



# **Automate, Innovate, Adapt:**

## The 2025 State of Medical & Life Sciences Manufacturing

How the medical and life sciences industry is navigating regulatory complexities, overcoming workforce challenges, and embracing automation to drive innovation and operational excellence.

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# ✓ Executive summary

## The state of medical and life sciences manufacturing

The medical and life sciences manufacturing sector is undergoing a transformative period, driven by increasing regulatory complexities, rapid technological advancements, and shifting global supply chain realities.

Ascential Medical & Life Sciences' 2025 State of the Industry Report sheds light on key trends, challenges, and best practices shaping the future of this critical industry.

## Objective of the report

Drawing on exclusive survey data and expert analysis, this report highlights how industry players can adapt to evolving conditions while maintaining compliance, quality, and efficiency. It also offers solutions that empower stakeholders to tackle regulatory challenges, integrate transformative technologies, and build sustainable operations.

By exploring the insights presented in this report, professionals across roles – including research engineers, development engineers, quality managers, and executive leaders – will learn about the tools and strategies needed to navigate the future.



## Key survey data and insights

### Regulatory challenges impact commercialization:

- ✓ **42%** of survey respondents cited regulatory compliance as the top barrier to commercializing medical products.

### Automation and personalized medicine continue to be top-of-mind:

- ✓ **69%** of respondents are using automation in some form, yet integration hurdles persist.
- ✓ Almost **31%** saw personalized medicine as the most challenging manufacturing trend in 2024.

### Reshoring faces significant obstacles:

- ✓ **56%** of respondents identified high labor and operational costs as the main hurdle to bringing manufacturing back to their home country.
- ✓ Skilled workforce shortages and regulatory constraints compound the issue.



## Emerging trends

- ▲ **Post-COVID supply chain adaptations:** Companies are redefining supply chain strategies to mitigate persistent disruptions.
- ▲ **AI and predictive analytics:** Manufacturers are increasingly leveraging AI to enhance quality assurance and operational efficiency.
- ▲ **Incremental automation adoption:** Only 9% of survey respondents reported fully integrated automation, underscoring the need for scalable solutions.

## Strategic opportunities

- ▲ **Regulatory compliance:** Best practices to streamline complexity and reduce costs.
- ▲ **Automation:** Addressing workforce readiness and cost barriers with actionable strategies.
- ▲ **Reshoring:** Overcoming operational challenges through cost optimization and training programs.

## Looking ahead

The medical and life sciences industry stands at a pivotal crossroads, where challenges like regulatory hurdles and labor shortages converge with opportunities in automation, AI, and personalized medicine.

Explore actionable insights and case studies in this comprehensive report designed for industry leaders shaping the future.

# Introduction

## Navigating the future of medical and life sciences manufacturing

The medical and life sciences manufacturing sector is at the forefront of global healthcare innovation. This industry is rapidly evolving, shaped by unprecedented challenges and transformative opportunities. In 2025, the landscape continues to be defined by post-COVID supply chain realities, technological advancements, and increasing regulatory demands, requiring stakeholders to adapt and innovate like never before.





## A rapidly evolving landscape

The post-pandemic world has catalyzed a shift in how manufacturers operate. Supply chain disruptions, workforce shortages, and rising operational costs demand new strategies and technologies. At the same time, advancements in automation, AI, and personalized medicine are presenting groundbreaking opportunities to enhance production processes and deliver tailored healthcare solutions.

However, these innovations come with their own set of hurdles. From integrating robotics into traditional workflows to navigating complex regulatory frameworks, manufacturers must overcome significant obstacles to realize their full potential and future-proof their operations.



**Join us in uncovering  
the key factors driving  
innovation and resilience.**

## The industry's critical role

Medical and life sciences manufacturing is a cornerstone of global healthcare, enabling the development and production of life-saving devices, treatments, and diagnostics. The sector's contributions extend beyond immediate healthcare solutions to impact patient outcomes, public health systems, and the future of medical innovation.

As the world increasingly relies on cutting-edge medical technologies, manufacturers bear a growing responsibility to ensure quality, scalability, and accessibility. The stakes have never been higher, making strategic partnerships and innovative solutions essential for success.

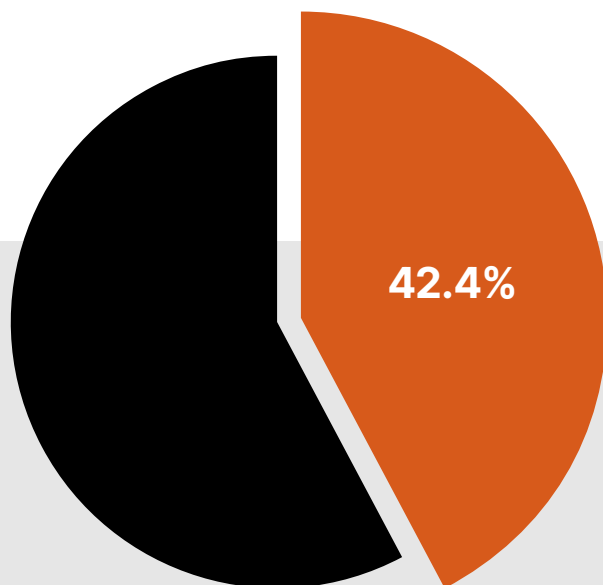


# ✓ Commercializing medical products

Bringing medical products to market is a complex endeavor, requiring manufacturers to navigate a minefield of regulatory requirements, cost pressures, and operational hurdles. Insights from our survey underscore the critical challenges and highlight the steps organizations are taking to overcome them.

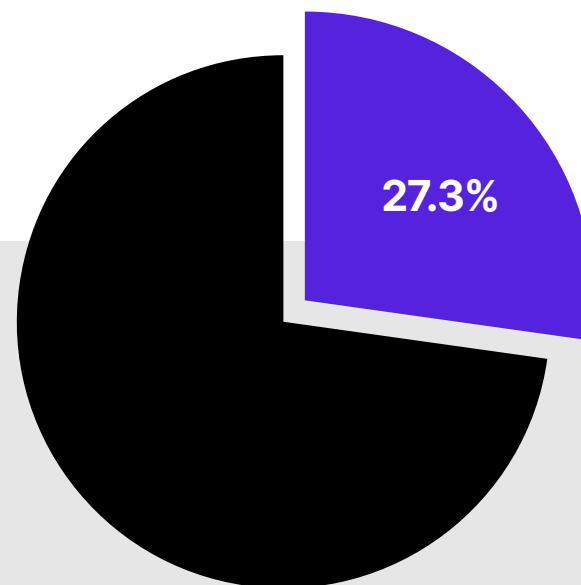


## Survey findings: Biggest obstacles to commercialize medical products



### Regulatory challenges

Regulatory compliance dominates the list of obstacles.



### Managing production costs

Striking a balance between pricing and quality remains a pressing concern.

# Analysis: Overcoming key barriers

## Regulatory challenges



Navigating the intricate landscape of compliance is critical to ensuring successful commercialization. Regulatory hurdles demand a structured approach and our Manufacturing Development Pathway provides a proven roadmap:

- ▲ **Assessment and goal definition:** Identifying compliance pain points and setting clear objectives for regulatory adherence.
- ▲ **Cross-functional team formation:** Ensuring diverse expertise, from legal to technical, to address evolving compliance demands.
- ▲ **Continuous improvement:** Using data-driven insights to optimize processes and stay ahead of regulatory changes.

## Managing production costs

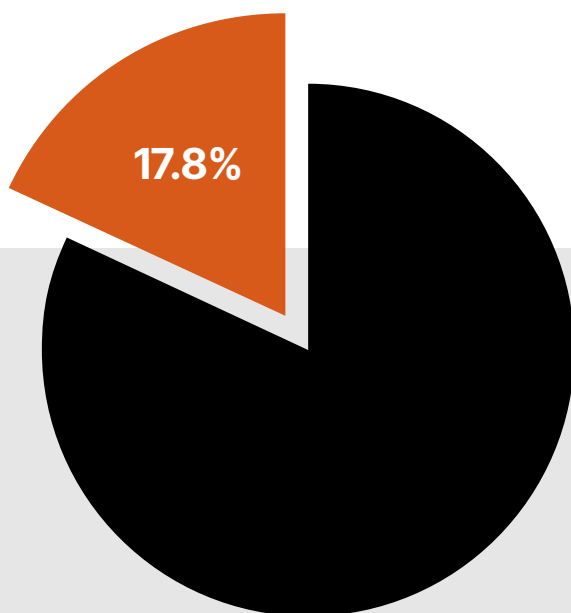


With cost pressures mounting, companies are reevaluating their processes to drive efficiency without compromising quality. Key strategies include:

- ▲ **Process mapping and design:** Identifying inefficiencies in production workflows and designing optimized systems.
- ▲ **Feasibility studies:** Conducting ROI analyses to ensure financial viability of new technologies.
- ▲ **Incremental implementation:** Phased adoption of automation and robotics to reduce upfront investment risks.

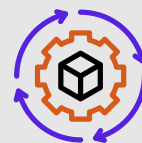
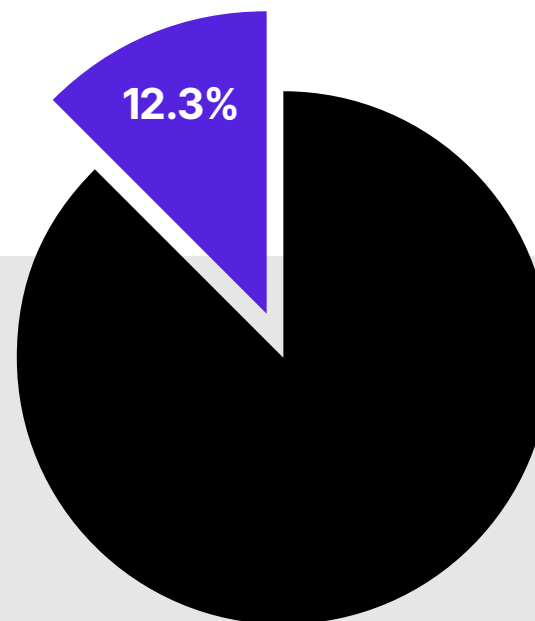


## Survey findings: Biggest obstacles to commercialize medical products



### Scaling with quality

Maintaining high standards while expanding production capacity is a key difficulty.



### Supply chain reliability

Persistent disruptions post-pandemic continue to hinder operational efficiency.

## Analysis: Overcoming key barriers

### Scaling with quality



Maintaining rigorous quality standards during expansion requires a focus on scalability and continuous monitoring:

- ▲ **Prototyping and testing:** Small-scale implementation to validate processes before full deployment.
- ▲ **Data integration:** Real-time monitoring to ensure consistent quality across expanded operations.
- ▲ **Training and skill development:** Empowering the workforce with the skills needed for advanced manufacturing systems.

### Supply chain reliability



Supply chain disruptions demand innovative solutions for resilience and adaptability:

- ▲ **Risk management and contingency plans:** Developing strategies to mitigate unforeseen disruptions.
- ▲ **Vendor selection and partnerships:** Building collaborative networks with reliable suppliers.
- ▲ **Post-covid optimization:** Adjusting logistics to adapt to evolving global conditions.



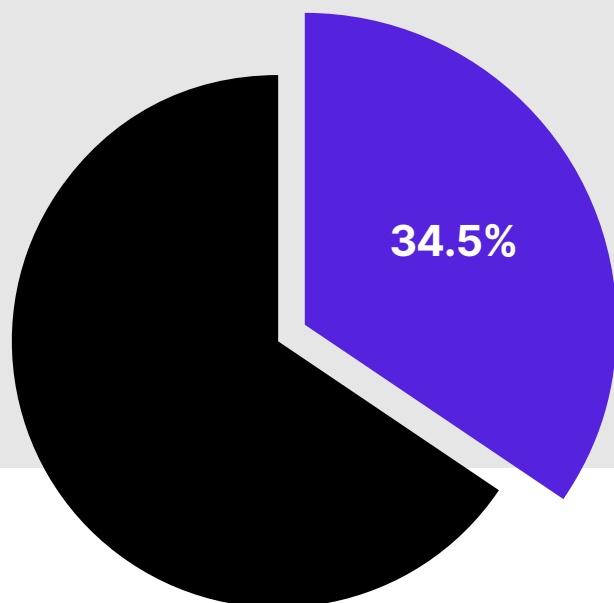
**By combining technology evaluation, scalability planning, and continuous improvement, manufacturers can overcome commercialization obstacles and succeed in a competitive market.**

# ✓ Emerging trends in manufacturing

As the medical and life sciences manufacturing landscape evolves, new trends are shaping the future of production and innovation. Insights from industry professionals reveal key areas of transformation that present both challenges and opportunities.



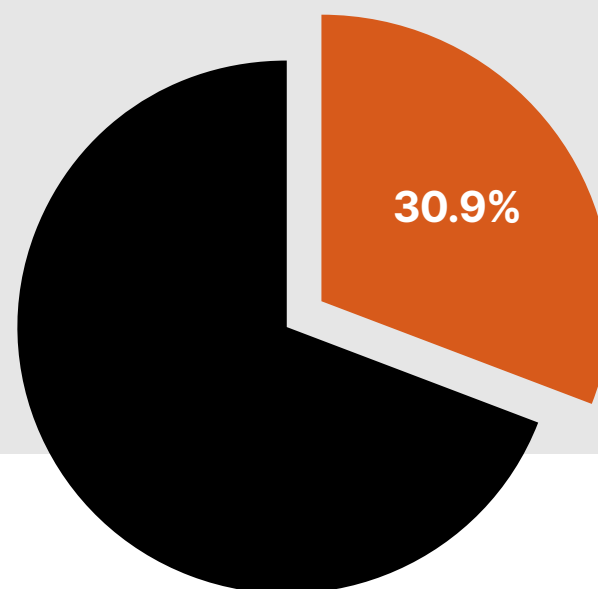
## Survey findings: The most challenging manufacturing trends – and how companies can address them



### Automation and robotics

**Overview:** While automation offers significant potential for efficiency, companies face hurdles in integrating these technologies and preparing the workforce to manage them effectively.

**Solution:** Incremental implementation of automation, paired with targeted training programs to upskill employees for advanced system management.

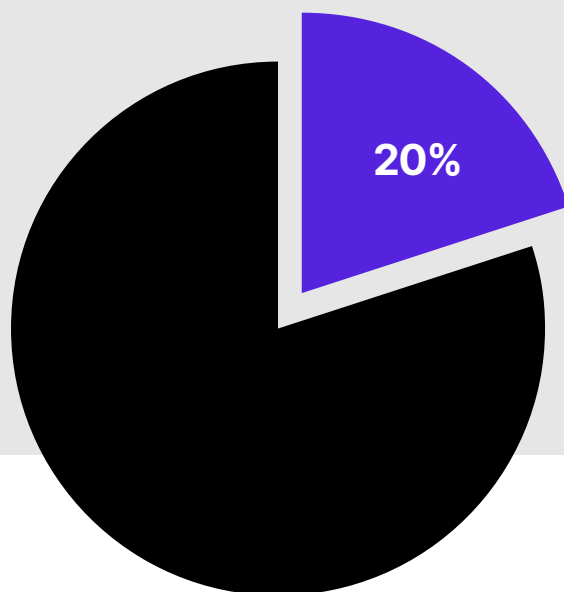


### Personalized medicine

**Overview:** The shift toward individualized treatments is driving innovation but adding complexity to production processes, often necessitating advanced automation.

**Solution:** Advanced process mapping and real-time monitoring systems allow manufacturers to handle small-batch, high-precision production effectively.

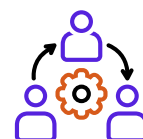
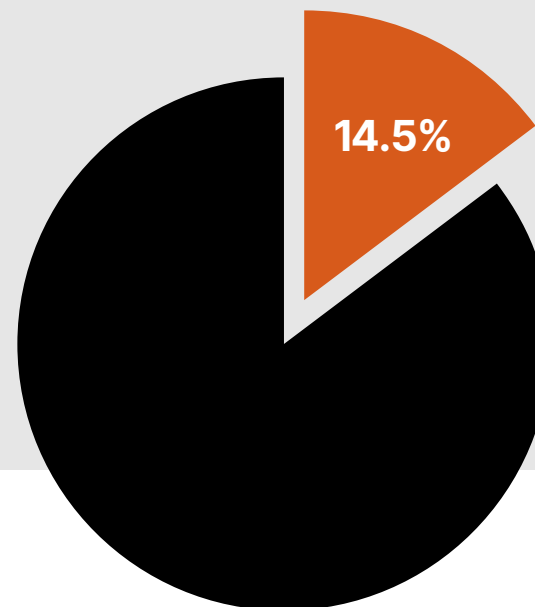
## Survey findings: The most challenging manufacturing trends – and how companies can address them



### AI/Machine learning

**Overview:** Predictive analytics powered by AI is revolutionizing quality assurance and operational efficiency, helping manufacturers anticipate and address issues proactively. However, leveraging AI can overwhelm existing infrastructures.

**Solution:** Predictive analytics tools powered by machine learning can allow manufacturers to identify trends, reduce downtime, and ensure consistent quality.



### Post-COVID supply chain management

**Overview:** Companies are managing and adapting to new supply chain realities, emphasizing resilience and flexibility to mitigate future disruptions.

**Solution:** Predictive analytics tools powered by machine learning allow manufacturers to identify trends, reduce downtime, and ensure consistent quality.

# ✓ Automation in manufacturing processes

Automation continues to transform manufacturing, enhancing efficiency, precision, and scalability. However, adoption rates reflect an industry still navigating the complexities of integration. Understanding these challenges and leveraging available opportunities is key to unlocking the full potential of automation in medical and life sciences manufacturing.



## Survey findings: How companies are using automation



**9.2%**

### Fully integrated automation:

A small minority of medical and life sciences companies have fully automated their processes, reflecting the complexity and cost of achieving full integration.



**59%**

### Partial or limited automation:

Most companies are adopting automation incrementally, incorporating technology into select areas to address specific challenges.



**31.4%**

### No automation:

Others are not using automation at all, demonstrating an opportunity for greater awareness and utilization.

## Barriers to Automation Adoption

**Costs:** The upfront investment in automation technologies and infrastructure can be significant, particularly for small to mid-sized companies.

**System compatibility:** Legacy systems often lack the interoperability needed to integrate with modern automation solutions, leading to implementation challenges.

**Workforce readiness:** The shift to automation requires training and upskilling employees to manage and operate new systems effectively.

# Opportunities in automation

Despite these barriers, the benefits of automation are clear. From reducing costs to improving quality and efficiency, automation technologies are reshaping the manufacturing landscape.

## Technologies driving integration

- ✓ **Collaborative robots (cobots):** These robots work alongside human operators, making automation accessible without requiring full system overhauls.
- ✓ **Predictive maintenance tools:** AI-driven systems monitor equipment performance, reducing downtime and increasing productivity.
- ✓ **Integrated Manufacturing Execution Systems (MES):** These systems enable real-time tracking and management of production, creating a more connected and efficient manufacturing process.
- ✓ **Automated quality control:** Vision systems and machine learning algorithms ensure consistent quality, reducing waste and rework.



## Driving the future of automation

The journey toward fully automated manufacturing is not without challenges, but the opportunities are transformative. With tailored solutions and a commitment to innovation, medical and life sciences companies can embrace automation at their own pace, ensuring success in an increasingly automated industry.

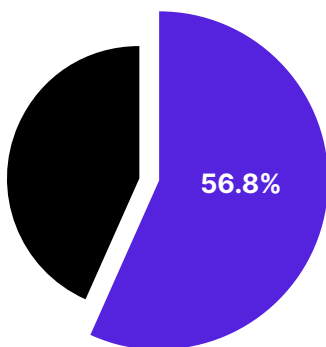
# √ Relocation and reshoring trends

The global manufacturing landscape has seen increasing discussions around reshoring in recent years, driven by supply chain disruptions, geopolitical tensions, and the push for localized production. Despite this, most manufacturers remain hesitant to relocate operations due to significant barriers.

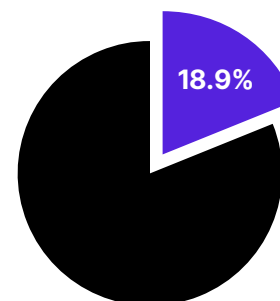
## Survey findings: Manufacturing relocation

According to our survey, **69% of respondents are maintaining their current manufacturing operations with no current or future plans to relocate due to obstacles like cost and labor shortages.**

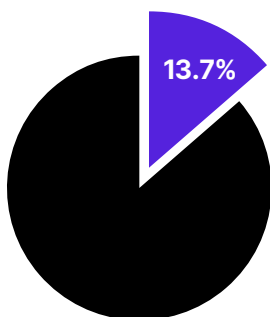
### Barriers to reshoring



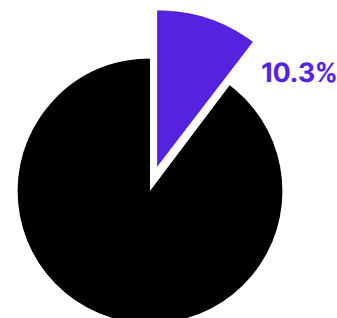
**High labor and Operational costs:** The costs associated with wages, infrastructure development, and ongoing operations in high-income regions deter many from reshoring efforts.



**Skilled labor shortages:** The medical and life sciences sector requires highly trained professionals. A lack of readily available talent poses a significant hurdle.



**Regulatory constraints:** Stringent and varying compliance requirements across regions add complexity and cost to relocation efforts.



**Facility footprint:** Having access to enough physical space is another consideration.



## Opportunities overcoming reshoring challenges

Reshoring presents opportunities for enhancing supply chain resilience and reducing dependence on global logistics. Companies can capitalize on these benefits by addressing key challenges strategically. **Our supply chain expert, Todd Bauman, shares his thoughts on the future of reshoring and supply chain management.**

**“The conversation about reshoring often overlooks a more strategic opportunity: Aligning supply chains geographically with customer needs,” said Todd.**

Historically, offshoring was driven by a “bandwagon effect,” with many manufacturers following trends rather than strategically evaluating total cost and operational risks. Today, however, tools like landed cost and total cost of ownership allow companies to make more informed decisions that consider not just cost but also proximity, risk, and resilience.

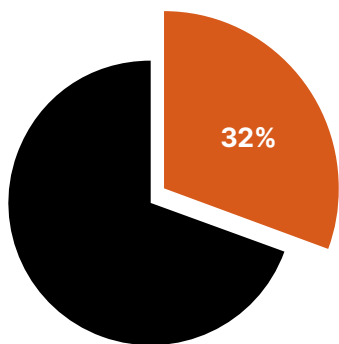
**The future of supply chain optimization lies in regional supply chains, not solely in reshoring.** By positioning operations near key customer hubs and embracing a nearshoring approach can balance cost efficiency with risk mitigation. This strategy incorporates considerations like geopolitical stability and environmental risks, ensuring robust and adaptive supply chains that meet customer demands while safeguarding against global disruptions.

# Production line integration

Integrating advanced technologies into production lines remains a critical challenge for the medical and life sciences manufacturing sector. While the promise of improved efficiency and output quality drives innovation, hurdles such as cost, workforce readiness, and system compatibility persist.

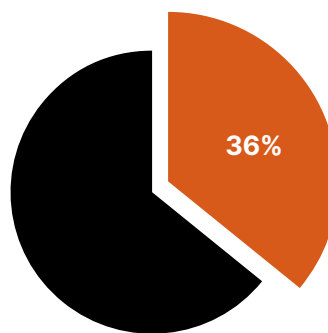


## Survey findings: Challenges with production line changes



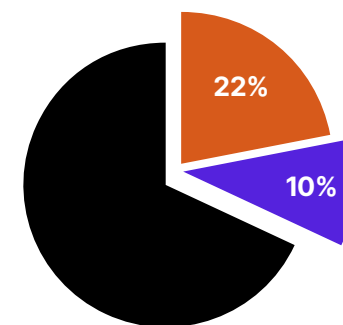
### High implementation costs

- ▲ Capital investments in advanced equipment and technologies can strain budgets, particularly for smaller manufacturers.
- ▲ Recurring costs for maintenance and upgrades further add to financial pressures.



### Workforce upskilling

- ▲ The rapid evolution of manufacturing technologies requires a highly skilled workforce capable of managing and maintaining complex systems.
- ▲ Training programs often lag behind technological advancements, leaving skill gaps that hinder seamless integration.



### Compatibility (22%) and quality concerns (10%)

- ▲ Integrating new systems with legacy equipment poses technical challenges, risking disruptions to production lines.
- ▲ Ensuring consistent product quality amid system changes requires robust quality assurance frameworks.



# Recommendations for cost-effective implementation

To address these challenges, medical and life sciences companies can adopt strategic approaches that balance cost, efficiency, and quality.



## Phased implementation

**Pilot programs:** Start with smaller-scale pilot projects to test and refine new technologies before full-scale deployment.

**Incremental rollouts:** Gradually integrate new systems into existing production lines to minimize disruption and manage costs effectively.



## Workforce development

**Training initiatives:** Invest in continuous learning programs focused on operating and maintaining advanced manufacturing technologies.

**Cross-functional skill building:** Develop cross-disciplinary teams to ensure a broad skill set within the workforce, covering both technical and operational needs



## Technology evaluation and vendor selection

**Compatibility focus:** Choose technologies that seamlessly integrate with existing systems, minimizing the need for extensive overhauls.

**Vendor partnerships:** Work with experienced vendors who offer comprehensive support, including training and ongoing maintenance services.



## Quality assurance frameworks

**Data-driven insights:** Use AI and machine learning tools to monitor and optimize production quality in real time.

**Standardized processes:** Develop and implement standardized operating procedures for quality assurance during integration phases.





# ✓ Strategic recommendations

This landscape demands strategic foresight and agility to navigate regulatory frameworks, adopt cutting-edge technologies, and overcome workforce challenges. The following actionable insights and resources from Ascential Medical & Life Sciences are designed to empower manufacturers with the tools and guidance needed to succeed.

## Actionable insights



### Regulatory navigation tools and best practices

**Compliance planning:** Develop a regulatory roadmap early in the product life cycle to anticipate and address compliance requirements.

**Digital documentation systems:** Implement systems for real-time tracking of regulatory changes and automated compliance reporting.

**Global perspective:** Leverage tools that provide insights into international regulations, streamlining multi-market approval processes.



### Roadmap for addressing workforce challenges

**Skills assessment:** Conduct a comprehensive evaluation of current workforce capabilities and identify skill gaps.

**Training programs:** Implement modular training that aligns with specific roles and technologies.

**Retention strategies:** Create growth opportunities within the organization to retain skilled talent.



### Steps for integrating automation with minimal disruption

**Phased implementation:** Begin with pilot programs to refine automation strategies before scaling up.

**Legacy system compatibility:** Invest in technologies that integrate seamlessly with existing equipment.

**Risk mitigation:** Develop contingency plans to minimize downtime during implementation.

## ✓ Conclusion

Medical and life sciences manufacturing stands at a crossroads of complexity and innovation. As organizations navigate regulatory pressures, workforce challenges, and technological advancements, the need for strategic partnerships and informed decision-making has never been greater.



# Summary of findings

## Key challenges

1. **Regulatory complexity:** Navigating stringent compliance standards continues to be a top challenge for medical and life sciences organizations.
2. **Workforce readiness:** Upskilling and retaining talent remains critical as technology reshapes operational landscapes.
3. **Automation integration:** High costs and system compatibility issues slow the pace of adoption.
4. **Supply chain resilience:** Persistent disruptions post-COVID highlight the need for robust risk management strategies.

## Key opportunities

1. **Innovation through automation:** Gradual implementation of advanced technologies drives efficiency and scalability.
2. **Embracing personalized medicine:** Tailored treatments create new pathways for growth while demanding precision in manufacturing.
3. **Strategic reshoring:** Overcoming operational barriers to reshoring presents a chance to improve supply chain reliability and localize production.
4. **AI and data analytics:** Predictive tools enhance quality assurance and decision-making processes.



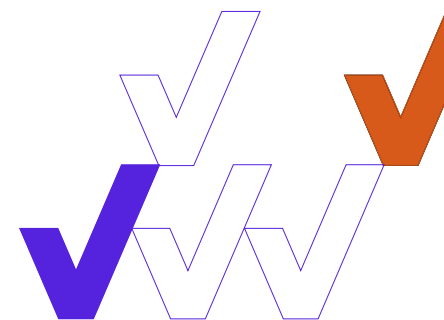
# The path forward

The future of medical and life sciences manufacturing is defined by those who embrace change, prioritize innovation, and seek strategic collaboration.

**Let's shape the future of manufacturing together. Contact us today to learn how we can support your journey.**

# Appendices

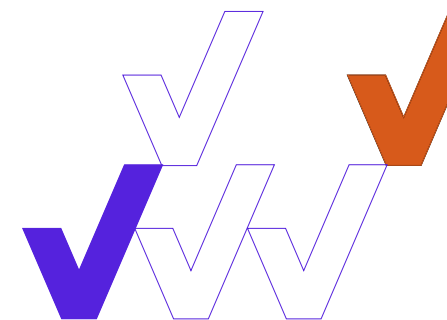
## Full survey results



1. In your opinion, which is the biggest obstacle to commercializing medical products?
  - Reduce/manage production costs: **27.3%**
  - Scale up while keeping quality: **17.8%**
  - Supply chain reliability: **12.3%**
  - Regulatory challenges: **42.4%**
2. Which of the following manufacturing trends do you think is the most challenging in 2024?
  - Integrate automation/robotics: **34.5%**
  - Personalized medicine: **30.9%**
  - Post-COVID supply chain management: **14.5%**
  - Using AI/machine learning: **20%**
3. How is your company currently using automation in your manufacturing processes?
  - Fully integrated: **9.2%**
  - Partially integrated: **29.6%**
  - Limited use for specific tasks: **29.6%**
  - Not currently using automation: **31.4%**
4. What is the biggest challenge you face when integrating changes into your production line?
  - High implementation costs: **32%**
  - Training/upskilling workforce: **36%**
  - Compatibility w/ my systems: **22%**
  - Maintaining quality: **10%**
5. Do you have any current or future plans to relocate your manufacturing? If yes, how immediate are your plans?
  - No: **69%**
  - Yes, less than one year: **7.2%**
  - Yes, 1-2 years: **10.9%**
  - Yes, 3+ years: **12.7%**
6. What is the biggest hurdle to bringing manufacturing back to your home country?
  - High labor and ops costs: **56.8%**
  - Strict regulations: **13.7%**
  - Shortage of skilled workers: **18.9%**
  - Having the facility footprint: **10.3%**

## Glossary of key terms

- 1. Regulatory compliance:** Adhering to the laws, guidelines, and specifications relevant to the manufacturing and commercialization of medical and life sciences products.
- 2. Personalized medicine:** A medical approach that uses individual patient data, such as genetics, to tailor treatments to specific needs, improving effectiveness.
- 3. Automation:** The use of technology and machinery to perform tasks with minimal human intervention, enhancing efficiency and precision in manufacturing.
- 4. Reshoring:** The practice of bringing manufacturing and production operations back to the country of origin from overseas to reduce supply chain risks and costs.
- 5. Artificial Intelligence (AI):** Computer systems designed to simulate human intelligence, used in manufacturing for predictive analytics, quality assurance, and process optimization.
- 6. Predictive analytics:** A form of AI that uses historical data and algorithms to predict future trends and outcomes, aiding in decision-making and operational efficiency.
- 7. Prototyping:** Creating preliminary models of a product to test and refine design and functionality before full-scale manufacturing.
- 8. Workforce readiness:** The preparedness of employees to adapt to and operate advanced technologies in a changing manufacturing landscape.
- 9. Supply chain resilience:** The capacity of a supply chain to withstand disruptions and adapt to changing conditions, ensuring consistent operations.
- 10. Incremental implementation:** A phased approach to adopting new technologies or processes to minimize risks and manage costs effectively.
- 11. Risk management:** The identification, assessment, and mitigation of risks to minimize their impact on operations, particularly in supply chain and manufacturing.
- 12. Scalability:** The ability of a manufacturing process to expand production capacity while maintaining quality and efficiency.
- 13. Data integration:** The process of combining data from various sources to provide unified, accurate, and actionable insights for decision-making.







Medical & Life Sciences

[info@ascentialtech.com](mailto:info@ascentialtech.com)

[mls.ascentialtech.com](https://mls.ascentialtech.com)

Contact us today to discuss how we can help tackle your toughest, most complex challenges and unlock the performance of your business.

**Impossible? Done.**