WHITE PAPER

REALIZING SMART MANUFACTURING FOR PHARMACEUTICALS

Abstract

The life sciences industry is undergoing unprecedented changes with innumerable opportunities to expand globally while contending with evolving market conditions and tremendous technological advancements. As a result, there is a dire need for manufacturing enterprises to be more agile and flexible while ensuring strict adherence to stringent regulatory guidelines. Digitalization of manufacturing is the imperative choice to overcome these challenges. This white paper provides insights into industry challenges and guidance on the required digital transformation for manufacturing. It provides a map for a successful transformation of the rigid batch manufacturing enterprise into a more flexible and responsive manufacturing setup utilizing the proven capabilities of digital technologies. It describes the framework for defining and implementing the digital strategy and illustrates the technical and business roadmap to help convert challenges into opportunities to exploit.

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Introduction

In the post COVID era, pharmaceutical companies have many opportunities to expand the market globally but must deal with increased competition. Traditional systems for manufacturing operations need a complete overhaul as personalized medicines are gathering traction and demand flexibility. Furthermore, as newer technologies for producing drug substances and drug products are increasingly adopted, it calls for better integration and complete utilization of manufacturing capacities. Digital technologies enable manufacturing in these industries to become more competitive, scale faster and produce different products using the same facilities. In this context, pharma manufacturing companies have also increased their focus on digital transformation, with an estimated USD 4.5 billion spend by 2030 and a 27% CAGR growth in applied data analytics spend1.

Challenges and Opportunities For Digitalization In Life Sciences Manufacturing

Industries are converging towards a more collaborative technological ecosystem in a connected world with an end-to-end integration across the value chain. Life sciences, particularly the pharmaceutical industry, are galloping towards this goal by adopting Industry 4.0 solutions to alleviate the triple pressures of achieving increased efficiency and improved compliance to increasingly stringent regulatory norms. Pharma manufacturing firms employing the Process Analytical Technology (PAT) framework are required to adopt guidelines for Good Automated Manufacturing Practices (GAMP) and ensure adherence to Food and Drug Administration (FDA) standards to gain a competitive advantage.

Figure 1 shows comprehensive solutions to the various challenges pharma and biopharma enterprises face . Digital transformation of the value network is gaining ground to address these critical concerns. A digital thread for traceability from sourcing materials, their handling, production processes and integrated operations across the value chain from supply to meeting demands of the end customer ensures the required health outcomes.

Traditional batch manufacturing needs more control and integration across other unit operations to eliminate inefficiencies. For example, there are hidden capacities as overall equipment utilization is significantly low at 40% to 70%, even in the best pharmaceutical companies. While many pharma companies have tools for visibility, they lack the capabilities to improve the availability of equipment and Operational Equipment Effectiveness (OEE) to world-class levels, as seen in other industries.

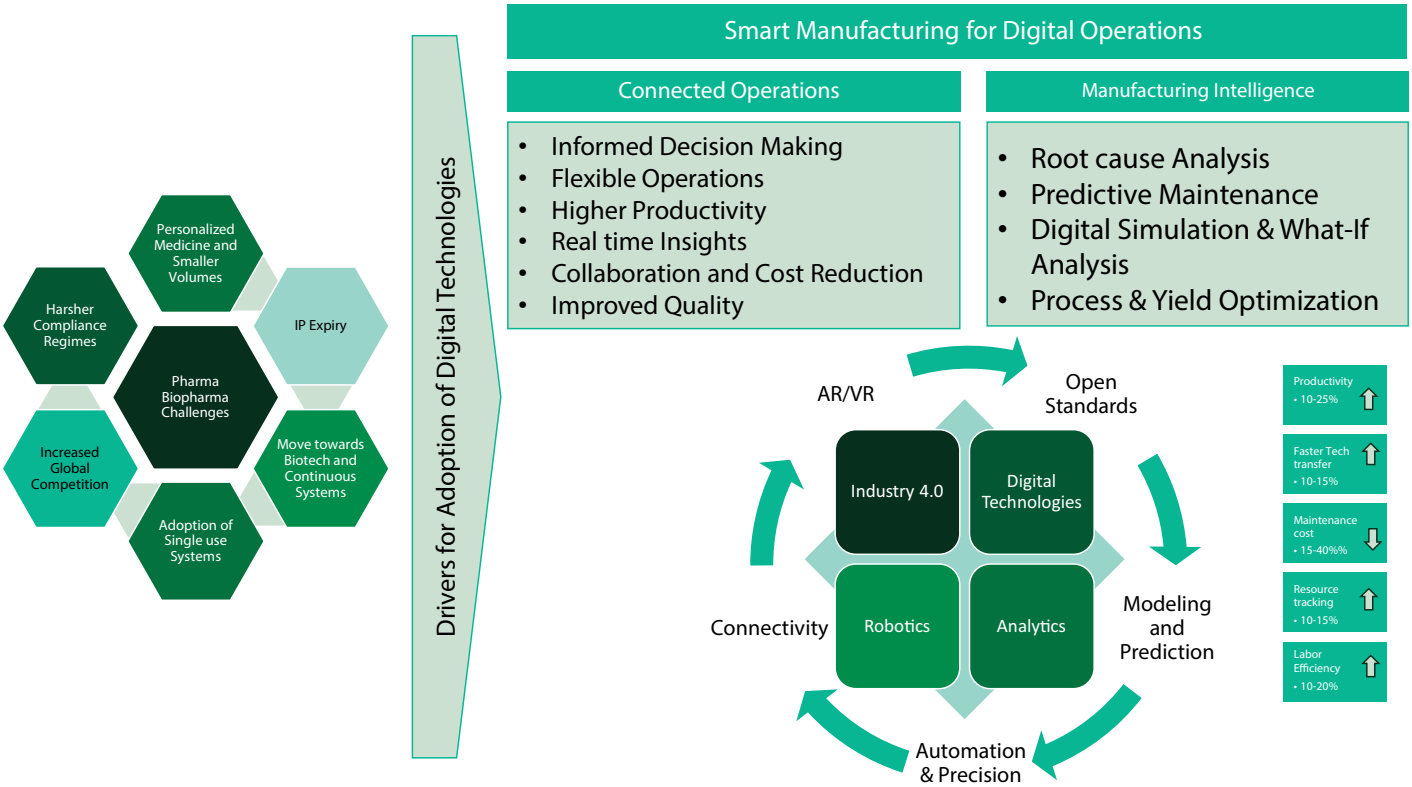

Figure 1. Tapping Opportunities from Challenges in Pharma industry through Digitalization

Newer sensing technologies like RFID and smart sensors are increasingly adopted in global supply chains. Pharma also uses sophisticated online and offline diagnostic tools whose timely integration provides immense opportunities to tighten efficiencies and make process improvements. Additionally, pharma companies facing a spurt in demand for personalized medicines are shifting to continuous manufacturing and a globalized supply chain network. Furthermore, Digital Twins connect process modeling to actual production to address different what-if scenarios to improve yields and quality.

The manufacturing setup needs to cater to both small-scale (labs or clinics) and full-fledged production setups to minimize time to market and shorten cycle times. This calls for increased agility of manufacturing processes coupled with intelligence across the automation hierarchy to enable flexible reconfigurability. Manufacturers are on the lookout for monetizing value chains to capitalize on the wealth of information captured during production and juxtapose them with the rich knowledge base of product engineering. Newer business models involving customer connect, process optimization and analytical services are increasingly adopted to enhance the customer experience and save time and costs with new contextual information.

Counterfeiting is a big menace endangering both the lives of patients and the reputation of pharmaceutical brands. The pharma counterfeiting market is an alarming USD 200 billion globally and growing.

The pharma manufacturing leadership must address these realities to sustain and achieve global competitiveness. This can be achieved by having the right levers with relevant contextual information to adapt to the dynamic market scenario. Therefore, newer technologies such as integrating advanced sensors for measurement, automation across the manufacturing systems hierarchy, connectivity across the value chain and employing information as a strategic asset are paramount for ensuring global leadership and capturing newer markets.

Digital Strategy for Pharma Manufacturing

Pharma and biopharma manufacturing has much to gain by adopting disruptive digital technologies for their operations. All aspects of manufacturing operations, from scheduling, manufacturing execution, laboratory management, packaging, quality inspections, and real-time release to warehouse and distribution, are influenced and transformed by this digitalization strategy. Figure 2 shows a detailed approach to implementing a digital strategy.

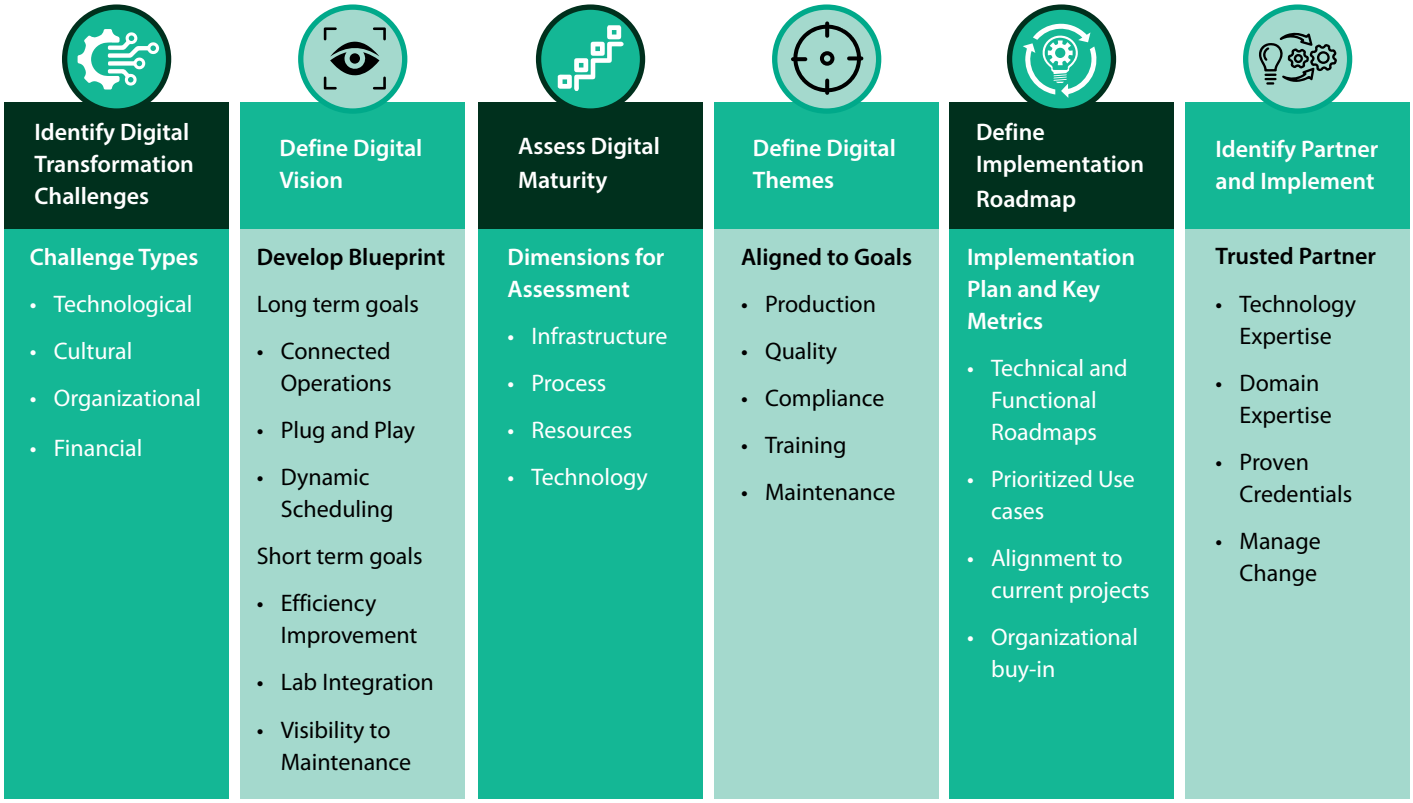

Figure 2. Steps to Implement a Digital Strategy in Pharma

Identifying the transformation challenges is key to shaping the digital vision by defining focused and achievable goals for the manufacturing organization. It needs a strong sponsorship that clearly appreciates the overarching benefits of a digital strategy that can have far-reaching effects on operations, reduce time-to-market for newer products and accelerate innovation. The technical footprint may need an overhaul. The organization may need to be aligned and create and nurture a right mindset for digital adoption. The vision identifies both the long-term and the near-term goals for the organization while considering both the external and internal factors impacting growth.

The digital maturity of the organization is assessed along key dimensions to define a technology roadmap to achieve identified business objectives. The Infosys digital assessment using the Acatech Industry 4.0 maturity Index2 provides a convenient means for a holistic evaluation of the enterprise to define further and detail the digital strategy. The implementation roadmap defines the path for evolving both the business functions as well as the technical landscape for digital operations.

It integrates the operations across departments and harmonizes processes across similar plants. It also provides the path for better use of the data collected and utilizes an analytics engine to transform business processes.

Figure 3 shows a typical digital operations roadmap for pharma. There is a phase-wise integration of different functions of production, quality, maintenance and R&D. This is realized by building a strong technical foundation layer backed by cultural and organization integration facilitated with well-equipped tools and facilities.

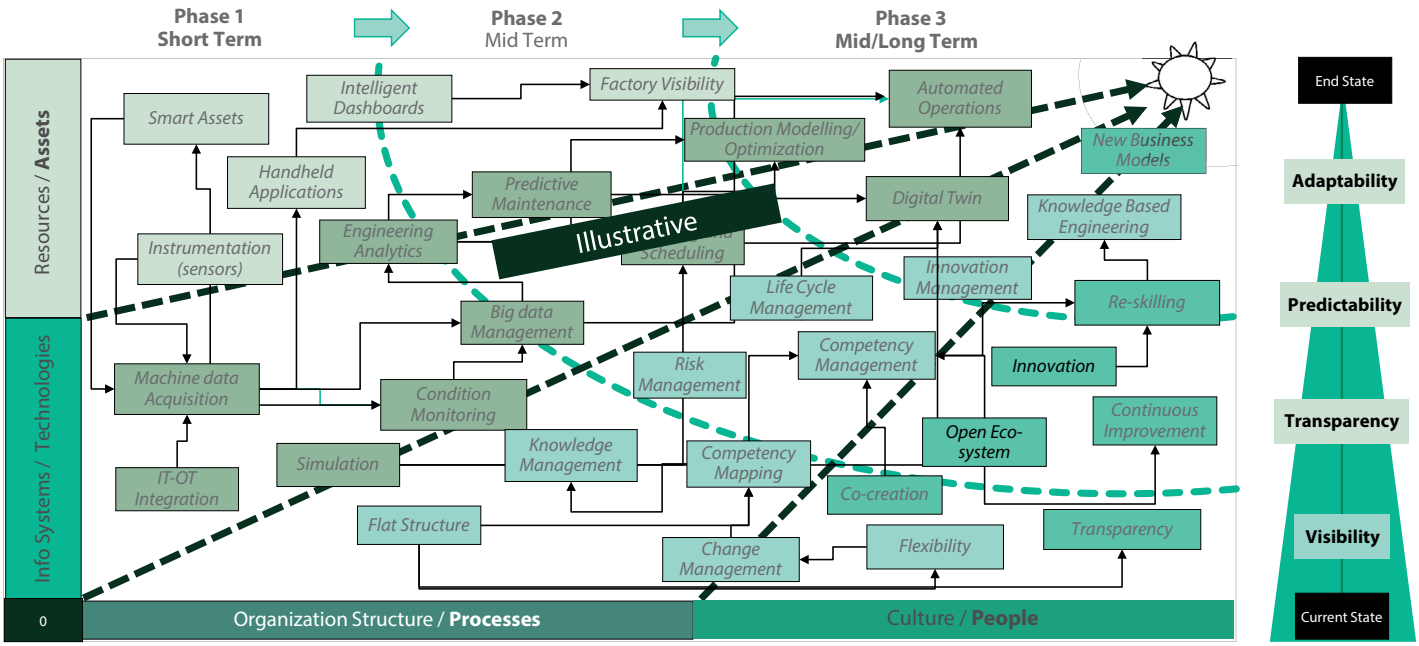

Figure 3. Illustrative use cases with phase wise realization of a digital strategy

Implementing Smart Manufacturing

Large life science companies have evolved through several mergers and acquisitions, resulting in a diverse technology landscape. In addition, the processes, resources and capabilities across production units would be diverse. Therefore, a plan for digitalization of manufacturing tailored for one unit may not fit another plant as the technology footprint could differ. Implementing smart manufacturing is not just rolling out a technical solution in this context. Still, it must be a confluence of factors shaping the business, the outcomes envisioned, process and methodology adopted, underlying technology and how it is adapted to the newer technical landscape and above all, the enablement of people who drive, implement and experience this change. Figure 4 gives a view of the major considerations for implementation.

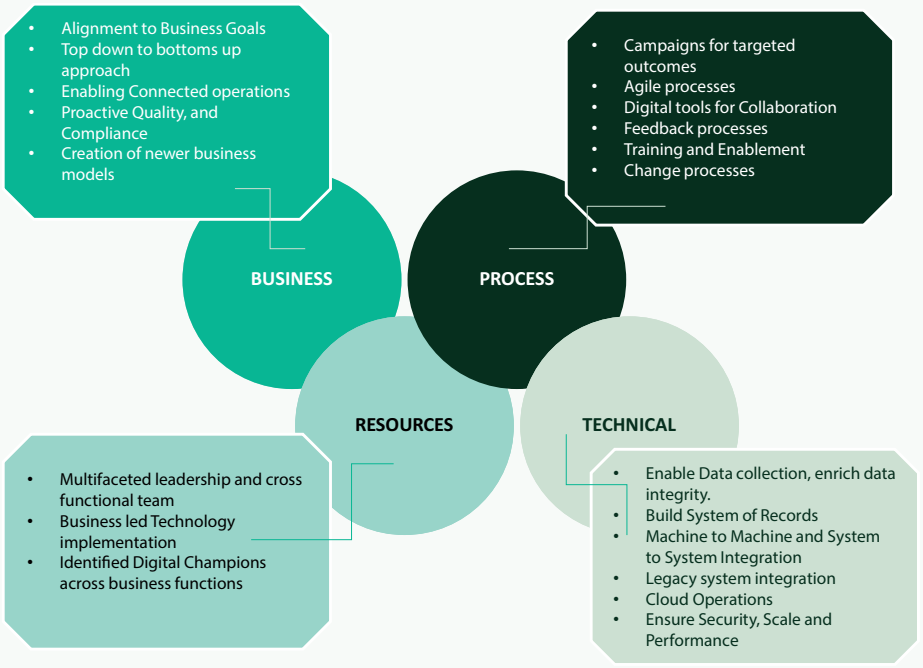

Figure 4. Factors influencing Digitalization of Pharma Manufacturing

Technical Considerations: The volume of data flowing from production processes is enormous and must be accurately captured, stored and made available for processing. Further, the context of information is invaluable, and systems like controllers, SCADA and MES provide important insights into manufacturing operations3. Different kinds of data are utilized for business decisions, and they need to be reliable. System of records for data of different kinds like manufacturing process, production, quality, maintenance, and product definition ensures data integrity, processing at scale and downstream integration for valued decisions. Legacy system integration is a major issue that needs to be adequately addressed at the initial stages of digitalization. Standards based integration and augmenting systems with additional sensors employing gateways are some ways to redress this issue.

Business Considerations: Opportunities to tap into a global market exist in the pharma and biomanufacturing ecosystem. At the same time, there is tremendous pressure to contain costs. With each enterprise having its own strategy and priorities to grow and capture different markets, the technical landscape should also align with implementing these strategies. For example, it could be globally source materials, have harmonized processes, align and schedule production in different plants and ensure contractual manufacturing, packaging or laboratory analysis. Capable systems must complement these critical business decisions to enable quicker decisions and flexibility in operations.

Resource Considerations: A digital strategy is never complete without the active participation of the people involved. A business led technical roadmap will more likely bear the fruits of digitalization and accelerate the overall adoption. Newer processes and information flows mean newer tools for operations. Cross-functional teams help innovate and bring new ideas to enable quicker deployment of the new operating model.

Process Considerations: Robust processes need to be in place for designing and implementing the digitization plan. Comprehension of the digital vision and the operating model with newer ways of working must be understood, appreciated, and accepted across different levels of operations. Change management tools and frameworks are handy in driving this consensus early into adoption. Data being the fundamental asset, it must be governed and managed to permit accurate information flow for decision making.

The Outcome of the Digital Strategy:

Figure 5 illustrates an example of a role-based outcome of a digital strategy for the pharma enterprise. Digitalization aids informed data-driven decisions across different business functions, from top leadership to shopfloor personnel. It connects the different functional domains of the enterprise, from R&D to manufacturing operations to external stakeholders. Each persona has more real-time information at their disposal, enabling them to carry out their activities effectively. This will enable reduced time-to-market, more targeted production at lesser costs and overall smart operations.

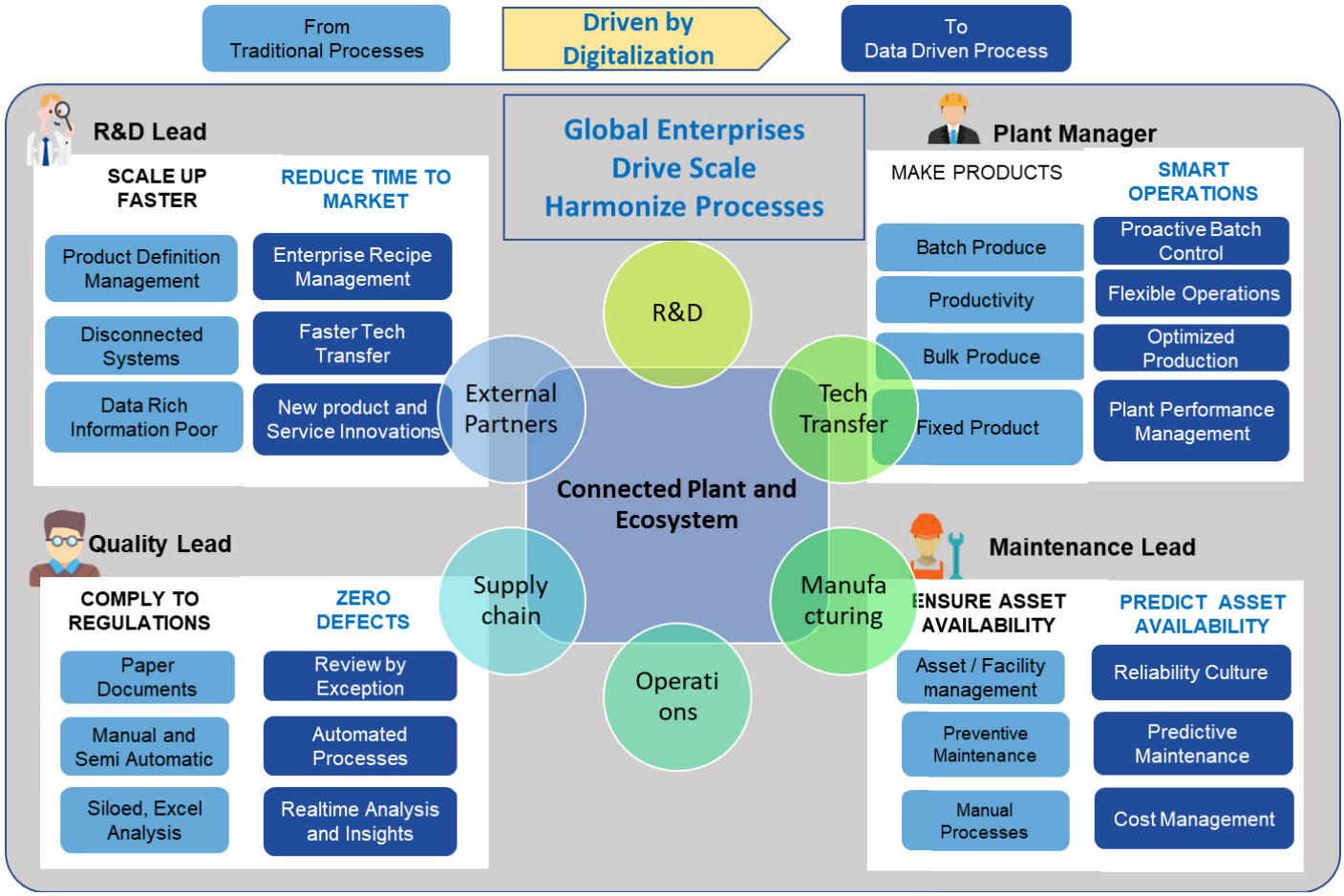

Figure 5 Transformation of Operations - Enabled personas for effective decision making

Conclusion

Smart manufacturing led by digitalization transforms the pharma industry into a highly efficient, flexible, predictive organization that is extremely responsive to market challenges. Defining the roadmap, implementation and realizing the benefits of smart manufacturing are nevertheless challenging. This paper presents a structured view of realizing smart manufacturing emphasizing business, technological and process considerations. It provides a proven roadmap for the successful transformation of the rigid batch manufacturing enterprise to a more flexible and responsive manufacturing setup utilizing the proven capabilities of digital technologies. It presents a framework for defining and implementing the digital strategy and illustrates the technical and business roadmap that could be useful for the industry to help convert challenges into opportunities.

About the Authors

Dr. Kumar M A

Senior Principal, Advanced Engineering and heads the Smart Manufacturing practice at Infosys.

Dr. Ravi Kumar G. V. V.

Associate Vice President and Head, Advanced Engineering Group (AEG), Infosys.

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