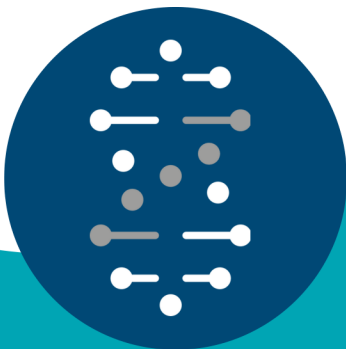




# **Jump Start Your Digital Transformation with a Modern Quality Management System**



The term "digital transformation" has become widely used in recent years. And as with many buzzwords, it seems that as it grows in usage, it's increasingly hard to tell what it actually means.

But in the case of digital transformation, separating the signal from the noise is essential because, beneath the hype, there is an important truth, especially for mid-size pharma companies. And that truth is that with the maturation of a new cluster of technologies, there are new opportunities for smaller pharma companies to gain competitive advantages in the marketplace.

These technologies are artificial intelligence, the datafication of manufacturing, and the Internet of Things (IoT). Mid-sized pharma companies can leverage these technologies to gain new competitive advantages over their competitors, including the larger, legacy vendors sometimes referred to as "Big Pharma."

The challenge, of course, is how to harness these technologies effectively to gain those advantages. Perhaps surprisingly, investing in a modern Quality Management System (QMS) is one effective path.

## **Distilling the Meaning of Digital Transformation in Pharma**

Digital Transformation is a very broad concept, but at its core, it means leveraging computers and other digital technologies to fundamentally change how a business operates.

One definition of digital transformation is:

"...the integration of digital technology into all areas of a business, fundamentally changing how you operate and deliver value to customers."

A simple example: Uber transformed the taxi industry by combining a mobile application for users, a digital dispatching system, and a digital payments model.

For Pharma companies, digital transformation means a shift to software technologies, including AI, so-called "big data," and IoT, to create new ways of developing, testing, manufacturing, and delivering drugs and therapies.

Here's an example of how digital transformation is needed in pharma. As cancer drugs become personalized to an individual's DNA, we need new ways to manufacture and deliver those drugs. Our current models for mass-producing generic medications will not meet the new requirements. Meeting those types will require transformational changes in the pharma industry, requiring whole new business models and processes.

Here's another example. Today, it is common to ask a patient to wear a monitor of some sort to collect diagnostic data. That means we need new ways to collect, transfer and analyze that data. And Bluetooth and the Internet of Things are perfect technologies to apply to this need. But our old systems and methods are not designed for those tasks, so the advancements in science and technology are not matched by the needed changes in our underlying models and processes.

## **An Opportunity for Competitive Advantage**

For mid-size pharma companies, the transition to new digital business models presents a remarkable opportunity to gain a competitive advantage. That's because whenever we see substantial shifts in platform technologies, new companies emerge, some existing companies thrive, and some become irrelevant.

This has happened several times in the last forty years. It happened when mainframe technology gave way to microcomputers and PCs. It happened when networks became prevalent, and it happened again with the advent of the Internet. Each technology transition shifted the competitive landscape, enabling smaller and more agile companies to outmaneuver the larger companies that dominated in the prior period. And that will happen again – in fact, it is already happening -- with this new cluster of technologies.

All of which raises a critical question. How do mid-size pharma companies get started exploiting the opportunity created by this latest generation of technologies?

It comes down to two words: assessment and investment.

## **How to Start Down the Digital Transformation Path**

Every mid-size pharma company needs to look carefully at how they execute clinical trials, manufacture their products, manage quality and meet regulatory requirements.

In each area, they need to look at their operations and score themselves on a "maturity model" to assess their current systems and processes. Then they need to make the investments required to climb up that maturity curve so that they have the flexibility to respond to the rapid changes that have already started in our industry.

They also need to look at how they manage regulatory compliance. That's because regulators are also changing and creating new requirements that assume or even require digital capabilities. Those assumptions become clear in what they require, not just regarding submissions, where they require electronic submissions, but also the specifications they issue for how we manufacture drugs and manage information.

If we get even more specific about where mid-size pharma companies need to start their digital transition and transformation, it becomes clear that investing in a modern quality management system is an obvious place to begin.

Starting with a modern QMS makes sense because there are reasonably-priced, off-the-shelf solutions available that can be readily implemented. In addition, a modern QMS will address regulatory requirements changes and act as a catalyst for cultural and process changes across the company.

### **A QMS as a Catalyst to Digital Transformation**

Managing quality processes remains an unautomated task for most mid-size pharma companies, driven mainly by compliance requirements. While there are Deviation, Corrective Action, and Change Request forms, they are often stand-alone forms – or even paper – that are not part of an automated system where each step in the process is connected to the next.

A modern QMS connects each step and each participant in the process to the next. Creating a Deviation or Complaint leads to an investigation, which is automatically assigned to the right people. The investigation leads automatically to a corrective action, which is then automatically routed for review and approval. In this way, the entire quality process is connected and documented.

Beyond the automation benefits, there are the monitoring and management benefits of a QMS because the system can tell us everything happening at any time. Key Performance Indicators can be constantly updated, telling us where each item is in the process, how long it has been in process and if it is stuck at a particular point. This is the datafication of the process, where the system is updating metrics constantly to allow us to monitor the overall system and to make adjustments to improve performance.

The QMS also makes connecting new components to the system possible. Since many instruments and systems are also generating data and reporting their own metrics, that data can be collected, distilled, and incorporated into a clear picture of the entire system.

And with that kind of information constantly available, AI technologies can be used to predict where issues will emerge. While AI is a very broad set of technologies, one particularly mature and effective area (predictive analytics) is looking at data sets for patterns and then using those patterns to identify likely outcomes. Outcomes such as forthcoming deviations and interruptions. In a sense, the QMS becomes a hub where all the related systems connect and report, data is collected and synthesized, and AI technologies can be employed to use that data. It becomes the center of a digitally transformed system.

Beyond the impact on manufacturing, an investment in a QMS will also impact the company's culture, heralding a transition to new ways of operating and signaling to every employee an atmosphere that encourages innovation and is focused on the future. The impacts will be felt across the entire organization, especially when it comes to retaining valued employees to recruiting new ones.

## Start Your Digital Transformation with a QMS

Digital Transformation seems at times like just another buzzword, but beneath the hype lies an important truth - a new cluster of technologies presents the opportunity for mid-size pharma companies to seize a competitive advantage.

Getting started is easier than it may appear because a modern QMS can leverage and integrate technologies like AI, datafication, and the Internet of Things to improve processes and, at the same time act as a catalyst to change across the organization, engendering the ongoing transformation of the enterprise.

### About Scigeniq's Quality Management System

Scigeniq QMS was built using modern technologies with a contemporary user experience, the ability to rapidly configure the application to each organization's needs, and workflows that address regulatory requirements and enforce proven best practices. It is a member of the Scigeniq family of applications that enable much faster implementation and ready user adoption.

Learn more about [Scigeniq QMS here](#).



### About Scigeniq

Scigeniq provides software and expertise to life sciences companies in the Middle East, Africa, South America, and around the world to accelerate their digital transformation. We provide expertise, guidance, and software solutions to our customers, which allows them to rapidly gain new capabilities and advantages based on proven technologies.

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