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Operations and Pharmaceuticals & Medical Products Practices

Operations can launch the next blockbuster in pharma

Pharma operations has long centered on avoiding missteps, especially in quality and compliance. But with the Fourth Industrial Revolution, operations could launch pharma's next innovation blockbuster.

by Ulf Schrader

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Most of the time, imagining the future involves little more than linear extrapolation—noting where we are now, the path taken to get here, and simply extending. But what if we put ourselves in the mindset of a Steve Jobs (Apple), or Elon Musk (Tesla), or Jack Ma (Alibaba)? How would they set up pharma manufacturing and supply? What would a more radical imagining look like? Let's give it a try with a few potential hallmarks of future pharma operations.

A radical reimagining of the future of pharma ops

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. A biotech batch record can comprise 5,000 to 45,000 manual entries! This is not just time consuming but also bears a high risk of errors. Many companies, therefore, have "batch right the first time" initiatives to eliminate mistakes. Nevertheless, the biggest delay in batch releases is related to the quality function, specifically, missing batch information and the cumbersome clarification process.

No time spent on data collection and documentation

In the pharma company of the future, standard documents would be generated automatically and all information would be documented and checked automatically, so a batch could be released in real time unless there was a critical process deviation. The technologies to facilitate this exist today—many companies invest in electronic batch records, and with increasing automation equipment, data can be used directly. In addition, one could imagine documentation systems similar to the Amazon Go store to document human interventions. Amazon uses sensors and video systems with deep-learning algorithms to track and document shopping behavior in their physical stores. No cashier is needed; the shopper just walks out and receives the bill on their smartphone.

Apart from the impact that "no-touch" documentation will have on cost, there is an even bigger benefit for compliance. In the past, systems were not transparent, but when applying artificial intelligence (AI) in pharma operations, it quickly becomes apparent that the quality of the underlying data is often very poor. Since the vast majority of the data was not used in the past, their poor quality was not a problem. Once these data are used to train AI models, however, it is critical that the data are correct. Empirical studies on human error show that accuracy is only 91 percent when documentation tasks are done manually, making an even stronger argument for automation.

No-touch supply-chain planning and scheduling

Unlike its longstanding priority position in other industries, supply chain was not considered a critical capability by many pharma companies until relatively recently. In a stable sales environment—with just a few key products and markets (notably, the United States) accounting for 90 percent of profits and ample inventories of eight months—the task was simple. Today, the situation has changed. Pharma companies' portfolios are growing in size and diversity, and volatility on both ends of the supply chain (from sourcing to sales) is increasing. So far, however, the systems and capabilities in pharma lag behind those of companies in other industries. In the future, we can expect that AI will manage supply-chain planning and scheduling. Wherever applied, we see that AI and, sometimes, even simple statistics are superior to human planning, leading to better forecast accuracy, less inventory, and more capacity.

In online businesses, we see no-touch supply chains delivering remarkable performance. We also see the first examples in pharma of digital twin planning and scheduling. The models mimic all the constraints that exist, such as demand, lead times, and equipment capacities, but also shelf life, different market authorizations, number of people on shift on a given day, and batch sizes. Instead of using master

data that are always hard to maintain, the models use real demonstrated performance and variability. Today, about 10 percent of staff is involved in planning and scheduling activities. In the future, these activities can be fully automated with only a small number of specialists to manage and maintain the systems. The main benefit, however, will be better utilization of the infrastructure, which currently shows an average utilization of only 40 percent.

Doubling asset productivity

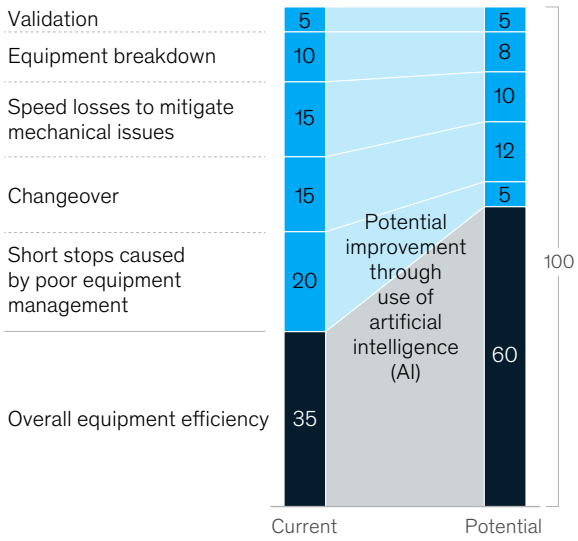
The average asset utilization in pharma, measured as overall equipment efficiency (OEE), is 35 percent. The main reason for such significant underutilization is poor management of the equipment, which leads to many, albeit short, stoppages. Often, the equipment is run slower to mitigate the impact of the mechanical issues. Over the years, tablet presses and the filling-and-packaging lines have become faster and more complex. The monitoring of the equipment and training of operators, however, has lagged behind. AI offers the opportunity to change this similar to the way it has changed Formula 1 racing over the last decades. During a race, gigabytes of data are collected, stored, and analyzed to optimize cars' settings and design. A similar approach is now used in pharma to increase the equipment speed up to the technical limit, and beyond, while adjusting critical machine settings, material specifications, and operator procedures to avoid stoppages. With the power of AI, companies can increase OEE by 50 to 100 percent (Exhibit 1).

At an industry level, the impact is huge. Based on an industry cost curve, which considers global demand as well as installed capacity and current asset productivity, only 30 percent of all sites globally would be needed if OEE were to increase to 60 percent. In other words, 70 percent of sites would become redundant and the associated cost could therefore be avoided, freeing up substantial resources for reuse (Exhibit 2).

Exhibit 1

AI has the potential to help pharmaceutical companies significantly increase their equipment efficiency.

Performance,[1] %



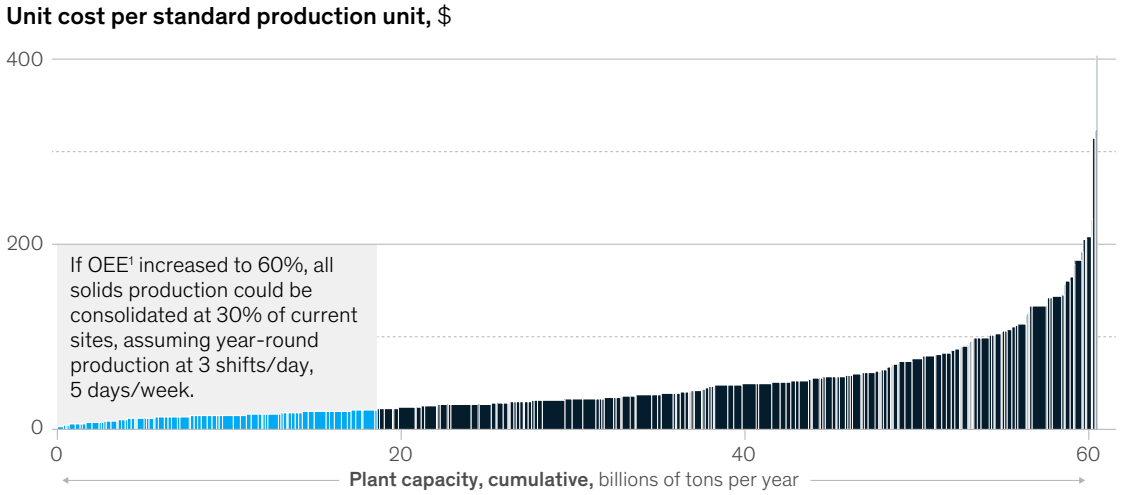
[1]Sample size: >27,000 pieces of equipment.
Source: McKinsey POBOS benchmarking database

Zero deviations

We see a world in which we can predict quality and avoid deviations before they occur. For example, we see autonomous vehicles on the roads today that navigate through new and moving environments and take decisions in real time to drive safely. In pharma, it had been a priority project to predict quality, especially as it relates to pharmaceutical regulation and the FDA. The industry issued several ICH guidelines on this many years ago. So far, however, there are only a few examples of drugs that are controlled within their defined design spaces and released immediately. But more and more efforts are being undertaken within the legacy portfolio. Based on several years of batch history, it is possible to understand and prioritize process-critical parameters and to simulate the influence they have on the batch outcome, notably, the conformity of the batch to specifications.

Exhibit 2

Increasing overall equipment efficiency from 35 to 60 percent would affect pharma production dramatically.



[1]Overall equipment effectiveness.
Source: McKinsey POBOS benchmarking database

Batch simulation is a reality today. It allows the industry to continuously reduce the number of quality tests to maintain a focus only on input controls. Today, 25 to 30 percent of manufacturing costs relate to quality—particularly quality-control lab costs—but the future promises a world where lab testing is the rare exception. Ultimately, we expect this much deeper understanding of process and product to lead to the near elimination of deviations based on a closed-loop system, which adjusts the process parameters in real time. The business process to manage deviations and CAPAs (corrective and preventive actions) is today absorbing a big portion of the senior management capacity in manufacturing.

A prerequisite for this zero-deviation future is to build historian systems, to store more data that can be leveraged, and to deploy additional sensors to collect information that is often missing today. Next-generation equipment should also be able to use the resulting insights and provide advanced process control—an all-too-common gap that nowadays is left to operators to bridge, with all the risks inherent in human intervention.

Pharma companies and OEMs often struggle to work in longer-term partnerships to drive this degree of innovation. The relationship typically remains largely transactional, which is very different from industries such as automotive.

‘Amazonification’ of the supply chain

We see a continuously increasing share of online purchases for many goods, including pharmaceuticals and medical devices. Amazon has entered into this segment through the purchase of pharmacies in the United States. So far, safety and regulatory concerns have kept this a slow-moving trend, especially for prescription medicines. COVID-19, however, has made a big impact on consumer behavior and regulations. It is therefore

more likely today that an electronic drug prescription from a doctor will be filled online and shipped directly to the patient. This requires pharma companies to connect their supply chains end to end to ensure speed and reliability. These patients are also consumers, who are now accustomed to having food delivered in 30 minutes and shoes delivered in a day. Their expectations for getting their drug prescriptions filled will be similar, as will their ability to choose a performance ratings—of 5 stars or of 2.

This new setup will also generate new data on patient preferences, behavior, disease evolution, and complaints. Banks and retailers have built strategic capabilities in online marketing, something that pharma companies also need to build going forward. While this is not strictly a supply-chain topic, it offers opportunities for the supply chain to design patient-centric offerings that make a difference.

Remote support for smart factories

In a world where pharma factories are connected to the IoT and a digital twin of the pharmaceutical production process, and supply chains are accessible from anywhere in the world, we see fewer reasons for indirect workers to be co-located at the manufacturing site. Considering the challenge in building new specialized skills to run a network of smart factories, as well as the risk of having "humans in production" in the context of COVID-19, we see more and more reasons to build hubs with control towers. Planning, quality investigations, maintenance support, audits, and operational-excellence projects can be run (largely) from these hubs. They are different from offshore locations that are built to execute transactional tasks, in that the transactional tasks would be largely automated through robotic process automation (RPA). Highly skilled knowledge work—which cannot be automated—would be supported through these hubs, which would have state-of-the-art technical infrastructure, advanced knowledge-support systems, and systematic talent-development and knowledge processes.

In silico launches and transfer

In other high-tech industries, where efficiency of both cost and time are in focus, new products are developed in computer-aided design systems and tested in simulators: airplanes, cars, and ships are all designed and optimized this way. We do not see this in pharma yet, but with more and more development projects for personalized drugs or drugs targeting small patient populations, and an increasing share of accelerated approvals for breakthrough therapies, development speed is becoming more critical in pharma. Any acceleration translates to faster time to market and, with this, huge value for patients and pharma companies.

In addition, a simulator could revolutionize the product-transfer process. In some industries regulators have pushed for the use of in silico testing, assuming that it would give a better understanding of quality and performance than a series of real-world tests. Why would this reasoning not be applicable to pharma, where we transfer products within our network without running validation batches? Transfer times would be reduced from months (or years) to a few days. Simulation would support a reduction in the underutilization of pharma networks, which often is the result of inflexibility and the inability to move products around.

We are seeing the first exciting steps toward in silico batch modeling, but more effort is needed to see the full potential.

A blockbuster opportunity

The World Economic Forum launched an initiative on the Fourth Industrial Revolution (4IR) some years ago. The objective was to scan the world and find "lighthouses" across industries that demonstrate the "art of the possible." To date, 44 lighthouses[1] have been identified, and two are pharma sites (Bayer, Garbagnate and GSK, Ware). The criteria for designating a company as a lighthouse includes more than just the adoption of breakthrough technology. Lighthouses have also achieved a step-change business impact and demonstrated profound changes in site operations.

[1] Stated number of 44 lighthouses reflects the status in Q1 2020. The number of global lighthouses are continuously increasing; the latest status can be found on the World Economic Forum website.

Launching a blockbuster in pharma is a company-wide effort requiring laser-sharp goals and the involvement of top talent.

Not surprisingly, the impact came in different flavors: productivity, quality, speed, agility, capacity, or working capital, to name a few. The percentage improvements ranged widely and had different associated values depending on the industry, but improvements of 50 to 90 percent were common across the various metrics. This shows the potential for pharma as a whole—and this is just the beginning.

Recapping the potential impact: 70 percent of pharma sites could be freed for other uses; 30 percent of labor spent on documentation could be automated; the 25 to 30 percent of resources allocated to quality testing, investigations, and release could be either removed or automated; and effective capacity could be increased by ten-plus percentage points through a digital twin for planning and in silico development. This would translate to a reduction of 80 to 90 percent of conversion costs. Based on cleansheet simulations, we estimate lead times to go down by about 60 percent and quality levels to go from three to five sigma levels.

These numbers seem high at first glance, and, indeed, they do not consider the new systems and skills needed to operate these systems or the continuing investment needed to drive the innovation process. These costs are not insignificant. But, even if we assume that only a 50 percent reduction in conversion costs is realistic, this would mean a value of $3 billion for a top-ten pharma company. And the value that comes from higher agility, faster time to market, and near-perfect quality might be equally high—although harder to estimate.

Does this forecast pass the common-sense test? Have we seen this before? Yes. Over the last century, employment in agriculture has gone down by 96 percent. The time to do genome sequencing went down by 99 percent, the inventories in Apple's supply chain went down by 95 percent, and the time for mortgage approval in banks went down by 98 percent. The list goes on. The point is that the improvement turns out to be much higher than people dared to believe at the outset. Why should we expect something different for the 4IR in pharma?

How to capture this opportunity

How do you launch a blockbuster? You appoint a leader who reports to the CEO, establish a cross-functional launch team, double down on your clinical program, establish governance for stage-gate reviews, and, above all, ensure that there is enough funding to maximize the asset. It is a company-wide effort with laser-sharp goals that involves top talent and takes place on the fast lane because every day counts.

How does this contrast with what we observe? A lack of funding, no payback, IT gaps, a lack of data scientists, technology immaturity, and limiting regulations are among the many reasons we hear for why a company's current strategy is relatively limited in its objectives. But are these arguments valid in

light of the above discussion? We see preparedness of senior management as a main limiting factor. Their past accomplishment was good execution in comparatively stable industry setup, but today, pharma needs visionary leaders who can drive innovations in their organizations. Just like the head of R&D, operations executives should be the ones to bring the science, technology, and business judgment together to decide where to double down and what to drop. The ability to make sound judgments, however, requires a good to very good understanding of the science and the technology.

Today's pharma leaders should be equipped to answer, with confidence and clarity, the following questions:

— What is the difference between machine learning and deep learning?

— What is the difference between the primary data layer and the feature layer?

— Where can you use APIs (application programming interface, not active product ingredient)?

These and similar questions are often hard for executives to answer, so they delegate these matters down in the organization and make tactical decisions rather than bold moves. Despite the fact that digital, analytics, and automation should be what senior executives spend the majority of their time on, based on their value and strategic nature, operational tasks nevertheless continue to dominate the senior executive's agenda. To get upskilled to the appropriate level, senior executives should dedicate one day a week or more to deepening their understanding of these increasingly critical tech topics.

In addition to a change in focus by senior management, other shifts need to happen. Often, the entire organization operates from a "make the budget, cut the budget" mindset. Increasing price pressures on the less innovative part of the industry only reinforces this perspective. What is needed instead is more design thinking. This is a view on strategy that puts the focus on what the patient or the operator would value, which is then translated in a creative and unconstrained process into a design vision, for example, for a planning tool.

The second skill required to turn this vision into a reality is developing agile ways of working. The concept of agile originated in the software-development industry, where projects took too long to complete and often failed to fully meet end-user needs. It builds on the idea of bringing the right people together to solve the problem irrespective of hierarchy or department. It also democratizes information, so everyone is best equipped to contribute, and organizes the team process to run and test a minimal viable product before investing months and years into full development.

Lastly, we see that pharma sites continue to compete for volume. In addition, they now compete on digital use cases. In this fragmented setup, pilots are often not scaled or scalable, and projects are often scoped to drive either infrastructure upgrades (for example, electronic batch records, MES) or incremental improvements (for example, electronic KPI dashboards). Pharma companies should take a global approach with a certain level of alignment and governance to drive innovation at pace and achieve scale on impact.

Disruption or incremental change?

We have described the blockbuster opportunity in operations and also the gap we see in how most companies tackle this. We have outlined the changes in capabilities, leadership, and culture that could close this gap. So, what happens next?

If we look at other industries, we see two triggers for disruptions on this scale. The first one is being caught in an existential crisis. Interest rates, for example, are currently at historic lows in much of the

world, which makes it very hard for banks to make money. This is why banks had to completely rethink their private-banking models and build digital banks to rebase their cost structure. Today, pharma still enjoys margins of around 30 percent, making it unlikely that it will face a similar situation.

The other possible trigger is that one player develops a vision through sheer management will and forces the other players to react. These disruptors often enter from the outside. Tesla is an example. It made the electric engine the new normal and forced others to react. By December 2020, the market cap of Tesla exceeded that of the next nine largest automakers combined. In pharma, this scenario may be more likely than the existential-crisis scenario, and it may be the trigger that drives a wave of fundamental change across the industry. The reality, however, is that we don't know what will happen. In pharma operations, we may see a disruption, or we may continue to see only incremental change.

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