Deloitte.

The digital edge in life sciences:

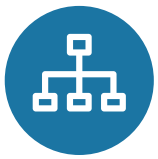
The business case for digital supply networks

Contents

Key considerations

The life sciences industry may not be taking full opportunity of the **benefits from the digitization** of the supply chain. A majority of life sciences companies are slow to adopt **digital supply networks**—this slow pace can expose challenges with value creation (page 2).

The life sciences industry is under pressure to deliver more value. Its pipeline paradigm, valued on the ability to develop and bring drugs or products to market, has led the industry to mainly **focus on growth rather than value**. But several factors are exerting pressure on the industry to create more value. These factors include the diminishing returns on R&D, rising costs and complexity of new therapies, **value-based and personalized health care**, as well as expectations of digitally savvy customers (page 3).



Digital supply networks can help the life sciences sector deliver more value. Based on the use of **advanced technologies such as machine learning** and additive manufacturing, digital supply networks can provide data flow and analytics, connectedness, and electronic tracking, and enable the merging of physical and digital worlds. These features can lead to lower costs, **higher efficiencies and capacity use**, **faster innovation and delivery, better product yield,** and improved compliance (page 6).

Creating a digital supply network typically requires a different approach from simply improving or **upgrading the existing supply chain.** With the advent of digital supply networks, traditional considerations are mapped against the new, more **transformational considerations** enabled by new technologies (page 11).

Staying competitive: Supply chain as value creator

The digital revolution is creating new possibilities for employing cutting-edge technologies. Companies across all industries have been transforming their business models, creating new products or services, improving operations, or enhancing distribution channels. Many companies have seen not only increased efficiencies and savings thanks to digital solutions but also significant revenue increases.

Digitizing the supply chain in life sciences has significant potential for improving business outcomes. An overwhelming majority of life sciences companies (94 percent) agree that supply chain can make a real contribution to the bottom line of any business—moreover, it can also play a key role in the fulfillment of wider business objectives.[1] Supply chain leaders recognize the importance of acting as business leaders. They see business skills, such as communication and influence (89 percent) and business strategy (87 percent), dominating a supply chain executive's profile by 2020.[2]

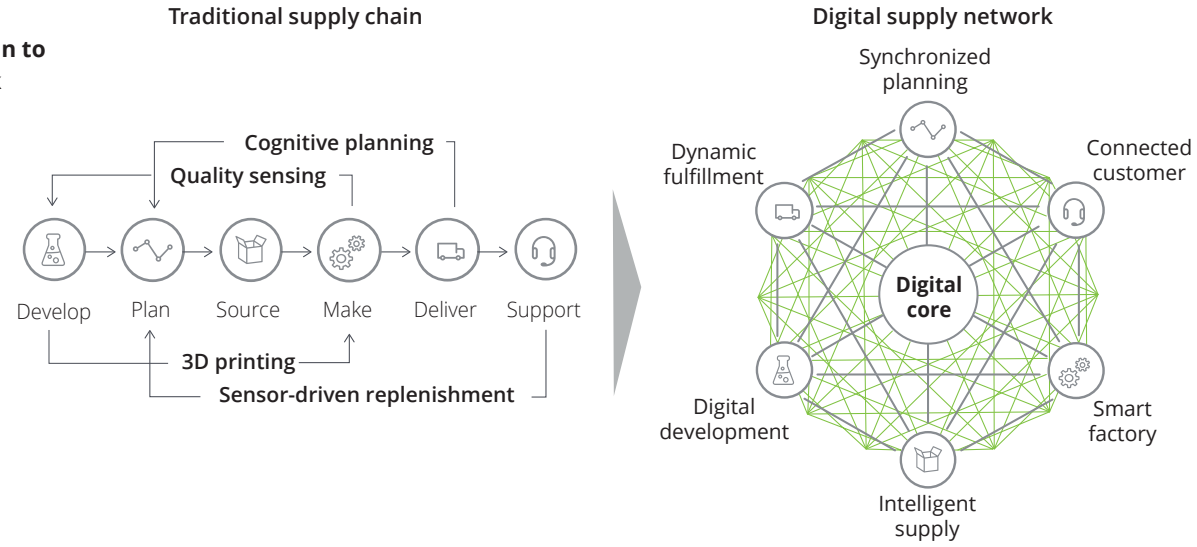
Business benefits can be achieved by transforming a traditional supply chain into a digital supply network. Unlike traditional supply chains, which are linear and siloed, digital supply networks are dynamic, interconnected systems that can more readily incorporate ecosystem partners and evolve to a more optimal state over time. This shift from linear, sequential supply chain operations to an interconnected, open system of supply operations could lay the foundation for how companies compete in the future.[3]

Many organizations already on the path to creating digital supply networks are using them to focus more holistically on how digital supply networks can become an integral part of strategic planning and decision making. The digital maturity of industries, and their level of adoption of digital supply networks, depends on many factors. Generally, the more customer-centric the companies, the more developed their capabilities, such as data and analytics.

This is one reason consumer products and retail typically lead in the maturity of these areas. The pharmaceutical and health care industries, on the other hand, tend to be at the opposite end of the scale. A majority of life sciences companies are slow about taking full advantage of the potential of digital supply networks. Less than 15 percent have actively embraced the possibilities offered by cloud computing and big data.[4]

The sector's low level of maturity in terms of digitization of its supply chain exposes challenges with optimal management of inventories, reliability and visibility of products moving across the supply chain, or operations efficiencies and product yields. In view of the forces affecting life sciences—pricing pressures, the emergence of value-based and personalized medicine, and the expectations of customers and regulators—creating a digital supply network can be a logical way to deliver value.

Figure 1: Shift from traditional supply chain to digital supply network



Triggers for digital supply networks in life sciences

How digital supply networks can help alleviate pricing pressures:

- Help control inventory levels, decrease waste, and increase capacity utilization by applying inventory tracking and analytics
- Predict maintenance and increase equipment uptime by utilization of connected sensors and machine learning
- Cut compliance costs and prevent compliance-based business disruptions by using data-driven methods

Pricing pressures

Based on a historical blockbuster drug growth paradigm, the life sciences sector has enjoyed healthy growth rates and achieved one of the highest profit margins across all industries. Its pipeline paradigm, valued on the ability to develop and bring drugs or products to market, has generally led the industry to focus on growth rather than value. But the pressures to increase efficiency and decrease waste have grown dramatically over the past few years.

Significant blockbuster drug patent expirations from 2012 through 2015 mean that many companies are now pouring money into R&D to boost their pipelines. Adding to the pressure, the costs of bringing a new medicine to market have never been higher. Deloitte's analysis of 12 leading biopharmaceutical companies shows that the costs of the traditional, fully integrated pipeline process from idea to R&D to commercialization have increased from $1.188 billion in 2010 to $1.539 billion in 2016.[5] Deloitte's analysis[6] reveals that annual R&D returns for large biopharmas declined from 10.1 percent in 2010 to 3.7 percent in 2016. This time around it is the biologic drugs, which are more complex and expensive to develop, that are expected to be the growth engine of the pharmaceutical industry, increasing the need for capital.

Health care reform and the shift to value-based medicine generally means that buyers of pharmaceutical or life sciences products need to deliver impactful patient care but with fewer resources, and they are not willing to pay blockbuster prices. Moreover, drug pricing is becoming a hot political issue globally, with societies balking at high drug prices. In the United States, for example, a couple of recent attempts at price increases were met with significant opposition. Additional factors exerting pricing pressures on the sector include increased regulatory compliance and globalization of health care, with governments negotiating lower drug prices.

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Personalized medicine

Personalized medicine is no longer a thing of the future. The approval by the FDA of tests developed by personal-genomics company, 23andMe, gives patients an opportunity to better understand their health risks for Alzheimer's or blood disorders. Empowering patients with information about their genetic proclivities means they will likely expect medications to ameliorate the risks presented by their specific genetic profiles. Kite Pharma is developing innovative cancer treatments that involve removing a patient's immune cells, engineering those cells to identify cancer, then infusing those cells back into the patient to kill cancer cells. Juno Therapeutics, which also develops personalized cancer treatments, stresses "the power of individualized treatment."

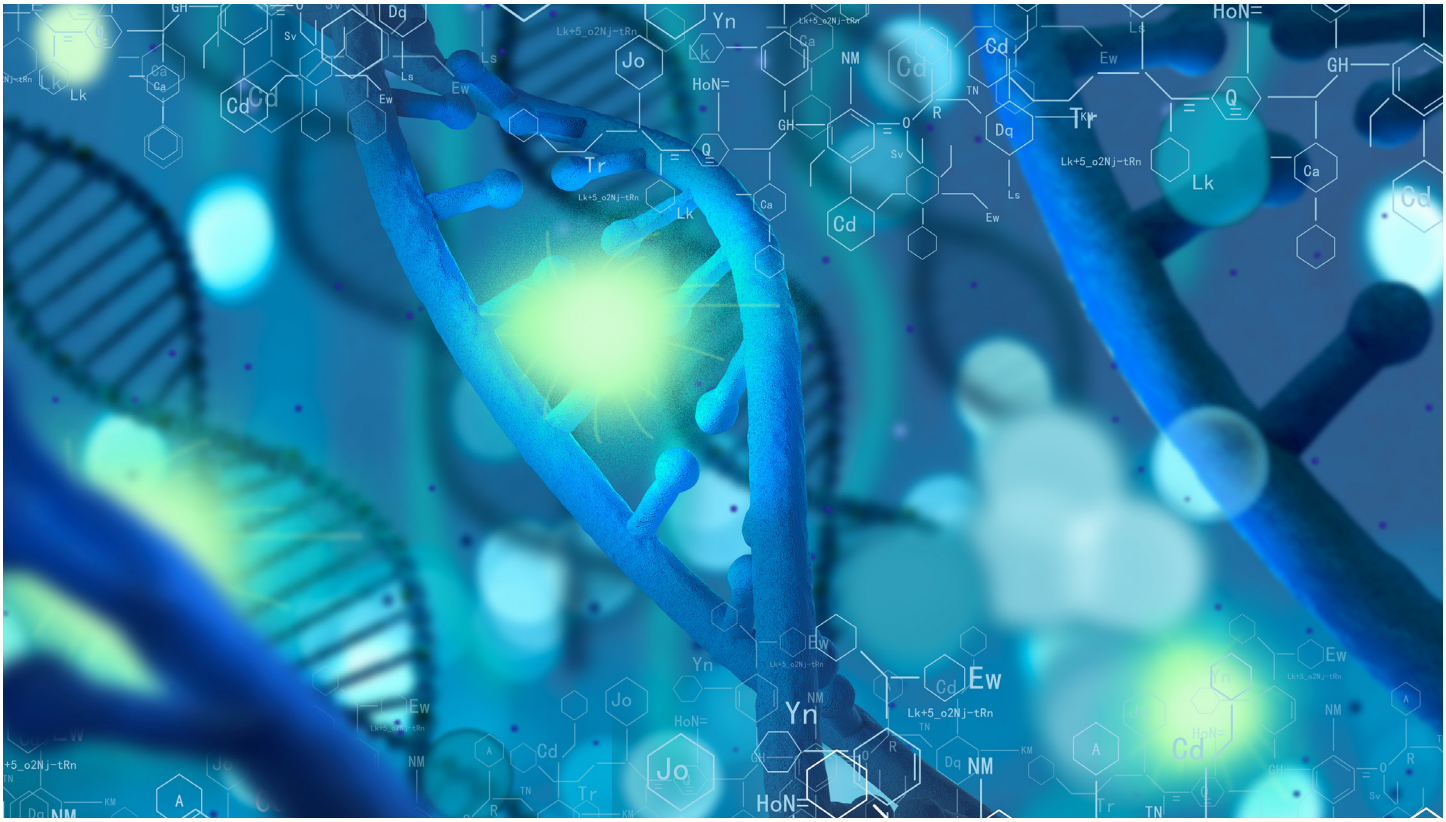
The manufacturing, dosages, and distribution of personalized medication can be exponentially more complex, expensive, and technology- and data-intensive than is true for chemical drugs. Personalized cancer treatments require blood to be collected, shipped, processed, shipped back, and re-injected. To ensure patient safety, it typically requires a complex supply chain, which needs to be carried through and recorded at every step, something that is next to impossible without a connected, electronic data transfer across the supply chain.

Thanks to technologies such as additive manufacturing (also known as 3D printing), medical devices—dental or knee implants, for example—are also best "made to order" based on specific patient geometry, thus improving outcomes.

The potential for medical outcomes from the personalized approach is reflected in the sector's growth projections. The US global personalized medicine market is forecast to reach $2.4 trillion through 2022 at a compound annual growth rate (CAGR) of 11.8 percent—more than double the projected 5.2 percent annual growth for the overall health care sector.[7]

How digital supply networks enable personalized medicine:

- Design and production of customized medical devices or medicines becomes possible thanks to technologies such as 3D printing and data analytics
- Transportation and delivery of personalized medicines is enabled by the connectedness, transparency, and speed of the digital supply network



Expectations of tech-savvy customers and regulators

The life sciences sector does not operate in a vacuum. Blurring of the lines between industries and the idea that there is just one single customer means that life sciences should meet the expectations created by the digital revolution. Just like any other industry—think of the impact of e-commerce on traditional retailers or the shift to self-driving technologies by traditional automakers—the life sciences sector is ripe for change. An increase in online pharmacy operators typically requires manufacturers to change their traditional sales and distribution models and become faster, more transparent, and more efficient. This is not going to happen when it takes inventory four months to move through a traditional supply chain.[8] Almost every executive from every industry cites Amazon when asked about customer experiences. Customers expect the quality, visibility, and speed of fulfillment that today's technologies enable, which is possible with a digital supply network in place.

Regulators are also increasingly expecting companies to conduct data-driven investigations, and to demonstrate the ability to trace design of manufacturing modifications, or prove the resolution of the root of a problem with a data trail. While the intense regulatory environment may be a challenge, it can also become an opportunity by applying digital supply networks. Another highly regulated industry, financial services, also runs on compliance. Its digital investing is typically geared for compliance at first, but financial executives are beginning to realize that their technology investment will go much further if they use it for other areas, such as becoming more customer-centric, for example. The life sciences sector has an opportunity to become more digital-driven and data-centric not only in compliance but also in business outcomes.

How digital supply networks meet customers' and regulators' expectations:

- Hospitals can get the supplies they need when they need them and cut waste thanks to electronic tracking and connectedness of digital supply networks
- Regulators receive data-driven reports or results of investigations thanks to data and analytics

Specific benefits for the life sciences sector

Provider enablement

A digital supply network can deliver on the ability to hit the market with the right products, of high quality, manufactured in target volumes, and delivered at the right time to the right customers. Such an ability can have a double benefit. It can provide customers with what they need so they can deliver health care, leading to better patient outcomes. It can also help life sciences companies, which are among the industries with the highest inventory-to-revenue ratios,[9] to better control inventory. Not surprisingly, demand sensing (demand planning, forecasting, and management) is the area where digitization will have the biggest impact (51 percent).[10]

Doctors in hospitals need to have the necessary devices at the ready in the operating room, and hospitals need to be able to locate all the surgical devices in their cabinets. Nurses can spend as much as 30 percent of their time searching for products that may or may not be used during a procedure—that is more than two hours per shift per nurse.[11] Such lack of visibility generally leads to financial losses. High-cost, high-value cardiological medical devices and implantables, such as stents and pacemakers, continue to flow through a highly inefficient supply chain. The inefficiency in the medical devices market alone leads to an estimated $5 billion in waste annually.[12] Hospitals spend more than $36 million per year on wasted orthopedic hip and knee arthroplasty implants.[13]

To stem their losses many hospitals and health care systems have been pushing responsibility for inventory management to their suppliers, resulting in a myriad of inventory models—and exposure of manufacturers. Manufacturers are currently managing many different types of inventory, with typically more than half of inventory being held either on consignment or by sales reps. This can make it more difficult to accurately account for supply levels, location, ownership, and usage, which further complicates billing and replenishment, and can lead to excess inventory. Vendor representatives also spend a considerable amount of time managing inventory on behalf of customers.[14]

A digital supply network can help eliminate waste from the system for both manufacturers and providers. Surgical kits are a good example of an area ripe for improvement. Typically, they contain several types of devices and are sold on consignment. Without digitization, hospitals generally send back the kits for re-provisioning after having used some items. After a 30-day lag, the manufacturer discovers which parts of the kits need to be replenished. To guarantee their customers enough supplies, most manufacturers keep sufficient consigned inventory, at a huge cost and a big impact on the rate of excess and obsolete inventory.

A digital supply network connects manufacturers with suppliers by, for example, having the kits tagged with RFIDs, which can be tracked by a hospital's smart cabinets. As soon as the kit or parts of it are removed, the hospital is billed, and the inventory replenishment process starts even before the other kit has been shipped back. That way, the companies are potentially able to lower consigned inventory by about 25 percent and reduce their excess and obsolete inventory by more than 50 percent.

Spine Wave, a medical device company, uses a tracking technology, iTraycer, to create a device-focused inventory management system. Sensors on the spinal equipment enable the company to remotely track individual units within a kit, replenish inventory, and activate invoicing.

According to Medical Tracking Solutions Inc., the maker of iTraycer, the technology can realize an improvement in operating margins of between 2 percent and 4 percent.

Supply assurance and risk: Data-driven visibility

When buying from Amazon, customers have complete visibility as to how their order is being processed and when it is scheduled for delivery. Such transparency and speed are possible thanks to an interconnected electronic platform, which collects and analyzes data from across the supply chain and puts it into action.

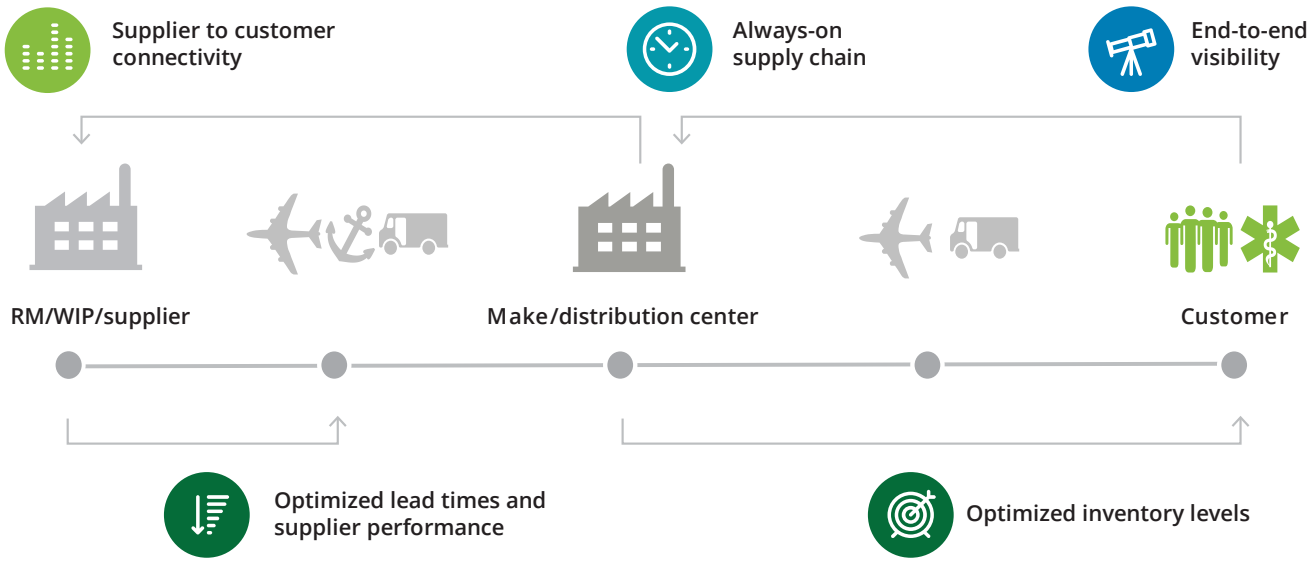
The life sciences industry recognizes the importance of data. Eighty-one percent of supply chain leaders see big data analytics as the most disruptive and important technology with respect to supply chain, during the period 2014 to 2016.[15] But while the industry is awash in data, it is generally not able to put it to optimal use. One of the issues is siloed data warehousing and databases that keep data in lockboxes, which make it very hard to access and derive insights, or even know what data is available. Data from different functions across the supply chain, including external stakeholders, could be combined, analyzed, and presented in dashboards that would, for example, alert to stock-outs or risks, such as changing of weather conditions or unavailability of certain raw materials.

But while the industry is based on science, it does not yet fully apply it to achieve data-driven business outcomes. Just 6 percent of life sciences companies have declared themselves fully on board with big data and cloud computing, while 52 percent intend to be looking at big data and/or cloud computing in the future.[16] In the meantime, vital insights can be missing, and decisions might be made based on a gut feel.

One life sciences company invested in a data-driven platform and analytical solutions for its global supply chain that allowed it to gain visibility based on data from multiple sources—and thus can understand and predict risks and events before they become issues, and take action. The heightened visibility also allows the company to make smarter decisions even when disruptions are not an issue. For example, shipping items via overnight air can be very expensive. Having a real-time insight into inventory at the destination site allows for more-informed economic decisions about shipping. This is especially important with some drug categories, such as biologics, which may require transport in specified temperatures and conditions, the so-called "cold chain." While the current state of the cold chain is likely adequate for the transport of personalized medication, necessary error rates of nearly 0 percent will pose the biggest challenge as unique medications and treatments are added to the process.[17]

Having created a data-driven platform to replace the typical reactive, fire-fighting mode of handling the supply chain, the company has significantly improved its efficiency and realized cost savings. Inventory benefits are from 10 percent to 15 percent, expedited shipments have been reduced by 5 percent to 8 percent, overtime costs have been reduced by 10 percent to 15 percent, and efficiencies due to backorder reduction have been improved by 2 percent to 4 percent.

Figure 3: Global control tower providing end-to-end supply chain visibility



Optimizing assets use: Preventive maintenance

Transfer of information helps allow manufacturing assets to be at the ready when needed by preventing unplanned downtime by using machine learning. This technology can supply information not only to address the issue that's causing current downtime, but also to alert as to what is needed to avoid stoppages in the future—what is referred to as predictive maintenance. Overall operational effectiveness, including machine uptime, is the top problem that supply chain leaders are looking to solve with digital technologies (45 percent).[18]

Technologies such as sensors and advanced analytics embedded in manufacturing equipment enable predictive maintenance by responding to alerts and resolving machine issues. A sensor can detect if a part is working within its parameters and activate a work order, automatically ordering parts or scheduling a preliminary service call.

An example of the use of Internet of Things and machine learning can be illustrated by predictive maintenance of machines used for manufacturing titanium implants. Titanium's hardness requires tools with diamond tips to cut it. The level of dullness of the diamond tips, and thus the optimal time to sharpen them, has been difficult to figure out because of many different variables that affect it. The use of vibration or sound sensors and torque monitors can help assess the state of the machinery, as dull tips move and sound differently.

The best human operators can assess the state of machinery by nuanced factors such as the amount of heat they feel on their faces coming from different parts of the machine, or from how hard it was for the molded piece to be ejected from the mold itself. To bring all other operators up to the same level, inexperienced operators can be equipped with virtual reality-type glasses that see and sense all that the experienced operators do. Such glasses can be used for detecting downtime and for guidance about the best time to perform maintenance procedures. The cost savings can run into the millions, as the cost of an hour of downtime went up $260,000 per hour, on average, between 2014 and 2016.[19]

Rapid product innovation: The merging of physical-digital

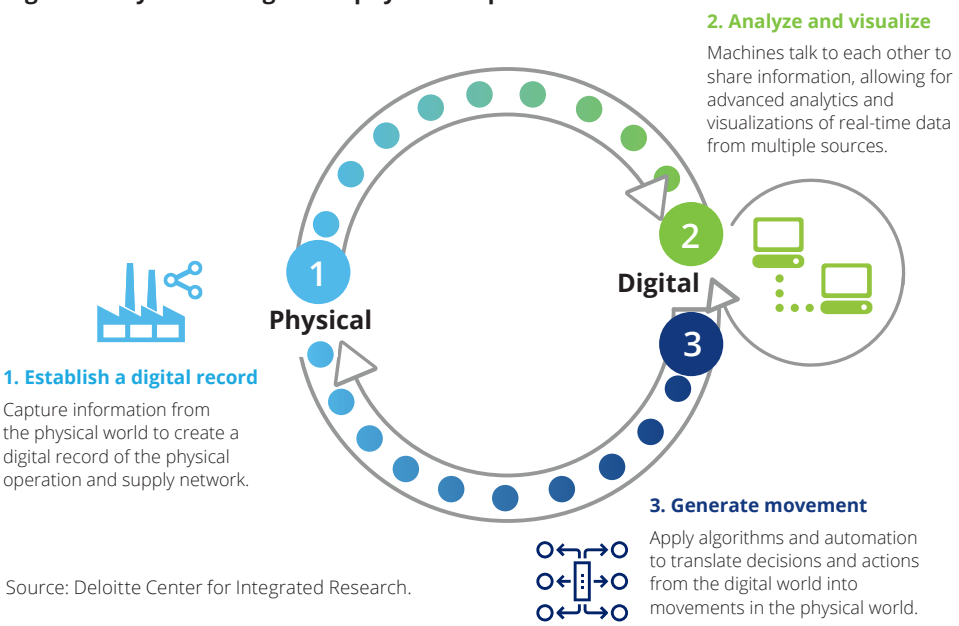
Digitization allows for merging of the physical and virtual worlds. Thanks to today's technologies, companies can create a digital twin—a model of their physical environment. It can be a specific design or manufacturing process, with the digital twin being a computer-based virtual simulation of the real thing. Designing, vetting, tweaking, or testing products virtually can be much faster than doing so in the physical world. Moving to the manufacturing stage can also be done electronically. Cutting out some of the most cumbersome and off-line elements of commercializing a product can speed up the start of production to three days after the design is finished, from three months to a year when done the old way.

Speed of innovation, design, and manufacturing is becoming even more important with customized products, which are designed to fit a specific patient. ConforMIS is a manufacturer of knee implants, customized to fit each patient's unique anatomy. The company has a proprietary iFit Image-to-Implant technology platform, which includes proprietary software and 3D-printing capabilities.

This technology platform enables a scalable business model that greatly lowers the company's inventory requirements, reduces the amount of working capital required to support operations, and allows it to launch new products and product improvements more rapidly, as compared with manufacturers of traditional implants.

It's not only good business but also better health care. A clinical study sponsored by ConforMIS[20] demonstrated that patients with the company's customized knee implants have motion patterns that more closely resemble those of a normal knee, compared with patients who have the traditional, off-the-shelf implant.

Figure 4: Physical-to-digital-to-physical loop



Source: Deloitte Center for Integrated Research.

Digital supply network-enabled quality and compliance

The quality function in the life sciences sector is used almost solely for regulatory purposes and is generally not seen as a competitive capability. Of course, compliance is a critical area. More than a third (35.6 percent) of companies in the life sciences sector reported that their companies experienced a business disruption because of a product compliance, safety, or quality-related issue within the past 12 months, compared with one-fifth (19.2 percent) of respondents across a range of industries in a recent Deloitte survey.[21] Losses incurred can be staggering. For example, the average monthly opportunity cost of an ANDA (Abbreviated New Drug Application) delay is $50,000.[22]

Compliance-based business disruptions can take longer to correct due to lack of traceability of specifications or modifications that have been made in the design or manufacturing process. In fact, regulators, such as the FDA, are pushing companies to become more data driven by issuing warnings or observations for investigations that are not supported by empirical data.

A slow response to a quality- or compliance-based disruption can have a threefold negative impact. It starts with the negative market perception around the time of the public announcement of a product recall or investigation, followed by delays in terms of responding to the regulatory agency and the enormous investment to compensate for the lack of having controls in place.

But there can be a better way to handle the inefficient and expensive practice of "putting out the compliance fires," which would not only speed up remediation but also prevent quality lapses or improve the quality of future products. This can be achieved with quality management system transformation or integrating a digitized quality management system into a digital supply network, starting with R&D and carrying through to product design, manufacturing, and service. Big data and analytics will be key enablers in unlocking the potential of disparate data and should improve the ability of companies to identify and quantify new and emerging compliance risks.

As opposed to a purely regulatory approach to quality, this approach would be business driven. Many life sciences companies maintain large and growing compliance functions at significant operational cost to ensure they maintain regulatory compliance. However, today many life sciences companies, lacking insights from data, do not know how much they spend on compliance. The initial benefit of digitizing and integrating the quality function into the digital supply network could be lowering the cost of labor. A digitized and integrated quality and compliance function can thus become a competitive advantage in terms of pricing, quality, and innovation.

Conclusion

The life sciences sector is ripe for digital transformation and can greatly benefit from digital supply networks to create value. They can help optimize operations and inventories and free up capital for R&D investment. They can also help improve customer satisfaction, fulfill regulators' requests, and speed up innovation. However, the industry needs to overcome its mind-set that the current inefficiencies are industry-specific, unique, and business as usual. There are several approaches to consider.

Identifying the business case.
Demonstrating ROI from technology investments has been tough across industries. This is especially challenging in the life sciences sector, which, because of its blockbuster-based growth paradigm and healthy margins, may not see the need for increasing value in the first place. The sector is also often not able to access, integrate, and analyze its abundance of data, and thus is often unable to calculate the cost of current inefficiencies or potential benefits. But the business case can, and needs to, be made. Both premises underlying the current mindset—high margins and lack of data analytics—should not become the hurdles that keep the sector behind its competitors. Apart from making a data-driven business case, it is also important to consider change management to deal with cultural and organizational biases.

Identifying top challenges and pain points.
Lack of an overall roadmap is seen as the top obstacle in beginning a digital pilot (45 percent).[23] Every company has its specific silos that stand in the way of a holistic transformation. Identifying these silos and pain points is especially crucial to the success of a digital supply network because the supply chain involves all functions and is a loop that needs to be integrated to function smoothly. There are some areas that may have traditionally operated separately, maybe because of different goals and incentives, that may be more difficult to integrate than others. It is important to identify these pain points of integration and devise a plan for how to incorporate them in a digital supply network. One of the top challenges is the present thinking about the separation of quality from manufacturing, which can slow down the flow because the quality function, both in terms of quality assurance and lab function quality control, lags behind.

Identifying the leaders.
Creating a digital supply network requires at least two capabilities: understanding the current inefficiencies, risks, and silos of the supply chain; and understanding the benefits of improving them with a digital supply network. At the same time, it calls for understanding of how technology integration can be used to create a digital supply network. Further complicating things, these capabilities should cover multiple functions and stakeholders, including external stakeholders. Since the creation of a digital supply network is aimed at business outcomes, it's best for the initiative to come from a business leader, who can set out goals, involve technology functions, align incentives, and be able to drive home the need for a digital supply network.

Creating a digital supply network requires at least two capabilities: understanding the current inefficiencies, risks, and silos of the supply chain; and understanding the benefits of improving them with a digital supply network.

Getting started

Recognized as a leader in digital supply chain planning and design consulting,[24] Deloitte has helped numerous clients define a digital strategy that aligns with their business objectives and enables their overall strategy against a "think big, start small, and scale fast" methodology. This approach allows organizations to think beyond functional silos and imagine a future where suppliers, providers, and customers are connected and information is shared in real time across the supply chain. Once this future-state vision is established, it is important to develop a plan based on manageable and realistic steps to begin the journey there. This allows organizations to achieve relatively quick wins and to realize immediate value while also applying learnings and continuous improvement as they go. Finally, as successes are realized, it is important to scale the benefits across the organization, and across the supply chain, to achieve the full value of digital supply networks.

Deloitte defines five distinct project types or phases to develop an organization's digital maturity.

Digital immersion

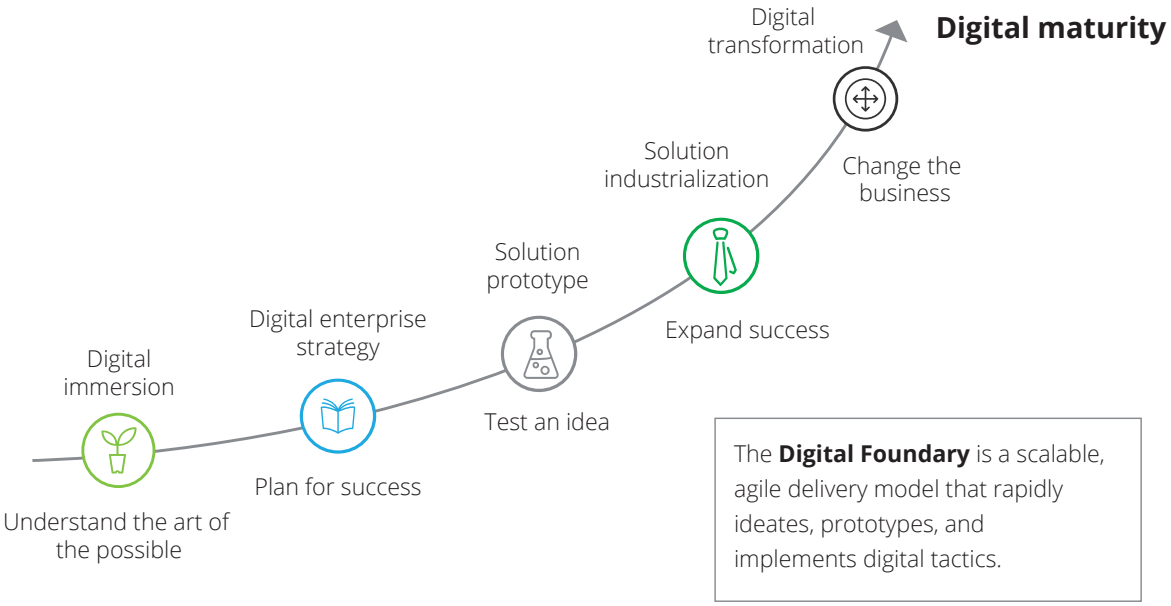
The digital immersion phase is designed to assist business and IT leaders with understanding the art of the possible: How digital technologies can be used to connect the various entities across the supply chain, providing greater access to information and enabling insights never before possible. Deloitte conducts the Digital Immersion sessions in the Deloitte Greenhouse™ Labs around the globe—cross-functional leaders from the client's organization are brought together for a one- to three-day workshop to begin to establish the future-state vision and high-level roadmap. The Deloitte Greenhouse™ Labs are state-of-the-art facilities where clients can see and demo many digital technologies—such as augmented reality wearables, 3D printing, and analytics, which can be leveraged as part of their futurestate strategy.

Digital enterprise strategy

The digital enterprise strategy phase is designed to align the client's digital strategy and roadmap with the overall business strategy and to develop the plan for success.

The digital enterprise strategy phase typically runs six to eight weeks in duration and results in leadership alignment around the digital vision and strategy as well as a prioritized list of potential initiatives to be piloted.

Figure 5: Digital project curve



Solution prototype

The objective of the solution prototype phase is to implement the prioritized set of prototypes to validate the feasibility of the digital tactics and to define the technology architecture required to support the solution. A sprint-based, agile approach is used to facilitate continuous ideation and prototyping and to provide a steady stream of prototypes to support the decision-making process. The solution prototype phase may last from one to six months, depending on the prototypes that are selected for implementation.

Solution industrialization

Solution industrialization projects are intended to expand the success from the solution prototype phase and deploy the scaled and refined prototypes across the enterprise. This also requires deployment of the plan to support the solution adoption as well as the required operating model to support the solution (e.g., processes, roles, responsibilities, and organization). A user support organization and training must also be established as well as a process for managing solution updates and upgrades.

Digital transformation

Digital transformation can establish the industrialization of multiple solutions across the enterprise, potentially resulting in a sustainable competitive advantage via continuous digital supply network transformation. It helps enable the development, deployment, and continuous improvement of multiple digital solutions and helps achieve realization of the defined strategic goals.

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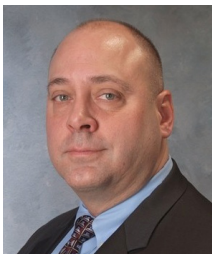

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