WHITE PAPER

A digital revolution in the pharmaceutical industry

A new era: smart and digital technologies

Digital transformation in the pharmaceutical industry is no longer an innovative vision but is becoming a strategic imperative for companies to be competitive in the market. Pharma executives are noticing the impact of digital technologies and realizing that it is crucial for their businesses to implement a strategy around it. The application of smart and digital technologies such as Artificial Intelligence (AI), cloud solutions, informatics platforms, and the Internet of Things (IoT) are enabling pharmaceutical companies to create connected digital ecosystems. Digital ecosystems are improving existing business and operational models as well as offering new ones. The creation of a digital ecosystem involves the evaluation of short and long-term strategies, and companies are beginning to create a new C-level position, Chief Digital Officer (CDO), to determine how best to execute on these goals.

A series of drivers are behind the need for digital transformation: avoiding the creation of data silos, connecting global teams and partners, and enabling research, development, and manufacturing teams to work more efficiently. However, the biggest driver for pharmaceutical companies is placing new, possibly life transforming treatments, into the hands of patients as quickly as possible. Pharmaceutical companies are beginning to rely more heavily on digital enablers such as the use of AI and data lakes to answer complex questions, laboratory information management systems (LIMS) to automate laboratory workflows, cloud enabled technologies to make data more easily accessible, and platform technologies to connect disparate laboratory instruments and software systems.

As an example, in rare disease discovery and development, AI is being used to filter through genome sequencing and phenotypic data to create a list of suspect genetic variants based upon rare disease definitions and clinical attributes. This data is stored in the cloud and made immediately available for teams to begin collaborating and analyzing. By using AI and cloud enabled technologies, the historically lengthy R&D process can be shortened, and life changing therapies can get to the market more quickly.

A digital strategy is not only important for the research, development, and manufacturing process but also for patient connectivity. Pharmaceutical companies are finding ways to become more digitally innovative, and work through regulatory challenges in order to connect with their patients. There has been an increase in pressure for these companies to be more transparent, and creating a connected digital ecosystem enables this. To be successful in the new digital era, pharma and healthcare companies must begin to strategize and implement a digital transformation within their businesses.

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Challenges limiting digital transformation

Although the application of digital technologies provides many benefits to businesses, there are concerns and challenges when it comes to implementing these systems. There is a tendency for digital technology investments to focus on near-term goals when in fact the potential for digital technologies will grow exponentially over time due to macro-environment changes.[1] Companies without a strategic vision for the role that digital technologies will play, struggle to see the long-term value that their investment will have. The involvement of a CDO allows companies to think strategically about the long-term vision and return on investment across multiple pharmaceutical functions. A CDO can work with department heads to determine where efficiencies can be made to make the company more agile and competitive. Leadership teams play a critical role in not only providing funding but also changing culture to value digital strategies.

The security of data, especially patient data, is a top concern for stakeholders. A common question surrounds the security of moving data to the cloud and if it will be less secure than maintaining data in their own data center. To address these concerns, Amazon Web Services (AWS) has laid out the main components to implementing a well-architected cloud environment: operational excellence, security, reliability, performance efficiency, and cost optimization.[2] AWS provides several security capabilities and services to increase privacy and control network access. Some of these controls include customer- controlled encryption in transit with Transport Layer Security across all services, automatic encryption of all traffic on the AWS global and regional networks, 24x7x365 monitoring, alert notifications, and visibility into Application Programming Interface calls.

In addition to the concern for data security, executives also want to know if a newly implemented digital ecosystem will meet the rigor that regulatory bodies require for electronic data systems at pharmaceutical companies. With careful and thoughtful implementations, the regulations can be adhered to and can provide a mechanism for streamlining the audit process. For example, during drug development, the implementation of a LIMS allows lab managers to quickly and easily provide audit records for sample management, assay performance and execution, equipment management, and assay approvals to an auditor. In the case of manufacturing, blockchain can be used to track and trace drug product and raw materials throughout the supply chain process reducing the complexity of adhering to the Drug Supply Chain and Security Act.

However, there are companies that recognize the need to implement smart and digital technologies but struggle to understand how to make these systems interoperable. Substantial efficiency gains are seen when these technologies can work and communicate seamlessly with one another. To help resolve this challenge, pharma companies rely on partners such as Thermo Fisher Scientific to determine how to implement a connected digital ecosystem.

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Determining digital enablers to address business challenges

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The American Pharmaceutical review outlined eight disruptive life science technologies that deliver innovative value.

DIGITAL MANAGEMENT
Progressive data management and mining of untapped date sources will create a springboard for elevated discovery agility and prescriptive insights.

MACHINE LEARNING
Boost foundational automation by deploying adaptive technologies to make fact-based decisions that will eradicate manual segments of the process sequence.

BLOCKCHAIN
Augmented information authenticity will enhance security, shorten transaction cycle times, and eliminate the need for reconciliations, for good.

COGNITIVE
Electronic brains will challenge the prevailing opinion, preform the scorekeeping and provide deep analytics; humans will drive dynamic insight generation.

CLOUD ERP AND EPM
Architect best-in-class application solutions and standardize end-to-end global processes, once for all.

NATURAL LANGUAGE PROCESSING
Unconstrained information accessibility from unconventional sources will allow managers to positively influence business outcomes in real-time.

ROBOTIC PROCESS AUTOMATION
Rapidly scale and dramatically reduce finance work-effort through elimination of repetitive, rules-based processes that require human intervention today.

DIGITAL ANALYTICS AND DELIVERY
On-demand, customized insight delivery will enable informatics to transcend the role of historical scorekeeper and become a strategic interpreter.

Figure 1: Technology Disruptors that can deliver innovation[3]

The first step in implementing a connected digital ecosystem should be to set goals, and evaluate current challenges, and digital enablers.

An example of goals, challenges, and digital enablers that a pharmaceutical company may identify for the R&D and manufacturing processes are as follows:

Goal	Current challenge(s)	Digital enablers
More agile R&D process	• Getting a drug to the market is a long and expensive process. • Data within R&D teams is siloed and not easily accessible, slowing knowledge share/transfer. • Filtering through genomic data to find relevant information is time consuming. • Biosimilars are reducing profits made by large pharmaceutical companies.	• AI • Big Data • Data Lakes • Platform technologies • IoT • LIMS • Automated workflows • Digital analytics • Cloud technologies
Streamlined manufacturing	• Manufacturing and supply chain operate in silos. • Data sharing across stakeholders and processes is limited. • Maintaining documentation and processes to meet regulatory standards.	• AI • Big Data • IoT • Cloud technologies • Blockchain • Digital analytics • LIMS • Automation

Figure 2: Breakdown of Goals, Challenges, and Digital Enablers

Industry leadership on digital transformation

Corporate leadership teams from pharmaceutical companies of all sizes recognize that in order to be the most innovative in their field they must reconsider how work has traditionally been done and implement new means to accomplish their objectives; digital technologies are becoming the way to accomplish this. “Conventional methods will not enable life science companies to keep up with the pace of change being set by new entrants…They will need to re-skill, re-hire, and invest substantially in new technologies or partner, even in a junior role with tech companies to fully realize the potential digitalization has to offer.” stated Vir Lakshman, Head of Chemicals & Pharmaceuticals at KPMG.[4]

Top pharmaceutical companies also recognize that they can compensate for the increased role biosimilars are playing in the market by implementing digital strategies. In an interview with Full Circle Group and Mckinsey & Company, Tammy Lowry, Head of Talent Innovation at Roche relayed “Digitization will transform the way we research and develop medicines and how patients and their physicians decide whether, when, and how to treat their diseases.”[5] Along with Roche, other top pharma companies such as Pfizer and Novartis, have taken the necessary steps to implement a digital strategy to make their research, development, and manufacturing processes more agile and competitive.

Pharmaceutical executive teams partnering with industry leader, Thermo Fisher, are collaborating on how to deploy a digital strategy and seeing value in a connected ecosystem. Richard Milne, VP and General Manager of Digital Science at Thermo Fisher told Scientific Computing World that “We’re increasingly seeing the growth of the concept of digital transformation…in many pharmaceutical processes there is the concept of how can we employ digital technologies to do one of two things- either accelerate the efficiency of science, by meaning we can flow data between two different necessary parties as quickly and efficiently as possible, or secondly, how can we drive more productivity, and that often tends to be productivity of assets and productivity of other lab based investments”.[6] These two goals can be accomplished with the implementation of digital technologies, and Thermo Fisher has made it a priority to ensure that its customers are enabled to reach their highest potential. Milne believes that the key to success is working holistically around four organizational pillars “the software, the instruments, the consumables and reagents, and the services” with a mechanism to connect these pillars.[6]

Connecting the digital ecosystem

Pharmaceutical executives are being confronted with the opportunity to use technology to transform their business models and have taken notice that in order to do so, digital technologies must be interoperable and connected. Currently, Thermo Fisher is developing technology to connect disparate software systems and laboratory instruments and provide a workflow engine for laboratory processes. Customers will have the ability to automate workflows, store data from multiple systems in one location, monitor experiments in real time, and completely visualize and manage data.

As described by Richard Milne, the four organizational pillars to working more holistically can be achieved with the implementation of a vendor agnostic ecosystem. This equips scientists to work more quickly, accurately, and efficiently. As an example, scientists could manage their scientific data and workflows, order reagents and consumables, and utilize AI to filter through datasets, all within one system. Such powerful visibility and connectivity provided by Thermo Fisher would mean that while a scientist is running a next generation sequencing experiment on the Ion Torrent™ Personal Genome Machine™ (PGM) system, they could also order more of the Ion Library Equalizer™ kits from Fisher Scientific, and capture and analyze all sequencing run data from a single interface. Digital enablers such as AI, data lakes, blockchain, LIMS and cloud applications, regardless of the vendor, could be engaged simultaneously to streamline R&D and manufacturing processes.

With other areas of Thermo Fisher enabling intelligent inventory and resource management through the use of telemetry data, and the broad range of business intelligence information available through innovative technologies across the company, the potential advantages to connecting these data sources are transformative.

Conclusion

Embracing digital transformation is essential for pharmaceutical companies to be innovative, address patent expirations, reduce the high costs of R&D and manufacturing, and facilitate communications with internal and external partners. Pharmaceutical drug development and manufacturing is a data intensive process and provides a strong opportunity for digital transformation. CEOs in the pharmaceutical industry who have already begun implementing a digital strategy are seeing gains from digital transformation and artificial intelligence. Thermo Fisher is dedicated to its mission of making the world a healthier, cleaner, and safer place; providing a mechanism to deliver new therapies to the market faster supports this mission. The future is now, its time to change the world together.

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