team.
- The majority of sub-assemblies (*i.e.*, structural, architectural, process, HVAC, etc.) are constructed just-in-time (JIT) in parallel, reducing overall project duration.
- Design details are coordinated using a collaborative 3D Building Information Modeling (BIM) system.
- Design that is compliant with all regulatory and code requirements based on the installed location.

The Modular Build Process in Four Phases

1. **Scope of Delivery Development and Approval**
   This phase involves defining the design basis and contractually agreeing on the scope, schedule, and cost of the manufacturing module. Depending on the level of complexity, this step can take anywhere from a few days to several months. Modular fabrication does require a higher degree of front-loaded information to enable rapid delivery. The phase is completed once sufficient funds are approved to procure materials and allocate factory capacity to the project. By the end of this phase, all required materials and personnel resources are identified, and planning has been initiated.

2. **Fabrication and Assembly**
   Design details necessary for fabrication and assembly are finalized while externally sourced materials arrive and undergo inspection in parallel. The fabrication and assembly process follows a predetermined sequence through the factory, ensuring each step of the build is prescheduled and completed in a controlled environment using standardized processes and materials. The buildout includes all rough-in scope and all final finishes, covering structural, architectural, mechanical, electrical and building management systems—down to lighting outlets, HVAC grills, hand wash sinks, and even door hardware. Quality control is critical, with each system undergoing rigorous documented inspections to ensure compliance with building codes and design specifications. Finally, inspection and approval are documented with an approved documented Factory Acceptance Test (FAT).

3. **Packaging and Transportation**
   Once fabrication and assembly are completed, modules are packaged and transported to the site. Depending on the size and distance, transportation methods may include trucking, rail, or shipping.

4. **Installation and Site Acceptance Testing**
   The final phase takes place at the host site and includes rigging, site connections, and Site Acceptance Testing (SAT). Rigging involves lifting modules off transport vehicles using cranes and then moving them into position. For multi-module setups, the units are secured together using fasteners or welding, and plumbing, electrical, and HVAC connections are completed, often using pre-installed channels within the modules. Modules are then

integrated into the host site's utilities and monitoring systems. The process concludes with an SAT to verify all systems are fully operational and meet the user's performance requirements.

Overall, modular facilities offer a streamlined and efficient alternative to traditional construction methods, providing advantages in speed, cost, quality, and sustainability.

REGULATORY AND QUALITY CONSIDERATIONS

When pursuing transportable, decentralized, or point-of-care manufacturing, regulatory and quality considerations are centered around the following key areas.

Defining a Manufacturing Site

Current regulations and guidelines were designed for traditional fixed-location, large-scale manufacturing facilities that require a specific geographic address to be registered. However, this requirement may be impractical, and not commensurate with the risk when dealing with mobile manufacturing units or networks of interconnected facilities. For installations of multiple yet similar manufacturing units, the listing of each address neglects the important relationships and interdependencies between the units.

Applying Quality Systems Across Sites

Traditional manufacturing sites have dedicated personnel responsible for quality oversight and management ensuring a strong quality culture. However, applying this level of oversight becomes more complex when dealing with mobile manufacturing units or multiple interconnected units spread across different locations. Additionally, maintaining connectivity across the related units is essential for managing quality events such as deviations, investigations, and change management effectively. Leveraging IoT (Internet of Things), digital tools and technology platforms can help to address these challenges.

Demonstrating Comparability

Traditionally, product comparability across manufacturing sites has been demonstrated through bioequivalence studies, process performance qualification (PPQ), and long-term stability studies to establish product equivalence. However, these approaches can significantly delay the implementation of a new site and become impractical (for both application and review) when deploying a large number of highly similar manufacturing units. Standardization across decentralized sites can reduce the risk of product non-equivalence, but questions remain: What level of evidence is necessary to demonstrate equivalence? How should it be maintained over time? How should it be reported to regulatory authorities?

Conducting Inspections

A portable manufacturing unit may transition between different inspectional jurisdictions, and multiple decentralized sites may span across regulatory boundaries. In each case, the question arises: Who holds the authority to ensure compliance with Good Manufacturing Practices (GMPs)?

Three major regulatory agencies—UK's Medicines and Healthcare products Regulatory Agency (MHRA), FDA, and European Medicines Agency (EMA)— have engaged the public to better understand the regulatory needs and challenges in transportable, decentralized, and point-of-care (PoC) manufacturing. Their focus has been on identifying barriers to implementation and proposed solutions. Following public consultations, each agency is working to adapt legislation and guidelines to accommodate decentralized manufacturing models.

- The MHRA shared the results of their public consultation in 2023 (14) and new regulations were established, coming into effect 23 July 2025 (15).
- The FDA shared the feedback they received from their discussion paper and public workshop in a 2023 report. Its action plan included developing guidance as appropriate, and coordinating with international regulatory agencies (16).
- The EMA's Quality Innovation Group held a Listen and Learn Focus Group meeting in 2023, gathering industry input. Its final report included an action item to develop appropriate guidance for decentralized manufacturing adoption (17).
- Additionally, the EU's draft pharmaceutical legislation amendment incorporates the concept of decentralized manufacturing (18).

Though formal regulatory expectations are still in development, public engagement has revealed several common themes:

- Industry and patient groups strongly support regulatory efforts to ensure a clear path forward for decentralized manufacturing (DM) and PoC manufacturing.
- Preliminary definitions of what constitutes PoC have varied somewhat, but agencies have indicated that they will refine these based on industry feedback.
- Sentiment has coalesced around the need for a centralized Pharmaceutical Quality System (PQS) to manage quality across geographic locations.
- The concept of a centralized hub responsible for quality oversight of DM locations is gaining support.

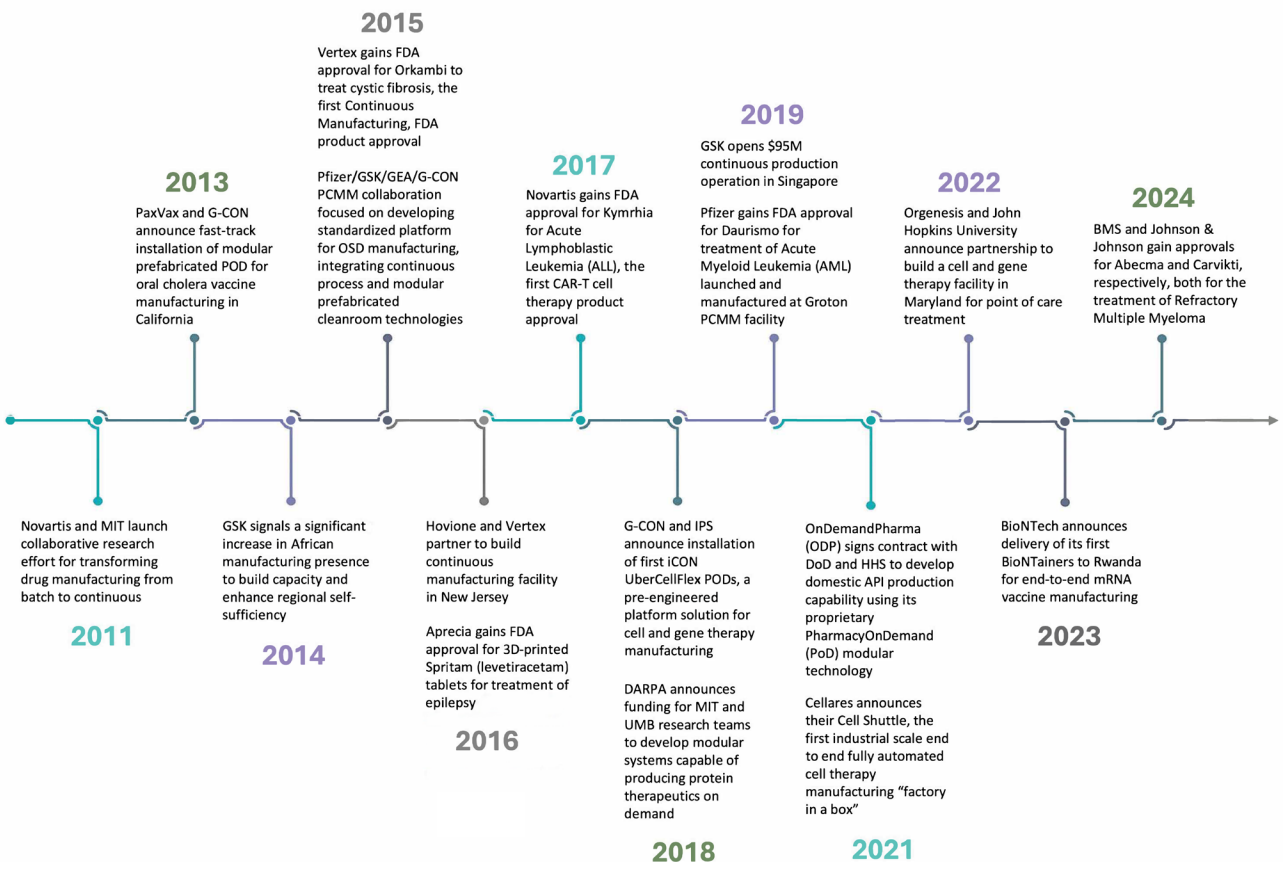
Proposed Regulatory Approaches

- The MHRA suggests implementing a master file to document quality oversight and serve as a comparability reference.
- The FDA has proposed risk-based assessments and regulatory tools such as Post-Approval Change Management Protocols (PACMP, see ICH Q12) to gain upfront agreement regarding testing and acceptance criteria for new or relocated sites.
- To ease resource strain from multiple DM or PoC sites, regulators favor a risk-based approach, prioritizing oversight at the central hub and streamlining it at distributed sites.

Decentralized Manufacturing: Regulatory Focus

1. Current regulations require specific geographic manufacturing location in regulatory submissions, and any site change requires

Figure 1: Timeline of specific transportable and point-of-care manufacturing initiatives.



notification, pre-approval inspection (PAI) etc.
2. Existing regulations are designed for a centralized quality system, which may need adaptation for decentralized models.
3. Validation of equipment and processes remains a core requirement, particularly for ensuring comparability and regulatory acceptance across multiple sites.

INDUSTRY PROGRESS OVER THE LAST DECADE

Over the past decade, investments in innovation and technology have accelerated the development of process and facility platforms, laying a strong foundation for transportable and point-of-care manufacturing. Advances in process intensification, single-use technologies, and continuous manufacturing—alongside progress in personalized medicines and therapeutics—have significantly reduced process footprints compared to traditional centralized models.

Smaller process footprints, along with reduced utility and operational demands, have enabled the development of transportable, rapidly deployable modular manufacturing platforms. As a result, several companies are now integrating advanced process, automation, and modular technologies to support decentralized and point-of-care manufacturing models.

Several vendors offer software solutions for real-time production management through process automation and control systems, data management and analytics, Industrial Internet of Things (IIoT) and digital twins to enhance efficiency. Some key vendors are AVEVA, Siemens, Rockwell Automation, Emerson, and SAP.

Despite technological progress in transportable and point-of-care manufacturing, commercial adoption remains limited. Most medicines and vaccines are still produced in centralized facilities due to challenges in ensuring consistent quality, navigating regulations, and lacking strong economic incentives [19].

DIGITAL IT PLATFORMS FOR TRANSPORTABLE AND POC MANUFACTURING

Although digital IT platforms play a crucial role in enabling and managing any manufacturing system, their importance is amplified with transportable and point-of-care medicines manufacturing operations. Digital IT platforms provide essential tools for monitoring, controlling, optimizing, and ensuring the quality of manufacturing processes. The unique challenges of decentralized manufacturing make the adoption of a variety of digital solutions essential to the success of this paradigm.

Cloud-Based Manufacturing IoT Platforms

By their very nature, modular transportable manufacturing systems will have a significant dependency on cloud-based manufacturing IoT platforms to remotely monitor and control