



**Digital Technology Adoption Roadmap**

# **Accelerating Digital Transformation in Canada's Biomanufacturing Sector**

**ICTC**  **CTIC**

**NGen**

Roadmap produced by the Information and Communications Technology Council (ICTC)  
in collaboration with Next Generation Manufacturing Canada (NGen)

# Preface:

ICTC and NGen are proud to present this digital technology adoption roadmap covering the Canadian biomanufacturing sector. The five-year roadmap details practical steps and considerations for Canadian biomanufacturing firms, particularly small- and medium-sized enterprises, interested in adopting advanced digital technologies, including artificial intelligence (AI), big data analytics, cloud computing, cybersecurity, digital twins, sensors and Internet of Things, and advanced robotics and industrial automation. The roadmap provides the biomanufacturing sector with strategic-level guidance on digital technology adoption. The roadmaps have been developed in consultation with industry and include real-world examples and use cases on how digital technologies are being used on factory floors across Canada and integrated into production processes.

## Other digital technology adoption roadmaps available for Canadian manufacturers in this series:



## About ICTC:

The Information and Communications Technology Council (ICTC) is a neutral, not-for-profit national centre of expertise with the mission of strengthening Canada's digital advantage in the global economy. For over 30 years, ICTC has delivered forward-looking research, practical policy advice, and capacity-building solutions for individuals and businesses. The organization's goal is to ensure that technology is utilized to drive economic growth and innovation and that Canada's workforce remains competitive on a global scale.

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## About NGen:

Next Generation Manufacturing Canada (NGen) is the industry-led, non-profit organization leading Canada's Global Innovation Cluster for Advanced Manufacturing. One of five national networks supported by Canada's ambitious Global Innovation Clusters Initiative. We are founded on the principle that digital transformation in advanced manufacturing will enrich the lives of Canadians, delivering better products and good jobs while generating the economic growth essential to a better future.

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# Executive Summary

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This five-year roadmap details practical steps and considerations for Canadian biomanufacturers, particularly small- and medium-sized enterprises and startups, interested in adopting advanced digital technologies and embarking on a digital transformation journey.

The roadmap provides a case study of real-world digital technology adoption in the Canadian biomanufacturing sector, covering barriers, challenges, and solutions to digital transformation. It outlines how manufacturing firms are adopting novel digital technologies, including artificial intelligence (AI), big data analytics, cloud computing, cybersecurity, digital twins, sensors and Internet of Things (IoT), and advanced robotics and industrial automation.

The roadmap also provides examples of practical planning tools to help Canadian biomanufacturers plan and execute their digital transformation journeys, including:

- 1. Digital technology use case matrix:** highlighting practical uses of the seven digital technologies in the biomanufacturing sector.
- 2. Return on investment (ROI) measurement framework:** outlining example metrics to assess ROI on digital technology adoption in categories including operational effectiveness, workforce productivity, capital productivity, market access, innovation, health and safety, and ESG measures, and align them with strategic firm objectives and investment inputs.
- 3. Change management checklist and digital transformation project phase gate framework:** providing a systematic, phased approach to developing organizational change management strategies, and technology pilots to support digital transformation.
- 4. Risk management tools:** demonstrating contemporary risks manufacturing firms may face when undergoing digital transformation in today's market, as well as an example risk register and risk management trigger scenarios.
- 5. Talent and workforce training insights to support digital transformation:** overviewing baseline digital competencies for advanced manufacturing, workforce training and delivery models for manufacturers, and organizational strategies to foster digital competencies in the manufacturing workforce.
- 6. Advice for developing strategic partnerships to advance digital transformation:** discussing key partnership verticals and example partnership models, as well as key considerations for data-sharing when developing strategic partnerships.

By providing these real-world case studies, insights, and practical tools, this roadmap seeks to accelerate the adoption of key digital technologies in Canada's biomanufacturing sector and support ongoing digital transformation efforts. Adopting novel digital technologies is critical for continued sectoral success, driving innovation and firm scaling in the Canadian biomanufacturing sector, and maintaining the sector's continued global success.

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# Acknowledgements

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This roadmap was developed in consultation with digital transformation leaders from the Canadian biomanufacturing industry, including six expert interviews and an industry roundtable. Representatives from biomanufacturers, digital technology vendors with expertise in the biomanufacturing industry, consultants, and other experts all contributed insights towards this roadmap.

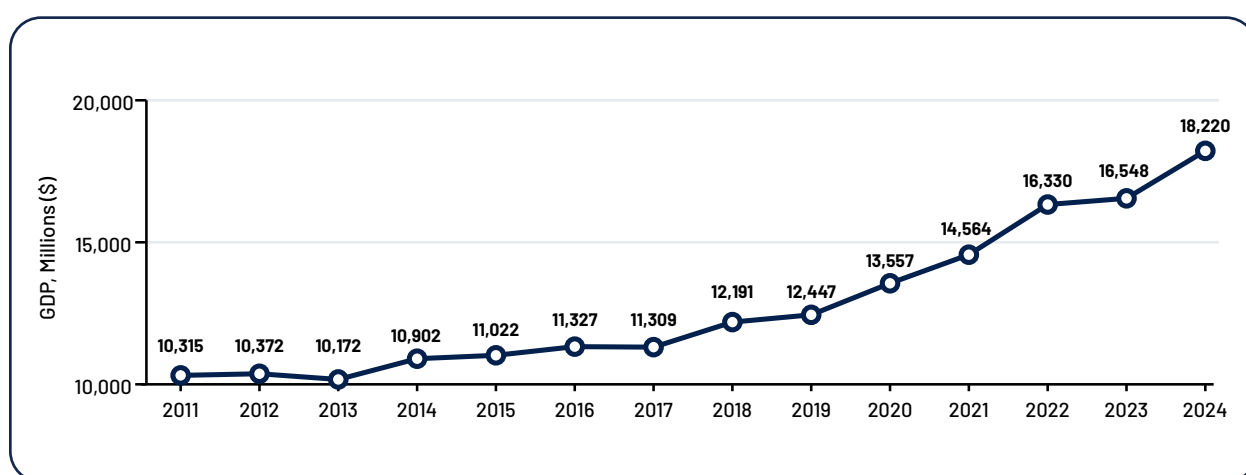
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# Why this Roadmap is Needed

Canadian manufacturing is facing notable headwinds from declining productivity, underinvestment, and economic uncertainty stemming from international trade disputes. However, the life sciences research and pharmaceutical and medicine sector, which biomanufacturing rests within, has not suffered from these same headwinds and has enjoyed robust growth in recent years (Figure 1). Indeed, Canada greatly benefits from a productive and innovative sovereign biomanufacturing capacity.

Figure 1. Biomanufacturing Industry GDP Value (2007-2024)



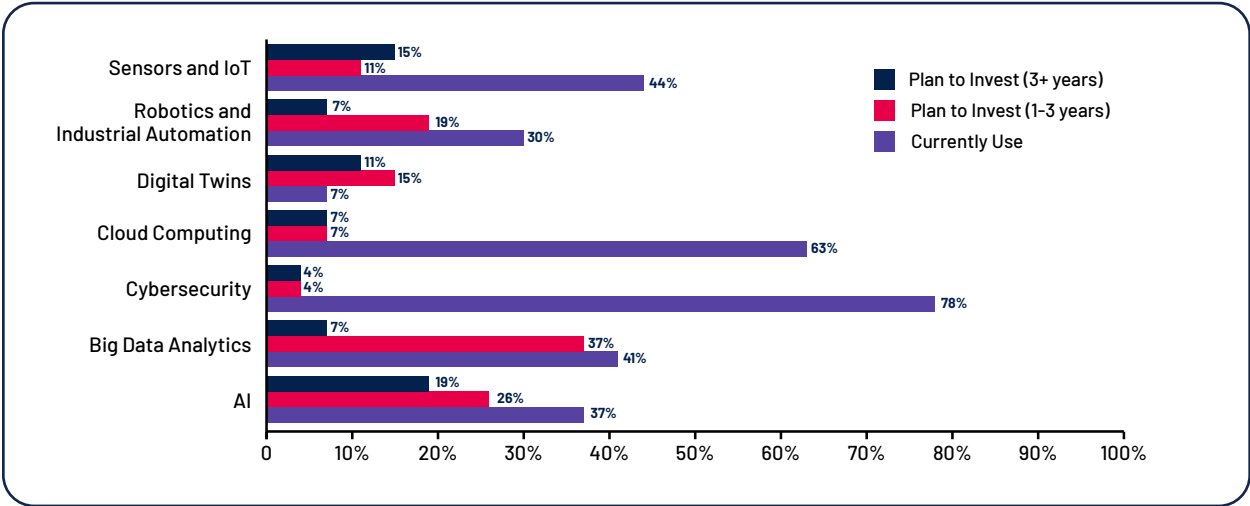
Source: Statistics Canada, Table: 36-10-0434-06 [NAICS 32541 & 54171].<sup>1</sup>

Industry growth has come at a time of technological disruption, brought on by rapid advances in digital technology, most notably in artificial intelligence (AI), but also in adjacent technologies such as advanced robotics, sensors and internet of things (IoT), and digital twins, alongside basic digital infrastructure like cloud computing. Promoting digital readiness throughout the sector has important implications for Canadian health security and resilience of its healthcare system.

Canadian biomanufacturers can increase productivity and accelerate growth by adopting more digital technologies across their manufacturing operations. An industry survey conducted by ICTC finds that critical digital technologies, including cloud computing, cybersecurity, and sensors and IoT technology are already widely being used (Figure 2).

<sup>1</sup> Statistics Canada (Government of Canada), "Gross domestic product (GDP) at basic prices, by industry, annual average, industry detail (x 1,000,000)," Table: 36-10-0434-06, release date January 26, 2026, <https://www150.statcan.gc.ca/t1/tbl1/en/cv.action?pid=3610043406>.

Figure 2. Canadian Biomanufacturing Digital Technology Adoption (2025)

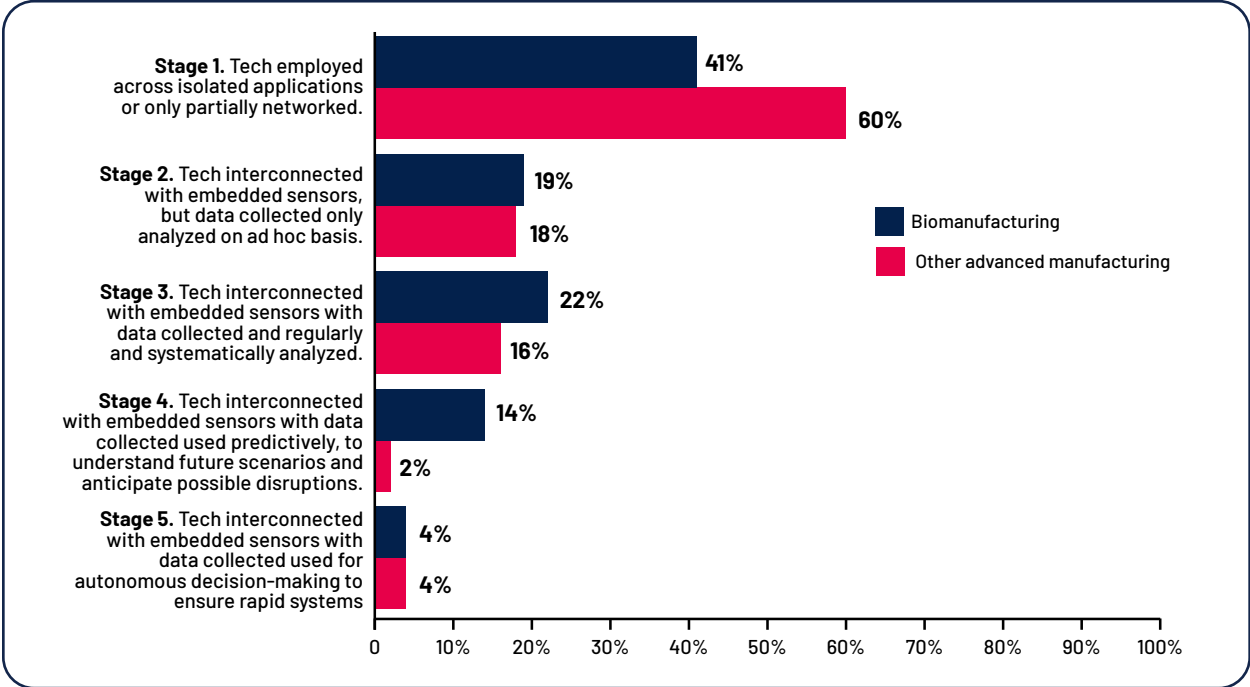


Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

Canadian manufacturing technology adoption shows mixed progress across industries. Within the Canadian biomanufacturing industry, ICTC’s Canadian manufacturing digital technology adoption survey found that 41% of biomanufacturers employed digital technology piecemeal, as isolated applications or only partially networked, 19% employed interconnected digital

technology but only analyzed collected data on an ad hoc basis, while 22% employed interconnected digital technology and analyzed collected data regularly and systematically. Furthermore, 14% used data collected from networked sensors for predictive analytics and only 4% for supporting autonomous decision-making within biomanufacturing operations (Figure 3).

Figure 3. Canadian Biomanufacturing Advanced Digital Technology Implementation Stage (2025)



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

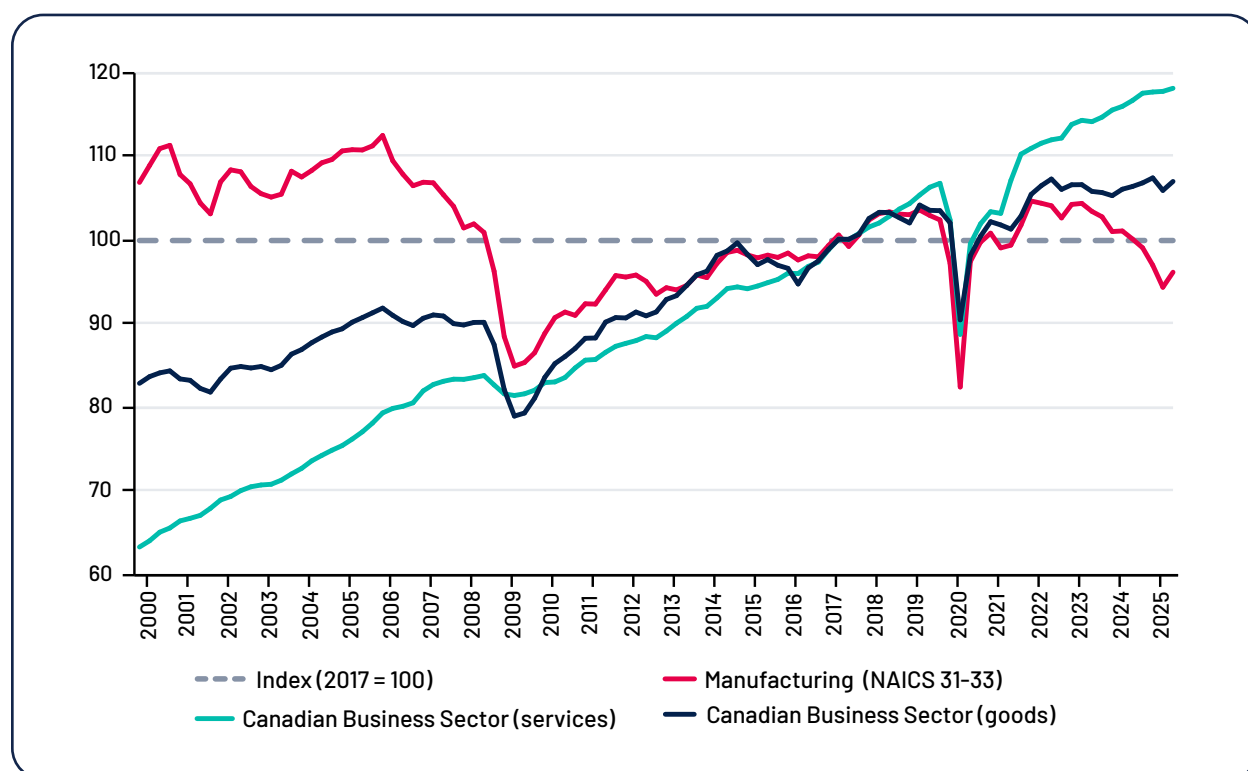
Further leveraging networked digital technologies towards integrated, autonomous operations across a manufacturing process, or even an entire manufacturing enterprise, could have a positive effect on labour productivity in Canada's manufacturing sector (Figure 4). This would be a welcome development, as lagging productivity amounts to a persistent drag on the Canadian economy.<sup>2</sup>

Productivity challenges are often discussed in national economic terms, but they have very real implications for individual businesses. Canadian manufacturers continue to lag behind peers such as the United States, which puts pressure on costs, pricing, and margins. For a typical biomanufacturing SME with \$20 million in annual revenue and a 15%

EBITDA margin, even a modest 5–10% improvement in overall equipment effectiveness (OEE) can make a meaningful difference.

Improvements enabled by tools such as production monitoring, predictive maintenance, or better data use can increase throughput and reduce downtime without major new capital investment. For example, a 3% increase in output combined with small cost savings could translate into an additional \$300,000–\$600,000 in annual EBITDA—amounting to a 10–20% improvement in operating earnings. Seen this way, digital adoption is not just about upgrading technology; it is about strengthening profitability and long-term business value.

**Figure 4. Index on Canadian Manufacturing Labour Productivity (2000 to Q2 2025)**



Source: Statistics Canada, Table: 36-10-0207-01.<sup>3</sup>

<sup>2</sup> Tim Sargent, "Productivity Growth in Canada: What is Going on?," University of Calgary, School of Public Policy Briefing Paper, October 2024, <https://www.policyschool.ca/wp-content/uploads/2024/10/FP-9-ProductivityGrowth-Final.pdf>.

<sup>3</sup> Statistics Canada (Government of Canada), "Indexes of labour productivity and related measures, by business sector industry, seasonally adjusted," Table: 36-10-0207-01, last update September 3, 2025, <https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=3610020701>.

# Seven Key Digital Technologies for Biomanufacturing

With an industry-wide need to adopt advanced digital technologies across Canadian manufacturing, including further adoption within Canada's biomanufacturing sector, ICTC and NGen evaluate the seven digital technologies (Figure 5) as being essential to the future of Canadian manufacturing.

Figure 5. Seven Key Digital Technologies Essential for Canadian Manufacturing

|                                                               |                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Artificial Intelligence (AI) and Machine Learning (ML)</b> | AI-enabled systems can quickly parse through large volumes of data, helping to optimize processes and predict outcomes, as well as automate decision-making tasks that would normally require human cognition. Machine learning models can ingest training data and learn to make predictions, or correct decisions, without explicit, hard-coded programming. |
| <b>Big Data Analytics</b>                                     | Methods and tools used to collect and curate, process and integrate, and analyze extremely large volumes of data across a manufacturing operation to glean insights and improve decision-making.                                                                                                                                                               |
| <b>Cloud Computing</b>                                        | On-demand, offsite computing services to access and store data, process information, and serve software applications via the internet. Cloud computing also allows manufacturers to dynamically scale their computing infrastructure as required.                                                                                                              |
| <b>Cybersecurity (IT and OT)</b>                              | Protecting sensitive networks and data from threats. In a manufacturing environment, cybersecurity includes protecting both information technology (IT), such as networks and data, as well as operational technology (OT), such as machinery, control systems, and sensors.                                                                                   |
| <b>Digital Twins</b>                                          | A virtual representation or model of a real-world asset, such as a piece of machinery, a production line, a manufactured product, or an entire manufacturing facility continuously updated with new data allowing the digital twin to mirror the status and condition of the real-world asset.                                                                 |
| <b>Sensors and Internet of Things (IoT)</b>                   | Networks of machinery, sensors, and other electronic devices can be networked together to gather and share real-time data across a factory or supply chain, often referred to as the Internet of Things (IoT) or the Industrial Internet of Things (IIoT).                                                                                                     |
| <b>Robotics and Industrial Automation</b>                     | Industrial robots have long been used in biomanufacturing, but advanced robotics, including cobots and humanoid robots, can be used in manufacturing across a variety of applications and integrated using technologies such as AI and IoT networks.                                                                                                           |

**Figure 6. Digital Technology Maturity Tiers for Advanced Manufacturing**

| Digital Transformation Stage | Maturity Tiers                        | Key Digital Technology                                                                                                           | Firm Digital Transformation Maturity Level                                                                                                                                       |
|------------------------------|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Basic                        | Foundational Technologies             | <ul style="list-style-type: none"> <li>› Cloud computing/ cloud ERP</li> <li>› Cybersecurity</li> </ul>                          | <b>Foundation:</b> establish prerequisite digital infrastructure.                                                                                                                |
| Intermediate                 | Operational Optimization Technologies | <ul style="list-style-type: none"> <li>› Sensors and IoT</li> <li>› Big data analytics</li> </ul>                                | <b>Integrate and optimize:</b> build data collection and analytical processes from foundational digital infrastructure. Provide data platform for transformational technologies. |
| Advanced                     | Advanced Transformation Technologies  | <ul style="list-style-type: none"> <li>› AI/ML</li> <li>› Robotics and industrial automation</li> <li>› Digital twins</li> </ul> | <b>Transformation:</b> adopt advanced digital technologies to transform enterprise manufacturing operations.                                                                     |

Source: ICTC analysis, 2026.

No single digital technology delivers its full value in isolation—the true business value for all of these technologies is unlocked only when they are adopted in tech stacks. Biomanufacturers can think of the seven key digital technologies as being in three maturity tiers (Figure 6):

1. foundational technologies (cloud computing/ cloud ERP, cybersecurity),
2. operational optimization technologies (sensors and IoT, big data analytics), and
3. advanced transformation technologies (AI/ML, robotics and industrial automation, and digital twins).

While any one of the seven digital technologies covered in this roadmap would, on its own, be consequential to advanced manufacturing in Canada, what makes these seven technologies truly impactful is how they interact with one another. These seven technologies can be digitally networked across a biomanufacturing operation or across an entire manufacturing supply chain, with significant gains in operational excellence, productivity, safety, product innovation, and market responsiveness.

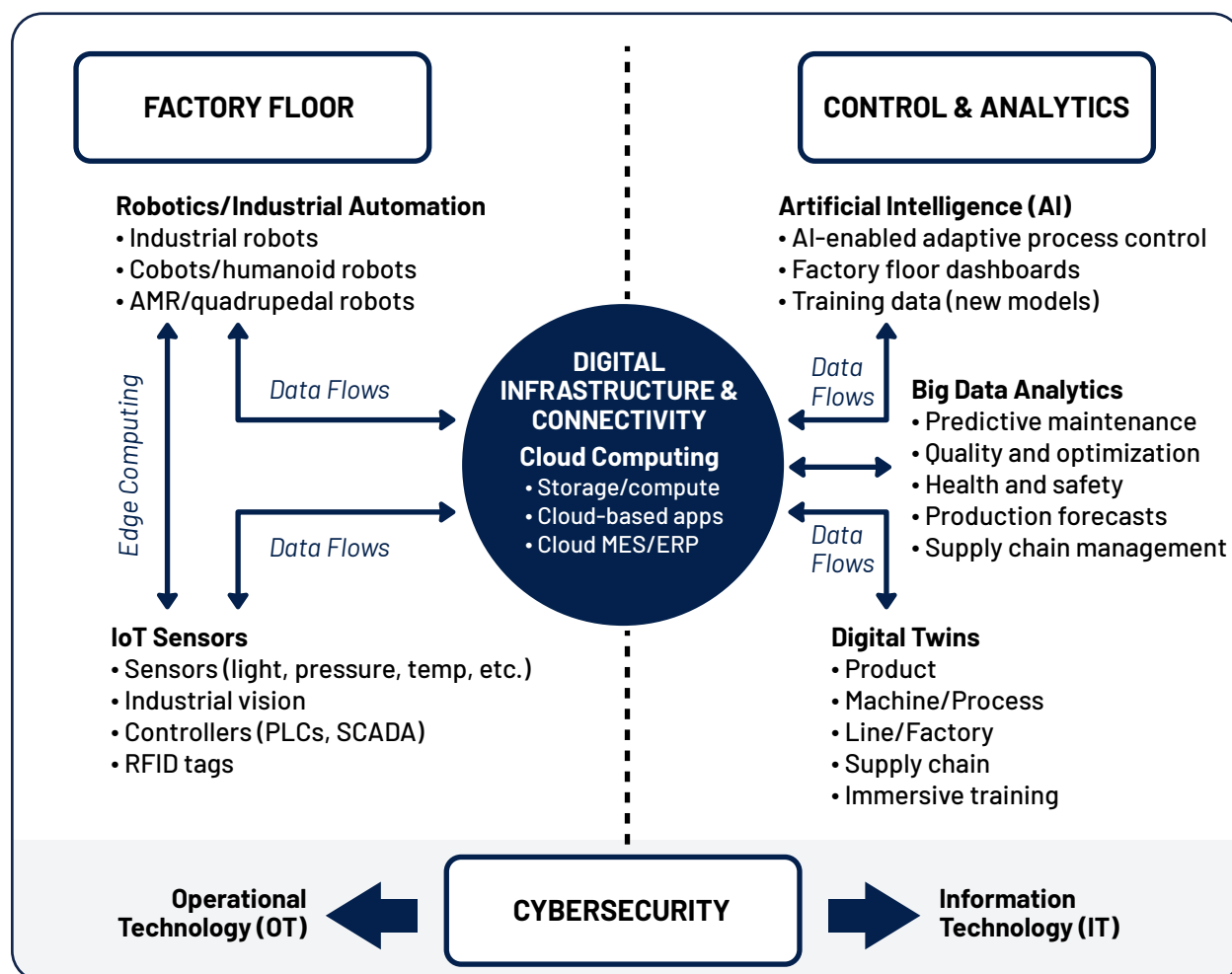
For example, sensors deployed across a manufacturing operation, on industrial robots and other production equipment, can collect significant

amounts of real-time data (i.e., big data) that can be stored and processed in a cloud environment. The data can be used to create digital twins of individual pieces of machinery and robots, manufacturing processes, products, and even the entire manufacturing enterprise.

The data can also be used to train AI models and run inference to help manage and optimize manufacturing operations. The digital infrastructure and valuable data, integrated across a manufacturing enterprise's information technology (IT) and operational technology (OT) assets, must be secured against cyber threats, such as data breaches and cyberattacks, through a robust cybersecurity program. Figure 7 outlines, at a high level, how the seven digital technologies covered in this roadmap can be integrated together on the lab or production floor and across an enterprise in the biomanufacturing industry.

The model presented in Figure 7 is aspirational and intended to provide an overview of what is possible in the long term. Today, most Canadian biomanufacturers have not achieved this level of total integration. Instead, Canadian biomanufacturers interviewed for this roadmap tend to adopt stacks of digital technologies incrementally, through strategic investments, pilot projects, experimentation, and organizational learning.

Figure 7. Advanced Digital Technology in Manufacturing Integration Model



Source: ICTC analysis, 2026.

## Digital Transformation and Digital Technology Adoption Time Horizons

When discussing digital transformation and technology adoption in Canadian manufacturing, it is critical to develop achievable, realistic timelines. The complexities of digital technology adoption, both technical and organizational, are significant. For biomanufacturers adopting novel digital technologies, such as AI, digital twins, or advanced robotics, for the first time, it can take years to derive the full value from the investment and get the most out of the new technology.

A phased, five-year timeline provides biomanufacturers, including those undergoing a digital transformation project for the first time, with a realistic timeline for effectively adopting digital technologies. Firms should expect to spend the first one to two years piloting new technologies, gathering data, and developing a full

business case, and then up to three years scaling successful pilots across their manufacturing operations and beginning digital integration with other manufacturing and enterprise systems. Regulatory requirements can shape pacing for biomanufacturing firms adopting new digital technologies into their operations for the first time.

Alongside piloting and adopting new digital technologies in the lab and production floor, biomanufacturers must also train their workforce, align HR policies and recruitment strategies towards digital transformation efforts, and provide training to the existing workforce. Furthermore, not all digital technology adoption initiatives will yield results. Biomanufacturers must also effectively manage risk when adopting new digital technologies into their manufacturing operations.

# Digital Technology Adoption in Canada's Biomanufacturing Sector

Canada's biomedical manufacturers are undergoing a deep technological shift, one that is redefining not only the therapies they develop, but the way those therapies are designed, validated, and produced. With advanced digital technologies revolutionizing the way these manufacturing processes are managed and refined, there are opportunities for meaningful advancements in efficiency, cost-effectiveness, quality, output, and innovation in biomanufacturing.

This case study brings together insights from companies operating at different points in the biomedical ecosystem, ranging from advanced cell-therapy manufacturers to emerging bioprinting innovators and to mRNA developers—each operating within different segments of Canada's biomanufacturing ecosystem.

## Industry Overview and Context

Biomanufacturing is the production of biological products like vaccines and cell therapies at the scale and quality needed for human use.<sup>4</sup> Biomanufacturing has become an important tool in biotechnological advancements and pharmaceutical drug research and development.<sup>5</sup> Canada's biomanufacturing industry is strategically positioned at the intersection of the advanced manufacturing and healthcare services sectors and forms the backbone of large-scale pharmaceutical

and therapeutics production. As Canada navigates a challenging global economy, the biomanufacturing industry stands as an important contributor to high-value job creation, innovation, and Canada's long-term economic strength.

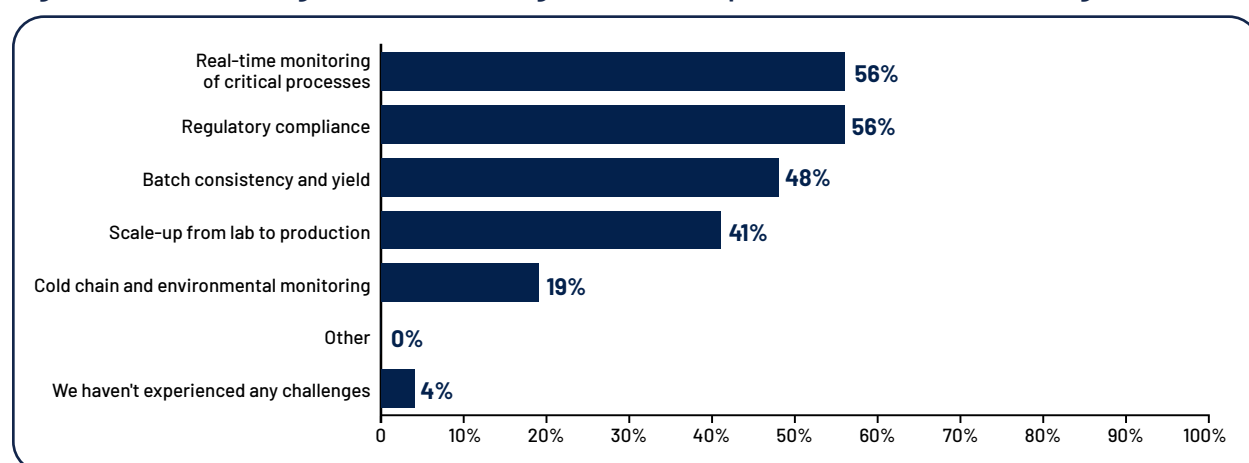
Canada's biomanufacturing sector is made up of a variety of firms including commercial-scale mature operations and contract development and manufacturing organizations (CDMOs), as well as early clinical firms and early-stage start-ups. Thus digital technology adoption priorities can differ depending on firm maturity and development stage.

Driving biomanufacturers' digital transformation is a need to solve practical business problems, including real-time monitoring of critical processes, regulatory compliance, batch consistency and yield, scaling up from lab to commercial production, and cold chain and environmental monitoring (Figure 8).

<sup>4</sup> Megan Levings and Robert A. Holt, "Why Canada's next big infrastructure investment should be in biomanufacturing," *The Conversation*, October 21, 2025, <https://theconversation.com/why-canadas-next-big-infrastructure-investment-should-be-in-biomanufacturing-254377>.

<sup>5</sup> Sibylle Gaiser and Michael Nusser, "Stellenwert der Biotechnologie in der pharmazeutischen Wirkstoffentwicklung," [The role of biotechnology in pharmaceutical drug design], *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen*, (2010), 104 (10), 732-737, <https://doi.org/10.1016/j.zefq.2010.05.001>.

**Figure 8. Most Pressing Business Challenges (Choose Top Three) – Biomanufacturing (2025)**



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

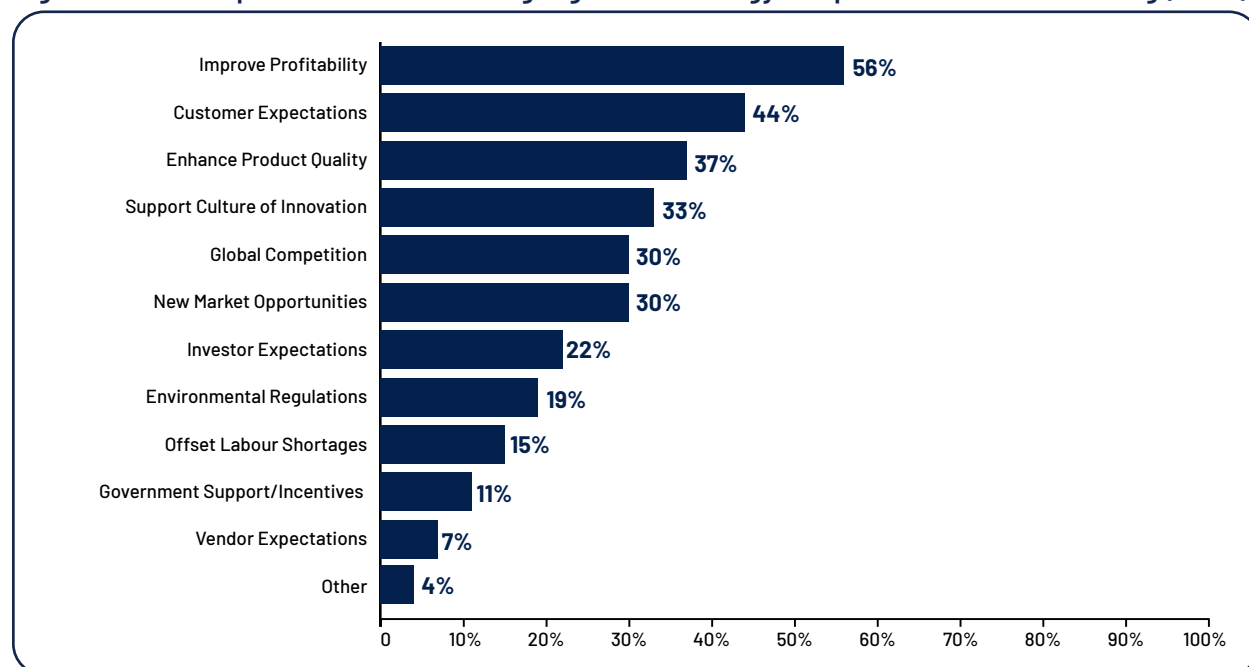
## Strategic Approaches to Digital Technology Adoption

For Canada's biomanufacturers, digital adoption is widely seen as essential to remain competitive and meet demand from the healthcare system for life-saving treatments. When deployed strategically, digital technologies can shift cost structures, streamline operations, and enable more automated, data-driven management. A key principle highlighted by every biomanufacturer ICTC engaged with for this research was the importance

of keeping a human in the loop, adopting digital systems augmented with human accountability.

What constitutes "strategic" adoption varies by specific firm context, but major strategic goals of digital technology adoption include improving profitability, meeting customer and vendor expectations, enhancing product quality, supporting a culture of innovation, and dealing with global competition and developing new market opportunities (Figure 9).

**Figure 9. Most Important Factors Driving Digital Technology Adoption – Biomanufacturing (2025)**



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

## Technology Applications in Practice

Across Canada's biomanufacturing and biomedical manufacturing firms, a wide mix of digital tools, automation, robotics, AI/ML, big data analytics, and digital design tools, are being deployed in ways that complement one another, helping to boost scale, improve quality, streamline workflows, and make production more predictable.

Despite operating in different segments of the biomanufacturing ecosystem, none of the firms that we interviewed were pursuing full "lights-out" manufacturing operations, instead pursuing a deliberate, phased strategy that balances innovation with risk, and adhering to regulations, and maintaining and improving patient safety. The pace of digital technology adoption undertaken by biomanufacturers is always dependent on firm scale, access to capital, and regulatory requirements.

A number of Canadian biomanufacturers ICTC engaged with for this roadmap report adopting digital and automated processes in practical, incremental ways. Exhibiting a staged digital evolution from manual cleanroom operations to automated closed-system manufacturing, robotics-enabled bioprocessing, and AI-driven optimization.

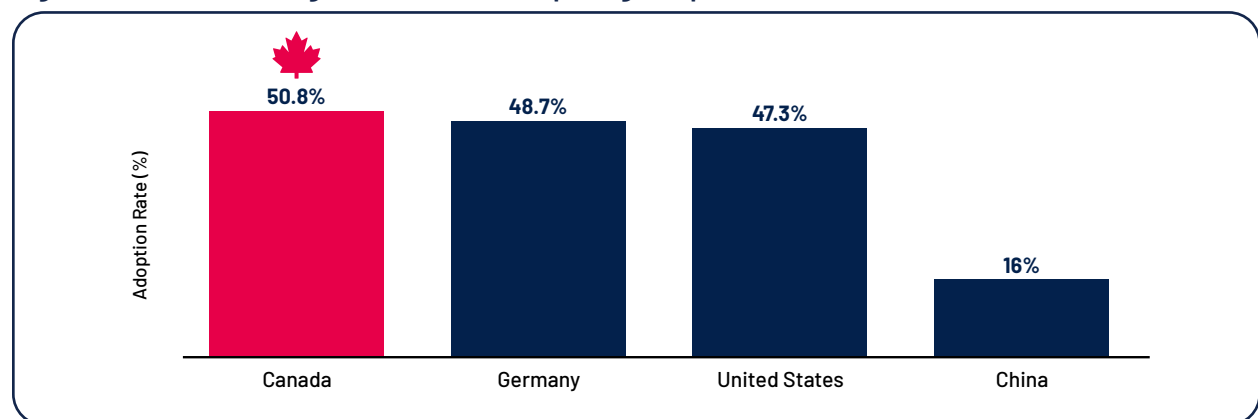
One contract development and manufacturing organization (CDMO) ICTC engaged with for this roadmap has adopted an automated production model that integrates robotic arms to handle cell processing and quality control tasks, enabling

24-hour operation, greater precision, and higher throughput than human-only workflows. For this CDMO firm, robotics are central to its vision, where lab robots handle repetitive, high-precision steps involved in producing patient-specific cell therapies.

Currently, on the production floor the firm utilizes a digital backbone that includes Snowflake for data extraction, SAP for supply-chain tracking, and LIMS for laboratory information management and electronic lab notebooks to connect systems end-to-end. Additionally, this firm uses AI tools to create feedback loops looking at "equipment usage, making sure that your slot schedule is done as efficiently as possible" and spotting when a machine is "starting to trend out of calibration before it does and before you are in a deviation situation."

Canadian manufacturers have been widely adopting cloud-based digital infrastructure such as ERP to act as a platform for digital transformation. Cloud computing enables manufacturers to run software, store files, and process large volumes of data without in-house servers. Cloud computing provides scalable storage and processing power, supporting everything from big data analytics platforms to product traceability data storage. Indeed, Canadian manufacturers compare favourably with those in peer economies such as Germany and the United States in their adoption rates of cloud computing, as shown in Figure 10.

**Figure 10. Manufacturing Sector Cloud Computing Adoption, Canada and Peer Economies (2022/23)**



Source: Statistics Canada, 2024; Info Institute, 2023; National Center for Science and Engineering Statistics, 2022; McKinsey & Company, 2022.<sup>6</sup>

<sup>6</sup> Statistics Canada (Government of Canada), "Information and communication technologies used by industry and size of enterprises," Table: 22-10-0117-01, September 2024, <https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=2210011701>; Info Institute, "Cloud Computing in Use at 46.5% of Companies in Germany," July 12, 2023, <https://www.ifo.de/en/facts/2023-07-12/cloud-computing-use-companies-germany>; Timothy R. Wojan, "Digitalization, Cloud Computing, and Innovation in U.S. Businesses," National Center for Science and Engineering Statistics, Working Paper NCSES 22-213, 2022, <https://ncses.nsf.gov/pubs/ncses22213>, Table 1; Kai Shen, et al., "Cloud in China: The outlook for 2025," McKinsey & Company, July 8, 2022, <https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/cloud-in-china-the-outlook-for-2025>.

In another example, a personalized mRNA company sees AI as a way to reduce the heavy, repetitive paperwork burden that are necessary to produce individualized vaccines. According to that firm, every patient file uses very similar template documents with customized content, meaning that, “filling it in shouldn’t require too much, it’s a lot of repetition,” while noting that when it comes to this task “you never want it to be fully digitized,” leaving humans to “read it, sign off on it,” and remain accountable, this as an obvious area where AI can pre-populate regulatory and clinical documents speeding up production efficiency.

Another firm interviewed for this roadmap reports leveraging AI to make its bioprinting process faster, cheaper, and more predictable. Their team built a machine-learning model to forecast how a new bioink will behave based on its early mechanical and biological properties, allowing them to test printability before committing expensive and scarce materials for full experiments. As the firm’s founder explains, the system can even “predict how these unknown inks would behave” using data from entirely different materials, turning what was once slow trial-and-error into a targeted, cost-saving workflow. The AI model acts as a digital twin to the real-world bio-ink.

Similarly, a firm that develops and manufactures vaccines and personalized cancer therapeutics, describes the possibilities of automation as a natural extension of its highly modular production process. Noting that each manufacturing run differs only in terms of “what is on that template,” noting that “anything downstream can be readily automated,” allowing material inputs to be mixed, purified, and finished with minimal human intervention. This shift would enable “sequential purification processes to be fully automated,” reducing the manual workload and increasing consistency across patient-specific batches.

Looking ahead, the company highlights that automation will be indispensable for scaling personalized vaccines, explaining that “you don’t want to have a wait list of 5,000 people and you’re making two vaccines a month.” While the firm is yet to implement these systems, it sees automation, and eventually more AI-driven document workflows, as critical to making individualized mRNA therapies efficient, timely, and widely accessible.

Despite the breadth of innovation, companies consistently emphasized that digital adoption must remain tightly aligned with rigorous regulatory requirements, particularly those governing chain of custody and identity, patient privacy protection, complex logistics pathways, and release testing standards.

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## Understanding ROI and Measuring Digital Transformation Results

Across all manufacturers interviewed for this roadmap, measuring the impact of digital transformation requires understanding the advantages of improved output and reduced costs, while noting the challenges of manufacturing using biological materials as inputs. Measuring ROI includes risk reduction, process stability and enhanced documentation quality, as well as measurable financial returns, which often emerges over time as production scales.

As one biomanufacturing firm shared, early results are tied, not to achieving full-scale automation, but to incremental gains that reduce failure risk and improve output consistency. For this firm, the biggest early gain is better visibility to production processes. Currently, handwritten batch records make it challenging to track patterns—as one executive at the firm notes, “to cross-check trends across batches, it’s very difficult in current setup.” The company’s new data tools help catch issues

earlier, for example equipment drifting out of calibration, which directly supports improved uptime and better patient outcomes.

One biomanufacturer notes that while digital systems can improve efficiency, the return on investment is slow and tied to the scale of demand for its products. As one business leader explained, “you’re starting to make these steps into AI, you don’t see your ROI right away, you’re going to see a 10% improvement, a 20% improvement—but you know those improvements require a \$10 million spend,” with this leader observing, “the scale just isn’t quite there yet. But, when we get to phase three and demand goes to a thousand doses a year, suddenly it’s a no-brainer.” This insight highlights how achieving ROI through digital technology adoption in biomanufacturing depends heavily on achieving both clinical maturity and production scale. For an industry characterized by small and medium-sized biomanufacturing firms producing

small batches of highly specific and expensive product, achieving economies of scale to justify investments in digital technology adoption remains challenging for many Canadian firms.

In another example, also arguing that in biomanufacturing ROI is not an early-stage incentive but rather one that emerges only after regulatory approval, higher batch volumes, and mature production processes make optimization and cost reduction possible, another CGT firm noted that “when you do commercial scale, that’s when you’re focused on the return on investment. You’re focused on how much can we charge, how little can we charge, or can we produce this batch for so that we can get the maximum output. That’s where we’re going to start focusing.”

For another cell therapy manufacturer, results are measured in fewer errors and more consistent handling of delicate cells. This firm stressed that automation is still new, explaining, “this is fairly world-leading new, we haven’t proven this yet,” noting how even small reductions in variability are important early indicators of success.

A Canadian bioprinting firm interviewed for this roadmap measures outcomes through time and cost savings in research and development. Their machine-learning system accurately predicts how new bioinks would behave, even when utilizing completely novel materials. As the firm’s founder

shared, “when it starts saving you lots of money, you’re like, okay!” Illustrating that in this segment of advanced manufacturing, ROI is demonstrated not through massive improvements in output, but through incremental yet tangible savings that can accumulate during product development and later stages of production.

Measurable outcomes can also be tied directly to quality, safety, and regulatory accountability rather than just speed or throughput. Digital tools are valuable when they can help strengthen traceability processes and reduce errors across complex, multi-step processes. As one mRNA manufacturer explained, even with increasing digitization, “somebody has to read it, sign off, and be accountable.” In this environment, success is measured through cleaner, more reliable documentation, fewer inconsistencies in batch records, and enhanced oversight of every decision point in production.

Rather than replacing human judgment and human accountability, digital systems improve the accuracy and defensibility of the work, ensuring that every step remains auditable and compliant. Overall, firms assess digital transformation through improved consistency, fewer errors, better visibility, and smoother decision-making, incremental results that build the foundation for larger impacts as production scales.

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## Barriers to Adoption

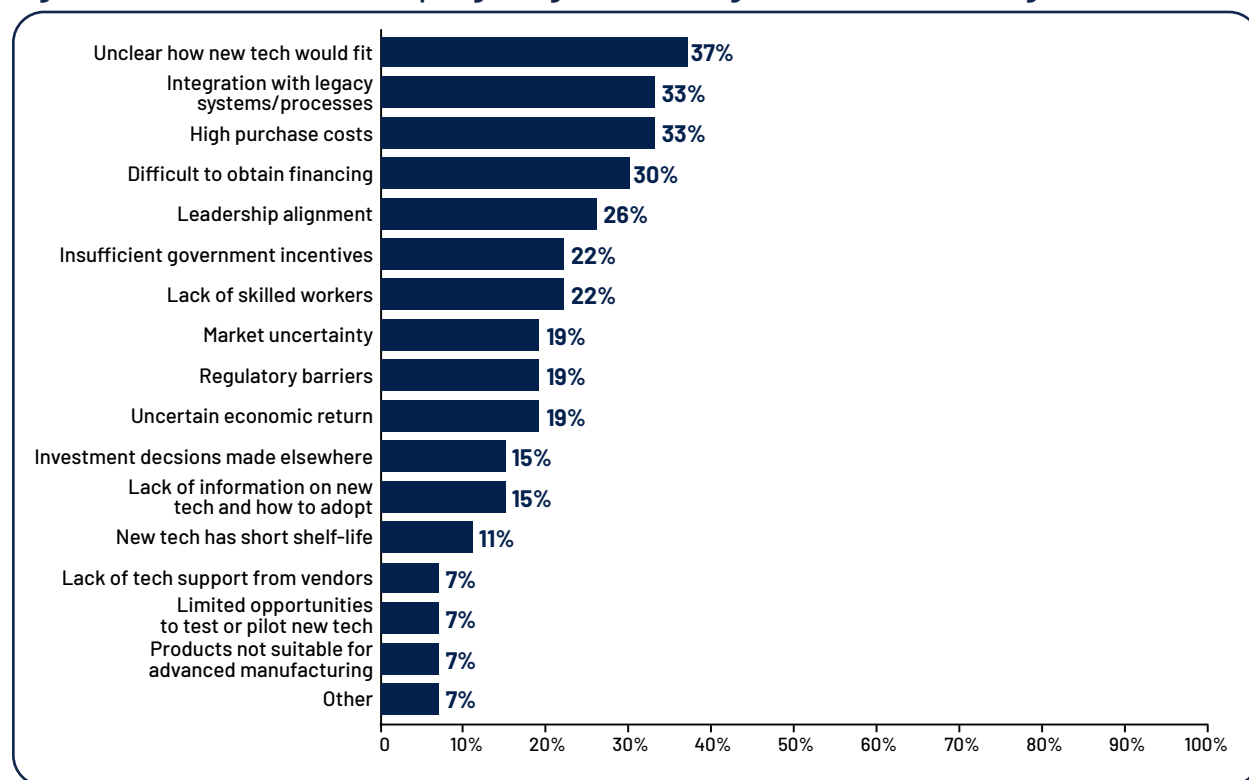
Despite strong interest in, and demonstrated benefits of, advanced digital technologies, research interviews with Canadian biomanufacturers reveal a range of persistent barriers that slow or complicate their adoption across the sector.

High purchase costs for digital technology was a universal barrier across all the firms that were interviewed for this roadmap. Regulatory and compliance issues also emerged as a defining barrier across the firms interviewed. Naturally, biomanufacturing demands rigorous documentation of chain of identity, chain of custody, batch records, safety testing, and release criteria. Data privacy and cybersecurity add another layer of regulation and complexity, especially in personalized vaccines and AI-assisted decision-making systems. Uncertainty around existing regulations, emerging AI safety and governance

requirements, and model validation risk were also reported by those interviewed for this roadmap as important adoption barriers.

Canadian biomanufacturers reported it being unclear how new digital technologies can fit into existing biomanufacturing operations, integrating technology into legacy systems and processes, as well as financial barriers including high purchase costs of new technologies and difficulty of obtaining financing to invest in digital technology adoption. Insufficient government incentives, leadership alignment, and a lack of skilled workers to implement new technology were also important considerations (Figure 11). During industry roundtables, regulatory barriers were also highlighted as a key barrier to adopting digital technology in biomanufacturing operations.

**Figure 11. Main Obstacles to Adopting in Digital Technologies – Biomanufacturing (2025)**



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

## Workforce and Skills Barriers

Workforce readiness and organizational culture emerged as major constraints across all biomedical manufacturing firms interviewed for this roadmap. While all the firms that participated in this case study were all highly technical scientific environments, companies across the board noted that their employees, despite being technically sophisticated experts in their fields, are not trained in automation, robotics, machine learning, or digital quality systems.

As one interview participant stated, “They’re all scientists but they don’t have an AI background.” This has created persistent capability gaps that can slow digital adoption and require significant internal upskilling. For example, at one cell and gene therapy manufacturer, the shift to AI and automation exposed a deep internal skills gap, as one of the firm representatives noted “we have no AI people. We really are building a team in-house.”

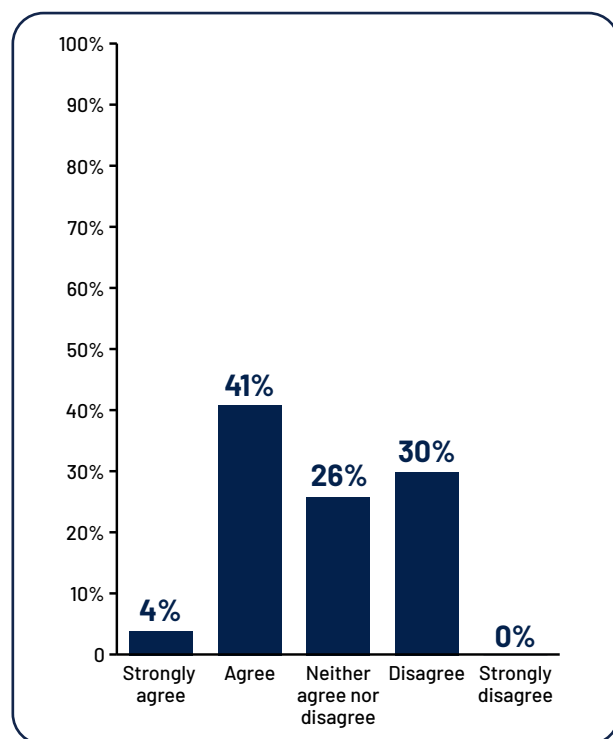
Managers emphasized that the main barrier was not outright resistance, but rather uncertainty and lack of confidence in unfamiliar tools. As one firm put it, staff “are not opposed to it, but it doesn’t mean they’re going to just use it right,” noting how biomanufacturing firms undergoing

digital transformation need to couple new digital technologies with a staff training plan, “They have no idea what they’re doing, so they need help. It needs to be implemented properly.” Similarly, the bioprinting company described how it had to cultivate machine-learning expertise internally, drawing on university courses and directed studies to build capability, because “there’s so much in the bioprinting space that still hasn’t been explored.”

When it comes to staff training and workforce development to drive digital transformation in biomanufacturing, Canada’s biomanufacturing industry reports to having the staffing required to implement new digital technologies, but under half of biomanufacturing firms have formalized staff training plans for adopting and implementing new digital technologies.

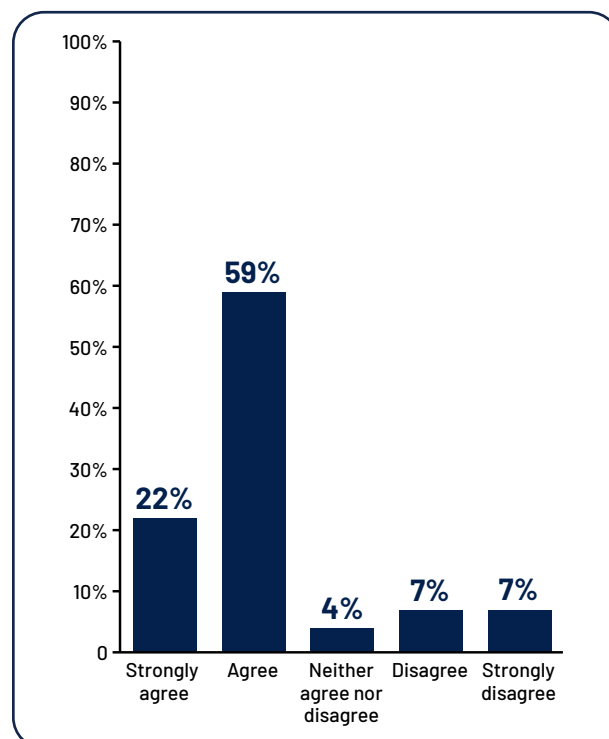
While 81% of biomanufacturers responding to ICTC’s digital transformation survey of Canadian manufacturers reported having staff with the digital technology skills needed to adapt to technologies, while 45% of biomanufacturers reported having a staff training plan to support digital technology adoption (Figures 12 and 13).

**Figure 12. Agree/Disagree: My organization has a staff training plan required to implement and adopt new digital technologies – Biomanufacturing (2025)**



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

**Figure 13. Agree/Disagree: My organization has staff with the digital technology skills required to implement and adopt new technologies – Biomanufacturing (2025)**



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

## Risk Management

According to the firms that participated in this case study digital transformation in advanced biomanufacturing is inseparable from rigorous risk management, spanning product safety, cybersecurity, compliance, and the fundamental sensitivity of living materials. Biomanufacturing leaders interviewed for this roadmap highlighted how automation must increase, not dilute, lab and product safety. Likewise, biomanufacturing firms interviewed for this roadmap noted the importance of creating governance boundaries around AI use, to guard against unsafe autonomy as AI becomes adopted more widely.

Interviewees also highlighted how biologics introduce unique biological uncertainty that automation alone cannot eliminate. As one manufacturer put it, “these really are living things, they are alive, these cells that we’re working with.” Because cells do not behave like chemicals, one biomanufacturing executive stresses that “you never know how the biology is going to react” and therefore “there will always be a human in the loop.” This need for human oversight significantly shapes how risk is distributed and the extent that automation can advance within biomanufacturing. When compared to other advanced manufacturing industries, working with less complex materials, comprehensive AI adoption will likely be slower in biomanufacturing.

Cybersecurity and research-security risks also emerged, particularly for firms handling patient data or sensitive IP. One company underscored that all digital systems must meet strict health-data protocols, noting “all of our systems need to be HIPAA compliant,” noting how this creates “unique challenges” in biomanufacturing when compared to other advanced manufacturing industries.

Another biomanufacturer with strong linkages to the Canadian post-secondary research ecosystem

described how federal Tri-council regulations regarding research security require heightened information security protocols, including screening of potential collaborators, and other safeguards around IP theft and misappropriation of sensitive research.<sup>7</sup> For biomanufacturing firms working closely with Canadian university labs dependent on Tri-council funding, carrying out requisite due diligence and research security protocols, is a mission-critical element of an information/cyber security program.

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## Considerations for Organizational Change Management

All four companies described significant talent challenges as they introduce more automation, AI, and digital tools into their operations. As previously discussed, a major theme was that the Canadian bioscience workforce is highly trained, but not necessarily in the digital skills that new systems require. This means that companies are hiring new digital technology specialists while upskilling existing staff, creating a blended workforce that can handle both traditional wet-lab work and emerging digital tools.

One biomanufacturing firm, with already advanced digital manufacturing capabilities, notes that as their operations grow, “the roles you would expect when you hear AI and robotics are all expanding,” prompting them to build out engineering, IT, and AI development teams alongside their core scientific and production staff. This firm notes that workers with even small amounts of previous digital experience, such as running manufacturing execution systems, are now key team members and “stand out from the crowd” because those skills are suddenly essential.

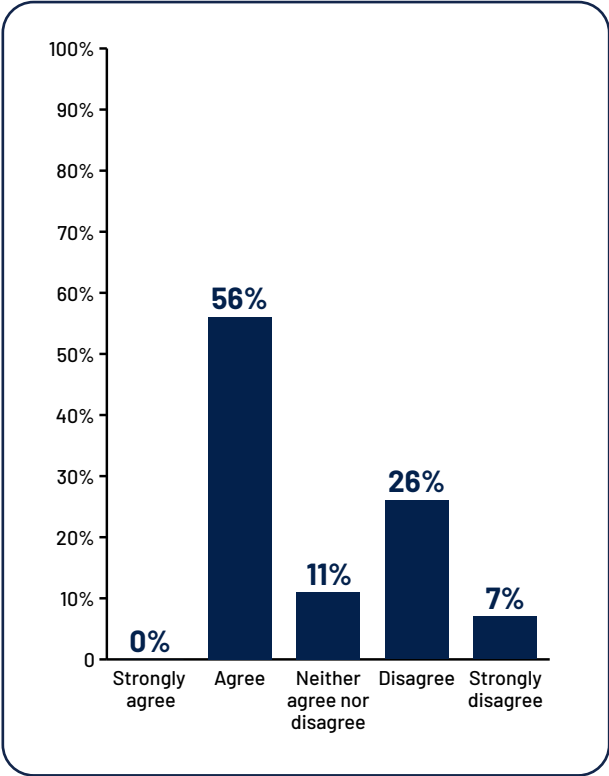
One firm has gone as far as hiring a dedicated in-house AI leader to push this transition forward. As their project manager explained, “We’ve been able to recruit a real industry lead in AI for cellular manufacturing, which I think has helped us to attract and grow our own team.” Bringing in this kind of specialist is seen as a catalyst in that it helps set a clear AI strategy, signals leadership commitment, and makes it easier to build out internal capacity around automation and data-driven manufacturing.

Biomanufacturers participating in ICTC’s digital transformation survey of Canadian manufacturers were forward-looking when it came to developing comprehensive digital technology adoption strategies and supporting a strong culture of change when supporting digital transformation. Fifty-six percent of manufacturers reported having a comprehensive digital technology adoption strategy and 52% enjoyed a culture of change aligned to digital transformation (Figures 14 and 15).

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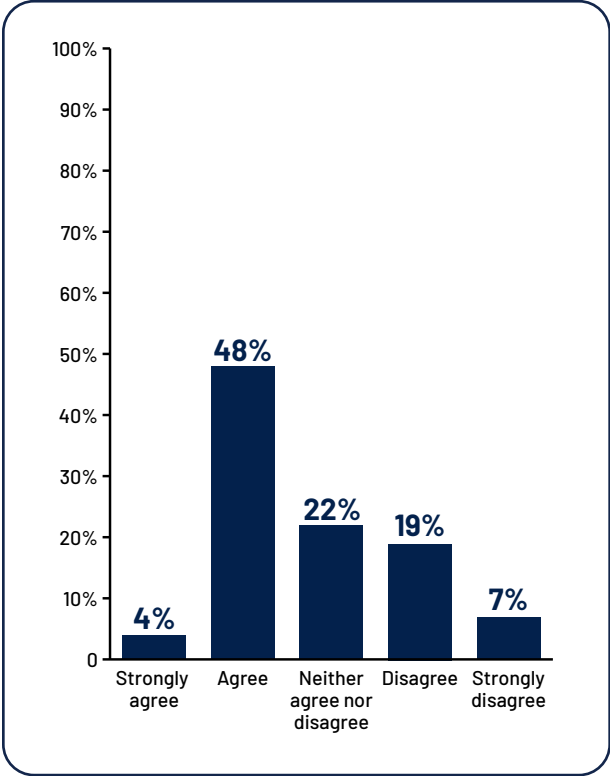
<sup>7</sup> See: Natural Sciences and Engineering Research Council of Canada (Government of Canada), “Tri-agency guidance on research security,” last update May 22, 2025, <https://nserc-crsng.canada.ca/en/funding/research-partnerships-and-collaborations/inter-agency/tri-agency-guidance-research-security>.

**Figure 14. Agree/Disagree:**  
**My organization has a comprehensive**  
**strategy for digital technology adoption –**  
**Biomanufacturing (2025)**



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

**Figure 15. Agree/Disagree:** There is a  
**strong culture of change aligning digital**  
**strategy, actions, and structure across the**  
**organization – Biomanufacturing (2025)**



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

# Digital Technology Adoption Horizon

As outlined in this case study, the technical and organizational complexities involved in adopting digital technologies and implementing digital transformation are immense yet not overwhelming. Biomanufacturers should plan digital technology adoption over a five-year horizon. Figure 16 outlines the time horizons for digital technology adoption in biomanufacturing.

Figure 16. Digital Technology Adoption Horizon

| Adoption Phase   | Time Horizon | Illustrative Examples                                                                                                                                       |
|------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| I. Pilots        | Years 1-2    | Initial production automation experimentation, adopt AI production scheduling tools, cloud-based dashboards, and predictive maintenance pilots.             |
| II. Scaling      | Years 3-5    | Expand successful pilots across production lines/plants, broaden workforce training programs, increased use of IoT sensors for real-time monitoring.        |
| III. Integration | Years 5+     | Integrate digital ecosystems (e.g., AI, IoT, cloud, digital twins) fully, implement enterprise-wide data platforms, and share data across the supply chain. |

*Note: This timeline reflects how firms in the case study see their own readiness and adoption pace. Actual timelines will vary by company size, resources, and market conditions.*

# Digital Technology in Biomanufacturing Use Case Matrix

Use cases specify how different digital technologies can be adopted into a biomanufacturing operation. Figure 17 provides a matrix outlining five example use cases for each of the seven digital technologies covered in this roadmap, alongside the benefits that can be derived for each use case. As there are likely dozens of use cases for each of these advanced digital technologies, with specific use cases relevant to different types of biomanufacturing operations, the use cases presented are intended to be illustrative rather than exhaustive.

Figure 17. Digital Technology Use Case Matrix – Biomanufacturing

| Technology | Example Use Case                                         | Benefit                                                                                                                |
|------------|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| AI/ML      | Predictive maintenance                                   | Decrease the risk of unscheduled downtime and reduce incidents of equipment catastrophic failure.                      |
|            | Cleanroom Environmental Monitoring and Anomaly Detection | Automate sensor network monitoring (temperature, humidity, air particulate) to detect variance.                        |
|            | AI-supported product/therapeutics formulation            | Accelerated R&D cycles, quicker product iteration, optimize formulations.                                              |
|            | AI-enabled production floor dashboard                    | Add predictive capabilities to data dashboards, automate routine decision-making.                                      |
|            | AI-enabled adaptive process control                      | Improve quality, increase throughput, reduce downtime, increase energy efficiency, and enhance production flexibility. |

| Technology                   | Example Use Case                                                         | Benefit                                                                                                                                   |
|------------------------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Big Data Analytics</b>    | Process optimization/root cause analysis                                 | Increase throughput, identify root causes of variance, improve quality, and reduce materials wastage.                                     |
|                              | Demand forecasting and inventory optimization                            | Increase market responsiveness, reduce waste, and optimize production scheduling.                                                         |
|                              | Supplier performance dashboards/monitoring                               | Real-time monitoring of supplier performance, predicting supplier performance variance, and predicting supplier shortages.                |
|                              | AI/ML training data collection for future AI model building              | Collect large volumes of real-world data from production operations to train ML models for future AI implementation.                      |
|                              | Energy/water consumption monitoring and analysis                         | Reduce energy and water consumption/costs, help meet ESG performance targets.                                                             |
| <b>Cloud Computing</b>       | Therapeutic safety and product traceability                              | Digital records of therapeutic and product traceability.                                                                                  |
|                              | Centralized data sharing across facilities/ production sites             | Seamless data-sharing across facilities and production sites, more efficient information flow.                                            |
|                              | Scalable cloud-based MES/ERP systems                                     | Increase MES/ERP flexibility, reduce risk of digital infrastructure/IT resource bottlenecks, and achieve cost savings.                    |
|                              | Digital twins hosting and scalable iteration                             | Host digital twins of the product, equipment, production line, or facility in a cloud environment.                                        |
|                              | Cloud-based LMIS platforms                                               | Reduce IT footprint, rapid scalability, centralized and secure data management, regulatory compliance visibility, enhanced collaboration. |
| <b>Cybersecurity (IT/OT)</b> | Intrusion Detection and Security Information and Event Management (SIEM) | Real-time detection, analysis, and response to incidents across networks and applications.                                                |
|                              | Pen-testing and red team exercises                                       | Stress-test critical IT/OT networks, identify vulnerabilities in networks and business processes.                                         |
|                              | Cybersecurity standards and best practices (e.g., ISO 27001)             | Enhance cybersecurity governance and compliance, reduce cyber risk, and adhere to insurance requirements.                                 |
|                              | Digital forensics                                                        | Collect OT/IT network data for forensic analysis following an incident and support law enforcement.                                       |
|                              | Secure backups and disaster recovery testing                             | Reduce the risk of catastrophic data loss and enhance business continuity.                                                                |

| Technology                                | Example Use Case                                                                       | Benefit                                                                                                                                       |
|-------------------------------------------|----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Digital Twins</b>                      | Process and quality digital twins                                                      | Link production process parameters, material inputs, and environmental conditions to quality and safety outcomes.                             |
|                                           | Virtual (VR/XR) equipment operator training                                            | Shortened training time for new hires, reduced time required to train workers on real equipment.                                              |
|                                           | Production line/facilities layout design/optimization                                  | Shortened retooling time, lower hours needed by technicians to relocate equipment.                                                            |
|                                           | Bio-ink optimization                                                                   | Optimize flow of supplies and materials inputs from warehouse storage to factory floor.                                                       |
|                                           | Digital twinning of universal cells.                                                   | Improve print reproducibility, reduce feedstock waste, speed up R&D.                                                                          |
| <b>Robotics and Industrial Automation</b> | Automated lab workstations                                                             | Reduce experiment variability, automate compliance and audit logs.                                                                            |
|                                           | Sanitation and hygiene automation                                                      | Less operator exposure to chemical cleaners, reduced use of cleaning agents and water.                                                        |
|                                           | Autonomous mobile robots (AMRs) for facility intralogistics                            | Reduce the need for human material handling, real-time monitoring of material flows, and the need for agile material flows.                   |
|                                           | Quadrupedal robots (i.e., “robot dogs”) for automated facilities/ machinery inspection | Identify variances in plant/equipment conditions to reduce the risk of unscheduled downtime.                                                  |
|                                           | Automated just-in-time (JIT) drone delivery                                            | Identify variances in plant/equipment conditions to reduce the risk of unscheduled downtime.                                                  |
| <b>Sensors and IoT</b>                    | IoT sensors for cold chain monitoring                                                  | Reduce spoilage risk by allowing temperature and humidity monitoring during transport.                                                        |
|                                           | Real-Time bioprocess monitoring                                                        | Reduce variance, automatic logging of production parameters, enable predictive control and batch reproducibility.                             |
|                                           | RFID tags for supply chain and inventory tracking                                      | Track products, materials, and assets within the production environment to reduce the risk of asset or inventory loss.                        |
|                                           | ERP/LMIS sensor integration                                                            | Support real-time dashboards, compliance data logging, capture complex process and production data for digital twin and AI/ML model-building. |
|                                           | IoT sensors and worker wearables for real-time hazard monitoring and detection         | Increase worker safety, reduce safety incidents, and shorten hazard resolution time.                                                          |

# ROI Measurement Framework

Like other business decisions, investing in digital transformation and the adoption of novel digital technologies should be assessed from a financial lens and should be aligned with strategic objectives, such as cost reduction, revenue growth, risk management, and alignment with high-level corporate strategy (Figure 18).

Figure 18. Digital Transformation Strategic Objectives

|                                |                                                                                                                                                                                                                                                                                         |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>I. Reduce Costs</b>         | Leveraging advanced digital technologies and undergoing digital transformation to reduce costs, both from an operational perspective, by increasing output efficiencies, and an enterprise perspective, by reducing overheads and inputs.                                               |
| <b>II. Grow Revenue</b>        | Leveraging advanced digital technologies and undergoing digital transformation to support revenue growth, by expanding market access, increasing process and product innovation, and improving output capacity per unit.                                                                |
| <b>III. Manage Risk</b>        | Leveraging advanced digital technologies and undergoing digital transformation to better manage operational, enterprise, and market risk, including reducing errors and improving quality, retaining customers, and improving workplace safety.                                         |
| <b>IV. Strategic Alignment</b> | Leveraging advanced digital technologies and undergoing digital transformation in pursuit of long-term corporate vision and enterprise strategic planning, particularly regarding factors such as market access, innovation, workforce development, human resources, and profitability. |

**Figure 19. Digital Transformation Investment Inputs**

| Category                                           | Investments/Spend                  | Illustrative Examples                                       |
|----------------------------------------------------|------------------------------------|-------------------------------------------------------------|
| <b>Digital Technology &amp; Equipment</b>          | Robotics (cobots, humanoid/mobile) | ABB IRB 360 “FlexPicker,” Stäubli Sterimove                 |
|                                                    | IoT/sensors                        | Sensors, controllers, RFID tags, machine vision cameras     |
| <b>Digital Infrastructure</b>                      | Networking and connectivity        | Industrial ethernet, 4G/5G, ISED NCLL spectrum <sup>8</sup> |
|                                                    | Cybersecurity program (IT/OT)      | Firewall, SIEM, endpoint protection, pen-testing            |
|                                                    | Cloud services subscriptions       | AWS, Microsoft Azure, Google Cloud                          |
| <b>Software Licensing</b>                          | IoT/IIoT platforms                 | Siemens MindSphere, Tulip, Cumulocity                       |
|                                                    | Big data/AI platforms              | Snowflake, IBM watsonx, Anthropic Claude                    |
|                                                    | Cloud/hybrid ERP                   | SAP ERP, GoldFinch ERP, Cegeka Pharma & Life Sciences       |
|                                                    | LIMS platforms                     | Veeva LIMS, Uncountable, LabWare                            |
|                                                    | MES/EBR platforms (GxP compliant)  | PAS-X MES Suite, FactoryTalk PharmaSuite                    |
| <b>Human Resources &amp; Workforce Development</b> | Workforce training/development     | Employee training, tech. mentorship/coaching                |
|                                                    | Digital talent recruitment         | Campus recruiting, co-op program participation              |
|                                                    | Change management                  | Internal communications, consultants                        |
|                                                    | HR management                      | Union negotiations, job description changes                 |

*Note: The software applications and hardware platforms mentioned in this table are intended to be illustrative examples and should not be construed as endorsements nor as procurement recommendations.*

Required investments will include hard costs, such as new technology and equipment, underlying digital infrastructure, and software licensing, as well as soft costs, such as training and workforce development, change management, and HR issues (Figure 19).

Figure 20 outlines an ROI framework for adopting digital technologies for a manufacturing enterprise. This ROI framework is categorized into classes of benefits, including operational efficiencies, workforce and capital productivity, market access, innovation, health and safety, and ESG

(environmental, social, and governance), and is cross-referenced with the digital transformation strategic objectives discussed above.

Detailed ROI calculations will be unique to individual manufacturers, including specific mixes of digital technologies and their associated use cases, and the presented ROI framework is intended to help manufacturers navigate ROI assessments and business case development. Like the use case matrix, the ROI framework is intended to be illustrative rather than exhaustive.

<sup>8</sup> Innovation, Science and Economic Development Canada (Government of Canada), “Non-competitive local licensing (NCLL),” last update February 19, 2026, <https://ised-isde.canada.ca/site/spectrum-management-telecommunications/en/licences-and-certificates/non-competitive-local-licensing-ncll>.

**Figure 20. Advanced Manufacturing Digital Technology Adoption ROI Framework**

| Benefits                 |                                    | ROI Metrics                               | Objective Alignment |              |             |                     |
|--------------------------|------------------------------------|-------------------------------------------|---------------------|--------------|-------------|---------------------|
| Benefit Types            | Potential Benefits                 | Example Metrics                           | Reduce Costs        | Grow Revenue | Manage Risk | Strategic Alignment |
| Operational Efficiencies | Increased production               | % increase in finished goods/hour         |                     | X            |             | X                   |
|                          | Scheduling adherence               | % decreased in scheduling variance        | X                   |              | X           |                     |
|                          | Reduced materials wastage          | % reduction in material scrap             | X                   |              |             |                     |
|                          | Reduced error                      | % reduction in error rate                 | X                   |              | X           |                     |
| Workforce Productivity   | Task automation                    | # labour hours saved                      | X                   |              |             |                     |
|                          | Workforce redeployment             | % role revised for higher value tasks     | X                   | X            |             | X                   |
|                          | Enhance employee engagement        | % increase in employee engagement         |                     |              |             |                     |
|                          | Reduce absenteeism                 | % decrease in absentee hours              | X                   |              | X           |                     |
| Capital Productivity     | Equipment utilization              | % increase in equipment utilization       | X                   |              |             |                     |
|                          | Production line flexibility        | % reduction in line retool time           | X                   |              |             | X                   |
|                          | Reduced equipment downtime         | % reduction in equipment downtime         | X                   |              |             |                     |
|                          | Efficiency of capital investment   | % increase in EBITDA per dollar PP&E      | X                   |              |             | X                   |
| Market Access            | New OEM customers                  | # new contacts                            |                     | X            |             | X                   |
|                          | Efficient business development     | % bid-to-win rate for new contacts        | X                   | X            |             |                     |
|                          | Customer retention                 | % of existing customers retained          | X                   | X            | X           | X                   |
|                          | Digital capability tie-ins         | % of RFPs requiring digital capabilities  |                     | X            |             | X                   |
| Innovation               | Reduced product iteration time     | % reduction in time to iterate design     | X                   | X            |             | X                   |
|                          | Digital pilot projects launched    | # of new digital tech adoption pilots     |                     |              | X           | X                   |
|                          | Prototype development time         | % reduction in prototype dev. Time        | X                   |              |             | X                   |
|                          | Reduce time-to-market              | # week reduction time-to-market           | X                   | X            |             |                     |
| Health & Safety          | Reduced lost-time incidents        | % reduction in lost time incidents        | X                   |              | X           |                     |
|                          | Reduced repetitive strain injuries | % reduction in repetitive strain injuries | X                   |              | X           |                     |
|                          | Fine particulate matter illnesses  | % reduction in workplace FPM illness      | X                   |              | X           |                     |
|                          | Reduced WCB premiums               | % reduction in WCB premiums               | X                   |              | X           |                     |
| ESG Measures             | Reduced carbon footprint           | % reduction in carbon footprint           | X                   |              | X           | X                   |
|                          | Increased energy efficiency        | % reduction in plant electricity use      | X                   |              | X           | X                   |
|                          | Reduced material inputs            | % reduction in material input per part    | X                   |              | X           | X                   |
|                          | Reduced water use                  | % reduction in plant water use            | X                   |              | X           | X                   |

# Change Management Checklist

Adopting digital technologies into existing manufacturing operations necessitates careful change management planning. Investing time and resources in a change management strategy to support digital transformation can increase the likelihood that a project will meet its objectives by a factor of 7, while producing a three-to-one to seven-to-one ROI, according to a 2025 whitepaper by Culture Partners.<sup>9</sup> Likewise, early engagement in change management can increase project ROI by 40-60%.<sup>10</sup>

Change management plans supporting digital technology adoption initiatives should include a project sponsor, a clear delineation of roles and responsibilities, identification of a champion to lead the change, and internal and external communication planning, as well as a staff training plan. Plans should also include pre-designed feedback loops, such as feedback portals, surveys, and staff town halls.

Lastly, they should include measurable goals and timelines to monitor progress, provisions to celebrate success when achieved, and options to scale successful pilots into larger digital transformation projects. Figure 21 below outlines a change management checklist for use in digital technology adoption initiatives.

**Figure 21. Digital Technology Adoption Change Management Checklist**

## **I. Pre-Implementation Phase:**

- › Secure executive leadership commitment and clear digital transformation vision.
- › Conduct comprehensive skills assessment and identify training needs.
- › Establish dedicated project team with representatives from all affected departments.
- › Create communication plan addressing concerns and benefits for all stakeholders.
- › Define success metrics and establish baseline measurements for ROI tracking.

## **II. Implementation Phase:**

- › Pilot technology with small, manageable scope before full deployment.
- › Provide hands-on training for all users, with special attention to production workers.
- › Establish feedback mechanisms and regular check-ins with implementation team.
- › Address resistance proactively through transparent communication and involvement.
- › Document lessons learned and adjust approach based on pilot results.

## **III. Post-Implementation Phase:**

- › Measure outcomes against established success metrics and ROI framework.
- › Celebrate early wins and recognize team contributions to build momentum.
- › Establish continuous improvement processes for ongoing optimization.
- › Plan for scaling successful implementations across additional facilities or processes.
- › Update training programs based on real-world experience and user feedback.

<sup>9</sup> Culture Partners, "Change Management ROI: Measuring Financial Returns and Business Impact," June 10, 2025, <https://culturepartners.com/insights/change-management-roi-measuring-financial-returns-and-business-impact/>.

<sup>10</sup> Ibid.

## Digital Transformation Phase Gates

When undertaking a digital transformation in manufacturing enterprises, a change management plan can be supported by structuring change through phase gates aligned with the digital transformation timeline outlined earlier in this document. When undertaking a digital transformation of a manufacturing enterprise, a change management plan can be supported by structuring change through phase gates aligned with the project timeline and the digital technology adoption horizon outlined earlier in this document.

For example, if a manufacturer were interested in installing IoT sensors on an existing individualized therapeutic production process cell, Gate 1 could verify that the equipment is compatible with the new sensors and that the area of the cleanroom the production cell is placed in has required connectivity for the sensors to transmit data to a cloud database. Between Gate 1 and Gate 2, a compliance review should be carried out.

Gate 2 is to validate whether the new IoT sensors reliably capture data over time and whether the data provides management with useful insights into the state of the production process. After Gate 2 is cleared, biomanufacturers should financially validate the pilot to measure ROI and adherence to strategic objectives (i.e., cost reduction, revenue growth, risk management, and long-term strategic alignment). Intermediate financial validation helps firms reduce the chance of falling for sunk costs.

Gate 3 would include staff training for all research scientists and production technologists, while Gate 4 would expand the technology adoption initiative and add IoT sensors to all therapeutic production operations. Figure 22 outlines such a phased gate approach to digital transformation in manufacturing, including illustrative examples for each of the seven digital technologies covered in this roadmap.

**Figure 22. Digital Transformation Phase Gates**

| Digital Technology           | Gate 1: Tech Readiness Check                                          | Compliance Review            | Gate 2: Pilot Validated                           | Intermediate Financial Validation Step                 | Gate 3: Workforce Trained                                   | Gate 4: Integration Approved                  |
|------------------------------|-----------------------------------------------------------------------|------------------------------|---------------------------------------------------|--------------------------------------------------------|-------------------------------------------------------------|-----------------------------------------------|
| <b>AI/ML</b>                 | Identify use case (e.g., predictive maintenance)                      | Regulation Compliance Review | Pilot AI model on one production line             | Predefined ROI metrics mapped to strategic objectives. | Train production techs to interpret outputs                 | Deploy across facilities                      |
| <b>Big Data Analytics</b>    | Ensure data capture infrastructure is in place on production process. | Regulation Compliance Review | Pilot dashboards for root cause analysis          | Predefined ROI metrics mapped to strategic objectives. | Train data analysts, scientists, and laboratory staff       | Scale to enterprise-level decision-making     |
| <b>Cloud Computing</b>       | Assess cloud vendorsolutions/ options                                 | Regulation Compliance Review | Pilot cloud-based MES/LMIS on a trial basis       | Predefined ROI metrics mapped to strategic objectives. | Train IT and lab managers on the new system                 | Fully migrate workflows to cloud MES/LMIS     |
| <b>Cybersecurity (IT/OT)</b> | Baseline security assessment                                          | Regulation Compliance Review | Pilot intrusion detection system                  | Predefined ROI metrics mapped to strategic objectives. | Train production staff on cyber protocols                   | Certify enterprise-wide compliance            |
| <b>Digital Twins</b>         | Develop a digital twin for one piece of lab equipment                 | Regulation Compliance Review | Validate the twin against real performance        | Predefined ROI metrics mapped to strategic objectives. | Train operators with simulations                            | Expand to line or facility-wide twins         |
| <b>Sensors / IoT</b>         | Install sensors on one process production cell                        | Regulation Compliance Review | Validate output improvement/ downtime savings     | Predefined ROI metrics mapped to strategic objectives. | Train lab techs to use new technology                       | Expand across the production line             |
| <b>Robotics</b>              | Assess cobot's/ robot's readiness for a lab task                      | Regulation Compliance Review | Pilot cobot on pipetting or liquid handling task. | Predefined ROI metrics mapped to strategic objectives. | Train lab techs on safety and cobot training and co-working | Integrate robotics into multiple lab benches. |

# Managing Risk

As with any new initiative, risk and uncertainty are inherent to change and should be accounted for in project plans. Figure 23 below provides an example risk register. Such tools can be used to document and specify risks associated with technology adoption and digital transformation.

Figure 23. Canadian Biomanufacturing Example Digital Transformation Risk Register

| Risk Category    | Specific Risk                    | Impact | Probability | Possible Mitigation Strategies                 |
|------------------|----------------------------------|--------|-------------|------------------------------------------------|
| Technical        | Integration failures             | High   | Medium      | Pilots/testing, vendor partnerships            |
|                  | Cybersecurity vulnerabilities    | High   | Medium      | Security framework, audits, response           |
|                  | Legacy compatibility             | Medium | High        | Assessment, middleware, migration              |
| Financial        | Cost overruns                    | High   | Medium      | Phased implementation, ROI metrics             |
|                  | Negative ROI                     | Medium | Medium      | Track ROI metrics                              |
| Human Resources  | Digital skills gaps              | High   | High        | Training, recruit for digital skills           |
|                  | Workforce resistance             | Medium | Medium      | Employee ownership                             |
| Operational      | Production disruptions           | High   | Medium      | Parallel ops, scheduled downtime               |
|                  | Supply chain disruptions         | High   | High        | Multi-region sourcing, stockpiling             |
| Vendor Risk      | Tech vendor reliability issues   | Medium | Medium      | Multi-vendor, SLAs, backup plans               |
|                  | Vendor lock-in                   | High   | Medium      | Open standards, portability, and exit strategy |
| Market/ External | Regulatory/policy changes        | Medium | Medium      | Monitoring, flexible compliance                |
|                  | Competitive pressure             | High   | Medium      | Market monitoring, agile strategy              |
|                  | IP theft/cyberattack/data breach | High   | Medium      | Cybersecurity, IP protection, pentesting       |

## Risk Management Trigger Scenarios

In addition to establishing a risk roster to support enterprise digital transformation, trigger scenarios can be adopted as a risk management tool. Trigger scenarios are indications that a risk is either occurring or is at a heightened probability to occur

in the future. Figure 24 below provides illustrative trigger scenarios with early warning indicators and suggested actions, showing biomanufacturers how to spot when a risk is rising and take timely steps to mitigate it.

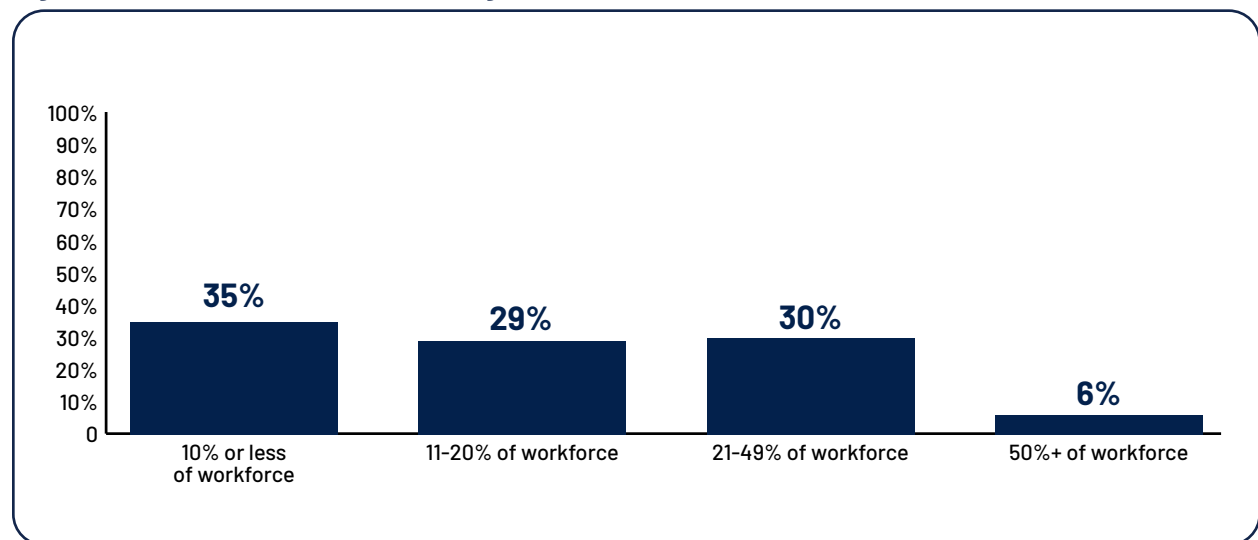
**Figure 24. Example Biomanufacturing Trigger Scenarios**

| Trigger Scenario                                                                   | Early Warning Indicator                                                    | Potential Action                                                                                                         |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| <b>I. Health Canada introduces new digital traceability compliance requirement</b> | Updated traceability clauses in RFQs or supplier contracts.                | Review product traceability policies and digital readiness; engage vendor for gap assessment.                            |
| <b>II. Key supplier shows signs of financial distress</b>                          | Late deliveries, quality slippage, credit rating downgrades.               | Identify alternate suppliers; build buffer stock; engage in contingency planning.                                        |
| <b>III. Workforce turnover spikes in laboratory production team</b>                | Increase in overtime reliance, exit interviews citing job dissatisfaction. | Launch retention measures; accelerate cross-training; adjust hiring plans.                                               |
| <b>IV. Equipment reliability declines</b>                                          | Rising unplanned downtime or repeated maintenance calls.                   | Initiate predictive maintenance pilot; carry out root-cause analysis of downtime; prioritize Capex replacement schedule. |
| <b>V. Customer demand shifts suddenly</b>                                          | Drop in firm orders or requests for new product configurations.            | Reassess production plan; explore using product digital twins; increase use of flexible automation.                      |

# Talent, Workforce Development, and Training

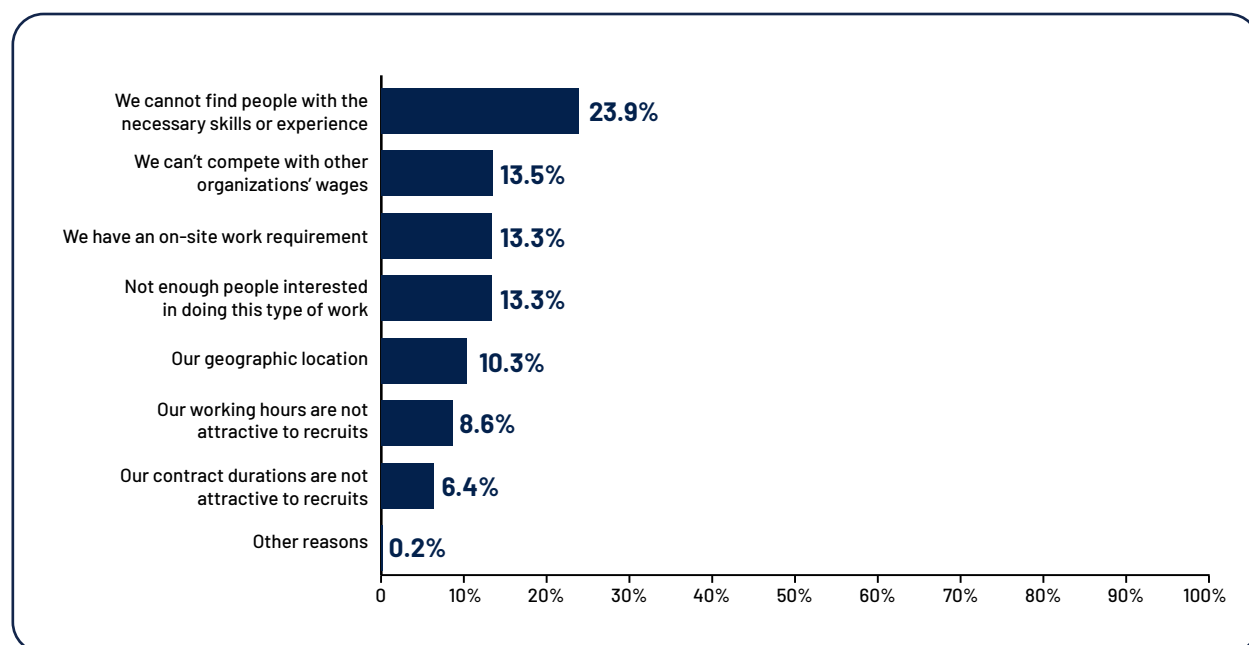
Developing a digitally skilled manufacturing workforce is essential to realize the full potential of digital transformation in Canada's biomanufacturing sector. The need to accelerate the proportion of the workforce driving digital transformation in biomanufacturing is important to sustain continued growth. Indeed, within biomanufacturing promoting advanced levels of digital literacy and digital transformation thinking is crucial in functional areas as varied as production, quality assurance, regulatory compliance, and sales and business development.

Figure 25. Workforce Dedicated to Digital Transformation at Canadian Biomanufacturers (2025)



Source: ICTC Canadian Manufacturing Digital Technology Adoption Survey, 2025.

**Figure 26. Canadian Employers' Challenges in Recruiting Technology Employees in Past 12 Months**



Source: ICTC's 2024 Digital Economy Employer Survey.

ICTC's 2025 survey on digital technology adoption in Canadian manufacturing found that 35% of biomanufacturers surveyed devote 10% or less of their workforce to digital transformation efforts (Figure 25). Competition for digital talent in adjacent sectors to manufacturing—such as infrastructure, energy and

natural resources, and technology—are immense. Indeed, recruiting technology workers with the needed mix of skills and experience was the top recruiting challenge faced by employers across Canada, according to ICTC's 2024 digital economy employer survey (Figure 26).<sup>11</sup>

<sup>11</sup> Maryna Ivus, Todd Legere, Christopher Lindstrom, Sheldon Lopez, and Faun Rice, "Digital Economy Pulse: Productivity and Employment Trends in Canada," Information and Communications Technology Council (ICTC), 2025, <https://ictc-ctic.ca/reports/digital-economy-pulse-productivity-and-employment-trends-canada-august-2025>, 22, Figure 9.

**Figure 27. Baseline Digital Competencies for Advanced Manufacturing**

|                                          |                                                                                                                                              |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Advanced Robotics Interaction</b>     | Safely and productivity interacting with advanced robotics in lab and biomanufacturing environments, including interactions with cobots.     |
| <b>AI and ML Basics</b>                  | Understanding capabilities and limitations of AI/ML systems and how autonomous systems are being adopted into biomanufacturing applications. |
| <b>Cloud Computing Applications</b>      | Working with cloud-based manufacturing and enterprise systems such as MES and ERP applications.                                              |
| <b>Cybersecurity Fundamentals</b>        | Basic IT/OT security awareness for laboratory and biomanufacturing environments.                                                             |
| <b>Digital Twin Operation</b>            | Managing and interpreting virtual representations of physical systems.                                                                       |
| <b>Data Analytics and Interpretation</b> | Understanding how to collect, curate, analyze, and act on large volumes of operational data.                                                 |

On top of recruiting and retaining skilled digital talent to drive digital adoption in Canada's biomanufacturing sector, there are significant opportunities to invest in upskilling and retraining programs for the existing workforce.

Manufacturers adopting digital technologies into their operations as they undergo digital transformation need to establish baseline, essential digital competencies across their workforces. This includes the following essential advanced manufacturing digital competencies outlined in Figure 27.

Most critically, biomanufacturers engaging in digital transformation need to create a culture of continuous learning amongst their workforces through deliberate organizational strategies and embracing innovative training models to foster digital talent.<sup>12</sup>

Learning should be structured in a practical manner that conveys hands-on knowledge and digital skill development. Figures 28 and 29 outline organizational strategies and training delivery models for fostering digital talent in biomanufacturing.

<sup>12</sup> The Conference Board of Canada, "Building a Digitally Skilled Workforce: Insights from Canadian Employers and Skills Leaders," The Conference Board of Canada and Future Skills Centre, March 2022, <https://fsc-ccf.ca/research/building-a-digitally-skilled-workforce/>.

**Figure 28. Organizational Strategies for Fostering Digital Competencies in Advanced Manufacturing**

|                                                              |                                                                                                                                                  |
|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Integrate Digital Skills into Existing Roles</b>          | Integration of digital competencies into existing job roles rather than creating separate digital positions.                                     |
| <b>Provide Recognition and Incentives</b>                    | Recognition and incentive systems that reward digital skill development and knowledge sharing.                                                   |
| <b>Develop Internal Digital Skills Training Capabilities</b> | Invest in internal training capabilities to reduce dependence on external providers.                                                             |
| <b>Include Workforce in Pilot Projects</b>                   | Create cross-functional teams made up of employees throughout manufacturing enterprise to launch technology adoption pilots, document learnings. |
| <b>Pursue Digital Talent Development Partnerships</b>        | Partnerships with post-secondary institutions, technology vendors, and other ecosystem actors for ongoing skills development.                    |

**Figure 29. Training Delivery Models for Fostering Digital Competencies in Advanced Manufacturing**

|                                     |                                                                                               |
|-------------------------------------|-----------------------------------------------------------------------------------------------|
| <b>Cross-generational Mentoring</b> | Pairing digitally skilled employees with experienced technicians and scientists.              |
| <b>Simulation-Based Learning</b>    | Using digital twin environments, coupled with VR/XR for safe, realistic training experiences. |
| <b>Micro-Learning Modules</b>       | Short, focused training sessions that accommodate shifts and production schedules.            |
| <b>Vendor-Supported Training</b>    | Leveraging technology supplier expertise for specific system training.                        |
| <b>Micro-credentials</b>            | Short, skill-focused, and flexible educational programs, often delivered online.              |

# Developing Strategic Partnerships

Canadian biomanufacturers do not need to undertake their digital transformation journeys alone. Indeed, there are plenty of outside organizations within the manufacturing industry and the public sector that biomanufacturers can develop strategic partnerships with. These include industry associations, as well as other ecosystem actors, such as industry working groups, industry-led training initiatives, and tech incubators. Post-secondary institutions can also be leveraged to provide workforce training, a pipeline of new talent, through work-integrated learning (WIL) initiatives, such as co-op programs, campus recruiting, and joint research. Indeed, many manufacturing firms can trace their origins directly to initial research taking place at university research labs.

Likewise, relationships with stakeholders such as customers, suppliers, and technology vendors should be taken into account when undergoing digital transformation. Figure 30 below outlines key

strategic partnership and stakeholder management verticals, which should be accounted for when undergoing digital transformation.

**Figure 30. Strategic Partnership Verticals**

| Customers                                                                                                                                                                                                                                                                                          | Vendors and Suppliers                                                                                                                                                                                                                                                                                             | Industry Associations and Ecosystem Groups                                                                                                                                                                                                                                                                                        | Post-Secondary Institutions                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>› Digital transformation co-investment and cost-sharing programs</li> <li>› Open digital platforms and interoperable data standards</li> <li>› Joint cyber/information security protocols</li> <li>› Joint digital transformation pilot programs</li> </ul> | <ul style="list-style-type: none"> <li>› Digital transformation co-investment and cost-sharing programs</li> <li>› Open digital platforms and interoperable data standards</li> <li>› Vendor training and technical mentorship/coaching programs</li> <li>› Joint cyber/information security protocols</li> </ul> | <ul style="list-style-type: none"> <li>› Industry working groups (e.g., joint digital transformation working group)</li> <li>› Technology/start-up incubator programs</li> <li>› Industry-led training and workforce development initiatives</li> <li>› Sectoral public affairs and governmental relations initiatives</li> </ul> | <ul style="list-style-type: none"> <li>› Workforce training and talent development</li> <li>› WIL programs (e.g., internships, co-ops, practicums)</li> <li>› Campus recruiting (e.g., job fairs, industry nights)</li> <li>› Joint industry-academic research</li> <li>› Industry curriculum advisory councils</li> <li>› Research security cooperation/safeguards</li> </ul> |

## Information and Data-sharing for Biomanufacturing Strategic Partnerships

In addition to the key partnership verticals listed above, biomanufacturers should be ready to jointly develop predefined partnership frameworks and agreements upfront between new partners. Co-developing a common understanding of partnership objectives, scope, and timelines is critical to foster successful partnerships.

Likewise, relationships with stakeholders such as customers, suppliers, and technology vendors should be taken into account when undergoing digital transformation. Biomanufacturers should also understand the types of potentially sensitive non-personal data, such as production and process, financial, supply chain data, that may be needed to share with partners (Figure 31).

**Figure 31. Strategic Partnership Information and Data-sharing Considerations**

### Strategic Alignment

- › Objectives, scope, and partnership timeline
- › Business case and ROI expectations (e.g., financial/performance metrics)
- › Governance model and decision-making processes (e.g. IP ownership, dispute resolution)
- › Knowledge sharing frameworks (e.g., publication agreements, joint workshops, user groups, technology demonstrators, pilots)

### Technical Data Requirements

- › Manufacturing systems and process (e.g., enterprise systems and control systems (MES/ERP), machinery/ equipment inventory)
- › Facilities connectivity (e.g., 5G, ethernet)
- › Non-personal data sharing (e.g., production and process, IP/trade secrets, quality, financial, safety/incident, supply chain)
- › Interoperability standards and data formats
- › Cybersecurity standards/data protection, Tri-council research security compliance

### Safety, Regulation, and Compliance Requirements

- › Quality standards
- › Health and Safety standards
- › Therapeutic safety and traceability regulations
- › Environmental/ESG standards
- › IP and confidentiality agreements

# Digital Technology Adoption: A Call to Action

Canada's biomanufacturing sector stands to benefit from increasing digital technology adoption throughout the laboratory and manufacturing enterprise. Canada's biomanufacturing industry is playing an important role in Canada's economy, as a significant locus of innovation and a producer of life-saving medicines and therapeutics. It is an important employer of highly qualified personnel, including scientists, engineers, and laboratory technologists.

Over the next five to ten years, there are significant opportunities in emerging digital technologies such as advanced robotics, AI, IoT, and digital twins, but digital infrastructure must be continuously upgraded, while biomanufacturing workforce needs to be continuously trained and upskilled to get the most out of novel digital technologies on the laboratory floor.

Likewise, to get the most out of digital transformation, biomanufacturing businesses need to understand and rigorously assess opportunities

brought about by novel digital technologies and incorporating them into their business plans and long-term corporate strategies, developing business cases, measuring ROI, evaluating risk, managing organizational change, and mapping stakeholders and strategic partners. All of these digital transformation activities must be done in a way that protects sensitive IP and patient data, meets regulatory requirements, takes AI governance and safety into account, and is carried out in a manner that is above all, human-centered.

## Action Steps

**Assess** Map your current processes and technological capabilities and identify digital gaps.

**Pilot** Start with a small project (e.g., a lab automation, predictive maintenance, or AI production scheduling tool).

**Train** Involve staff early, build digital change champions on the lab floor, recruit digital technology talent.

**Partner** Engage with vendors and suppliers, post-secondaries, industry associations and ecosystem groups, and customers for expertise and shared resources.

**Scale** Expand proven pilots across lines, labs, or product families.

**Integrate** Network successfully scaled technology adoption initiatives into a cohesive technology stack to drive profitability, cost savings, and productivity.

**Iterate** Repeat technology adoption cycle as new technologies emerge and markets evolve.

# Research Methods

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This roadmap for the Canadian biomanufacturing sector is informed by mixed methods research, including an industry survey of Canadian advanced manufacturers, a series of key informant interviews, an industry roundtable, and a comprehensive literature review.

ICTC carried out an industry survey of Canadian manufacturers (n = 133) from June and July 2025, which included responses from 27 firms from Canada's biomanufacturing sector. Due to the wide variety of firm types involved in fabricated metal products manufacturing and a relatively small sample size, survey data may not fully reflect the state of all Canadian manufacturers. ICTC also carried out six semi-structured key informant interviews with senior executives, technical leaders, and other experts from the Canadian biomanufacturing sector. ICTC also hosted a

biomanufacturing sectoral roundtable with industry leaders in January 2026.

Prior to carrying out primary data collection, ICTC conducted a comprehensive literature review on digital transformation, digital technology use cases in manufacturing, and the current state of advanced manufacturing in Canada. Insights collected during the literature review helped to inform questions asked to research participants during the industry survey, key informant interviews, and focus groups, as well as design the final roadmap document.