



Life Sciences

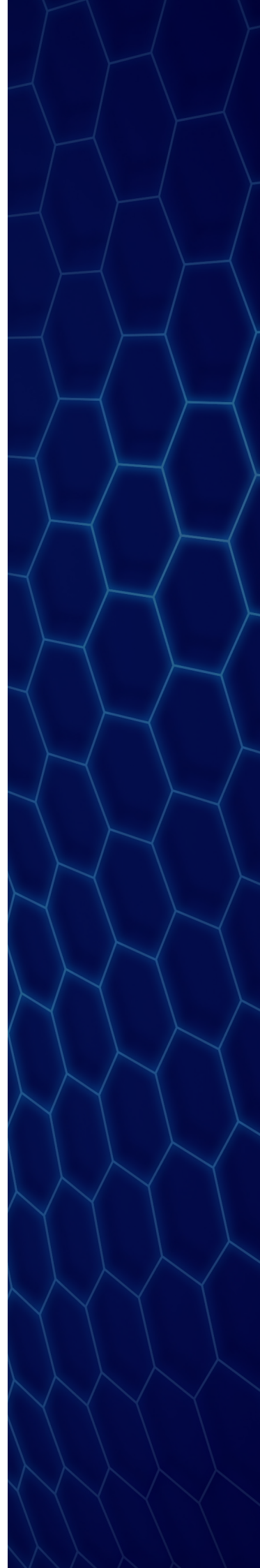
Pharma 5.0: The new reality of pharma manufacturing

Building on pharma's digital foundations: Intelligent,
human-centered ecosystems for the next era of life sciences



Contents

Executive summary	03
From digital foundations to intelligent manufacturing	04
Pharma 5.0: What it is and why it matters	05
The pharma 5.0 manufacturing model	06
Pharma 5.0 in action: From connected operations to intelligent execution	08
Predictive quality in action: Anatomy of a deviation that never happened	09
Readiness for pharma 5.0: What it takes	10
From efficient plants to intelligent ecosystems	12
How Cognizant helps bring pharma 5.0 to life	12
References	13

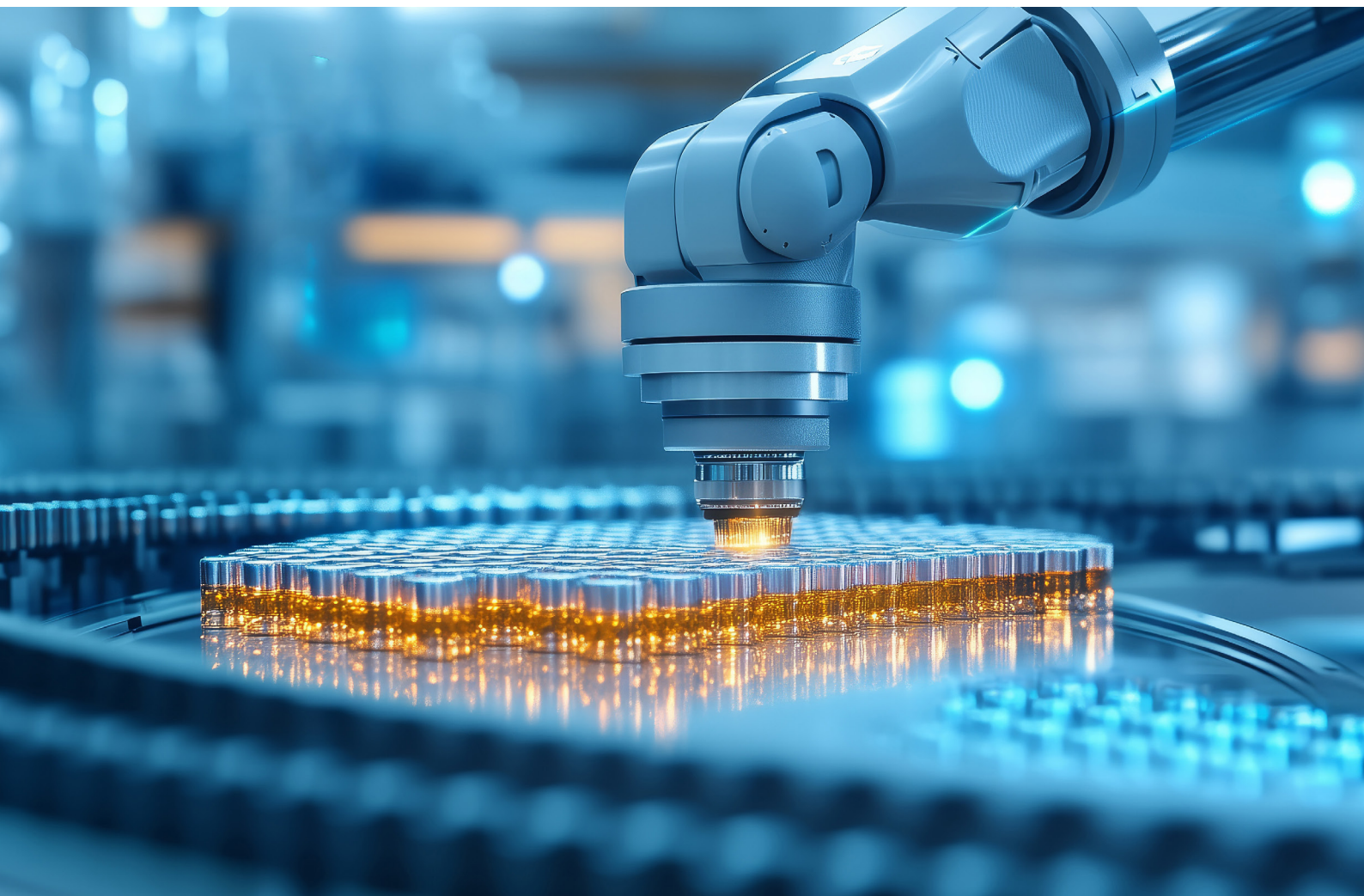


Executive summary

Pharma 5.0 represents the next operating model for life sciences manufacturing, bringing together intelligent technologies, human judgment, patient-centric production, sustainability and resilient operations. It enables manufacturing systems to use connected data not only to monitor execution, but also to anticipate events, recommend actions and continuously improve outcomes within established human and regulatory oversight.

We make efforts to define how manufacturing landscape is changing and transitioning to pharma 5.0. We leverage our experience to identify opportunities for value creation within the core manufacturing processes of the life sciences ecosystem by facilitating the transition to pharma 5.0. By gaining insights into the needs of life sciences executives and shop-floor operators, we have identified the benefits of several high-impact pharma 5.0 enablers. These enablers can facilitate advanced manufacturing practices and foster innovation within the manufacturing ecosystem, all while considering the cost and time required for implementation.

Finally, we emphasize the need for a cautious and strategic approach for successful transition to pharma 5.0 ecosystem. We assess the organization's preparedness by examining the alignment of vision, the readiness of the data and technology infrastructure and the availability of skills necessary for executing pharma 5.0 use cases.

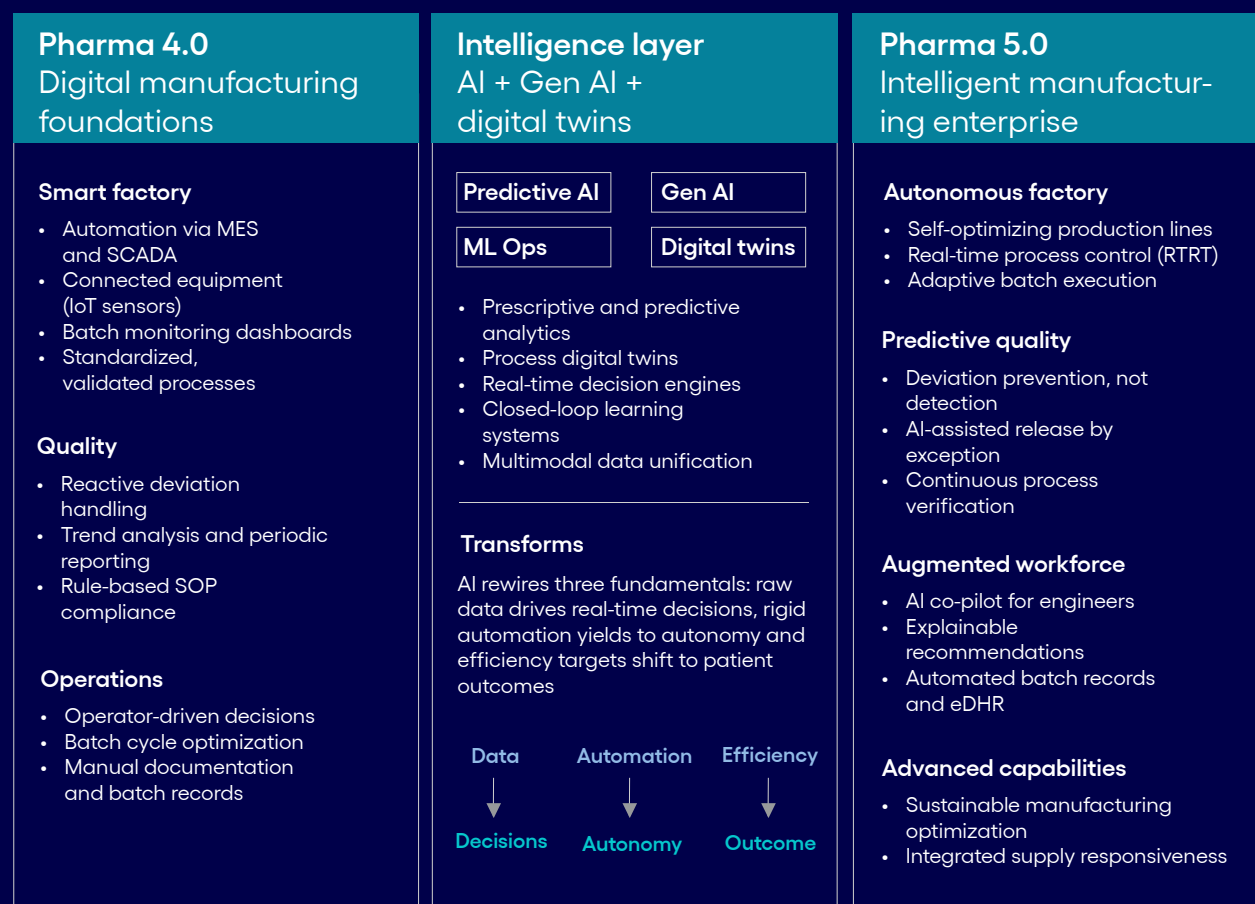


From digital foundations to intelligent manufacturing

Pharma 5.0 is the next operating milestone for human-centric, patient-centric, sustainable and quality-first evolution of the pharmaceutical industry. The goal is to create outcome-focused end-to-end value chains across research, manufacturing, supply and patient engagement. It is built on its predecessors' foundational values to add real-time decision intelligence, autonomy and human-centric strategy. The main objective is to move from running efficient plants to operating an intelligent, self-optimizing and closed-loop manufacturing ecosystems.

For life sciences leaders, this evolution matters because it can strengthen quality and compliance, increase manufacturing agility, support more personalized production and improve outcomes for patients, workforce and the environment—while keeping human judgment and regulatory oversight at the center.

This white paper explains how pharma 5.0 extends the industry's digital foundation into an intelligent manufacturing model and provides a practical view of the transition. It examines the model's defining pillars, illustrates how connected data and intelligent technologies can improve execution through high-impact use cases, and outlines the technology, data, workforce and strategic capabilities organizations need to assess their readiness and scale adoption responsibly.



Pharma 5.0: What it is and why it matters

The conventional approach to manufacturing execution, albeit simpler, is inflexible and inefficient, leading to longer cycle times, delayed quality control, larger compliance costs and indecision. The drug needs of today's patients are shifting toward personalized medicines and high-precision, patient-specific cell and gene therapies. Pharma manufacturing is shifting from stable, standardized and large-scale production to complex, personalized and interconnected ecosystems. This has led to less reliance on economies of scale and increased global interdependencies. However, recent geopolitical restrictions have exposed the inflexibility of the global supply chains, prompting manufacturing SMEs to prioritize resilience over costs. It means that SMEs expect real-time visibility and adaptive planning for the foreseeable future that would allow faster drug availability and faster release to the market. Despite an explosion of data from IoT devices, system logs, patient records, real-world evidence and pharmacovigilance systems, manufacturing operations remain insight-poor and struggle to unlock value from this wealth of information.

Pharma 5.0 builds on connected systems, automation and data visibility, established through earlier digital manufacturing investments. It adds an intelligence layer that contextualizes data, anticipates outcomes and supports timely action, enabling manufacturing operations to become more adaptive, human-centric and outcome-led.



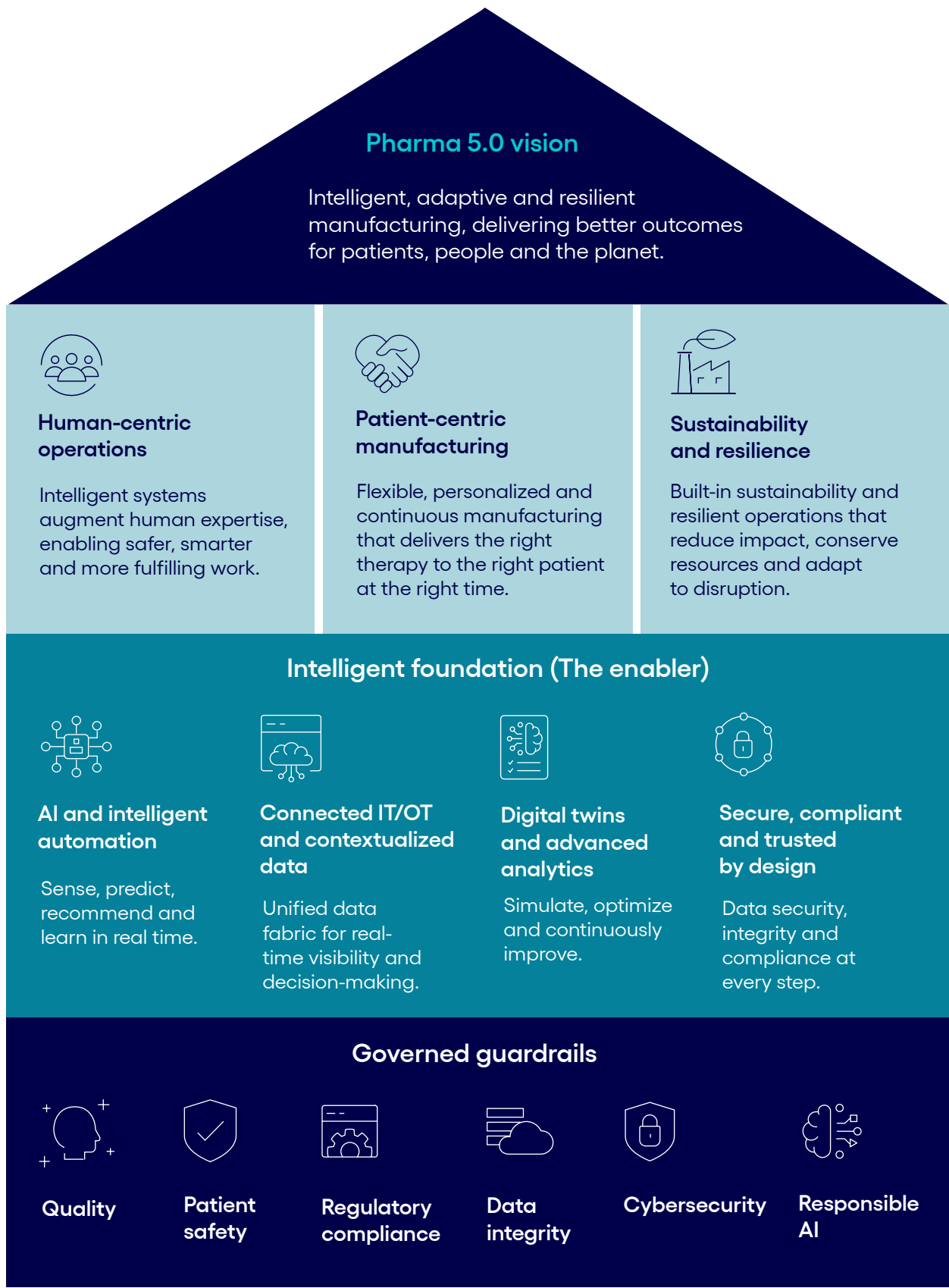
The pharma 5.0 manufacturing model

Pharma 5.0 brings together human-centric operations, patient-centric manufacturing, sustainability and resilience, supported by an intelligent technology and data foundation. They are governed by quality, safety, compliance and ethical controls. Pharma 5.0 capabilities are built on the following transformational pillars:

- **Human-machine collaboration:** Intelligent systems are built to enhance human creativity and intuition. AI and machines automate repetitive tasks and processing while humans solve tricky problems using context, judgment and critical thinking. One of the examples here is the use of collaborative robots (cobots). They are designed to work alongside humans or independently in high-risk environments such as sterile processing and cleanrooms, where contamination risks are critical.
- **Patient-centric and personalized manufacturing:** It represents a fundamental shift from the pharmaceutical industry's traditional one-size-fits-all approach to individualized therapies that are tailored to each patient's unique clinical and biological profile, driven by the rise of advanced modalities. At the same time, the adoption of continuous manufacturing and on-demand production has opened new frontiers for innovative technologies to mature. Among these, additive manufacturing techniques such as inkjet 3D printing are gaining traction, enabling the production of complex, customized dosage forms, including multidrug tablets with tailored dosing. These capabilities are no longer experimental as they've achieved regulatory acceptance, demonstrating their viability in real-world pharmaceutical manufacturing. CIOs believe that 90% of strategies will revolve around patient-centric digital ecosystems by 2028.
- **Sustainability and resilience:** Sustainability in pharma 5.0 isn't just a nice-to-have or achieve-when-convenient concept anymore, it has become a foundational principle that is embedded in every decision. Practitioners are enabling sustainability-by-design in core process from scratch instead of relying on beneficial side effects of digital transformation. The goal is to go further than renewable energy adoption and waste-reduction strategies to introduce bioeconomic thinking. Reducing waste is not enough anymore, pharma 5.0 aims to eliminate it by design through real-time quality improvement on manufacturing lines through digital twins. Social sustainability in pharma 5.0 might be the sharpest distinction from its predecessors. The concept supports human work to build an industry that is more resilient and centered around employee well-being rather than serving as a means to operational efficiency alone.
- **A core engine of technologies accelerated by AI:** AI acts as an intelligence layer across the connected manufacturing ecosystem, enabling systems to sense changing conditions, anticipate outcomes, recommend or initiate appropriate actions and learn from execution. This supports autonomous and adaptive operations while retaining human authority and operating within validated process and control boundaries. Process digital twins extend this capability by allowing manufacturing teams to simulate outcomes and optimize execution before intervening in the physical process.

The pharma 5.0 core pillars

Human-centric. patient-centric. Sustainable. intelligent by design



Pharma 5.0 in action: From connected operations to intelligent execution

The principles of pharma 5.0 translate into practical manufacturing capabilities that anticipate quality and asset risks, augment the workforce and continuously optimize execution. The following examples illustrate how intelligent technologies can improve decision-making and manufacturing outcomes while retaining human oversight.

Use cases/ tech	Pharma 5.0
Continuous and predictive quality assurance	• Continuous inline monitoring of critical quality attributes, with AI triggering automatic corrections in real time • Deep learning vision systems simultaneously inspect every vial, tablet and unit at full line speed, catching defects invisible to the human eye and logging every rejection directly into the electronic batch record • Zero-defect manufacturing as AI explains deviation and corrective action while QA validates and provides oversight
Predicting failures to prescribing solutions	• Beyond flagging, the solution tells operators exactly what to do and when, auto-generating work orders timed around production schedules and confirming spare parts availability, resulting in near-elimination of unplanned downtime • Context and environmental awareness (batch, product, process conditions)
Immersive human-machine collaboration on the factory floor	• Operator support system to interact with factory shopfloor through virtual reality environments for SOP execution, training and step-by-step maintenance guidance • AR overlays show equipment health status, predicted failure points and optimized maintenance schedules directly on machinery • Actions are automatically captured into the electronic batch record, eliminating manual documentation errors
A living virtual factory with digital twin of the manufacturing line	• Synchronized virtual replica of the physical line runs what-if simulations, identifies golden batches and reoptimizes production schedules dynamically in response to real-time quality or equipment events • Enabling self-optimizing manufacturing lines as digital twin provides the virtual model and simulation layer while autonomous process control closes the loop by adjusting parameters in real time

Predictive quality in action: Anatomy of a deviation that never happened

One signal, traced across the Pharma 5.0 stack.

- **Signal:** At 8:42 a.m., during granulation of a high-volume oral solid, an in-line NIR probe detects moisture trending toward the upper edge of the validated range. The measured value is still within the accepted range, but drifting toward a limit and could become a problem if no action is taken.
- **Data:** The reading streams to the historian and is tagged by the MES to the exact batch, recipe step, equipment train and operator on shift—full batch genealogy and no manual lookup.
- **Intelligence:** The process digital twin runs the trend forward against the approved design space and predicts a dissolution risk three steps downstream if the drift continues.
- **Recommendation:** Instead of a late deviation, the system prescribes a precise drying-time adjustment—surfaced to the operator with the supporting data and the control-strategy rationale attached.
- **Human decision:** Final review and electronic sign-off rest with the operator, and with QA where required. The system observes and calculates—humans retain authority.
- **Compliance trail:** Every signal, prediction and decision is written to the electronic batch record in real time, feeding continued process verification automatically.
- **Outcome:** The batch is corrected before any defect can take shape. By addressing the drift at an early stage, the intervention kept it from escalating into a confirmed quality event. As a result, no deviation, investigation or CAPA is necessary, and the learning is fed back to tighten the control strategy for the next campaign.

This illustrates the practical value of pharma 5.0. Connected process data is converted into timely intelligence, enabling the manufacturing team to intervene within the approved control strategy before a process drift becomes a quality event. While robust quality 5.0 specific outcome data have not yet emerged, industry benchmarks suggest over 65%–80% reduction in deviation rates at predictive maturity.

Readiness for pharma 5.0: What it takes

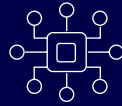
Major organizations are actively investing in advanced manufacturing technologies across the value chain. However, data indicates that while roughly 55% of pharma companies have partially integrated digital technologies into operations, fewer than 20% have fully implemented digital transformation, still lagging the 35% cross-industry average.

While adoption and spending are improving, technological development continues to outpace the maturity of implementation within organizations. Moving toward pharma 5.0 requires more than deploying additional technologies. Organizations need an integrated technology foundation, contextualized and trusted data, people equipped to work with intelligent systems and clear alignment between use cases and measurable manufacturing outcomes. Readiness should therefore be assessed across four interdependent dimensions: technology, data, skills and strategic value.

- **Unified technology foundation:** Organizations must prioritize interoperability and integration across systems, allowing technological readiness and maintaining the flexibility to scale and adapt quickly. It provides a robust IT and OT infrastructure, featuring high-performance computing resources, integrated cloud services and effective data management that enables seamless data flow and real-time decision-making.
- **Digital skill availability:** A 2024 GlobalData survey found that nearly 50% of pharma organizations stated digital skills and talent as one of the biggest challenges in AI adoption and digital transformation. Leaders must invest in attracting top talent and equip their employees with the essential frameworks, skills and tools needed to derive tangible value from AI and pharma 5.0 initiatives. Pharma 5.0 emphasizes collaboration between humans and machines, not replacement.
- **Data operationalization and process harmonization:** According to DATAVERSITY 2024 survey, 68% of organizations cite heterogeneous, fragmented data as their top digital transformation challenge. Even in connected ecosystems, generating exponential data and actionable insights remain minimal. Pharma 5.0 is a data-first transformation, requiring mature master data management and advanced analytics to enable prescriptive intelligence and decision scalability. This demands consistent standards such as ISA-95 and ISO, data contextualization through metadata and process context and agile governance. Equally critical is process harmonization, which includes standardized workflows, terminologies and data capture points anchored to ISA-95 that simplify contextualization and form the operational backbone for scalable automation.
- **Strategic alignment and value articulation:** A December 2025 Gartner survey of 197 CXOs and senior business leaders found that only 27% of executives have a comprehensive AI strategy, and just 20% believe their workforce is truly AI-ready. The primary reasons why digital transformation use cases fail to deliver sustainable success and ROI are the lack of alignment on strategic business value and the absence of a well-defined implementation roadmap. Organizations must create a sharp vision and a digital north star to guide them toward measurable and well-defined business outcomes. Refer figure 1 below to understand the strategic path to pharma 5.0 implementation at scale.

Build technology vision

Develop a comprehensive AI strategy aligned with the organization's long-term goals.



Understand business goals

Identify and prioritize business objectives that AI can help achieve.



Deliberate and identify use cases

Evaluate potential AI applications and select those with the highest impact.



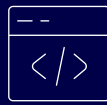
Establish KPIs

List down the KPIs for each use case.



Prototype and iterate

Make the prototype for a particular use case and implement it.



Monitor and measure

Monitor the whole process and measure the KPI for the prototype.



Deploy at scale

Expand it across the whole manufacturing process at each level.



Figure 1: Strategic path to pharma 5.0 implementation at scale

Once these readiness dimensions are understood, organizations can translate ambition into a phased implementation path that connects priority use cases with the technology, data, governance and workforce capabilities required to scale.

From efficient plants to intelligent ecosystems

Pharma 5.0 marks the shift from connected manufacturing operations to intelligent manufacturing ecosystems. Data that has already been generated across plants, systems and processes is converted into timely decisions, allowing organizations to anticipate risks, adapt execution and improve outcomes while retaining human judgment and regulatory control.

But getting there requires discipline. Pharma 5.0 cannot simply be purchased as a technology stack. It must be built through maturity with strong data foundations, validated control strategies, trusted governance and people who are ready to work with more autonomous systems. Regulators are already charting this course, so for manufacturing leaders, the real question isn't whether to follow, but how thoughtfully to do so. The organizations that lead will be those that combine ambition with a practical blueprint and maintain human judgment at the center of even the most advanced manufacturing environment.

How Cognizant helps bring pharma 5.0 to life

Cognizant's Life Sciences consulting offerings aim to accelerate enterprise-wide pharma 5.0 adoption and significantly upgrade digital competencies and capabilities across the life sciences value stream. We provide leading biopharma and medical device manufacturers with a full complement of business and technology support, including business consulting, technology consulting and operations services across research and development, manufacturing and supply chain and commercial operations. This helps organizations adapt to the evolving market landscape and enhance both top-line and bottom-line performances. Our expertise combines deep domain knowledge with digital and technology capabilities at scale to deliver compliant solutions, whether deploying industry platforms, infrastructure assets or Cognizant tools that deliver business value across every part of the life sciences value chain. We bring the capacity, infrastructure, IP and perspective to enable digital business at scale.



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