ENABLING THE INTELLIGENT PRODUCTION SYSTEM OF THE FUTURE

Five common pitfalls that life sciences operations experience on their digital transformation journeys

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INTRODUCTION

In the life sciences industry, there is a symbiotic relationship among Supply Chain, Manufacturing and Quality. These groups must work as one to allow for the smooth scale up, transfer, and care of assets and achieve efficient, high-quality production at scale.

But while these functional areas are inextricably linked to performance and outcomes, many organizations fail to integrate them in a meaningful way. This issue is exacerbated by dynamic forces in the market, such as the shift to smaller batches, the increasing number of large molecule therapies, specialized medicines, a surge in merger and acquisition (M&A) activity, and ever-evolving regulation. A suboptimal connection among these groups inhibits breakthroughs and creates significant risk of degrading current performance and, ultimately, product safety and efficacy.

To compete and win in this new landscape, life sciences organizations must embrace Intelligent Manufacturing principles to enable the safe, efficient, and reliable end-to-end production, release, and delivery of therapies, as well as ensure that current good manufacturing practice (cGMP) quality and compliance are maintained and enhanced. An Intelligent Production System, a central component of an Intelligent Manufacturing system, leverages solid data and architecture, lean thinking, and sound people and culture fundamentals to integrate these partner groups and implement the innovations needed to achieve sustainable breakthroughs.

While Intelligent Production Systems present a strong value opportunity to life sciences organizations, this model is not without its challenges. In this article, we look at some of the common pitfalls that organizations may experience as they build Intelligent Production Systems and how to avoid them.

PITFALL 1: NOT HAVING A DEDICATED TRANSFER TEAM

Transfer of assets – the handoff between R&D and production or the movement of on-market assets from one location to another – is a critical point in the product lifecycle. And yet, many organizations do not have a dedicated team that owns this process.

Instead, in many companies the period between where R&D ends and manufacturing begins is managed jointly with either side picking up responsibilities ad hoc. On its face, this is inefficient; it also introduces risk in that safety and compliance could suffer if there is miscommunication or miscoordination between these two teams.

For organizations that do not have a dedicated team that focuses exclusively on the transfer of the asset between R&D and production, establishing and sponsoring a small, dedicated transfer organization with matrixed connection to key functional areas is likely the most logical and impactful step they could take to improve end-to-end transfer time and transfer Right First Time.

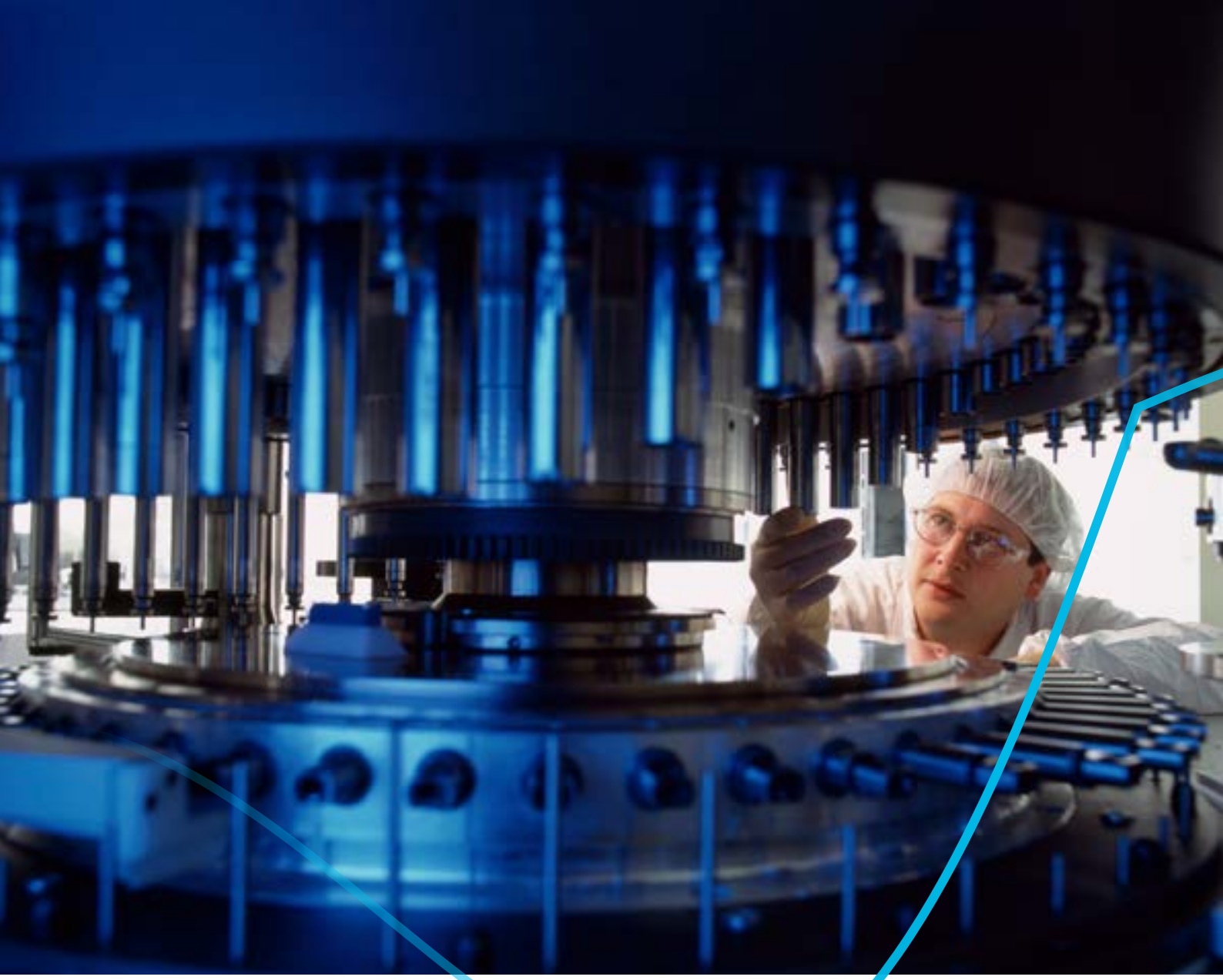
PITFALL 2: FOCUSING ON INCONSEQUENTIAL METRICS

As in most industries, in the life sciences sector product costs will increase anytime there's an inefficiency in the production system. These costs can be driven by any number of issues: equipment failures, overstaffing, rising raw material costs, excessive waste, or even shipping delays.

However, not all metrics or areas of focus are created equal. Some, like overall equipment effectiveness (OEE) in packaging, may drive cost savings but fall short of delivering meaningful value. Afterall, packaging is typically not a constraint. As a result, metric development and focus in this area often garners less benefit than a similar investment in other areas.

By comparison, metrics that are linked to Right First Time or flow at constraint points are far more important and should be prioritized. For example, incurring a penalty for having a product removed from the market due to patient safety concerns or the risk of external audit observations stemming from poor investigation and corrective and preventive action (CAPA) are far more significant and ultimately more costly for the business than suboptimal packaging OEE. As such, focusing on indicators that drive efficient transfer and Right First Time will deliver more value to the business. Although also core, inventory and machine downtime metrics and others are important to monitor but are lower in overall priority in setting improvement objectives.

For this reason, organizations must take a discerning eye when it comes to metrics and performance indicators and prioritize improvement efforts not in those areas where change may be easiest, but where it will deliver the most value.



PITFALL 3: FAILURE TO LINK DATA AND ARCHITECTURE STRATEGY WITH USE CASES

Most organizations have come to understand the importance of data and its supporting architecture. Put simply, data must be timely, accurate, and accessible to the people and teams across the organization to drive better decision making and, in turn, unlock new levels of performance.

At the same time, designing an effective data architecture – meaning the strategy and digital solutions and technologies that manage analytics and access – is not an independent exercise. Rather, it must be built in conjunction with the business's use cases. The data strategy will be informed by the use cases; and the use cases will be dependent on the company's data capabilities.

These are two steps that must be taken in tandem and reevaluated regularly based on the business's changing needs.

PITFALL 4: RELYING ON POINT SOLUTIONS TO DRIVE THE TRANSFORMATION AGENDA

While organizations are tempted to drive improvement through targeted point solutions, a true business transformation agenda must be holistic in nature.

An Intelligent Production System is just that – a system. In the same way, efforts to transform must also be system-based. Each function must not only be optimized, but also connected to other components and processes. To some extent, investments made in one area – such as the use of a digital twin within a smart factory – will be of limited value if the technology cannot draw on data from other areas of the business or integrate with other systems.

To be successful, the organization must consider transformation as an enterprise-wide journey. While technology certainly plays a role in enabling the future state, it is not the solution itself and life sciences companies must think through their comprehensive digital strategy, as opposed to deploying point solutions.

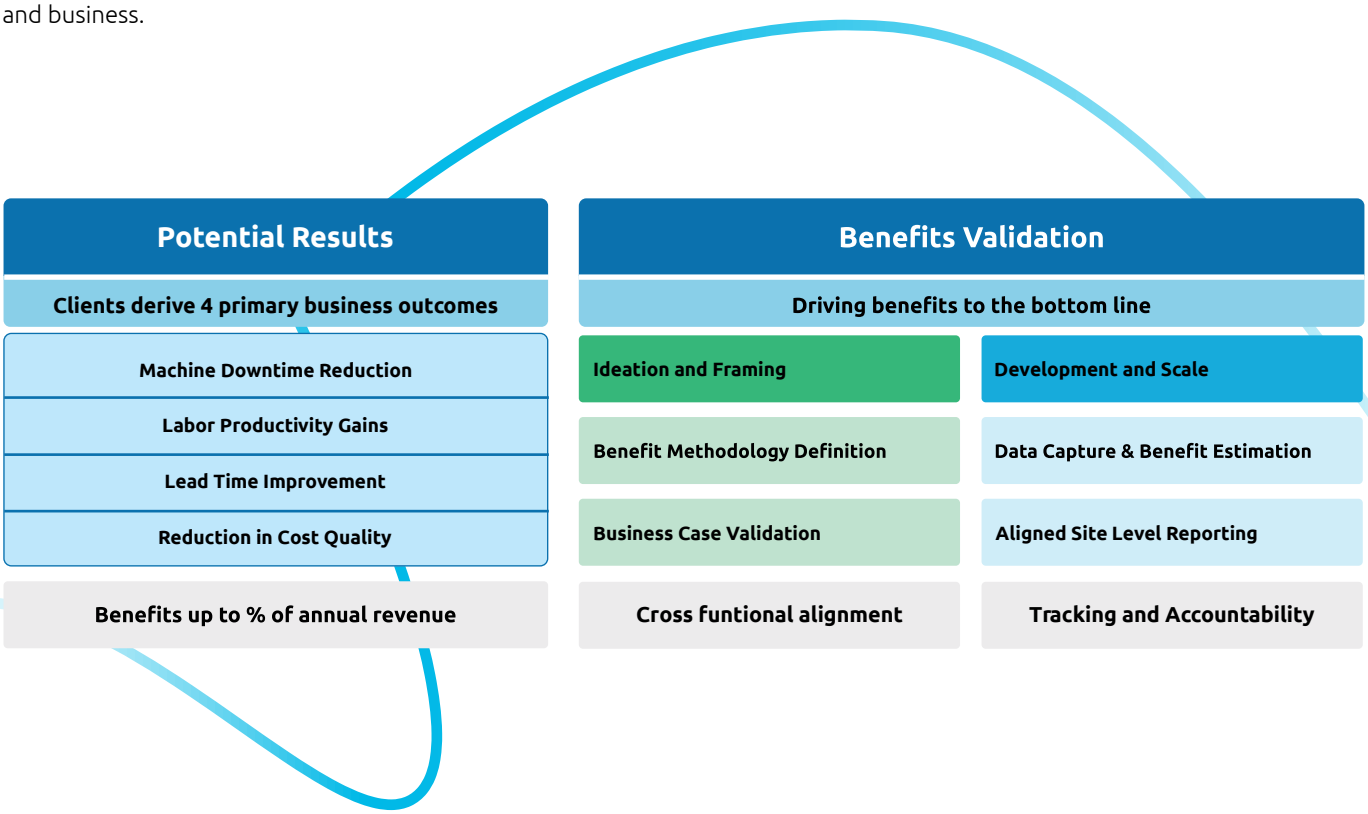
PITFALL 5: INACTION LEADS TO MORE (NOT LESS) RISK

For many life sciences organizations, change is synonymous with excessive risk. Any changes made to validated, on-market products and the processes by which they are produced must be assessed for regulatory risk and potentially mitigated prior to being undertaken. Even the most minute alteration can set off a chain of events that could ultimately damage safety and compliance.

This is certainly true. But, at the same time, organizations should not fall into the trap of thinking that maintaining the status quo means that risk will remain low. In fact, in many ways, taking an ultra-conservative approach may heighten risk, be it to patients through product safety and quality failures, to customers via failure to supply, and to the business itself in the form of increased costs.

For example, onboarding additional raw material suppliers always introduces some risk: the suppliers engaged may not meet quality standards; they may fail to deliver on time and in full; or they may perform in a suboptimal way. At the same time, overreliance on a single supplier can also be a source of risk if that source is compromised for any reason.

In embracing an Intelligent Production System model, the organization can leverage data and analytics to identify areas for change, as well as formulate and make risk-based evaluations. By incorporating data along with subject matter expertise and regulatory acumen, companies can lower the risk associated with change, while also reducing the risk of inaction to the patient, customer, and business.



TAKING THE NEXT STEP TOWARDS INTELLIGENT MANUFACTURING

Nearly all life sciences companies have organized programs that leverage data and analytics to drive operational improvements. Unfortunately, many of these efforts fail outright or fall short of realizing their full potential because they do not take the comprehensive and cohesive approach needed to enable a true Intelligent Production System. By learning from these known pitfalls, it is possible to begin building the foundation of an Intelligent Manufacturing system of the future, today.

Ready to address the issues facing your organization? Contact our author today to learn more about how Capgemini can help your business enable an intelligent production system of the future.

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