**Digital Transformation in Pharma Manufacturing: X Steps to Achieve Company-wide Adoption**

Digital technologies are changing the face of business. Digital transformation is everywhere, including pharma manufacturing. The pandemic, undeniably awful, did provide a push forward to digital transformation. The pandemic created a world of human distancing, and it also increased the need for more pharmaceuticals. This combination of variables created an environment ‘ripe and ready’ for digital transformation.

Even though a pharma company is ready for digital transformation, it is a big step with many challenges. To make this step even more challenging, it needs to be company-wide. In order for digital transformation to succeed, it must be done company-wide. Everyone involved needs to work together. The challenge then becomes, ‘’How to get the whole company to adopt it?’’

In the next pages, we will outline the steps needed for a smooth company-wide journey forward into the digitalization of your company’s pharma manufacturing.

**What is digital transformation?**

Generally speaking, digitalization is defined as ‘the process of converting information into a digital format’. In business, the meaning of digitalization is more expansive. For business, digitalization means improving existing business processes with the aid of new technologies. Switching from paper to digital record-keeping is one example. Digitalization accompanied by automation, whereby machines and artificial intelligence carry out processes with little to no human intervention. Digitalization can result in both productivity increases and cost reductions, but the processes themselves remain largely unchanged.

[Digital transformation](https://www.cio.com/article/240957/digital-transformation-why-its-important-to-your-organization.html) (DX) involves critically examining business processes from a customer-centric perspective and leveraging new technology including AI, to radically change and improve customer experience and business results. Digital transformations are *business* transformations. They relate directly to the business value the company is offering -and, most importantly, prepare businesses for an unsure and shifting future, safeguarding against changes in product and production, and positioning them as disruptors rather than disruptees.

It bears noting that [digital transformation](https://www.cio.com/article/230425/what-is-digital-transformation-a-necessary-disruption.html) is driven by changes in customer expectations of products and services. Digital transformation indicates that a business is rethinking its use of technology and process, the role of employees, as well its quest for novel business models and additional revenue streams.

For many manufacturers of traditional merchandise, this transformation is the building of digital products and requires that they keep pace with software companies. The premise being that there is more value created through software.

Since cross-departmental collaboration is required for successful digital transformation, the CEO, together with senior members of the business, take the lead in combining efficient application development models with business-focused philosophies.

**What does digital transformation mean for pharma manufacturing?**

[Industry 4.0](https://www.ibm.com/topics/industry-4-0) is revolutionizing the way companies manufacture, improve and distribute their products by integrating new technologies, including the IoT, cloud computing, analytics, AI and machine learning into their processes and throughout operations. Similarly, pharmaceutical companies have adapted this 4.0 revolution to the pharmaceutical industry. This revolution enabled pharmaceutical manufacturing to evolve, keeping-up with the technical evolution. Done wisely, employing available expertise and experience, the company is better able to meet the every-changing and ever-growing needs of its customers.

Digital transformation has been the catalyst for the pharmaceutical industry’s adaptation of Industry 4.0 -or [Pharma 4.0](https://ispe.org/initiatives/pharma-4.0). Pharma 4.0 is the 21st century industrial revolution of pharmaceutical manufacturing, and is the result of the rapid change to connectivity, machine-to-machine communication, data analytics, advanced automation, etc.

The Covid-19 pandemic brought a significant change to the pharmaceutical industry, exposing risks and dangers that had not been previously considered. Progressive, leading-edge pharmaceutical companies accelerated their digital transformation, gaining competitive advantage. By accelerating Pharma 4.0, digital transformation has enabled the production of systems that allow manufacturers to use resources more efficiently and prevent, or alleviate, debilitating supply chain disruption. Across the pharmaceutical supply chain, [these innovations](https://www.thermofisher.com/blog/connectedlab/the-future-of-pharmaceutical-manufacturing-your-roadmap-to-pharma-4-0/#:~:text=Digital%20transformation%20is%20enabling%20the,%2C%20data%20analytics%20%26%20advanced%20automation) push the limits of agility, efficiency and quality.

With digital transformation, the future of pharma manufacturing reflects an expectation of better alignment between product development and production processes, and less time between product conception and delivery. The next-generation manufacturing will benefit from the smarter decision making and enhanced innovation that are derived from the leveraging of data from all phases of the product life cycle -design and delivery.

**Improving pharmaceutical manufacturing and distribution**

When done well, digital transformation positively impacts the ability of the pharma company to follow-through with strategies that support its manufacturing and distribution, enabling cost effective adjustments throughout the company.

Let’s take this apart and see why this happens.

The use of IoT provides real-time information or real-time data (RTD) – this means relevant, vital information (i.e., changes or quantity of drugs ordered) can be worked expeditiously into the system, ensuring a smooth manufacturing chain.

Along these same lines, RTD collected from sensors from manufacturing units, used in combination with predictive solutions and algorithms, can be used for predictive analytics and maintenance. The RTD information, when applied to the predictive algorithms can be used to correlate the impact of multiple variables including temperature and drug component proportions, along with predicting trends with statistical precision. For example, these predicted trends can serve to alert personnel that there is Y% probability that problem X will occur during a specific time period; this alert, having been created from RTD, allows for the responsible personnel to implement preventative measures and fix problem X before it occurs. In this way, data analytic tools, which are part and parcel of the digital transformation, bolster the efficacy of the pharma manufacturing processes and provide the real-time monitoring of critical

**Benefits of Digital Transformation for Pharma Manufacturers**

Clearly digital transformation is changing the way we do business and clearly making the decision to join this transformation is necessary for any business wanting to remain relevant in the upcoming years.

While change is often difficult, we suggest that digital transformation in the pharma industry is something that should be celebrated. The world is changing. There is more information (data) that needs to be dealt with, there opportunity for drug discovery has increased, government regulation is increasingly rigorous, client (patient/physician) demands are greater in scope and number and security has never been a bigger challenge.

For pharma manufacturers, these challenges have a solid solution -digital transformation. Digital transformation is a powerful tool that the pharmaceutical industry can employ to support growth and relevancy using. Using AI to accelerate drug discovery and the digitalization of clinical trials to keep trials on time and accurately reported are just some benefits for the pharma industry as a whole. Pharma manufacturers joining the digital transformation are able to keep up with the overwhelming about of information (big data) with digital analytics and blockchain software for security is a game changer. This software enables tracking of supplies, ensures that supplies are kept in required conditions and have not been tampered with.

**Current State of Digital Transformation for Pharma Manufacturers**

[The pharma industry](https://research.aimultiple.com/digital-transformation-pharma/) is in the midst of digital transformation. Pharma manufacturers are implementing various digital technologies to improve production and provision. Currently manufacturers are seeing the benefits of this transformation with improved distribution of pharmaceuticals, reduced costs and more transparency within the supply chain.

Based on a survey published in [Pharmaceutical Technology,](https://www.pharmaceutical-technology.com/news/covid-19-accelerated-digital-transformation-of-the-pharma-industry-by-five-years-poll/) roughly one third of respondents to their survey believe Covid-19 accelerated the digital transformation of the pharmaceutical industry by more than 5 years. Digital transformation in the pharmaceutical industry is crucial for improved patient care, cost-effectiveness, greater transparency, improved production, and drug development. While the pandemic did much to propel the transformation forward, there is still a way to go. Digital transformation is ongoing and the hardiest viewpoint is that it an ongoing journey.

And now the part you’ve all been waiting for, the steps.

[Leadership](https://www.mckinsey.com/business-functions/people-and-organizational-performance/our-insights/unlocking-success-in-digital-transformations)

In order for the transformation to take place, it is key to have on-board leaders who are familiar with the digital technologies to be employed. These leaders should be engaged for transformation-specific roles (leaders who are dedicated full time to the change-effort, each with a specific initiative) and be committed to their key roles. Such leaders may have titles such as chief digital officer or technology information managers.

Define employees’ roles & hire special staff

Before beginning the transformation, it is important that the individual employees understand and are ready to ‘take on’ their roles and responsibilities that align with the goals of the transformation. Having people on board who are able to bridge the gap between the traditional and digital parts of the business.

Empower your employees

Engaging employees, reinforcing ways of working through formal mechanisms and giving employees a say on where digitalization could and should be adopted will encourage employee commitment to the changes.

Build consensus

There needs to be consensus about the priority of projects -an understanding about why the transformation is happening the way it is happening. This involves conversations with employees. This is an extension of empowerment.

Use digital tools; choose the right technology

1. Adopting digital tools to make information more accessible across the organization more than doubles the likelihood of a successful transformation.
2. Implement digital self-serve technologies for employees and business partners; transformation success is twice as likely when organizations do so.
3. Technology focused on company operations; modify standard operating procedures to include new technologies.

Define objectives and create strategy

Determine the current level of digitization and try to align the current state and long-term digital goals. This is a crucial step towards organizational synergy.

Build a feasible game plan by selecting areas of improvement and starting to integrate digital systems from those areas. The objectives should be a step-by-step process.

Ask questions

When doing digital transformation, understanding the human component and knowing what to expect from humans can help align attitudes and behaviors that will be good business. For every technology-based project, ask yourself this list of questions:

1. Who will use it?

2. How much of their job will it represent?

3. How much does the manufacturing process depend on correct human usage?

4. How much training will it require?

5. What are the consequences if technology isn’t used correctly? If it’s ignored?

6. Will this technology feel threatening to workers?

7. What will be needed to deploy at scale?

**Digital Transformation and QMS**

Before we continue, it is important to discuss the importance of compliance with GMP. [**GMP** or, **Good Manufacturing Practice**](https://ispe.org/initiatives/regulatory-resources/gmp/what-is-gmp)**,** are the regulations promulgated by the FDA. Although labeled as regulation, the GMP is law, requiring that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. Failure to comply with GMP regulations can result in very serious consequences including recall, seizure, fines, and jail time.

Furthermore, the FDA ensures the quality of drug products by monitoring drug manufacturers' compliance with its [Current Good Manufacturing Practice (CGMP)](file:///C%3A%5CUsers%5Cuser%5CDesktop%5CRachel%20Gross%20Marketing%5CMPGrow%20-MichaelEyal%5C%E2%97%8F%09https%3A%5Cwww.fda.gov%5Cdrugs%5Cpharmaceutical-quality-resources%5Ccurrent-good-manufacturing-practice-cgmp-regulations) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations ensure the safety of a product, that it has the ingredients and strength it claims to have. The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMPs. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

Cloud based, end-to-end quality management throughout the product value chain is a necessary to increase the speed to market, meet regulatory requirements, and protect both company and patient safety while meeting increasingly complex regulatory demands.

### With [Dot Compliance eQMS](https://www.dotcompliance.com/pharma/), you can manage your entire quality ecosystem within a single source of truth, promote collaboration, and enable your organization and outsource suppliers to get the required visibility in real-time. You can easily manage your quality processes through the entire product lifecycle from clinical trials, manufacturing, and post-market surveillance. Quality and compliance enforcement across the entire supply chain.

Pharmaceutical and biotech companies that rely on Dot Compliance QMS can make real-time decisions with a proactive quality management approach. Data from a single source can be translated and connected to their entire quality processes, then analyzed with a click of a button through integrated reports and dashboards. This is all accomplished with the most innovative technology, including AI, Machine learning, IOT integration and big data analytics.

More and more life science companies are embracing not only manufacturing 4.0 principles, but also [Quality 4.0](https://www.dotcompliance.com/manufacturing/). Best in class manufacturers now demand a completely digitized quality and compliance manufacturing and reporting process that spans across the entire supply chain. Manufacturing products in an efficient, cost effective, and compliant manner is not an easy task. It is critical to continuously increase efficiencies without negatively impacting operations, and product quality or regulatory compliance.

Quality itself is no longer the focus. Instead, the focus is about properly managing quality. Quality management is vital at every stage of clinical research, from drug discovery to drug safety and distribution. Inconsistent quality assurance in the pharmaceutical manufacturing phase can lead to unnecessary recalls and result in unexpected losses. Sometimes new complexities that were not evident during drug development, may appear when the drug manufacturing is scaled to commercial production. Those are the most vivid examples of failed quality management practices.

Data analytic (i.e., wireless temperature sensors and vacuum sensors) tools support the effectiveness of pharmaceutical manufacturing processes, enabling real-time monitoring of critical variables on the production line. What is more, data analytics can be used to improve quality at the drug discovery stage. The data collected from medical devices provides insights that enables pharmaceutical professionals to make swift data-driven decisions to refine every subsequent experiment.