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# Decentralized manufacturing and edge computing

**Pioneering advances in life sciences**

Crafting personalized medicines, meeting local market needs, and fortifying supply chains are just some of the benefits that life sciences organizations can gain from operating under a “decentralized manufacturing” model.

Biotech firms, device makers, and other life sciences companies are particularly well suited for this visionary production process. Decentralized manufacturing involves making and distributing products at multiple, strategically located facilities near the products’ end users: patients themselves.

When combined with decision-making at the local level—and enabled by “edge computing” to leverage onsite data—decentralized manufacturing can result in a more agile, responsive, and effective production process.

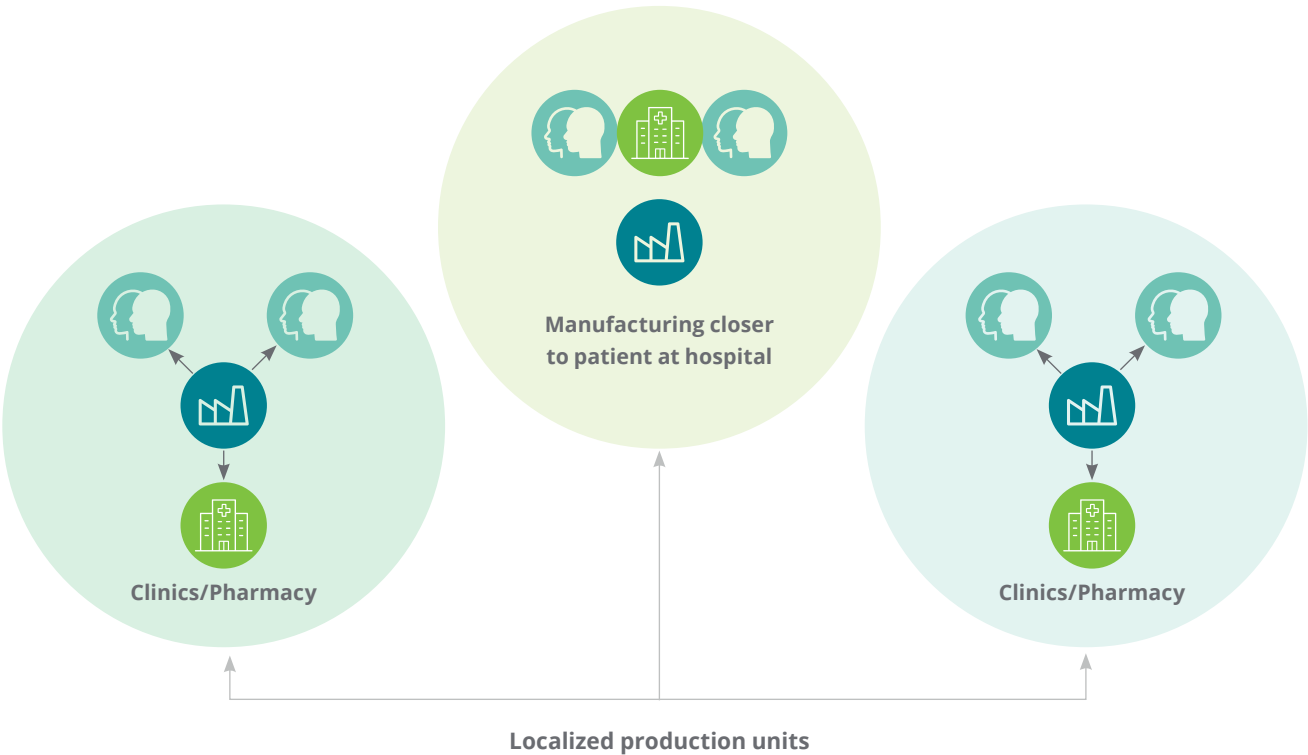
The mode below has been gaining traction in recent years as demand increases for personalized treatments and customized medical devices. Agility and responsiveness are the cornerstones of this concept.

Decentralized manufacturing can offer managers and employees greater control of the production process, boosting overall operational efficiency. The process can cut transportation costs and carbon footprints, accelerate lead times, and boost customer satisfaction with products tailored specifically for their needs.

A localized manufacturing model also fortifies a company's resilience against global supply chain disruptions, which can occur in the ever-evolving geopolitical landscape. Similarly, the model addresses challenges posed by numerous, complex regulatory requirements that can vary widely from where a product is developed, approved, and manufactured, and where it ultimately is used.

For these and other reasons, an increasing number of large pharmaceutical and other life sciences companies are looking at decentralized manufacturing to streamline approval processes, speed tailored products to market, and satisfy customers.

Decentralized manufacturing in life sciences



# How does it work in the real world?

Organizations are seeing three key archetypes of decentralized manufacturing emerge:

1. **Contract development and manufacturing organizations (CDMOs)/alliances:** Strategic alliances between health care providers, pharmaceutical companies, and specialized manufacturers form a cohesive unit, streamlining the development and production of cutting-edge medical products.
2. **Distributed manufacturing:** Small-scale, agile facilities spring up closer to patient populations, ensuring swift and efficient delivery, each guided by local expertise or advanced automation.
3. **Point-of-care (PoC) manufacturing:** Production units are embedded directly within hospitals or clinics, crafting custom treatments on the spot and revolutionizing patient care with immediate, tailored solutions.



# Edge computing: The enabler

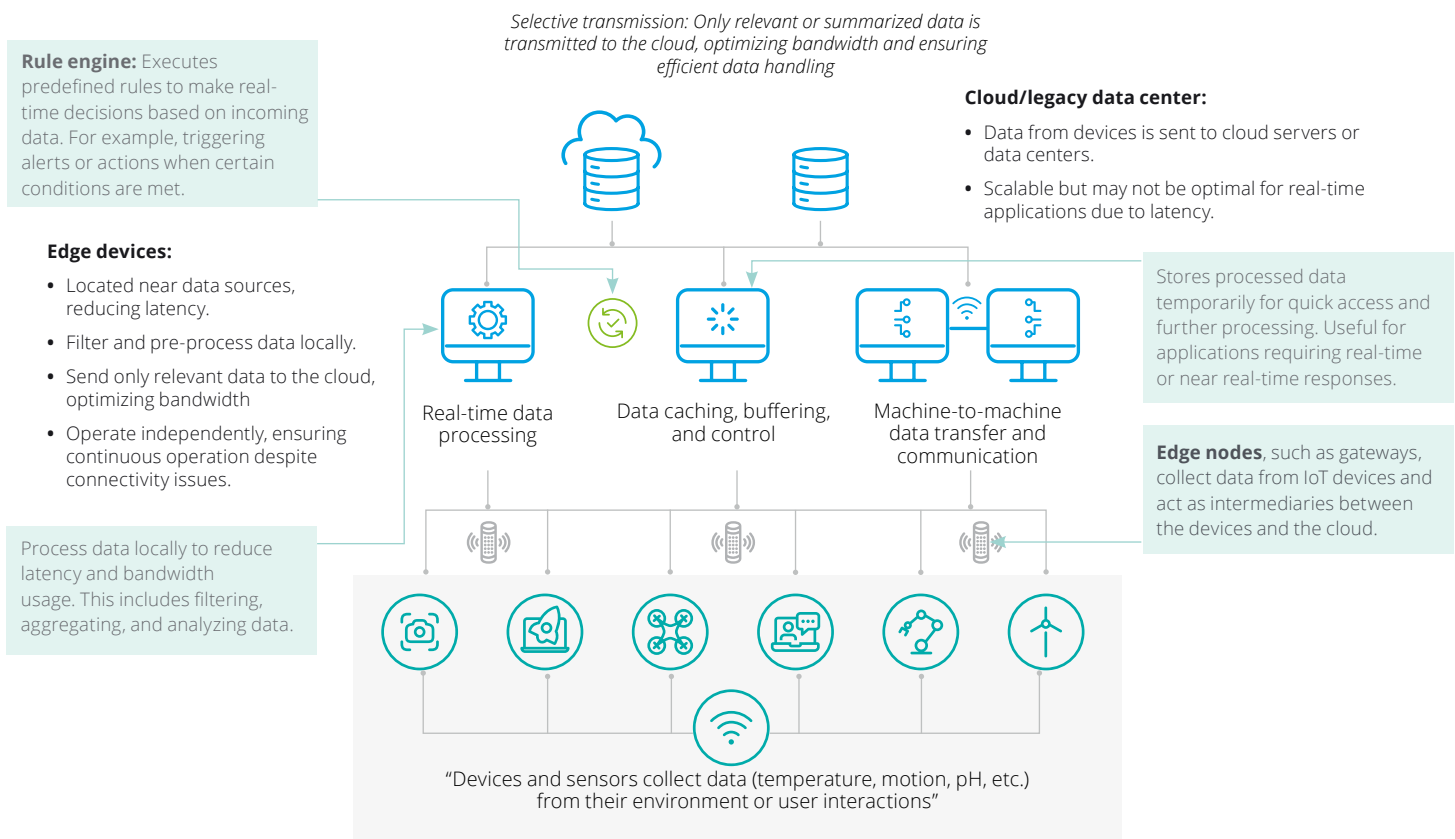
Underlying the success of each archetype above is the use of “edge computing,” which brings together the best of the physical and digital worlds.

Edge computing leverages localized data processing to reduce latency, improve real-time decision-making, and minimize the need to transmit large volumes of data to centralized cloud servers. Using this technology, decentralized manufacturers are able to quickly adapt to local demands, drive innovation, and ensure quality control.

Proximity to data at its source can deliver additional business benefits, including faster market insights, improved response times, and better bandwidth availability.

Advantages of using edge computing include:

- **Real-time data processing:** Leveraging edge computing for real-time data processing and decision-making at local sites enhances responsiveness and efficiency.
- **Internet of Things (IoT) devices:** Deploying IoT devices to monitor and control manufacturing processes in real time enables predictive maintenance and reduces downtime.
- **Data analytics:** Utilizing data analytics to gain insights into production performance, identify bottlenecks, and make data-driven decisions with visualization capabilities and real-time monitoring systems.



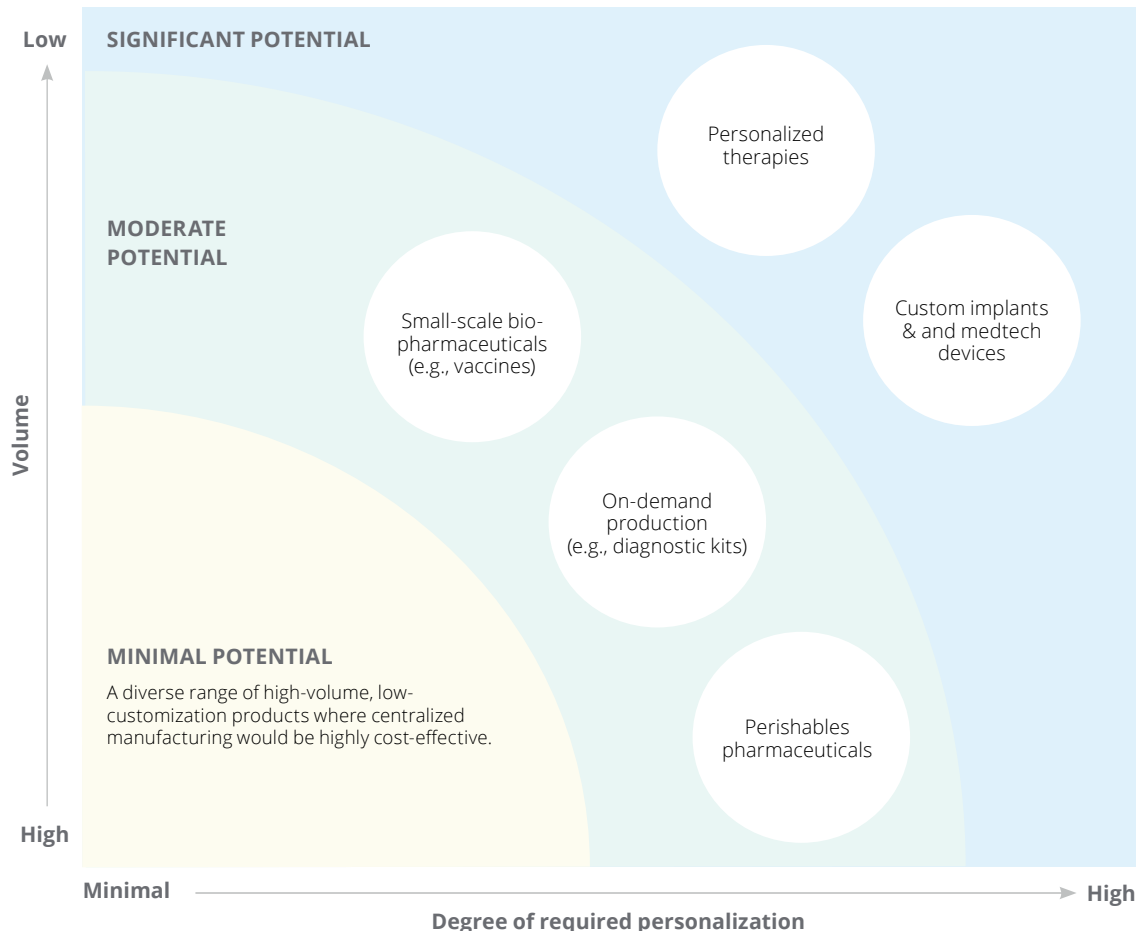
# Decentralized manufacturing: Is the model right for your company?

When it comes to production, organization leaders should determine if decentralized manufacturing is a right fit for their company. The model's potential can be evaluated first by examining the company's manufacturing output through the lens of **volume versus the degree of required personalization**. Using this axis:

**Significant potential** is realized when production volume is relatively lower and personalization is high. Products in this category include personalized therapies, customized implants, and customized medtech devices.

**Moderate potential** is found when both production volume and personalization are at mid-levels. Products here include small-scale biopharmaceuticals (e.g., vaccines) and perishable pharmaceuticals.

**Minimal potential** is found when production volume is high and personalization is minimal. These include a wide range of products where centralized manufacturing remains most cost-effective.





But volume and degree of product personalization are not the only influences on decentralized manufacturing. To truly weave the vision into reality, several guiding principles should also be considered and evaluated to ensure the strategy meets an organization's priority. These include:

1. **Customization and flexibility:** Creating production lines that can swiftly pivot to meet the unique needs of local markets, crafting personalized treatments and devices with precision.
2. **Localized production:** A network of nimble production hubs that reduce the reliance on sprawling supply chains, instead delivering goods directly to the communities they serve.
3. **Distributed control and decision-making:** Empowered local managers or sophisticated automated systems making real-time decisions, ensuring each facility adapts swiftly to changing demands.
4. **Supply chain resilience:** Robust web of manufacturing sites, each capable of weathering disruptions and ensuring continuous supply even amid global uncertainties.
5. **Scalability and modularity:** Modular production units that can be easily expanded or reconfigured, scaling up operations as demand grows.
6. **Sustainability:** Eco-friendly practices taking root, from minimized waste to energy-efficient processes, fostering a greener production model.



# The case for decentralized manufacturing in life sciences

While many factors can influence the strategic decision to move toward decentralized manufacturing, four key pain points can drive the case for change.

1. The demand for **personalized treatments and customized medical devices** is a growing area of opportunity for small-scale, decentralized, patient-tailored production models.
2. **Slow market responsiveness** due to long lead times and high transportation costs makes it difficult to adapt to changing customer demands. Bringing manufacturing closer to the patient reduces these delays and costs.
3. Increasingly **strict regulatory requirements** that vary by region can pose a challenge to traditional manufacturing models. A more adaptable and localized approach can ensure compliance and streamline approval processes.
4. **Inefficient production volumes** and high per-unit costs dissuade small batch production, but a decentralized model can generate value from smaller batches.

By addressing these multidimensional challenges, life sciences organizations can develop a comprehensive strategy for setting up decentralized operations, ensuring the organization is well-prepared to handle the complexities of this new operational model.



# Challenges of transitioning to decentralized manufacturing

As with all aspects of the life sciences field, transitioning to a new manufacturing model brings its own challenges that should be carefully addressed through detailed roadmaps, execution planning, and leadership support.

The following are some key challenges and potential solutions that organizations should thoroughly evaluate as they consider moving toward a decentralized manufacturing model.

Operations division between decentralized sites and central organization:

- **Challenges:** Ambiguity in defining clear roles, and persistent gaps in establishing effective communication channels between central and local teams can lead to misalignment, inefficiencies, and lack of accountability across the organization.
- **Solutions:** Setting up decentralized operations involves pinpointing core functions, clearly defining roles, and establishing robust communication channels to ensure alignment and accountability.

## Distributed governance and decision-making:

- **Challenges:** Struggling to develop a balanced governance framework, facing uncertainty in decision-making protocols, and encountering difficulties in empowering local leadership with adequate resources and authority can result in inconsistent governance, delayed decisions, and reduced effectiveness at the local level.
- **Solutions:** Governance and decision-making require a balanced governance framework, clear decision-making protocols, and empowering local leadership with the necessary resources and authority. Leveraging advanced technology and edge devices can support governance and ensure compliance.

## Sustained operations:

- **Challenges:** Difficulty in attracting and retaining local talent, inconsistency in process standardization, and lack of well-defined KPIs to effectively monitor and measure operational performance can hinder long-term operational stability, continuous improvement, and innovation.
- **Solutions:** Ensuring sustained operations involves attracting and retaining local talent, standardizing processes, developing KPIs to monitor processes, fostering continuous improvement, and ensuring robust technology and infrastructure focused on innovation that must be enabled early in the process.





# Deloitte's specialization and solutions

Deloitte offers a broad suite of services and solutions to help clients achieve decentralized manufacturing enabled by edge computing.

Our experience spans across various critical aspects, including process and operations, people and talent, regulatory compliance, technology, and sustainability. We bring our best people to provide strategic insights, industry best practices, and operation-based perspectives to help organizations drive toward their priorities for growth.

Pillars	Capabilities
Process & Operations	<ul style="list-style-type: none"> <li>• Implement flexible and efficient processes that adapt to local demands and variations.</li> <li>• Enhance logistics to ensure timely delivery of raw materials and distribution of finished products.</li> <li>• Use advanced systems to track and manage stock levels.</li> </ul>
People & Talent	<ul style="list-style-type: none"> <li>• Train local talent to operate and manage decentralized units.</li> <li>• Build strong local supplier partnerships.</li> <li>• Facilitate seamless communication and coordination between units.</li> </ul>
Regulatory Compliance	<ul style="list-style-type: none"> <li>• Understand specific manufacturing regulations in each location.</li> <li>• Develop and implement a consistent quality management system.</li> <li>• Protect intellectual property rights by understanding local IP laws.</li> </ul>
Technology	<ul style="list-style-type: none"> <li>• Leverage edge computing for real-time data processing.</li> <li>• Deploy IoT devices to monitor and control manufacturing processes.</li> <li>• Utilize data analytics to gain insights into production performance.</li> <li>• Evaluate organizational risk posture and develop tailored cyber strategies.</li> </ul>
Sustainability	<ul style="list-style-type: none"> <li>• Implement sustainable manufacturing practices.</li> <li>• Optimize resource usage to minimize waste.</li> <li>• Encourage the use of locally sourced materials to reduce carbon footprint.</li> </ul>

# Decentralized manufacturing: A key competitive advantage for life sciences

Evaluating and prioritizing decentralized manufacturing will become a key competitive advantage for life sciences companies as the industry navigates a constantly evolving landscape of patient circumstances, geopolitical shifts, digital technologies, and regulatory requirements.

While enabling decentralized manufacturing may seem daunting, Deloitte's Life Sciences consultants have in-depth manufacturing strategy experience and are ready to collaborate with your organization to identify opportunities to leverage decentralized manufacturing.

## Continue the conversation

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