

## Technology-enabled Transformation of Local Pharmaceutical Manufacturing, Distribution, and Patient Engagement in sub-Saharan Africa

Africa is home to 11 percent of the world's population but carries 25 percent of the world's burden of disease, and yet it consumes less than 1 percent of global health expenditure.<sup>1</sup> Unmet health needs due to limited access to high-quality and affordable medicines, vaccines and diagnostic tools result in high morbidity and mortality, creating a vicious cycle of poverty, disease, disability and death. In economic terms, the direct and indirect impact of malaria, one of many diseases afflicting the population, results in an estimated US \$12 billion annual income loss in Africa, which translates to a 1.3 percent annual loss in growth domestic product (GDP) in malaria-endemic countries.<sup>1</sup> To meet the unmet medication needs of its population, Africa still relies heavily on imports and global non-profit organizations to procure medicines produced elsewhere. Over decades, efforts to increase local production of high-quality medicines in sub-Saharan Africa (SSA) have met with limited success. Africa, which is similar to India in population size, has fewer than 400 drug manufacturers; whereas India has more than 10,000 drug manufacturers.<sup>2</sup> As a result, more than 80 percent of medicines are imported, and a significant volume of what is produced locally does not meet the "current good manufacturing practice" (cGMP) standards.<sup>2</sup> Unstable supply, and infiltration of substandard and falsified medicines into the supply chain,<sup>3</sup> limit and delay patient access to needed treatments. The positive health impact and economic potential of a self-sustaining regional pharmaceutical production and distribution ecosystem remain untapped.

Med Aditus is mobilizing technologies that will bring about exponential change in pharmaceutical manufacturing ecosystem in SSA. The state-of-the-art **modular continuous manufacturing technology** will be deployed and a **blockchain-powered digital quality management architecture** will be integrated into the manufacturing and distribution/supply chain operations. Med Aditus will build the pharmaceutical manufacturing facility in Kisumu, Kenya, with a **pre-engineered portable customized factory system (Podtech™)** in a **partnership-driven business model** to produce and distribute high-quality pharmaceutical products at affordable prices in Kenya, for the East African market and subsequently for exports across the African continent.

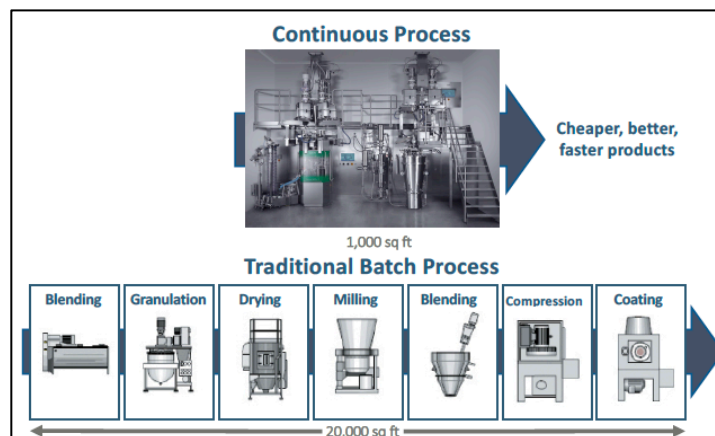
### Portable Continuous Modular Manufacturing

Several multinational pharmaceutical companies have invested in the development of the Portable Continuous Modular Manufacturing (PCMM) technology with the goal to decentralize manufacturing and create regional production capacity. Over the past few years, these companies have been transitioning their operations from the traditional batch manufacturing to continuous manufacturing, and this transition will continue to accelerate. This technology is the future of pharmaceutical manufacturing. Med Aditus plans to deploy this PCMM technology in SSA in partnership with the Kisumu County Government ([www.kisumu.go.ke](http://www.kisumu.go.ke)) – it will be the first PCMM system deployed in Africa.

The advantages of PCMM over the traditional batch manufacturing process are:

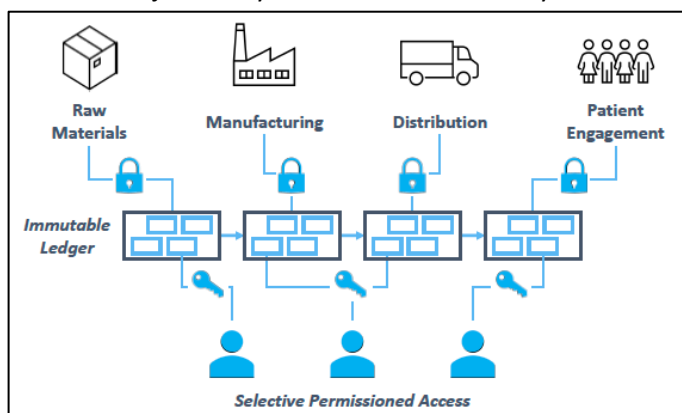
1. Compact footprint, yet high production capacity
2. Operations integrated into a single unit

3. Continuous production, 24/7 operations
4. From mixing to tablets in minutes
5. Process Analytic Technology (PAT) for real-time quality control
6. Real-time product release
7. Readily scalable over wide range of lot sizes
8. Quick changeover among different products
9. All these features reduce cost of production and produce high quality medicines



### Blockchain Data Architecture for Quality Management, Supply Chain Integrity, and Patient Engagement

Med Aditus acknowledges that trust in the quality of the medicines that are manufactured locally or imported from Asia is justifiably low. This trust can only be earned by consistently developing and deploying high-quality



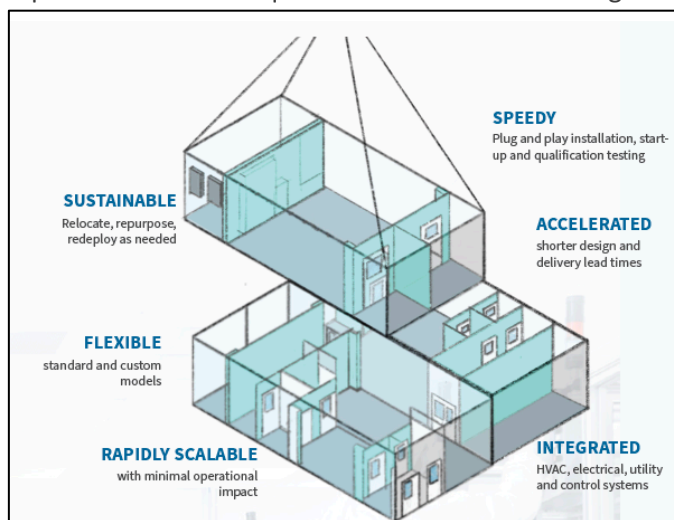
processes and producing high-quality products, and ensuring chain of custody and product integrity throughout the distribution operations. Blockchain data architecture, which encompasses immutability of data combined with automatically generated audit-trail, is the answer to a lack of trust in product quality and product security across the pharmaceutical sector in Africa. Med Aditus will deploy a blockchain-powered quality management system in partnership with Rymedi

([www.rymedi.com](http://www.rymedi.com)), a company specializing in healthcare application of blockchain technology. The system will provide several important benefits:

1. The block-chain-powered electronic quality management system will enable cost-effective and sustainable implementation of the cGMP standard in manufacturing operations
2. The blockchain architecture of the system will make it possible for Med Aditus to seek expedited product approvals by sharing real-time cGMP compliance data with regulatory agencies
3. Such innovations will strengthen the regulatory system in sub-Saharan Africa, a key factor in driving the growth of pharmaceutical manufacturing in the region
4. The system will help create a secure and efficient supply chain, and reduce the prevalence of substandard and falsified medicines
5. Blockchain will enable development of patient-reported data on medication treatment adherence and health outcomes without divulging patient identity and sensitive information. These data will assist healthcare authorities and global health organizations to promote better policies and practices for improving health outcomes.

## Pre-engineered, Portable Biopharma Factory Systems - Podtech™

Med Aditus plans to build a facility in partnership with Podtech™ Lifecare Pvt. Ltd. ([www.podtech.company](http://www.podtech.company)), which will comprise custom-designed pods to meet the specifications and requirements for manufacturing Med Aditus products. Podtech™ is a cost-effective start-to-finish solution for rapidly scalable pharmaceutical product development and manufacturing. Each unit is a cluster of single or multiple modules (podules™), available in standard or custom models. Every podule™ is a modular prefabricated construction, comprising a weather-proof, seismically designed, reinforced steel structure, and vinyl flooring. The HVAC, electrical, utility and control systems are integrated into the unit. Each unit, in customizable configurations, is built by Podtech entirely offsite and shipped to the manufacturing site whole and pre-validated. The structure can be relocated, repurposed, and redeployed, which can lower the carbon footprint and achieve sustainability goals cost-effectively. With short design and delivery times, plug and play installation, start-up, and qualification testing, the operations can be rapidly started and scaled with minimal operational impact.



## Societal Impact of the Project

Med Aditus predicts that upon adoption of these highly customizable and scalable technologies, the local manufacturing capacity in SSA will be scaled up rapidly by several fold, decreasing the dependence of the continent on imported and donated medicines. Furthermore, Africa's technology enabled scaling of pharmaceutical production will allow it to become an exporter of medicines like India and China. Patients will benefit by improved access to affordable high-quality medicines since it is well established that medicines contribute significantly to the quality of life and to increase in life expectancy. Med Aditus' plan to collect and disseminate patient-reported data on medication adherence and health outcomes using the secure blockchain data platform will help governments, healthcare agencies, and global health organizations in their strategies and planning for improvement in healthcare. The growth of the manufacturing sector as well as improvement in healthcare will spur economic development in the region. By leveraging the blockchain data architecture, which enables permissioned sharing of specific data sets, Med Aditus will pursue regulatory innovation by providing real-time access of the operations and processes to the regulatory agencies for virtual and remote oversight of c-GMP compliance.

## Project Details

Med Aditus' initial project site is in Kisumu county, Kenya, where the County Government has offered to lease 15-acre land to Med Aditus, provide the necessary infrastructure, and apply for the gazettelement of the land as


Special Economic Zone, which will qualify Med Aditus for financial and administrative incentives offered by the Kenyan government. The manufacturing operations can begin in three years upon receiving the funds. The project costs are estimated at US \$25 million, comprising (i) \$20 million capital cost for manufacturing machinery (two production lines), blockchain quality management system, and facility pods with associated infrastructure; and (ii) \$5 million for personnel and operations over first two years. By developing strategic partnerships (e.g. Med Aditus, Rymedi, Podtech, Kisumu county, equipment companies – Glatt, Gericke), and by engaging regulatory authorities in the planned technology/regulatory innovations, Med Aditus expect to de-risk the project significantly. For example, the continuous manufacturing line will be assembled, tested, and qualified before it is shipped to Kenya for re-assembly. Similarly, Podtech will assemble and qualify the manufacturing space before shipping it to Kenya. The partners will provide long-term technical support, training, and maintenance of the facility. Med Aditus is requesting the African Development Bank’s support to put together financing of the project. Med Aditus is prepared to bring other institutions, such as Global Fund, into the financing discussions.

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*References cited in the document are hyperlinked to the original sources.*

