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## A call to action for pharma manufacturers: Rise to the challenge of global medicine access with the help of digitalization

Operational efficiency and visibility brought on by digital transformation can help improve how pharmaceutical manufacturers do their critical part in improving equitable access and availability of medicine around the world.

By RAMAN BHATNAGAR, June 10, 2022

In the last few decades, technology advancements have been pivotal in improving global access to health practitioners and diagnoses. Even in rural areas and lower income countries, patients are often able to communicate with medical professionals via telemedicine, a resource that was previously unheard of. This has made healthcare more accessible, but without a way to “download” actual medicine, availability challenges remain. According to the World Bank and World Health Organization, [half of the world](#) lacks access to essential health services.

Global pharmaceutical companies are rising to this challenge, starting to embed access to medicine into their business practices. For instance, Pfizer just [announced](#) it will sell its patented drugs at non-profit price in low-income countries. And, according to the Access to Medicine Foundation’s [2021 Access to Medicine Index](#), progress is being made – other leaders like GSK and Novartis have mature approaches in place to improve access – but there is more to be done, and pharmaceutical companies have a responsibility to take action. According to the Index, “Pharmaceutical companies have a unique role to play here, as they have the capacity to develop urgently needed health products and to improve products’ availability across socioeconomic divides.”

In parallel, pharmaceutical companies are embracing digital transformation, the FDA’s Advanced Manufacturing initiative and the International Society of Pharmaceutical Engineers’ (ISPE) Pharma 4.0 framework to improve efficiencies and faster drug manufacture. In fact, according to a

2021 [research](#) study, *Culture Reimagined: How Pharmaceutical Firms Can Use Data and AI with Confidence*, companies that have a more advanced digital culture use data effectively across all aspects of drug manufacture. Eighty percent of such “digital culture leaders” in the research say their vaccine manufacturing capacity will be significantly impacted by digital technologies going forward.

There is certainly no easy or “one size fits all” solution to how pharmaceutical companies can better contribute to global medicine access. But for those that are prioritizing access-to-medicine strategies as a top business priority or initiative for the [UN’s Sustainable Development goals](#), digitalization is a viable path to turn to. Digitalization is already improving the efficiency and visibility of drug and vaccine manufacture, and it could also help pharma companies improve their access strategies in remote areas of the world or low- and middle-income countries.

### Improving manufacturing efficiencies

Digitalization is allowing pharmaceutical companies to experience efficiencies that were simply not possible 10 years ago. Digital technologies are having a ripple effect on everything from product quality and yield to on-time delivery. Digital transformation is optimizing outcomes across the entire pharma value chain and evolving traditional supply chains to be more resilient. Take electronic batch records as just one example of digital transformation. Electronic batch records, coupled with automated product release, contain the logic and rules

that enforce manufacturing workflows, improve data integrity, minimize opportunities for error, and limit held inventory waiting to be released. In another example, predictive and prescriptive maintenance give pharma companies sufficient warning that a piece of equipment is degrading. They can take action before a costly breakdown occurs or avoid taking equipment offline for scheduled maintenance that may not be needed.

The more efficiencies that are gained, the quicker and more cost-effectively a drug can be commercialized. When production is leaner, there are fewer faulty batches, quicker time to market and overall reduced production cost. [According to McKinsey](#), pharmaceutical companies show an estimated 70% improvement in overall equipment effectiveness with the use of artificial intelligence. Naturally, this can have a trickle-down effect on pharma’s ability to make medicine more available and less expensive, without sacrificing margins.

### Optimizing for better drug design

Considerations for how novel and mass-market drugs will be made available in underserved areas are not always factored into the up-front design of the medicine, and this often limits distribution. Once a drug is approved, it is cumbersome and expensive to re-configure manufacturing processes and subsequent revalidation. This means specific distribution needs that may be required for vaccines in remote areas, for example, are not easily accommodated. We saw this with the Covid-19 vaccine, which required cold chain storage. Cold chain storage is difficult in rural, tropical climates, and has made global Co-

vid-19 vaccine distribution challenging.

Digital workflows powered by data are bringing drug design considerations to the fore. Digitalization has been transformative in the visibility and insights pharma manufacturers have gained across the value chain. With more data, that can be optimized with Industrial AI and advanced analytics, pharma manufacturers are empowered to learn from existing processes and improve drug design.

For instance, modern Process Analytical Technology (PAT) is a powerful enabler of quality by design principles and process analytics. It allows manufacturers to monitor critical quality and performance attributes to ensure final product quality in a compliant environment. Modern PAT ensures stringent process design, monitoring and control, rather than resorting to identifying poor quality by inspection after the fact.

Digital technologies like PAT that improve drug design and mitigate issues before they arise, can help accommodate for, and de-risk, distribution variables that add complexity to global medicine access. Critical decisions on how to get new drugs, as well as common drugs for chronic conditions like diabetes, into the

hands of underserved communities can be thoughtfully considered with more visibility and foresight into the entire drug design and manufacture process. Decisions such as where a drug or vaccine will be manufactured, the cost, how it will be shipped, requirements to administer, and local clinic accessibility, no longer need to be made retroactively.

### **Uniting efficiency and visibility in the drug manufacture process**

For pharmaceutical companies that endeavor to improve their access strategies, they could consider starting early in the pipeline with small batches of new drugs. The incurred business risk is smaller when access is considered at the onset of small batch drug design and distribution, and efficiencies are already embedded into the manufacturing process with the help of digital solutions. Then, with a successful initiative under its belt, the organization has a proven framework to scale going forward as it builds and improves upon its access strategy.

As the population grows, so will the demand for medicine and the pressure on the pharmaceutical industry to rise to meet

the challenge of a more sustainable world. Operational efficiency and visibility brought on by digital transformation can help improve how pharmaceutical manufacturers do their critical part in improving equitable access and availability of medicine around the world.



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As a seasoned professional with more than 20 years of experience, Raman has a proven track record of leading business critical transformations. Raman is a change manager with a strong technology and operational excellence background. He most recently served as CEO at Camo Analytics, the market leader of a compliant analytics suite for PAT in GMP environments. AspenTech acquired Camo Analytics in 2020.

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