

strategy&

*Digitization
in pharma*

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**Gaining an edge
in operations**



Contacts

Berlin

Peter Behner

Partner, PwC Germany

+49-30-8870-5841

peter.behner

@strategyand.de.pwc.com

New York

Dr. Marcus Ehrhardt

Principal, PwC US

+1-212-551-6421

marcus.ehrhardt

@strategyand.us.pwc.com

About the authors

Dr. Marcus Ehrhardt is an advisor to executives on life sciences strategy with a special focus on strategy-based transformations. Based in New York, he is a leader in the life sciences strategy business within Strategy&, PwC's strategy consulting group. He is a principal with PwC US.

Peter Behner is the pharma life sciences sector leader for Strategy& in Europe, the Middle East, and Africa, and he leads PwC's European health industries practice. He covers clients in the pharmaceuticals, healthcare, biotech, and medical device industries. He is a partner with PwC Germany based in Berlin.

Executive summary



The digital revolution has been disrupting business and daily life, and the pace of adoption is accelerating. Executives across industries are executing digital transformations as part of their corporate strategies. The first wave of the digital revolution focused on using technology platforms and data analytics to better understand customers — and, in the case of life sciences companies, to better understand patients in order to increase patient engagement and develop new go-to-market approaches. However, the next wave of the digital revolution is about transforming operations.

The pharmaceuticals and life sciences industry has been very cautious in applying digital technology to improve manufacturing and supply chain operations thus far, yet that caution is becoming a hindrance. As the pharma industry faces growing challenges — including globalization, great supply chain complexity, price and cost pressure, and personalized medicine, among others — digitization holds tremendous potential in helping companies adapt.

By applying digital technology, companies can significantly increase visibility into their supply chain operations and make better and faster decisions. Digitization allows companies to fully integrate their supply chains and improve operational processes, making them more adaptive and responsive. As a result, planning accuracy, manufacturing efficiency and productivity, inventory levels, and service levels improve.

Capturing this opportunity requires building a digital supply chain ecosystem, including virtual supply chain control tools, cloud-based information architecture, and a digitally enabled physical supply chain. When these elements come together synchronously, humans, machines, and resources communicate as a cyber-physical system, leading to improvements in all stages of the operations value chain: plan, source, make, and deliver. Moreover, companies need a structured road map for implementation that addresses risk factors such as cybersecurity.

Digitization is a complex task and risk factors like cybersecurity are concerns, but as other industries that are more advanced already show, digital transformation offers a clear opportunity to gain a competitive advantage. Given the rapid pace of change in technology, pharma companies need to make digitization of their operations and supply chain a priority, starting today.

The opportunity to digitize pharma operations and supply chains

The digital revolution continues to disrupt business and daily life, and the pace of adoption is accelerating. Smartphone users worldwide now number more than a billion. Projections estimate that, by 2020, there will be 50 billion connected devices. And in five years, 80 percent of companies are expected to have a digitized value chain in some form.

The pharmaceuticals and life sciences industry is generally quite advanced in its application of technology. Regarding operations, however, the industry has been very cautious in adopting new technologies thus far, still relying on supply chain and manufacturing paradigms that have been around for a long time. One key reason is the regulatory environment in which pharma companies operate. High margins have traditionally been another reason, leading to a stronger focus on new product development and sales rather than on optimizing operations.

Yet evolving industry trends pose significant challenges for the pharma industry, specifically with regard to operations and the supply chain. Consider these escalating challenges:

- A global market requires that companies operate across geographies with an ever-growing number of SKUs, which makes supply chain management, regulatory compliance, and life-cycle management increasingly more complex.
- The number of supply chain partners (suppliers, contract manufacturers, wholesalers, distributors, and third-party logistics partners, among others) is higher than ever before. A lack of integrated planning across the network hinders real-time decision making.
- Increasingly competitive price (and therefore cost) pressures require more efficient operations and supply chain management. Currently, many companies operate with cumbersome, inefficient networks that struggle to respond to dynamic shifts in supply and demand.

- More complex product portfolios and an increase in personalized medicine call for greater customer and supply chain segmentation, challenging companies to produce low volumes efficiently.
- A growing risk of counterfeit drugs demands greater transparency and tracking in the value chain, so that companies can monitor the supply chain from end to end.
- Rising regulatory scrutiny around the world calls for better quality control and more visibility. Companies need better access to data about products in transit and at global nodes.

Digitization holds tremendous potential to help pharma companies address these challenges. In all industries, companies are improving operations through a set of emerging technologies collectively known as Industry 4.0. Specifically, that term refers to new tools and processes that are enabling smart, decentralized production via intelligent factories, integrated IT systems, the Internet of Things, and flexible, highly integrated manufacturing systems.

Industry 4.0 is a term that represents the fourth industrial revolution and was originally an initiative introduced by the German government to link resources, information, objects, and people, creating an “Internet of Things and Services.” (The first three industrial revolutions were mechanized production, mass production, and automated production, respectively.)

For the pharma industry, digitization and Industry 4.0 have the potential to significantly transform supply chain operations, fundamentally improving processes and boosting productivity. Specifically, digitizing the supply chain will allow companies to address the above-mentioned challenges by enabling the following:

- *Real-time visibility and faster decision making.* Sensors throughout the supply chain can transmit information on an ongoing basis, providing real-time insights across the value chain and enabling sales and operations leaders to make dynamic decisions in response to changing conditions. This will allow significantly shorter lead times — days rather than weeks or months. Paired with better planning accuracy, this will reduce stockouts, and ultimately save patients’ lives.
- *Improved operational processes and maintenance.* Pharma plants typically experience high levels of downtime. Through digitization and analytics, this downtime can be reduced by 30 to 40 percent, significantly improving overall equipment effectiveness (OEE). Innovative software solutions and analytics can integrate data,

Through digitization, downtime in pharma plants can be reduced by 30 to 40 percent.

transforming information into actionable metrics. Machine-to-machine communication and machine-learning algorithms allow for seamless processes, predictive maintenance, and automatic corrective actions.

- *End-to-end supply chain integration and greater network scalability.* Pharma companies have extremely complex supply chains, including suppliers of raw materials (from active pharmaceutical ingredients to packaging material), contract manufacturing organizations (CMOs), third-party logistics providers, wholesalers, and distributors to hospitals, pharmacies, dispensing doctors, and patients. Through digitization, including cloud computing, companies can develop global integrated supply chain networks. Cloud-based networks make it much easier to link all players through a single integrated network, even those with different IT architectures or ERP systems, thus making networks more scalable.
- *Manufacturing efficiencies and productivity gains.* Automation and digitization can deliver major manufacturing efficiencies in areas such as filling, loading, replenishing, and troubleshooting. Technological innovations such as 3D printing can make decentralized production cost-efficient even at low volumes. Advanced robotics and augmented reality will provide a step change in human-machine interaction and automation.

The bottom line: Digitizing the supply chain can help pharma companies significantly improve their supply chain and operations performance and ultimately strengthen their financial outlook. When implemented effectively, digitization of the supply chain gives pharma companies a true source of competitive advantage.

The digital pharma supply chain ecosystem

We are still in the early stages of the digitization in pharma, and many executives are struggling to define what “digital operations” really means. There is a tremendous amount of noise and hype, and systematic, structured frameworks are lacking. Based on our research and work with clients, a digital supply chain includes three synchronized layers that form a robust ecosystem (*see Exhibit 1, next page*).

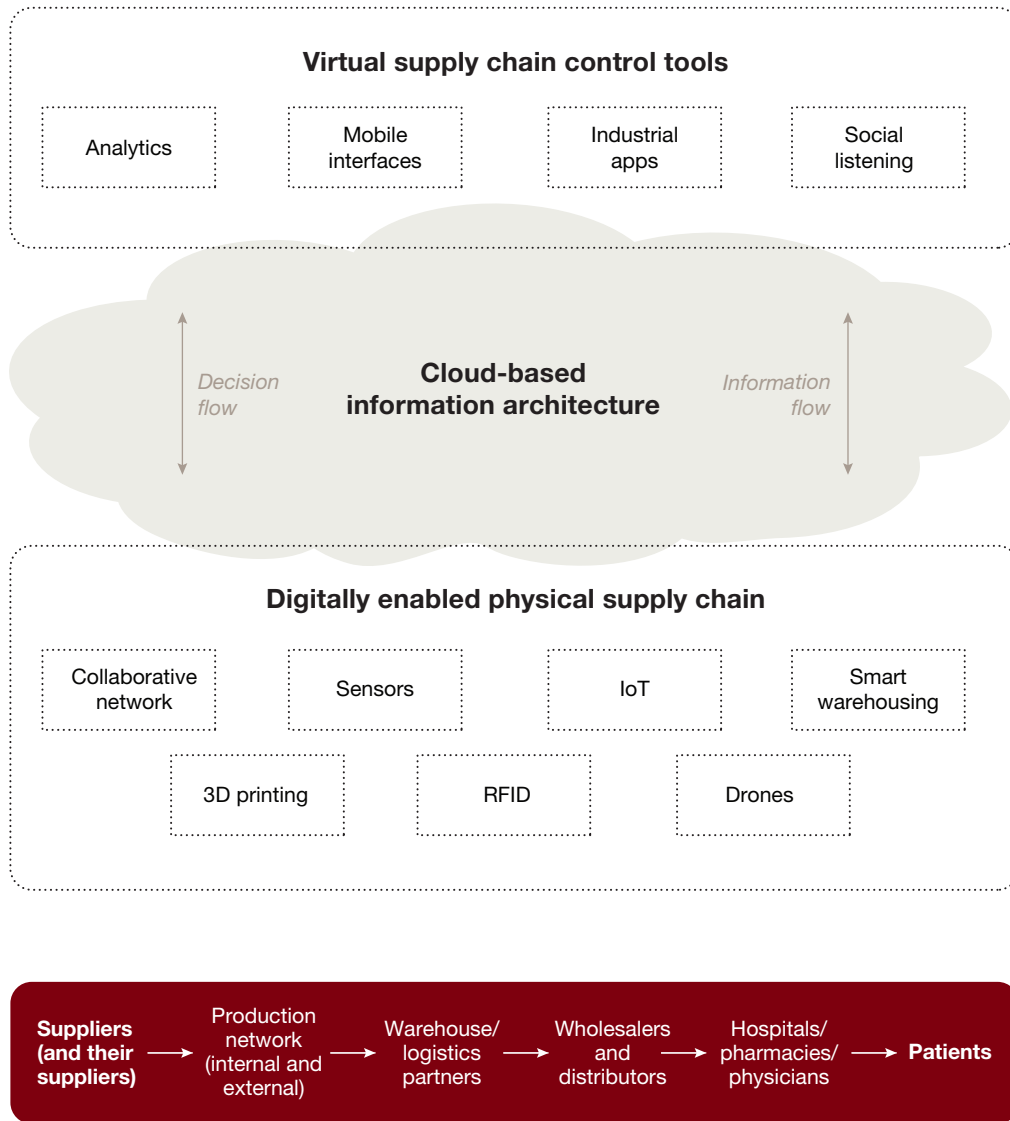
Virtual supply chain control tools

The first layer is a set of virtual tools that provide mobile, collaborative, and dynamic decision-making interfaces, allowing supply chain managers to oversee and manage operations across the entire supply chain. Data from all elements and nodes of the supply chain — raw material suppliers, CMOs, factories, warehouses, distributors, logistics partners, and hospitals/pharmacies/physicians — is processed by data analytics tools and is accessible via computer and mobile devices. Industrial applications and optimization tools run analytics, generating insight on all aspects of operations and the supply chain — such as demand/supply orders; inventory levels; goods in transit; manufacturing performance by plant, line, and individual machine; utilization; and many other metrics — and enable managers to make real-time decisions.

With these tools in place, managers have full access to and transparency on any supply chain parameter, and they can run comparisons by product, plant, production line, supplier, or business partner. Similarly, they can analyze their risk exposure and get suggestions for handling unplanned incidents, or figure out how to further improve their current processes, not only within the enterprise but across all interconnected supply chain elements — all on a handheld mobile device.

Not only do these tools offer analytics results presented in useful visualizations — allowing managers to interact with data to make

Exhibit 1
The digital supply chain ecosystem



Source: Strategy& analysis

real-time decisions — but they also send immediate notifications to help monitor operations and address problems that might arise.

Cloud-based information architecture

The second layer is the information backbone — a cloud-based IT architecture that enables rapid computing for different types of data and systems from the physical network across all nodes of the supply chain. This architecture provides flexibility in physical assets and in managing the network of supply chain partners, since participants can easily be added/integrated or deleted. Furthermore, cloud computing is built over existing ERP systems at various nodes, allowing for easy integration and scalability. Collecting, translating, and storing all data in the cloud makes it accessible to everyone at any time via multiple databases (rather than the prevailing approach of isolating information in silos).

Digitally enabled physical supply chain

The third layer is the actual physical supply chain, including all elements, devices, manufacturing units, storage, and logistics. These elements are now digitally enabled as “smart” components of the system, constantly providing and exchanging real-time data via sensors, RFID tags, wireless transmitters, and other technologies, and — with the first two layers in place — bringing the Internet of Things to life in the pharma supply chain.

Imagine smart factories with manufacturing lines containing thousands of sensors that track and report performance so adjustments can be made. Machine-to-machine communication and machine-learning algorithms allow for highly integrated manufacturing processes and automatic corrective actions. In warehouses, scanning drones, packing robots, and automatically guided vehicles perform highly automated work. Materials and products transmit their location through the network. Smart storage cabinets and refrigerators in hospitals and pharmacies track and report consumption data and replenishment requirements.

When all three layers come together and work in a synchronized way, cyber-physical systems are formed, so that humans, machines, and resources communicate as in a social network. This fundamentally transforms the supply chain from today’s mostly segmented/silo structures into truly integrated supply chains. Companies can implement innovative applications in all key areas of the operations value chain: plan, source, make, and deliver (*see Exhibit 2, next page*).

Exhibit 2

Digital pharma operations applications

Plan

- Real-time supply chain monitoring
- Near-real-time scheduling
- Demand management
- Inventory replenishment
- Compliance management
- Supply chain optimization
- ...

Source

- Automated order processes
- Online/mobile approval
- Enterprise-level spend analysis and dashboards
- Supplier relationship and quality management
- Contract management
- ...

Make

- Real-time shop floor and production flow monitoring
- Automated, real-time process analytics
- Equipment downtime monitoring
- Predictive maintenance
- Additive manufacturing/3D printing
- ...

Deliver

- End-to-end product visibility (supporting track-and-trace initiatives)
- Automated product stocking
- Automated inventory and delivery via drones
- Improved internal logistics via automated guided vehicles
- ...

Source: Strategy& analysis

Plan: Digitally enabled planning

In recent years, the planning capabilities of all industries, including pharma, have been significantly enhanced via new tools both within and on top of ERP systems. Yet companies still struggle to generate true end-to-end visibility across the network, and visibility is even harder among supply chain partners, due to disconnected/disparate systems, data incompatibility, and other challenges. Digitizing planning processes using cloud platforms and data analytics applications enable true collaborative planning among suppliers, manufacturers, trade and logistics partners, and customers such as hospitals and pharmacies. Regardless of what types of planning or ERP systems different supply chain partners use, they can all be integrated into the cloud-based architecture. And data management processes generate a “single source of truth.”

In addition, some companies are taking a new approach to demand planning, leveraging information from completely new sources. Think of a smart refrigerator in a hospital with RFID-tagged drug packages, or smart pill bottles that transmit information on drug usage that can be used for demand planning, or Internet user data being leveraged for demand sensing.

The digital supply chain allows for real-time monitoring of every data parameter, on every node in the network, with applications that range from day-to-day planning (such as production planning or inventory management and optimization, including automated replenishment) to complex scenarios and risk evaluations not only within a given supply chain element but across the entire end-to-end chain.

Source: Digital sourcing and procurement

The digitization of sourcing and procurement processes changes how companies interact with their suppliers, as well as how they perform sourcing management-related processes internally. New procurement applications and software allow for touchless order processes, alerts, mobile approval of purchase orders, automatic invoice creation, and other ways to make procurement more seamless. These solutions — typically cloud-based — also offer spend-related analytics that provide valuable insights into all procurement-related activities, synthesized in easy-to-navigate dashboards that enable smarter procurement decisions.

Make: Digital manufacturing

The Industrial Internet — seen as the fourth revolution of industrialization — includes a range of technologies that are enabling smarter and more decentralized production. Pharma executives who want a glimpse of what's possible can look to other industries (like electronics or auto manufacturers) that are further along in their application of these technologies.

For example, companies such as Siemens, with its Digital Factory offering, are investing heavily to offer digital production solutions for their customers in many different industries, including decoupled, fully flexible, and highly integrated manufacturing systems with dynamic, flexible (rather than sequenced) production lines. Similarly, GE's Brilliant Manufacturing suite, a software platform that GE uses for its own production and also sells to other companies, optimizes manufacturing through real-time analytics, process monitoring — such as predictive maintenance and bottleneck identification — and sensor-enabled automation. In a smart factory, RFID chips guide carriers that are integrated into the production process and move freely and independently to individual units for functions such as filling, closing, or labeling. Smart factories allow humans, machines, and resources to all be connected via cyber-physical systems that communicate as in a social network. (GE itself plans to increase the connectivity of its machines and materials by 400 percent this year.)

In short, digitized production allows pharma companies to improve OEE, increasing throughput and quality and reducing machine downtime. And in the near future, we expect new production techniques — including continuous manufacturing, robotics, and additive manufacturing of drugs (such as 3D printing) — to break through the boundaries of today's pharma production environment, which is driven by scale and challenged by increasing complexity and the trend toward personalized medicine. Some may call this science fiction, but the first 3D-printed drug was approved by the FDA in 2015.

Deliver: Smart warehousing and distribution

Warehouse operations today are still highly manual and labor intensive, but that will soon change. Already, digital innovations in warehousing and distribution are emerging, particularly in the logistics sector. One of the cutting-edge users of RFID tags is Amazon. The company's tag readers can find the desired product, box it, and prepare it for shipment without human involvement. All that's needed is a final manual inspection to make sure the order is correct and packed properly.

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Similarly, some online mail-order pharmacies are highly innovative in how they apply technology and run extremely automated processes.

More broadly, product serialization and track-and-trace regulations (implemented in response to the growing issue of counterfeit drugs) will require companies and supply chain partners to build new digital capabilities — such as barcoding and RFID tagging — to better control material flow and ensure patient safety. But the use of these technologies and data capabilities should not stop here; rather, companies should take additional steps leveraging the technology to improve supply chain performance. For example, RFID tags in the warehouse can facilitate automated picking systems, and scanning drones can help to provide inventory information. In distribution, RFID-tagged pillboxes and storage cabinets in hospitals will generate data that will enable the automated replenishment of drug stocks.

Additionally, drone technology has the potential to complement the current wholesale-to-retail distribution network. Drones offer myriad benefits: Delivery to hard-to-reach locales becomes easier and more economical; direct warehouse-to-consumer shipments become feasible; and medications needed on a regular basis can be delivered on a set schedule right to a customer's doorstep.

Global shipping companies are starting to test the delivery of drugs to remote locations via drones. In Rwanda, a startup company is testing the use of drones to deliver drugs to hospitals. And in Switzerland, Matternet is using drones that determine their own flight paths to deliver medicines to and pick up medical samples in hard-to-reach places.

Success factors and risks

Pharma companies that want to digitize their operations and supply chains face a complex task. They must develop solutions not within their own four walls but in alignment with many external partners along the supply chain, even as the technology continues to change rapidly. To meet this challenge, companies will need to be very open and overcome highly entrenched ways of working and resistance from organizations and employees who are overly accustomed to familiar processes that have been in place for decades. Moreover, there is a good deal of hype to cut through and risks to manage. And regulatory aspects add an additional layer of complexity — not only new requirements for companies but also a dynamic environment in which regulators face a learning curve as well.

There are several key success factors on this journey. Companies need to start with a clear understanding of the ecosystem and evolving technologies. They also must have the right resources in place, including a cross-functional team of experts and the requisite capital to make needed investments. Collaboration with partners is crucial if players are to develop truly integrated end-to-end supply chain solutions. And — critically — companies need to recognize that this is a journey and will require prioritizing a few projects, including a mind-set of experimentation and learning by doing.

At the same time, pharma companies will need to manage several key risks and concerns. The biggest concern regarding digitized operations that our clients report is cybersecurity. As with the financial sector — which continues to be the target of cyber-attacks — pharma executives fear the threat of hackers getting control over digitized physical assets and machinery. Similarly, ensuring secure flows of sensitive data on the cloud (including demand, supply, pricing, and contract information) is a baseline requirement that cannot be emphasized enough.

Also, with such a wide range of technologies and rapid development cycles, the industry will require some level of standardization to ensure interoperability among different systems and devices. Policymakers and industrial associations can help with these challenges in particular, by advocating uniform industrial standards and promoting efficient rules for data security and data protection.

The biggest concern regarding digitized operations is cybersecurity.

How to get started

Pharma operations executives should start the digitization process today, potentially giving themselves a head start over the competition. To do so, we suggest following a structured four-step approach (see Exhibit 3):

1. First, the core digital operations team should scout the technology landscape and develop a deep understanding of the possibilities and the overall digital supply chain ecosystem.
2. Define the company's overall digital operations strategy for three to five years into the future (aligned with overall company strategy and its differentiating capabilities). Assess the potential from specific technologies and prioritize among them to define a starting point, including a business case.
3. For identified priority areas, design solutions — including process, organization, and technology elements — and launch pilot projects.
4. Scale up successful projects and roll them out across the company. In parallel, develop the required digital capabilities within the company.

Exhibit 3 Road map to a digitized pharma supply chain



Source: Strategy& analysis

Conclusion

Digitization has the potential to fundamentally transform pharma operations, opening the door to step-change improvements in performance. Pharma companies should get started on this journey, taking immediate steps to digitize their operations and supply chains and develop a strategy and road map for the next three to five years. Those companies that seize the initiative can give themselves a sustainable competitive advantage; operate with greater agility, cost-efficiency, and control; and ultimately provide better care for patients.

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