Reinventing biopharma from lab to line

Fueling smarter, faster and scalable biopharma production with intelligent technologies

Authors

Anne Marie O'Halloran
Life Sciences Supply Chain &
Operations, Americas Lead

in

Anne Marie brings over 25 years of experience guiding global pharmaceutical biotechnology, and medical technology companies through complex operational change. As Accenture's Americas Lead for Life Sciences Supply Chain and Operations and Industry X practice, Anne Marie oversees a diverse portfolio of client engagements focused on digital transformation, operational resilience and patient-centric innovation. Her leadership spans the full value chain, from strategy through execution, across domains such as integrated planning, manufacturing and logistics. Anne Marie is a key contributor to Accenture's thought leadership in life sciences, shaping industry perspectives on topics such as digital manufacturing to contract manufacturing organization collaboration and autonomous supply chain.

Hagen Späth
Life Sciences Industry X
EMEA Lead

in

Hagen is a Managing Director responsible for Accenture's Industry X Life Sciences offering in EMEA. He has approximately 25 years of experience in manufacturing, with a specific focus on large biopharma manufacturing for the past 12 years. Hagen has led numerous high-profile projects for large biopharma companies, including IT/OT partnerships, clinical study control towers and digital therapeutics development. He helps clients achieve flexibility and operational excellence through digital transformation in the life sciences sector.

Selen Karaca-Griffin
Products and Life Sciences Thought
Leadership, Accenture Research

in

Selen is Accenture's Research Lead for Products and Life Sciences globally, where she oversees a team of 30+ researchers. She shapes the industry's thought leadership agenda, driving insights on scientific innovation, the convergence of science and technology, and market disruptions redefining the future of industries. Selen brings deep experience across both strategy consulting and research leadership. In her current role, she develops CEO perspectives and curates Accenture's annual Life Sciences CEO Forum, engaging industry leaders on the most pressing issues of the future. Prior to consulting, Selen worked as a scientist and process development engineer at leading biopharmaceutical companies, where she focused on cell line development and bioprocess design. Based in Boston, Massachusetts, she also serves on the Biotechnology Industrial Advisory Board at Northeastern University.

Contributors

Brendan Hughes, Ph.D
BPHughes CMC Consulting

in

Barry Heavey
Former Accenture Life Sciences Industry X
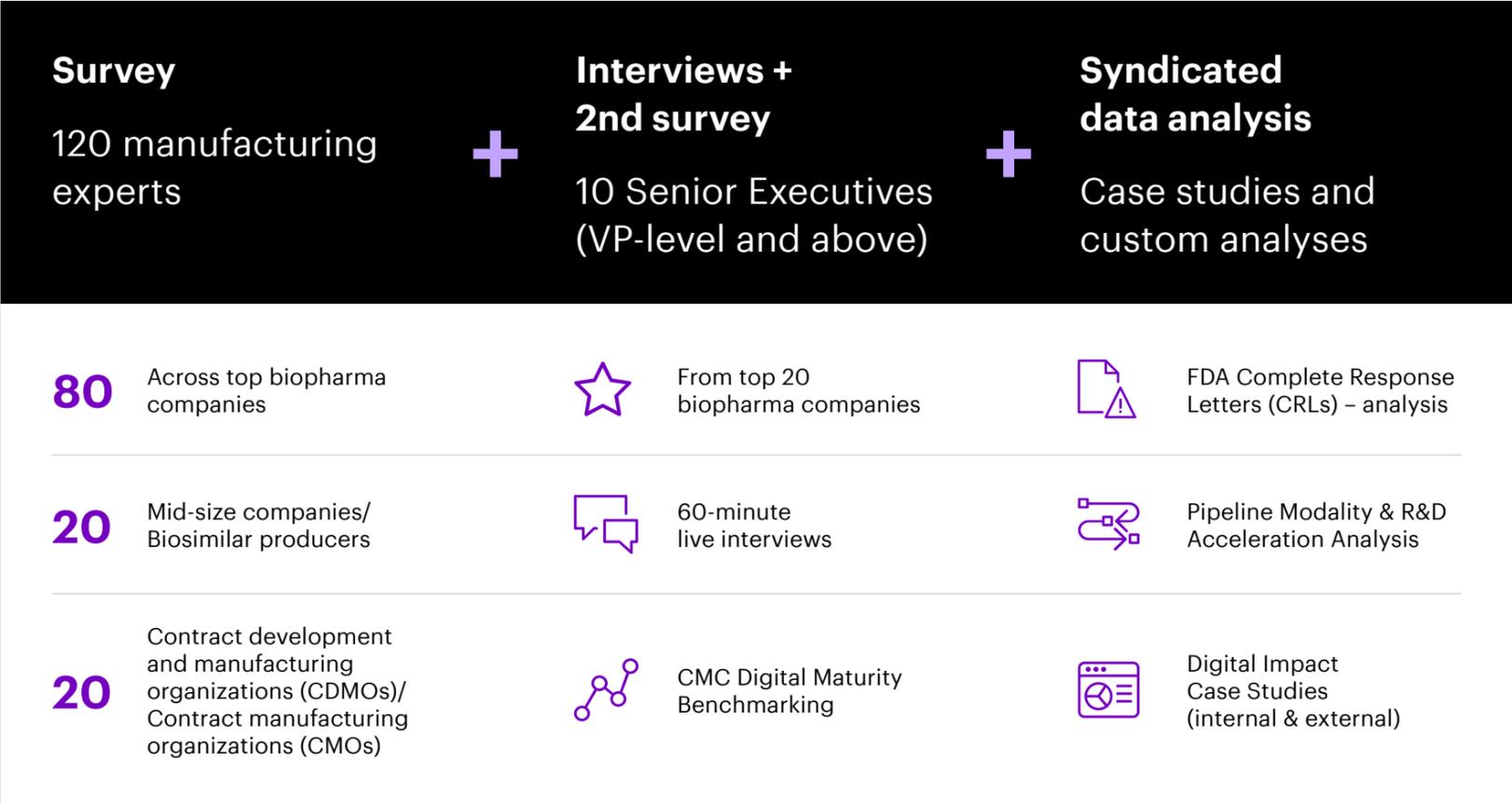and Supply Chain & Operations, Global Lead

in

About the research

Survey		Interviews + 2nd survey		Syndicated data analysis
Survey 120 manufacturing experts	**+**	**Interviews +** **2nd survey** 10 Senior Executives (VP-level and above)	**+**	**Syndicated** **data analysis** Case studies and custom analyses

What we did

80 Across top biopharma companies	From top 20 biopharma companies	FDA Complete Response Letters (CRLs) – analysis
20 Mid-size companies/ Biosimilar producers	60-minute live interviews	Pipeline Modality & R&D Acceleration Analysis
20 Contract development and manufacturing organizations (CDMOs)/ Contract manufacturing organizations (CMOs)	CMC Digital Maturity Benchmarking	Digital Impact Case Studies (internal & external)

Scope

This report focuses on biopharmaceutical manufacturing and supporting technical operations functions, including process development, chemistry, manufacturing and controls (CMC) and manufacturing science and technology (MS&T).

Throughout the report we will use the terms "manufacturing" and "technical operations" interchangeably to refer to the functional landscape.

The term "intelligent technologies" is used to describe digital solutions such as advanced data analytics, AI, generative AI, agentic AI, digital twins, automation and robotics.
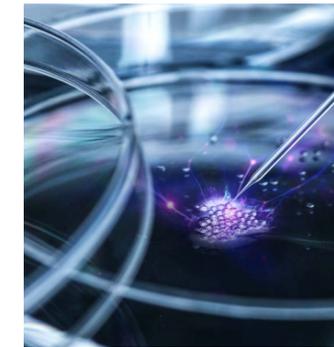
Table of contents

Executive summary

By scaling intelligent technologies across the product lifecycle—from robotic high-throughput process design to AI-augmented real-time analytics and decision making—biopharma leaders can reduce costs, accelerate launches and build more reliable, adaptive manufacturing systems.

Manufacturing is now on the critical path to delivering essential medicines to patients, a pivotal moment that demands tighter integration from lab to line to ensure speed, reliability, and quality. Complex biologics pipelines, AI-accelerated R&D and mounting geopolitical and economic pressures have catapulted manufacturing to a top priority, and with good reason—**64% of drug-launch delays in 2024 stemmed from chemistry, manufacturing and control issues**.[1]

A new generation of integrated digital ecosystems, powered by advanced analytics, AI, digital twins, intelligent agents and robotics, promise to transform biopharma manufacturing and process development. Organizations that lay the right data and infrastructure foundations are realizing competitive advantage including **faster time-to-market** in a crowded therapeutic landscape, **lower production costs** through smarter, more efficient processes and a **reliable, uninterrupted supply** that safeguards patient access.

Although **28% of our global survey respondents from top biopharma companies already have access to advanced intelligent tools**—supporting predictive or even partially autonomous processes—most companies are still in the early stages of scaling these capabilities with digital innovation confined to isolated initiatives. Even among companies achieving high digital maturity levels, certain teams operate with advanced capabilities while others still depend on legacy tools and manual workflows. With so many levers yet to be pulled, there is significant untapped value in more broadly embedding intelligent technologies across technical operations.

What should biopharma companies do to realize the full potential of intelligent technologies? Building on our experience delivering over 2,000 projects across industries, this research provides a pragmatic playbook for success, anchored in three key focus areas: Lead with value, build a solid data-and-systems foundation and reinvent workflows and ways of working.

Data, AI and other intelligent technologies are already rewriting the rules across the industry. As these capabilities advance, manufacturing has the potential to become a powerful engine for transformation rather than a limiting factor. Leaders who act now, with purpose and coherence, can transform manufacturing into a catalyst for enterprise-wide innovation and sustained competitive advantage.

Biopharmaceutical manufacturing stands at a critical inflection point

As the complexity of modalities in drug pipelines increases and AI-accelerated R&D compresses development timelines, manufacturing has stepped into the spotlight. Once a behind-the-scenes function, it now holds the potential to become a strategic differentiator, a source of competitive advantage. On the flip side, manufacturing could become a bottleneck in bringing therapies to market if neglected.

The pressure on manufacturing and technical operations continues to mount, driven by three powerful forces:

Increasing molecular complexity, with biologics now representing 55% of clinical pipelines.[2]

AI-driven acceleration of drug discovery and clinical trials, which demands that process development and manufacturing keep pace.

Broader external challenges, including geopolitical and economic volatility, supply chain disruptions, and intensifying competition.

These dynamics are reshaping what it takes to succeed in manufacturing. Teams must make their operations more resilient, scalable and adaptable— all while managing rising costs of goods sold and growing uncertainty.

The urgency for change is clear. Our analysis of FDA Complete Response Letters (CRLs) issued to top pharmaceutical companies between 2009 and 2024 shows that last year was unprecedented: over half (64%) of market delays were due to chemistry, manufacturing and controls (CMC) issues, delaying both patient access and revenues.[3] Most of these setbacks stemmed from the production of complex biologics, underscoring the strain on today's technical operations functions.

We won't be able to optimize the cost of goods unless we digitalize. So suddenly, this becomes R&D's problem and commercial's problem too—and that's the opportunity for manufacturing and CMC to step in and lead."

Head of Digital & AI Transformation
Top 20 large biopharma company

The key to building resilience to potential disruptions impacting pharmaceutical manufacturing lies in harnessing the power of data and intelligent technologies. In an era where data itself is a strategic asset, improving data connectivity and applying advanced analytics, AI, process twins, robotics and AI agents can dramatically boost speed and efficiency. These technologies can also reduce costs and strengthen preparedness for current and future challenges. The next frontier belongs to those who can leverage intelligent technology to augment—and even automate—critical workflows, enabling workers to work alongside intelligent systems.

For executives, the stakes could not be higher. Our research found that companies modernizing their manufacturing operations stand to capture three critical advantages:

- Accelerated time-to-market in an increasingly competitive landscape.
- Significantly lower production costs.[4]
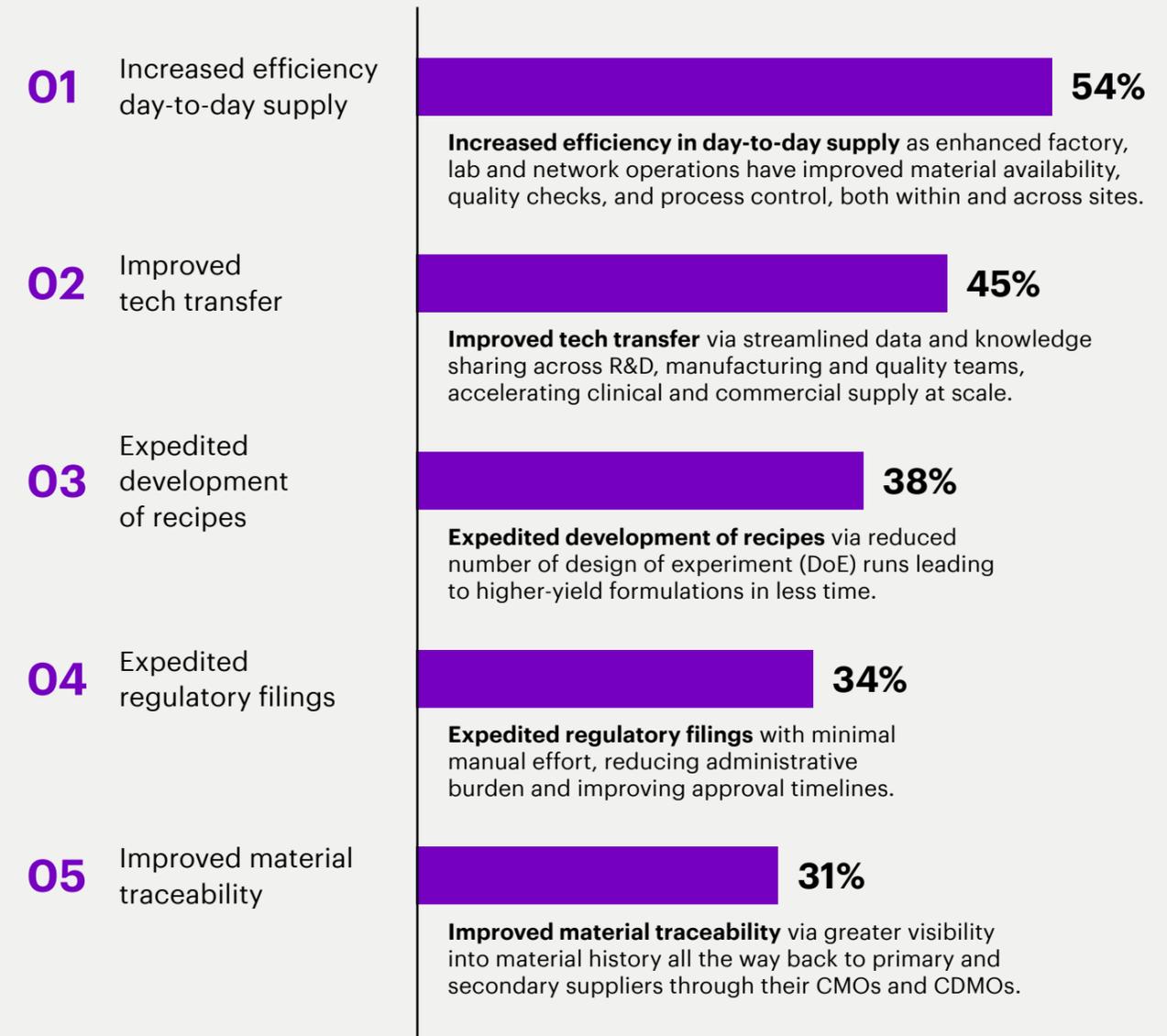- Secure an uninterrupted supply of medicines to patients.

The current state: Progress amid persistent challenges

Our research indicates that the pharmaceutical sector is at a pivotal juncture in its digital transformation journey. A new wave of advanced analytics and AI is rapidly emerging, yet adoption varies significantly across organizations.

In our global survey,[5] a significant portion of top biopharma organizations remain "stuck in the middle" of their digital journey. **35% of surveyed executives** indicated their companies function as **"connected organizations."** Our follow-up interviews revealed that even among those achieving high levels of advanced intelligent technologies adoption, significant disparities persist across business units, modalities and sites. **19% of top biopharma executives** reported operating in a **"predictive"** environment.[6] This means they are leveraging integrated systems that combine historical and real-time data with AI models to enable proactive process optimization, enhance operational efficiency and support data-driven decision-making. Less than **10% of respondents** reported operating in an **"adaptive"** environment, having partially autonomous, self-optimizing processes powered by AI, machine learning (ML) and robotics.

The value delivered by intelligent solutions, even for those in **"connected organizations"** stage is no longer hypothetical. Companies are reporting measurable impact across key areas of technical operations (see Figure 1).

Figure 1:
Large biopharma companies are seeing measurable gains across key technical operations areas

01 Increased efficiency day-to-day supply — **54%**

Increased efficiency in day-to-day supply as enhanced factory, lab and network operations have improved material availability, quality checks, and process control, both within and across sites.

02 Improved tech transfer — **45%**

Improved tech transfer via streamlined data and knowledge sharing across R&D, manufacturing and quality teams, accelerating clinical and commercial supply at scale.

03 Expedited development of recipes — **38%**

Expedited development of recipes via reduced number of design of experiment (DoE) runs leading to higher-yield formulations in less time.

04 Expedited regulatory filings — **34%**

Expedited regulatory filings with minimal manual effort, reducing administrative burden and improving approval timelines.

05 Improved material traceability — **31%**

Improved material traceability via greater visibility into material history all the way back to primary and secondary suppliers through their CMOs and CDMOs.

Source: Accenture Research Survey 2025; Top pharma companies (n=80)

"We've been systematically improving the predictive capabilities of these tools. Last year, we had the fastest tech transfer ever—of an asset that came through an acquisition.

We had very little prior knowledge, but we were able to de-risk the tech transfer and improve process performance, all of it **"in silico."**

Head of Digital & AI Transformation
Top 20 biopharma company

Increased efficiency in day-to-day supply

A majority of top biopharma executives (54%) reported improvements in day-to-day supply efficiency, translating into faster time-to-market and leaner cost structures. An advanced example, shared by an executive from a leading global biopharma company, involved embedding AI and real-time analytics into its manufacturing operations. This approach was used to address variability in their key biologic product. By continuously analyzing thousands of real-time process variables using machine learning, the system identified 10–15 key predictors that most strongly influenced yield. This enabled operators to intervene proactively—within validated ranges—before deviations could impact outcomes.

As a result, the company has created a smarter, more adaptive production environment that ensures higher efficiency and product quality, reducing waste in manufacturing. All of this was possible because of embedding AI directly into live manufacturing operations.

Improved tech transfer

Similarly, 45% of executives highlighted major advancements in technology transfer.

One company implemented computer-based simulation modeling (known as in silico modeling) to predict optimal manufacturing parameters prior to physical execution. This approach proved especially valuable during the transfer of an acquired asset with limited prior documentation. As a result, they achieved their fastest tech transfer of an asset through acquisition to date.

The roadblocks on the way to scale digital initiatives

While there are great success stories, most companies today stand at an inflection point (see Figure 2). Those that succeed in industrializing their digital capabilities have the opportunity to scale rapidly and progress toward fully autonomous, end-to-end operations.[7]

Yet, this potential remains largely untapped. Our research reveals three persistent barriers holding back progress:

- Digital pilots are often confined to low-risk, low-impact areas.
- Core data infrastructure and systems are not yet ready to support scale.
- Initiatives remain siloed within functions, eg. product development, MS&T, regulatory and quality and IT/digital.

The result? Fragmented solutions with limited return on investment (ROI), digital initiatives that cannot scale and a growing number of "digital dead ends".[8] These disconnects are widening the gap between ambition and execution. If left unaddressed, the industry's digital momentum could stall, or worse require costly rework.

While these hurdles have stalled progress, they also reveal a clear opportunity to rethink the role of intelligent technologies and unlock improvements across the entire product development lifecycle.

Figure 2:
Crossing the inflection point from experimentation to execution calls for reinvention
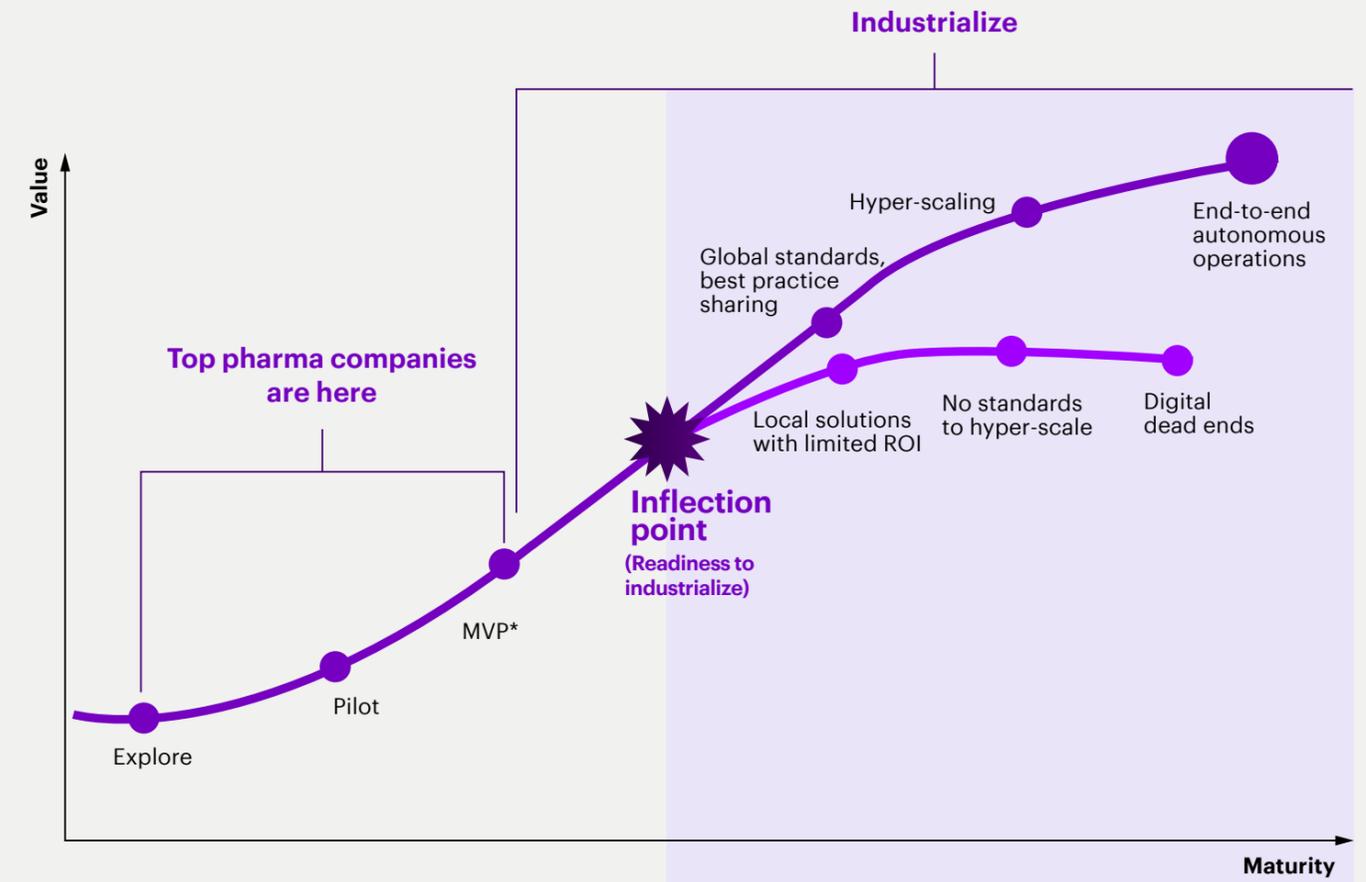
*MVP-minimum viable product

Source: Accenture analysis

Reinventing the product development lifecycle with intelligent technologies

Reinventing the product development lifecycle demands a bold, clear vision. To allocate human capital and spend wisely, technical operations leaders should work "from the future back," first conceptualizing and designing the optimal AI-enabled technology stack supporting a true digital thread and then asking, "What does good look like—and how do we get there together?"

Envision an end-to-end, AI-powered platform that reshapes every stage of the product lifecycle. For the purpose of this report, we'll use an antibody-drug conjugates (ADCs) as a proxy for an advanced modality that can progress through the product lifecycle at pace. AI or machine learning tools can accelerate this process by identifying optimal targets and optimizing antibody sequences.[9]

This, coupled with predicting the best linker-payload combinations and simulating efficacy and toxicity profiles can significantly reduce early-stage development timeline.[10]

As groundbreaking as it is, AI-accelerated drug design also puts technical operations under growing pressure, requiring the creation of an equally fast development process.

To fully capture the economic benefits of accelerated R&D, companies must optimize the entire product lifecycle, from product development labs to production lines —and intelligent technologies can play a pivotal role across every function at every stage of technical operations (see Table 1). With the right digital capabilities in place, organizations can significantly shorten timelines from initial candidate to approval.

Table 1:
How to leverage intelligent technologies across functions to improve the product lifecycle [illustrative examples, not exhaustive]

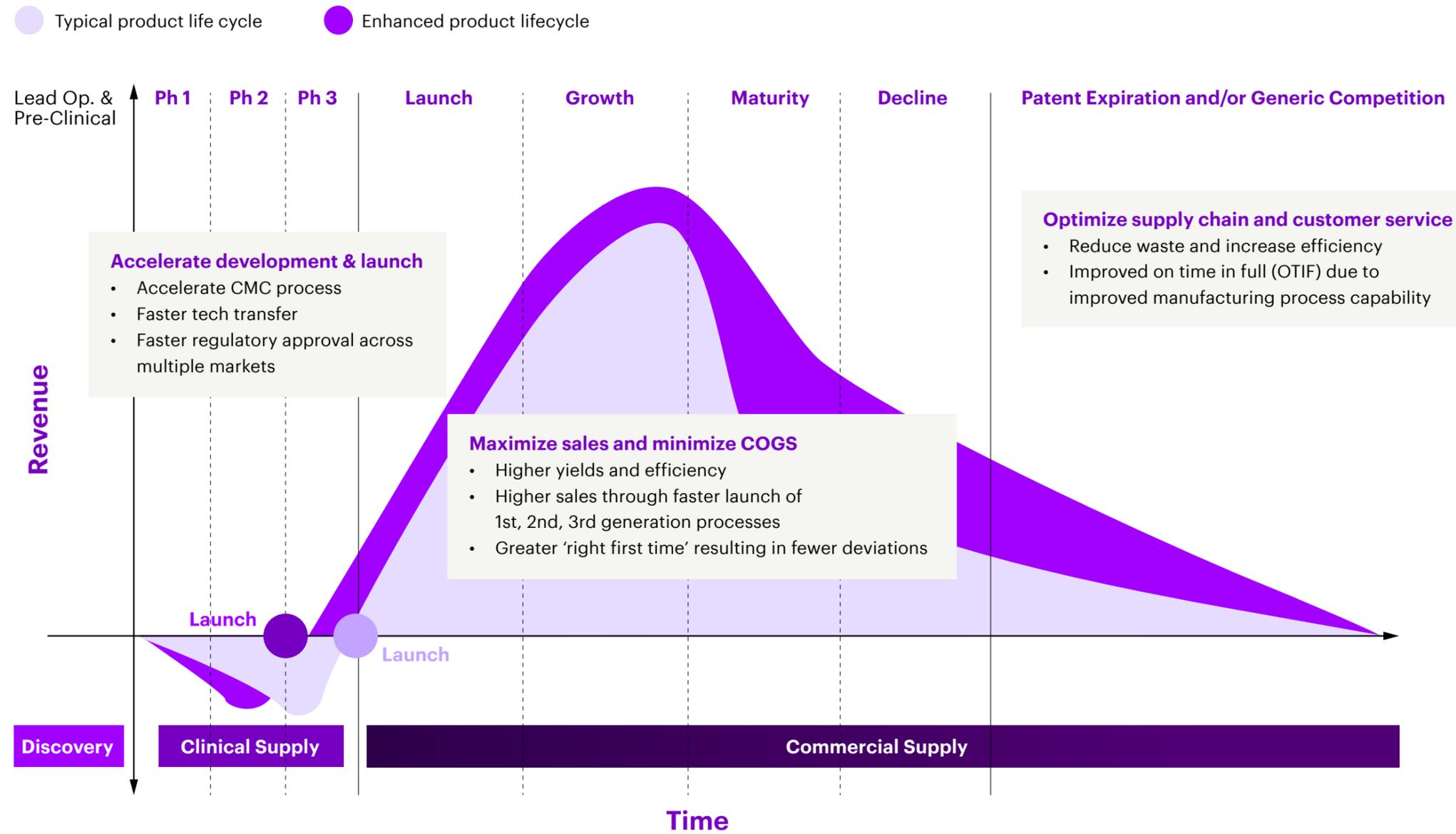| Stage	Intelligent technologies	Outcomes
Process Development	AI/ML-enabled process modeling (robotic high-throughput DoE)[11]	Reduce lab work, accelerate development (e.g., faster identification of optimal cell lines, conjugation conditions and optimal process parameters) and improve yield
	Digital twin process simulation (virtual process replica)[12]	Consistency and scalability while reducing process development time
Analytical Methods	Process analytical technology (PAT) and real-time monitoring	Ensure consistency and scalability and reduce batch release times, improve supply chain predictability
Tech transfer/ Scale up	AI-powered enterprise knowledge management tools	Predict process variations, mitigate risks and ensure seamless transitions from early-stage production to commercial-scale manufacturing
	Digital product lifecycle management (PLM) system with dynamic process flow descriptions	Eliminate static document inefficiencies, reduce errors in knowledge transfer
Regulatory submissions	Generative AI-powered documentation automation	Accelerate CMC dossier compilation, submissions and responses to regulatory queries
Post-launch	Continued process verification (CPV) analytics using AI/advanced analytics	Maintain consistent product quality over time and regulatory compliance by documenting stable operations and fast corrective actions

Our experience, research and industry case studies show clear quantifiable benefits of adopting intelligent technologies in the product development lifecycle:

- Reduced time-to-market by up to **40%**[13]
- Improved throughput in process development by **30%**[14]
- Yield enhancements of over **400%** in upstream (cell culture) processes, with further cumulative gains possible across downstream and conjugation steps, lowering costs, carbon footprint and future capacity needs[15]
- Batch lead time reduction of up to **50%**, minimizing work-in-progress inventory[16]
- Increased efficiency in deviation investigations, cutting analysis time by over **50%**[17]

As seen in Figure 3, adoption of intelligent technologies across the product lifecycle can unlock unprecedented value for biopharma companies.

Figure 3:
From good to great: reinventing the product lifecycle

● Typical product life cycle ● Enhanced product lifecycle

Lead Op. & Pre-Clinical | Ph 1 | Ph 2 | Ph 3 | Launch | Growth | Maturity | Decline | Patent Expiration and/or Generic Competition

Revenue

Accelerate development & launch
- Accelerate CMC process
- Faster tech transfer
- Faster regulatory approval across multiple markets

Optimize supply chain and customer service
- Reduce waste and increase efficiency
- Improved on time in full (OTIF) due to improved manufacturing process capability

Maximize sales and minimize COGS
- Higher yields and efficiency
- Higher sales through faster launch of 1st, 2nd, 3rd generation processes
- Greater 'right first time' resulting in fewer deviations

Launch

Launch

Discovery | **Clinical Supply** | **Commercial Supply**

Time

By following this transformation blueprint, biopharma companies can:

01 **Accelerate drug development and launch** by accelerating all underlying activities like CMC process development, tech transfer and regulatory submissions across multiple markets.

02 **Maximize sales and margins** with higher yield and efficiency, fewer deviations and faster launches of right first-time processes.

03 **Optimize supply chain and increase customer satisfaction** by reducing waste, improving on-time in-full (OTIF) due to improved manufacturing and reducing issue resolution time.

A roadmap for unlocking the value of intelligent technologies in technical operations

Drawing on insights from more than 2,000 projects implementing intelligent technologies across industries,[18] we provide a clear and practical guide for executing successful digital CMC transformation programs. These recommendations are grounded in findings from our global survey of 120 technical operations experts and in-depth interviews with senior executives, offering a view into how digital transformation plays out in real-world CMC environments. The insights are organized around three key focus areas that together define what it takes to scale intelligent technologies effectively in manufacturing and technical operations.

01

Lead with value

Anchor every initiative in a quantified business case

02

Build a solid data-and-systems foundation

Standardize data, integrate platforms and automate flows

03

Reinvent workflows and ways of working

Redesign roles and processes to exploit the new digital capabilities
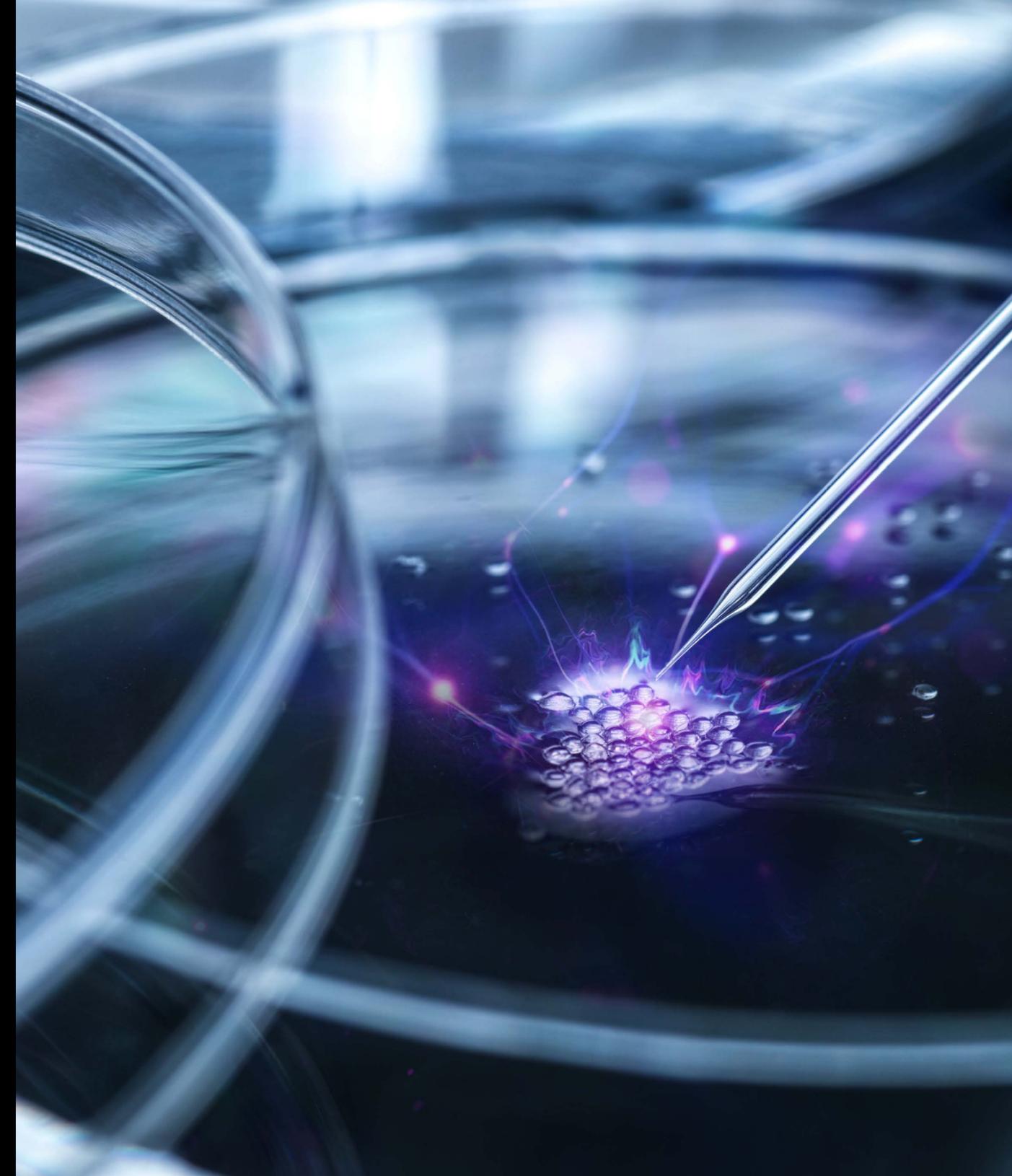
Focus area 01

Lead with value

The recent MIT NANDA State of AI in Business 2025 report warns that 95% of organizations are seeing no returns from their generative AI investments.

The few that achieve results focus on tailoring solutions to specific processes and assessing tools through the lens of measurable business outcomes.[19] A sharper focus on ROI—and on the potential value lost by not acting—is essential.

Using intelligent technologies to systematically accelerate innovation, enhance operational capabilities and fuel long-term growth requires a new mindset: one that moves beyond isolated proofs of concept and instead reimagines how core processes and systems can be fundamentally transformed. Organizations that adopt this value-first approach are best positioned to unlock the full promise of digital reinvention.

Focus area 01
Lead with value

Action 01

Harness the power of intelligent technologies in technical operations with a bold end-to-end vision

A vision where intelligent technologies support the product delivery end-to-end (from lab to line) is essential to establish fully robust and resilient biopharma production processes. With strong leadership commitment, technical operations can become powerful growth drivers—enabling faster decisions, stronger portfolio delivery and a lasting competitive edge.

"We began discussing digital transformation in terms of additional molecules and new opportunities. If we could implement [specific digital capabilities] we could take on two more molecules a year without increasing headcount."

Head of Digital & AI Transformation, Process Development
Top 20 biopharma company

Focus area 01
Lead with value

Action 02

Be value-led in every business capability you reinvent

Every digital transformation program—even at the pilot stage—should be anchored in clear success metrics and KPIs. Business cases that show both operational improvements and measurable financial gains build organizational confidence in intelligent technologies and justify continued investment in scaling digital capabilities.

"Just this year, we increased throughout by 30% simply by changing the operational strategy— without adding more people or buying more equipment, just by running the plant differently. (...) That has an immediate P&L impact— you don't have to hire additional people, which translates directly into cost savings."

Head of Digital & AI Transformation, CMC and R&D
Top 20 biopharma company

Action 03

Align cross-functional transformation goals and regularly communicate progress with functional leaders

Because business problems in technical operations rarely align neatly with organizational boundaries, it is essential to have multidisciplinary teams developing capabilities that span business and digital/IT functions, from data science to process science. To maximize efficiency and ROI, these teams should have direct access to leadership and meet regularly to review the portfolio, programs, digital capabilities and strategy. Ongoing transparency ensures that digital gains translate into enterprise-wide value.

"Those things [the work of data science teams and new tools, capabilities, and technologies they develop or implement] don't surface to this level of governance, but they are going to transform the organization. So we all need to pay attention to them and be accountable to our leaders."

Head of Digital Transformation, Manufacturing Science and Technology
Top 20 biopharma company

Case study

A top global biopharma company set to double yearly launches by learning from industry frontier

A top global biopharma company wanted to move beyond the industry's product development curve. An emergency sprint program during the pandemic demonstrated the power of digital tools and streamlined decision-making. Building on that momentum, leadership set a bold ambition: bring lessons learned from industry on "best in class" business practices to double yearly launches from two to four assets. Achieving this required more than automation—it called for a strategic redesign of the product development process, with the goal of anchoring it in data, digital systems and future-ready ways of working.

Over an 18-month transformation, Accenture and the client co-developed an interconnected digital transformation roadmap from development and scale-up through to commercialization.

At the core of the solution was a reimagined digital CMC and New Product Introduction (NPI) model[20]— one that leverages digital method transfer, push-button material setup, real-time process transfer and demand visibility. Pain points across more than 250 CMC activities were systematically mapped and addressed. The outcome: up to 3,900 days saved across CMC processes and 26,000 hours of subject matter expert time freed up per NPI.

This enabled the organization to:

- **Double yearly launches with the same headcount**
- **Set the stage for cumulative productivity gains of over $80 million within four years**

This transformation exemplifies what it means to lead with value. By anchoring its vision in a solid business case underpinned by a digital transformation roadmap, technical operations paired disciplined execution with executive backing and proved that CMC can be a strategic growth engine, not merely a cost of doing business.

Focus area 02

Build a solid and secure data-and-systems foundation

Imagine a technical operations or CMC command center where every scientist, engineer data-scientist and quality lead can open a single, secure dashboard and see, at a glance, the real-time status of raw-material quality, reactor conditions, deviation investigations, batch-release testing and dossier-ready e-submissions. With that kind of seamless visibility, tech transfers would be orchestrated with "click-to-transfer" data packages, and regulatory updates could flow as structured data directly to health authorities, enabling faster, more successful approvals.

Whilst every function operates within their own systems and data structure, it's a stark reminder that fragmented, un-governed information is throttling speed and compliance.[21]

The missing element is what Accenture calls the digital core: a technology-enabled backbone that integrates cloud, data, AI and security across enterprise and partner ecosystems. Companies that build this foundation are 1.8x more likely to achieve best-in-class performance and unlock the continuous reinvention that intelligent technologies now demand.[22]

Today, most organizations are a long way from that vision. Accenture research finds that 67% of companies do not trust their data enough to use it effectively. Additionally, 55% still rely on largely manual methods just to discover where data resides.

Focus area 02
Build a solid and secure
data-and-systems foundation

Action 01

Standardize CMC data around shared ontologies and global guidelines

Integrating CMC process, quality and regulatory data with recognized standards such as ISA-88/95, ICH Q8–Q12, HL7 PQ/CMC and eCTD v4.0 creates the foundation for seamless interoperability. Consistent, structured data flows accelerate traceability, enable automated submissions and power AI to deliver actionable intelligence across development, manufacturing, quality and regulatory domains.

"One thing that I would ask you to do, more than anything else, is focus on data standards and frameworks—not only for the large biopharma innovators, but also for the CMOs and the instrument providers. It's about thinking of the whole ecosystem and everybody has a role to play."

Head of Digital & AI Transformation, Process Development
Top 20 biopharma company

Focus area 02
Build a solid and secure
data-and-systems foundation

Action 02

Adopt a 'data-as-a-product' operating model—owned by the domains that deliver the value

Empower MS&T, QC and regulatory teams to curate their own data products—cell-culture genealogy graph, sterile-fill deviation library or validated CPP/CQA23 time-series feed. Each product has a dedicated owner, service-level targets and zero-trust access controls and is explicitly tagged as GxP or non-GxP. Version-controlled, reusable products cut redundant validation and give data scientists a trusted foundation for AI, digital twins and automated e-submissions.

"You need to define what master data is—and someone needs to own it. That creates new roles in manufacturing that aren't really IT or analytics roles, but business roles focused on managing master data. From there, you can see the layers: raw data, master data, and then data products. (…) Your data strategy then becomes about defining what these foundational data products are and working backwards from the needs of the business."

Head of Digital & AI Transformation, CMC and R&D
Top 20 biopharma company

Focus area 02
Build a solid and secure
data-and-systems foundation

Action 03

Instrument, virtualize and predict—then close the loop with autonomous control

Integrating IoT sensors, edge analytics and digital twins elevates technical operations into proactive engines of growth. Simulated "what-if" scenarios and AI-driven control strategies optimize resources, strengthen resilience and accelerate product release— transforming workflows into agile, intelligent value streams.

"By embedding digital twins throughout development—from modeling plant and process behavior to product performance—we reduce the need for costly large-scale experiments (...) When applied to platform technologies, these models are reusable across modalities, cutting development timelines by 12 to 24 months and accelerating patient access to critical therapies."

Head of Digital Transformation, Manufacturing Science and Technology
Top 20 biopharma company

Case study

Harnessing product and platform knowledge from lead optimization to launch through a unified digital PLM backbone

A leading global pharmaceutical company faced a familiar yet critical challenge: fragmented data, inconsistent documentation and time-intensive processes were stalling innovation and regulatory responsiveness in its technical operations. Key pain points included the lack of end-to-end product and process traceability, manual document preparation and approvals, and disparate master data without a single source of truth. These gaps not only slowed post-approval changes but also undermined the company's ability to scale digital capabilities across its network. To address these issues, the company partnered with Accenture to initiate a global product lifecycle management (PLM) program.

The transformation began with a comprehensive discovery phase and a PLM proof of concept to inform vendor selection. Accenture then led a multi-stream effort encompassing vendor assessment and use case prioritization to redesign the business process.

This was followed by the technical deployment of QbDVision, a cloud-based platform purpose-built to manage product and process knowledge using structured, regulatory-ready data. A global roadmap and transformation office were established to ensure governance, cross-functional alignment and long-term value creation.

This resulted in a strong digital foundation for CMC and technical operations:

- **Doubling the availability of findable, accessible, interoperable and reusable (FAIR) data**
- **Reducing post-regulatory change timelines by 84%**

The shift to a unified digital platform exemplifies how companies can operationalize the digital core—enabling real-time visibility, better data integrity and a scalable path toward the vision of an integrated command center for technical operations.

Reinvent workflows and ways of working

The next wave of transformation will demand a reinvention of how work is designed, executed and experienced rather than just technology implementations. As one executive noted:

The biggest challenge ahead will be cultural—shifting mindsets to see data as a core asset and workflows as dynamic systems ready for disruption.

Intelligent technologies are fundamentally reshaping not only how work is performed, but also what skills are required. Generative AI has already become embedded in functions like software engineering and data science, driving new ways of working and accelerating productivity. Similarly, advanced AI research and reasoning tools—now widely adopted across industries—are changing how discovery, R&D and process development are approached, shifting them from manual, linear activities to highly augmented, iterative ones.

This shift shows no signs of slowing. The rise of AI-powered digital and physical agents will augment the human workforce, freeing employees from repetitive tasks, reducing operational risks and accelerating cycle times. Our latest research, conducted in collaboration with the Wharton School of the University of Pennsylvania, estimates that agentic AI could unlock $180–240 billion in annual value for the US biopharma industry, with approximately 55% of working hours impacted across the enterprise.[23]

The effect on technical operations and commercial manufacturing will be significant: approximately 60% of working hours are expected to be impacted across insights and analytics (including manufacturing analytics) roles, 50% in R&D and 40% in manufacturing strategy, production scheduling, optimization and execution.[24]

Crucially, this transformation is not about replacing human workers but equipping them with new tools— or even intelligent agent companions—to help them perform more effectively and competitively. With a clear vision and targeted investment in upskilling, leaders can reshape talent models to align with digital capabilities and data-centric ways of working. This will pave the way for greater agility, innovation and long-term enterprise value.
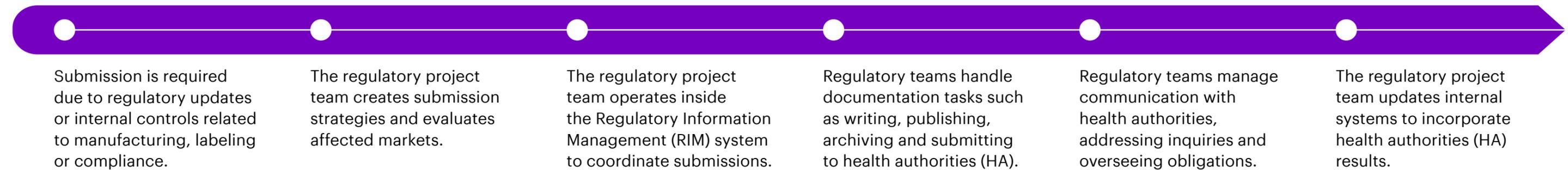
**Figure 4:
Working hours to be impacted**

Insight and analytics (including manufacturing analytics)	60%
R&D	50%
Manufacturing strategy, production, scheduling, optimization and execution	40%
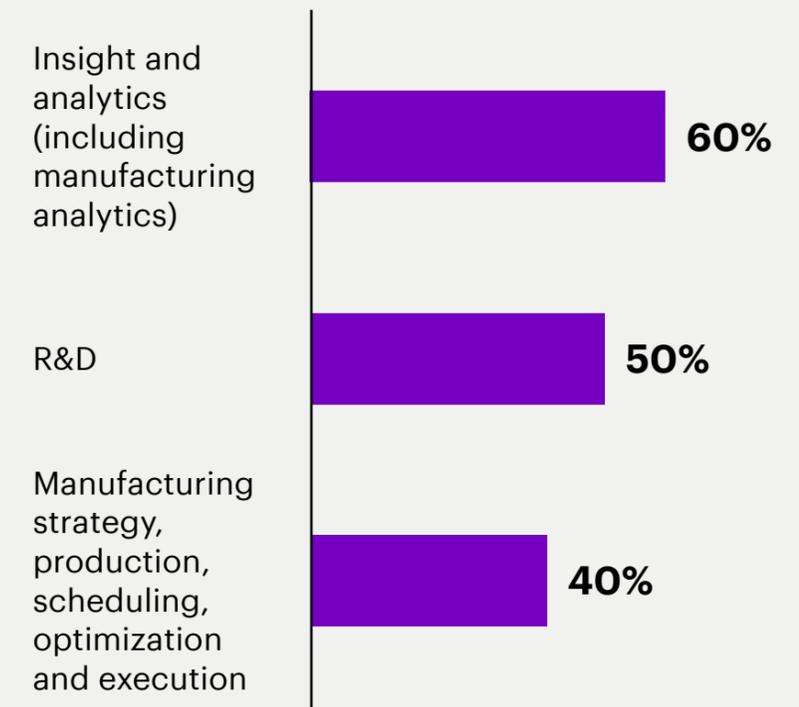
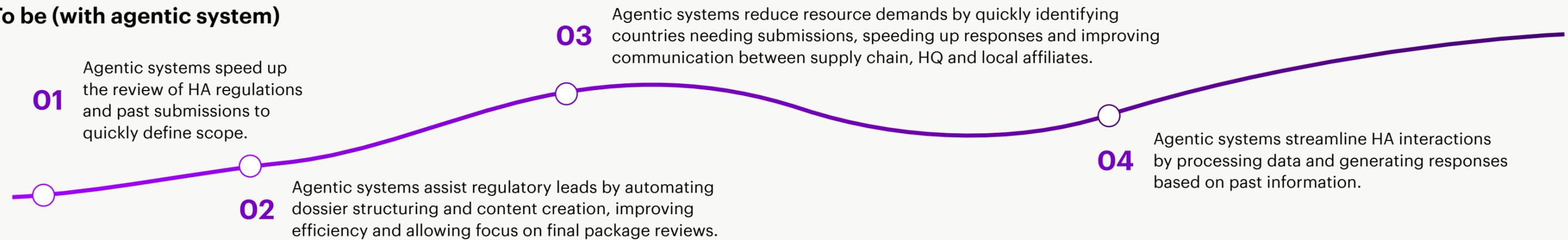**Source:** Accenture Research leveraging BLSand ONET data

Figure 5: An example of reinventing workflows to connect manufacturing and regulatory affairs

The transformation shown here illustrates how intelligent and agentic systems can modernize regulatory workflows—moving from manual, sequential processes to a connected, data-driven model. By linking manufacturing, technical operations and regulatory through shared data foundations, organizations can accelerate submission readiness, reduce CMC-related delays, and free regulatory experts to focus on high-value review and strategic decision-making.

As is

| Submission is required due to regulatory updates or internal controls related to manufacturing, labeling or compliance. | The regulatory project team creates submission strategies and evaluates affected markets. | The regulatory project team operates inside the Regulatory Information Management (RIM) system to coordinate submissions. | Regulatory teams handle documentation tasks such as writing, publishing, archiving and submitting to health authorities (HA). | Regulatory teams manage communication with health authorities, addressing inquiries and overseeing obligations. | The regulatory project team updates internal systems to incorporate health authorities (HA) results. |

To be (with agentic system)

01 Agentic systems speed up the review of HA regulations and past submissions to quickly define scope.

02 Agentic systems assist regulatory leads by automating dossier structuring and content creation, improving efficiency and allowing focus on final package reviews.

03 Agentic systems reduce resource demands by quickly identifying countries needing submissions, speeding up responses and improving communication between supply chain, HQ and local affiliates.

04 Agentic systems streamline HA interactions by processing data and generating responses based on past information.

Benefits

Simplifies drafting submission dossiers by generating initial drafts and ready-made content summaries.

Enhances efficiency by simplifying collaboration and sharing workflows.

Improves accuracy by providing teams with the most up-to-date data.

Minimizes time needed to research current regulations, guidelines and gather information.

Action 01

Strengthen cross-functional collaboration and data flow

Improving collaboration and data flow across discovery, product development, quality, MS&T, regulatory and commercial manufacturing is essential to unlock the transformative potential of intelligent technologies. One example of how companies can achieve this is by moving away from fragmented workflows and adopting centralized knowledge and product lifecycle management (PLM) systems. These platforms create a single source of truth for product and process data during tech transfer and enable faster, more confident decisions that accelerate delivery of new therapies.

"I'm asking people to fundamentally rethink their workflows so they are enabled and ready for artificial intelligence. Taking away Excel from their hands. Put this on record, please. There is no way biopharma can scale while continuing to work in Excel and present results in PowerPoint".

Head of Digital & AI Transformation, Process Development
Top 20 biopharma company

Focus area 03
Reinvent workflows and ways of working

Action 02

Improve collaboration between technology and business teams

Companies leading in digitalization succeed by forming integrated business-technology teams working towards shared goals. Scientists and engineers must understand the possibilities of technology, while technical teams must grasp the realities of the business—only then can organizations deliver real solutions to real problems.

"All scientists are really bad at writing these requirements—maybe one percent isn't. Engineers are better, because it's explicit and something they're used to doing. But this is the communication mechanism between IT and the business, we need to lower the barrier between them."

Head of Digital & AI Transformation, Process Development
Top 20 biopharma company

Action 03

Empower employees and cultivate data literacy

Sustained transformation requires employees to gain the skills, confidence and mindset to thrive in a data-driven environment. Leaders must emphasize that AI augments, not replaces, humans. Companies need to invest in structured upskilling programs to help employees maximize their multidisciplinary ways of working. The implementation of tools with a user-centered design, and supportive leadership create a culture where data is treated as a strategic asset and AI is viewed as a trusted partner in decision-making.

"How do you select the right skills? The most valuable people we've found are internal employees who pick up data science. (...) With the right courses and exposure, they return with fresh perspectives—proposing dynamic dashboards, automated workflows and entirely new ways of working."

Head of Digital Transformation, Manufacturing Science and Technology
Top 20 biopharma company

Case study

Reinventing workflows to bridge the gap between research and technical operations

A global pharmaceutical company's R&D division faced mounting pressure to accelerate innovation but struggled with fragmented workflows and siloed data. The lack of standardization across research and development functions, combined with limited traceability and reliance on tribal knowledge, made effective cross-functional collaboration difficult. These inefficiencies delayed cycle times, hindered visibility and limited the organization's ability to scale innovation. The company partnered with Accenture to fundamentally rethink how work is designed and executed.

Together, the teams co-created a NextGen PLM strategy, grounded in a North Star vision to build a connected, intelligent R&D ecosystem—where data

flows seamlessly, decisions are driven by insights and teams collaborate across functions to accelerate innovation and deliver medicines to patients faster. By prioritizing high-impact use cases such as product and process genealogy, tech transfer and risk management, the program aligned digital investments to measurable business value.

Through process harmonization and organizational change, the initiative is redefining collaboration by introducing standardized workflows, structured data capture and improved cross-functional transparency. Importantly, the program empowers functional experts and change advocates as "super users," fostering a culture of ownership, continuous learning and readiness for future tech-enabled capabilities.

This transformation demonstrates that reinventing workflows is not just about system implementation—it's about enabling people to work smarter, faster and more collaboratively. The initiative not only lays a scalable digital foundation but also sets the stage to achieve ambitious goals:

- **50% time savings, shifting researchers' effort fom repetitive, manual and low value areas to higher impact activites**
- **Accelerated time-to-patient**

Most importantly, it equips the workforce with the tools and mindset needed to thrive in a data-driven, innovation-led future.

The future of biopharma production is driven by technology

As tech ops or CMC adopts intelligent technologies, across the full value chain from lab to line, there is real opportunity to expand the revenue curve, to shorten the launch curve and extend the life cycle of therapies. This transformation is a fundamental shift in how companies view and manage their operations; building not only plants or labs of the future, but a 'lifecycle of the future'.

Early adopters have already seen significant improvements in efficiency, cost reduction and time-to-market. Yet, most companies find themselves in precarious middle ground, recognizing the need for change but grappling with the complexities of scaling these innovations. The journey is fraught with obstacles, from misaligned digital initiatives to fragmented data governance and functional silos that stifle broader impact.

Large biopharma, like every other sector, will inevitably be changed by the power of data and intelligent technologies. For companies that lead this transformation, the impact will go far beyond incremental gains in isolated metrics. They will lead with value, strengthen their digital core and reinvent their workflows to redefine how they operate, drive profitability and ultimately benefit the patients.

How Accenture can help

In response to the increasing complexity and pace of change in biopharmaceutical production, Accenture supports organizations seeking to optimize their technical operations with intelligent technologies. Our deep industry expertise and leading technology capabilities across lab to line systems equip us to partner with our clients to generate tangible business outcomes. Our approach focuses on prioritizing process reinvention, establishing robust data foundations, implementing scalable agentic architectures, and empowering employees in their transformation journeys. These interventions address operational challenges and enable sustainable performance improvements across manufacturing environments.

To deliver tangible outcomes, we focus on three core areas that underpin successful digital transformation:

- **Lead with value.** Using intelligent technologies across the entire product lifecycle to systematically accelerate innovation, enhance operational capabilities and fuel long term growth.

- **Build a solid data-and-systems foundation.** Implementing data infrastructures with advanced computing power to support rapid analytics, digital twins and building digital target product and process profiles for improved tech transfer and manufacturability. Leveraging Accenture's proprietary agentic architecture to build scalable AI and agentic workflows to enhance the product lifecycle.

- **Reinvent ways of working.** Taking a 360-degree approach to process reinvention by identifying and prioritizing specific processes and personas, reducing friction and streamlining operations. In addition, leveraging the latest AI-enabled practices to transform the workforce's capabilities

Research methodology

Survey

Accenture surveyed 120 technical operations leaders across 10 countries from top-tier biopharma companies, small to mid-sized biopharma companies, biosimilar manufacturers, as well as CDMOs and CMOs to gain perspective on current challenges, priorities, digital maturity levels, and opportunities for accelerating digital transformation in the manufacturing of advanced modalities, in order to improve efficiency, reduce costs and enable faster, more reliable supply. The survey was conducted between November and December 2024. The global sample has a margin of error +/- 8.95%.

Types of companies surveyed:
- Top biopharma companies (80)
- Small-mid size biopharma companies/Biosimilars producers (20)
- CDMOs/CMOs (20)
- Senior/Associate Directors

Countries surveyed:
- United States
- Japan

- Europe:
  - Germany
  - United Kingdom
  - Italy
  - France
  - Switzerland
  - Denmark
  - Spain
  - Sweden

Modalities of focus:

Survey respondents have experience working with at least one biologic modality and often with a broad range of modalities.
- Recombinant proteins
- Vaccines
- Oligonucleotides
- Gene or cell therapies
- Peptide therapeutics
- Small molecules
- Plasma-derived therapies
- Radiopharmaceuticals

Executive interviews and digital maturity benchmarking survey

Interviews

To complement the research, Accenture conducted in-depth interviews with 10 senior executives from the top 20 global biopharmaceutical companies between December 2024 and February 2025. All participants held VP-level or higher roles and represented a balanced mix of leaders from process development and manufacturing science and technology (MS&T) process development and manufacturing science and technology functions. The interviews explored organizational priorities, digital transformation challenges, and leadership perspectives on accelerating innovation in technical operations.

Digital maturity benchmarking survey

To build on these qualitative insights, the interviews were followed by a targeted survey benchmarking the digital maturity of technical operations across leading biopharma companies. This enabled a comparative view of top biopharma organizational capabilities, priorities, and progress across the industry. The survey was conducted between March and June 2025. Accenture gathered responses from 9 respondents from top 20 global biopharma companies.

CRL analysis

Accenture conducted an analysis of Complete Response Letters (CRLs) issued by the US Food and Drug Administration (FDA) to the top 25 global biopharmaceutical companies between 2019 and 2024. The objective was to understand the primary reasons for CRL issuance, as well as the potential impact on product launch timelines, product types (biologic vs. non-biologic), and the underlying technology platforms (e.g., small molecules, monoclonal antibodies, CAR-T cell therapies).

Scope and criteria

- **Product focus:** Drug-related CRLs, including products involving a drug-device combination (e.g., inhalers, injection devices, infusion pumps, digital sensors)
- **Company selection:** Top 25 global biopharmaceutical companies by 2024 prescription sales
- **Timeframe:** CRLs issued between January 2019 and December 2024, with public disclosures reviewed through July 2025

Data collection approach

A structured review of publicly available, English-language sources was conducted. Sources included:

- Corporate press releases, SEC filings (e.g., 10-Ks) and investor presentations
- The FDA website, including CRL updates through July 2025
- Industry news outlets and trade publications

Data categorization

Each CRL was classified based on the primary reason(s) cited by the FDA, including:

- CMC (chemistry, manufacturing and controls)
- Efficacy
- Safety
- Other (e.g., labeling issues)

Multiple tags were applied when applicable.

Deduplication methodology

For products that received multiple CRLs related to the same issue and indication, only the initial CRL was included to avoid duplication.

Limitations

This analysis is based exclusively on publicly disclosed information. Publicly traded companies are legally required to report material events—such as regulatory actions that could affect financial performance—including CRLs that may delay product approvals or launches. It is therefore assumed that most material CRLs are disclosed.

However, in cases where insufficient information was provided on the reason for the CRL, those CRLs were excluded from classification and broader analysis.

Digital maturity scale

Acknowledgement

The naming convention for maturity levels and the use of a 1–5 scale in our survey and scorecard are based on BioPhorum's Digital Plant Maturity Model 3.0.24 While we drew on the structure of BioPhorum's framework, we adapted the definitions to reflect a broader, organization-wide perspective—beyond the plant or site level.

Survey questions and definitions

Survey question: How would you classify the current digital maturity level of your manufacturing organization? Response options and definitions: The following predefined digital maturity levels were provided as response options in the survey, each with a corresponding definition:

1. **Pre-digital organization:** The organization predominantly relies on manual, paper-based processes across functions. Data capture, storage and processing are fragmented, with minimal or no use of digital tools or technologies. Collaboration and decision-making are heavily dependent on human judgment and physical documentation.

2. **Digital islands organization:** The organization has implemented isolated pockets of digitalization—"islands of data-driven decision-making or automation"—within specific functions, teams or facilities. While these islands may enhance efficiency locally, they remain disconnected, with little to no integration across systems or processes. The adoption of data-driven decision-making is sporadic and tool-dependent. Most collaboration with external organizations is paper-based, resource-intensive and time-consuming.

3. **Connected organization:** The organization has achieved a moderate level of automation, integration and system standardization across many functions. Data flows seamlessly across departments, improving operational efficiency and decision-making for products within that modality platform. There is a growing emphasis on leveraging data analytics and insights from integrated systems, though advanced technologies like AI and machine learning are not yet pervasive. Significant challenges persist in enabling data-driven collaboration with external organizations.

4. **Predictive organization:** The organization operates with an integrated network of systems that enable elements of in silico predictive process optimization, using historical experience and real-time predictive analytics for ongoing experiments or batches. Data is consistently leveraged to rapidly optimize processes for quality, scale, yield and robustness, and to anticipate and proactively address issues in experimental, clinical or commercial production. This enhances overall performance. AI is beginning to play a role in reducing the need for wet experimentation during process development and supports decision-making by combining human expertise with AI-driven insights to improve efficiency and outcomes. While advanced technologies like AI are widely adopted, full autonomy or widespread self-optimization has not yet been achieved. Some progress has been made in data-driven and predictive collaboration with select external organizations.

5. **Adaptive organization:** The organization represents the pinnacle of digital maturity, functioning as an "enterprise of the future." Routine process development experiments operate largely autonomously with self-optimizing capabilities, driven by the pervasive use of advanced technologies such as AI, machine learning, robotics and digital twins. Routine production and quality processes are largely "lights-out," requiring minimal human intervention, with data-driven support for complex root cause analyses during investigations. Plug-and-play adaptability, data-driven quality risk management and seamless collaboration across the enterprise and with external parties define the organizational culture, with a continuous focus on innovation and improvement.

References

1. Based on Accenture's analysis of Complete Response Letters issued by the US Food and Drug Administration to top biopharmaceutical companies.

2. Accenture Research analysis leveraging Global Data, 2025.

3. Accenture Research analysis, 2025. Analysis of Complete Response Letters (CRLs) received by the top 25 global pharmaceutical companies. The analysis is based on publicly available information, including the recent batch of CRLs released by the FDA. The scope includes all publicly released CRLs related to drugs and drug–device combination products (e.g., inhalers, injection devices, infusion pumps).

4. Allison Proffitt, Amgen's Jerry Murry on the next steps in bioprocessing and manufacturing, BioProcess Summit, August 27, 2024.

5. For detailed definitions, please refer to the appendix: Digital Maturity Scale.

6. The naming convention for maturity levels and the use of a 1–5 scale in our survey and scorecard are based on BioPhorum's Digital Plant Maturity Model 3.0. For detailed descriptions, please see the appendix.

7. Accenture, The front-runners' guide to scaling AI, May 6, 2025.

8. "Digital dead ends" refer to systems and data that have been digitized but remain isolated within a single department or function, preventing their integration and flow across the wider organization.

9. Meijing Liu and Xiaogang Wang, From ADC to XDC: Opportunities and challenges for AI in next-generation drug conjugates, The Innovation, December 18, 2024.

10. Lantern Large biopharma unveils innovative AI-powered module to improve the precision, cost and timelines of antibody-drug conjugate (ADC) development for cancer, Lantern Large biopharma, January 27, 2025.

11. AI empowering analysis of heterogeneous data from numerous analytical instruments and probes, enabling multiparametric simulations.

12. Digital twins use mechanistic models and real-time data to mimic the actual manufacturing process, allowing engineers to test "what-if" scenarios and predict process behavior without physical experimentation. Digital twins can continuously ingest sensor and process data, updating the simulation in real-time and providing a comprehensive view of the process state.

13. Thomas Zahel, How to reduce time to market by >50%, Körber Large biopharma, November 10, 2022.

14. Based on 9 interviews conducted by Accenture Research between Dec 2024 and Feb 2025.

15. Dirk Müller, Lukas Klein., et al, Process intensification in the biopharma industry: Improving efficiency of protein manufacturing processes from development to production scale using synergistic approaches, Chemical Engineering and Processing - Process Intensification, January 2022.

16. How a digital manufacturing solution embeds quality into cellular therapeutics production, MasterControl.

17. Pharmaceutical: Electronic batch record management, New Ocean Group, April 15, 2025.

18. Accenture, Making reinvention real with gen AI, March 6, 2025.

19. MIT NANDA, State of AI in Business 2025, July 2025.

20. The cross-functional process by which new drugs are industrialized, transferred to manufacturing and prepared for commercial launch.

21. Accenture, Making autonomous supply chains real, May 21, 2025.

22. Accenture, Reinvention in the age of generative AI, January 11, 2024.

23. Accenture, Human, AI and Robots, https://www.accenture.com/us-en/insights/strategy/humans-ai-robots, March 17, 2025.

24. Critical Process Parameter, Critical Quality Attribute.

About Accenture

Accenture is a leading solutions and global professional services company that helps the world's leading enterprises reinvent by building their digital core and unleashing the power of AI to create value at speed across the enterprise, bringing together the talent of our approximately 784,000 people, our proprietary assets and platforms, and deep ecosystem relationships. Our strategy is to be the reinvention partner of choice for our clients and to be the most AI-enabled, client-focused, great place to work in the world. Through our Reinvention Services we bring together our capabilities across strategy, consulting, technology, operations, Song and Industry X with our deep industry expertise to create and deliver solutions and services for our clients. Our purpose is to deliver on the promise of technology and human ingenuity, and we measure our success by the 360° value we create for all our stakeholders.

Visit us at **www.accenture.com**

About Accenture Research

Accenture Research creates thought leadership about the most pressing business issues organisations face. Combining innovative research techniques, such as data-science-led analysis, with a deep understanding of industry and technology, our team of 300 researchers in 20 countries publish hundreds of reports, articles and points of view every year. Our thought-provoking research developed with world leading organisations helps our clients embrace change, create value and deliver on the power of technology and human ingenuity. For more information, visit Accenture Research on **www.accenture.com/research**