The role of digital transformation in achieving Pharma 4.0

Pharma 4.0 represents the next step in the evolution of pharmaceutical manufacturing, and is heralded as providing manufacturers with better efficiencies, higher output and quality, as well as flexible production. Here, Dr Saly Romero-Torres highlights some of the key trends in digital transformation and explains why a strong informatics infrastructure enables pharmaceutical manufacturers to unlock the benefits of Pharma 4.0. She also discusses the importance of a people-centred approach.

COMPANIES ACROSS industries and sectors worldwide, including pharmaceutical, have recognised the need for digital transformation in order to work more efficiently and increase productivity. Building on the idea of Industry 4.0[1], Pharma 4.0 focuses on the technologies and processes unique to the pharmaceutical sector and provides a framework for adoption.

While pharmaceutical manufacturers are at different points in the Pharma 4.0 journey, common trends are emerging, which serve to highlight how data availability and integrity are at the heart of digitalisation. These trends include the need to access information from systems quickly and securely, gain visibility across the whole manufacturing segment of the value chain, connect data from the laboratory to the manufacturing

environment, and enable data analysis for artificial intelligence (AI) and machine learning (ML) to drive continuous improvement and control.

There has been a pivotal shift in the way that data management is considered within the industry. No longer is it just a necessity from a regulatory perspective; companies now want to draw on informatics to better understand their performance and learn ways to improve it. It is important to note that achieving a successful digital transformation depends not only on creating an effective manufacturing and laboratory informatics infrastructure (essentially having a connected software ecosystem), but also on involving the organisation's employees and implementing a robust change management strategy.

The importance of Pharma 4.0

Pharma 4.0 focuses on connecting every segment of a manufacturer's value chain to create new levels of transparency and adaptivity for digitalised laboratories and plant floors. This will enable faster decision-making and provide better control over business, operations and quality.

Central to Pharma 4.0 is an operating model built on a foundation of digital maturity and data integrity by design, from which the four critical elements of resources, organisation and processes, information systems, and the working culture of the business are developed.[2] These four cornerstones are essential to achieving a successful transition to a Pharma 4.0 operating model.

The model shows the need to adopt a holistic approach to both the value network in information systems and the control strategy applied to organisation and processes. Avoiding siloed thinking is crucial for achieving the advantages that digitalisation can bring. Such advantages are described in the National Academies report entitled 'Innovations in Pharmaceutical Manufacturing on the Horizon: Technical Challenges, Regulatory Issues, and Recommendations',[3] which offers a valuable overview of the ways in which adopting Pharma 4.0 can provide significant company benefits.

The report outlines several key opportunities, such as: new routes to drug substances; co-processed active pharmaceutical ingredients (APIs); process intensification; additive manufacturing; modular systems; and advanced process control and automation. It is primarily the latter of these opportunities wherein the use of informatics and laboratory software solutions can bring truly transformational results.

Indeed, companies that have made greater investment in digital automation, as well as smart instruments, have the capabilities to improve product quality more easily. This outcome was highlighted by the St. Gallen Quality Metrics Research Report commissioned by the US Food and Drug Administration (FDA),[4] where The QC Lab Robustness High Performers demonstrated several markers for improved performance. These "High Performers" showed better performance across all key performance indicators and had a substantially lower invalidated out-of-specification (averaging a rate of 12 per 100,000 tests). Notably, these 'High Performers' had a significantly higher level of laboratory automation.

As more organisations commit to adopting Pharma 4.0 principles, those manufacturers who do not will undoubtedly be at a competitive disadvantage. The risks for these manufacturers include falling behind their competitors, finding it difficult to attract and retain talent, and the possibility of requiring more frequent inspections.[5] »

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Furthermore, since digital transformation is inevitable, such manufacturers will find themselves faced with considerable modernisation costs in the future if they do not have the foundation and infrastructure in place.

Informatics is key to Pharma 4.0

In order to achieve Pharma 4.0, the need to realise digital maturity is paramount. The success of an organisation's evolution will partially depend on the volume and richness of information available in its digital systems, and this data must be of the highest quality.

The ability to easily access data is an essential early step in the journey to Pharma 4.0, and switching from traditional paper systems or localised electronic databases to a centralised system makes this possible. Using such systems means scientists can capture as much detail as possible from samples or products, and this valuable data can be mined effectively.

These systems also offer pharmaceutical manufacturers significant benefits, including greater efficiency and compliance, and the capability to explore more advanced analytics tools. Additionally, they provide the ability to access and reuse accurate data quickly and easily, while aiding a move towards paperless laboratories. Furthermore, centralised databases enable scientists to combine data from multiple sources from the same batch; thereby affording improved characterisation (or observability)[6] of the process or product.

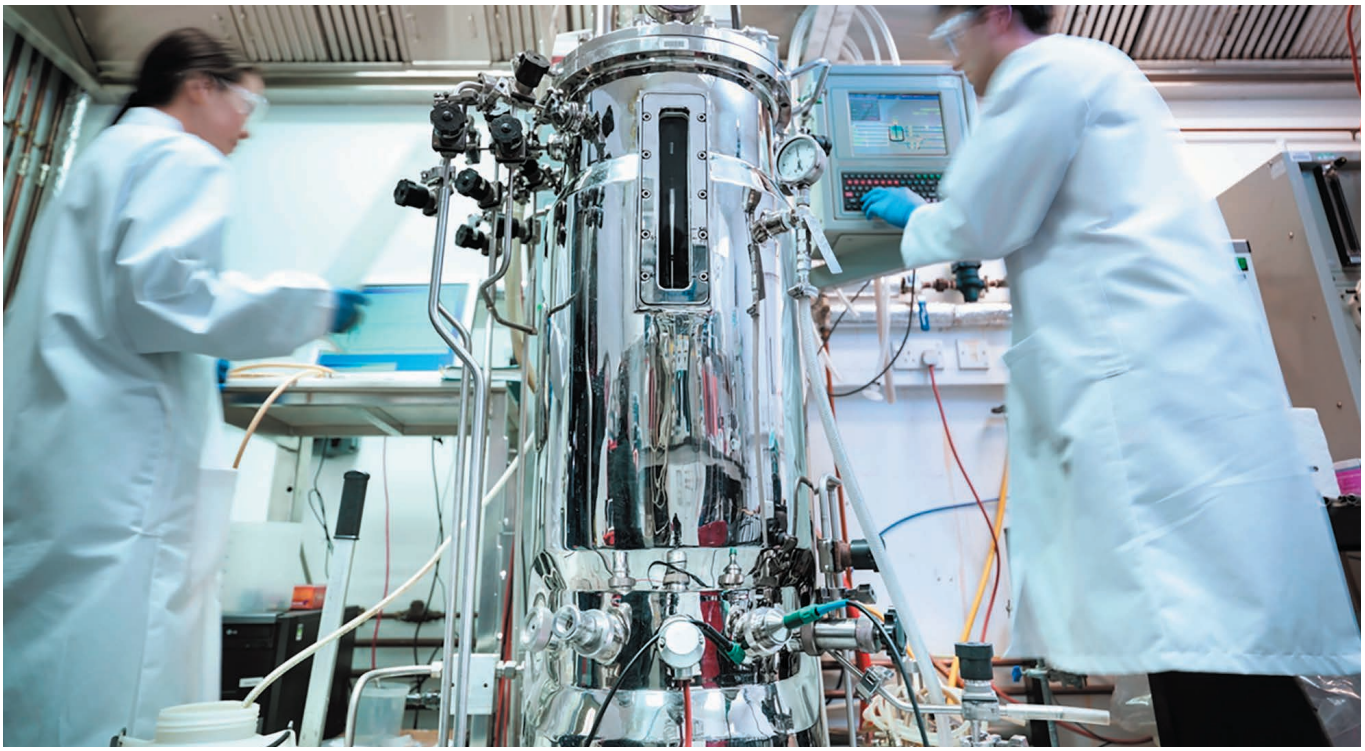
Adopting a strong informatics infrastructure, with a laboratory information management system (LIMS) at its core, can add value through improved data management and accessibility, especially when such a system is integrated across the organisation. Furthermore, a robust informatics infrastructure brings efficiency gains across the business. Greater visibility over inputs, the production process and how these factors influence product outputs improve the ability to deliver products to market.

A LIMS provides a foundation for adding further functionalities in the future, such as automation and execution, AI and ML. The importance of data analytics, AI and ML cannot be overstated, as these technologies have the ability to turn data into scientific insights to drive discovery, innovation and control.

Digital transformation may be achieved incrementally, with a focus on first creating a strong informatics infrastructure and analysing data to understand the effectiveness of the current pharmaceutical production system, such as supplier reliability, operational stability and laboratory robustness. By better understanding the production systems, scientists can more easily identify bottlenecks and areas for potential improvement.

A people-centred approach is essential for digital transformation

It is vital that a people-centred approach is taken in any digitalisation process. While new technologies, such as automated tools and AI and ML, are important; so too are the scientists working in the



laboratory. After all, these are the people who will use the informatics solutions to help progress their work to new heights.

Where there is hesitancy in moving to Pharma 4.0, the most commonly cited reasons include concerns related to cost, lack of skilled staff, new terminology, or cultural resistance. These barriers may be overcome by involving different teams and departments in the conversations and planning, and communicating the relevant and overall value of Pharma 4.0 in order to gain support from all corners of the business. There is a need to balance long- and short-term investments, and to create a workforce competency model that guides employee development and hiring plans. Focusing on change management is a good way to achieve a successful digital transformation now and in the future.

In addition to utilising LIMS, pharmaceutical manufacturers will need to invest in and embrace other digital technologies, such as internet of things (both at the lab and shop floor level), and create an effective informatics infrastructure. These technologies can enable remote working as well as provide an improved experience for staff. By contrast, organisations that continue to rely on paper systems are likely to face difficulties in attracting the scientific talent they will need in order to prosper.

Digital transformation can optimise manufacturing

Ultimately, Pharma 4.0 is an inevitable evolution for the industry, and the manufacturers who are embracing it are already reaping the rewards. Clearly, building an underlying strong informatics system allows pharmaceutical manufacturers to achieve the benefits of digital transformation, such as better efficiencies, higher throughput and quality, flexible production and supply chain reliability.

The new technologies critical for Pharma 4.0, including AI and ML, need appropriate configurations and data repositories to draw on for their intelligent analysis, and to offer the insights to optimise production. Here, LIMS has a key role to play by collecting, centralising and managing data, automating laboratory processes, and delivering connectivity and data integrity, thus improving observability across every stage of the manufacturing process.
In addition to implementing data systems, effective change management and the involvement of multiple departments across the organisation are important steps for delivering successful digital transformation.

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Saly Romero-Torres

Saly has over 15 years of experience in process analytical technologies and advanced manufacturing of biopharmaceuticals with a focus in the use of advanced sensors, advanced process control, data analytics, machine learning and operational excellence tools.
Her personal mission is advancing pharmaceutical manufacturing processes to enhance plant operations and, more importantly, improving patients' access to critical therapies. Dr Romero-Torres received her PhD in analytical chemistry from Purdue University and is also a North Carolina State Biomanufacturing Training and Education Center fellow.