

Scaling medical device innovation

How material choices affect quality, compliance and supply continuity



Introduction

Medical device manufacturers are under pressure to do more at once. They must accelerate innovation, maintain product quality, manage regulatory expectations and build supply chains that can support reliable commercialization. At the same time, manufacturing leaders are navigating inflation, tariffs, consolidation and other pressures that are reshaping how devices are developed and produced.

Several healthcare trends are adding to that complexity. Manufacturers are responding to rising safety expectations, growth in chronic conditions such as diabetes, demand for more convenient formats like prefilled syringes and wearable devices and increasing interest in lower-carbon and more recyclable solutions. As device and packaging formats evolve, a material strategy can influence how companies effectively respond to changing market needs.

In this environment, material selection has become a more strategic decision. It is no longer enough to choose a material based only on a narrow set of performance criteria during early development. The right material strategy can influence process stability, validation timelines, documentation readiness and long-term supply continuity. Decisions made early can help reduce downstream risk. Decisions made too late can introduce avoidable complexity.

Across markets, manufacturers also face stronger expectations around traceability, documentation and lifecycle oversight. For medical device teams, that means product development choices must stand up not only to engineering demands, but also to manufacturing, regulatory and quality requirements.

Material selection sits at the center of that challenge. A material can affect how a part performs under sterilization, how consistently it runs in production, how much scrap a process generates and how easily a device moves from pilot to commercial scale. It can also influence how well a manufacturer is prepared to manage change control, maintain supply continuity and support product claims with the right documentation. These are not isolated technical considerations. Together, they shape business outcomes.

For medical device companies, the cost of getting material strategy wrong can be significant. Late-stage changes may require additional testing, process adjustments or new documentation. They can delay launch timelines, strain internal resources and create unnecessary uncertainty during commercialization. By contrast, companies that evaluate material decisions through a broader, cross-functional lens are often in a stronger position to scale with confidence.

This paper explores why material selection should be treated as a strategic lever from the start of device development. It outlines the factors product development, manufacturing, quality and sourcing teams should evaluate early, and it highlights how a more integrated approach can help reduce risk and support more resilient growth. For organizations working to bring medical innovations to market faster and more reliably, material choices can play an important role in improving outcomes across the product life cycle.



Executive summary

Medical device innovation depends on more than design ingenuity. It depends on whether a product can be manufactured consistently, validated efficiently and supplied reliably at commercial scale. In today's environment, material selection has a direct impact on each of those outcomes.

Too often, materials are evaluated mainly for immediate performance needs, then revisited only when problems emerge later in development or scale-up. That approach can create unnecessary risks. A late-stage material change may affect processing, tooling, sterilization compatibility, documentation and validation plans. It can also disrupt timelines and increase pressure on engineering, quality and sourcing teams that are already working under tighter market and regulatory demands.

A more strategic approach begins earlier. It considers how a material will perform not only in the final application, but across the full commercialization process. That includes mechanical requirements, biocompatibility considerations, sterilization performance, processability, supply continuity and the level of technical and regulatory support available from a supplier. When these factors are assessed together, teams are better equipped to make decisions that support both device performance and operational readiness.

This broader view matters because the medical device landscape is becoming more complex. Manufacturers are responding to evolving regulatory expectations, stronger quality system requirements and ongoing pressure to improve manufacturing resilience. They are also working to reduce inefficiencies, manage supply chain disruption and accelerate time to market without compromising quality. Material decisions can either support those goals or work against them.

For example, a material that meets core performance targets in development may still create downstream obstacles if it introduces variability in processing, limits scale-up flexibility or lacks the documentation support needed for a regulated

application. In contrast, a material strategy that includes manufacturing, quality and sourcing perspectives at the outset can help reduce rework, improve transfer to production and support a more stable path to commercialization.

This paper makes the case for treating material selection as a strategic business and technical decision, not just a specification exercise. It also highlights the value of working with experienced material suppliers that can support performance needs, provide relevant material documentation and help manufacturers evaluate supply continuity. Manufacturers remain responsible for determining whether their finished products meet applicable regulatory and compliance requirements.

Key takeaways

- **Material choice influences more than end-use performance.** It can shape manufacturability, validation, quality outcomes and supply continuity.
- **Late material changes can increase cost and delay commercialization.** Rework often affects testing, documentation, processing and internal resources.
- **Cross-functional evaluation improves decision-making.** Engineering, manufacturing, quality, regulatory and sourcing teams all bring essential insight to material selection.
- **Regulatory and quality expectations are increasing.** A stronger material strategy can help teams prepare for more rigorous documentation and lifecycle oversight.
- **Supply continuity should be treated as part of product performance.** Commercial success depends on stable access to materials and supplier support over time.

Why material selection has become a strategic decision

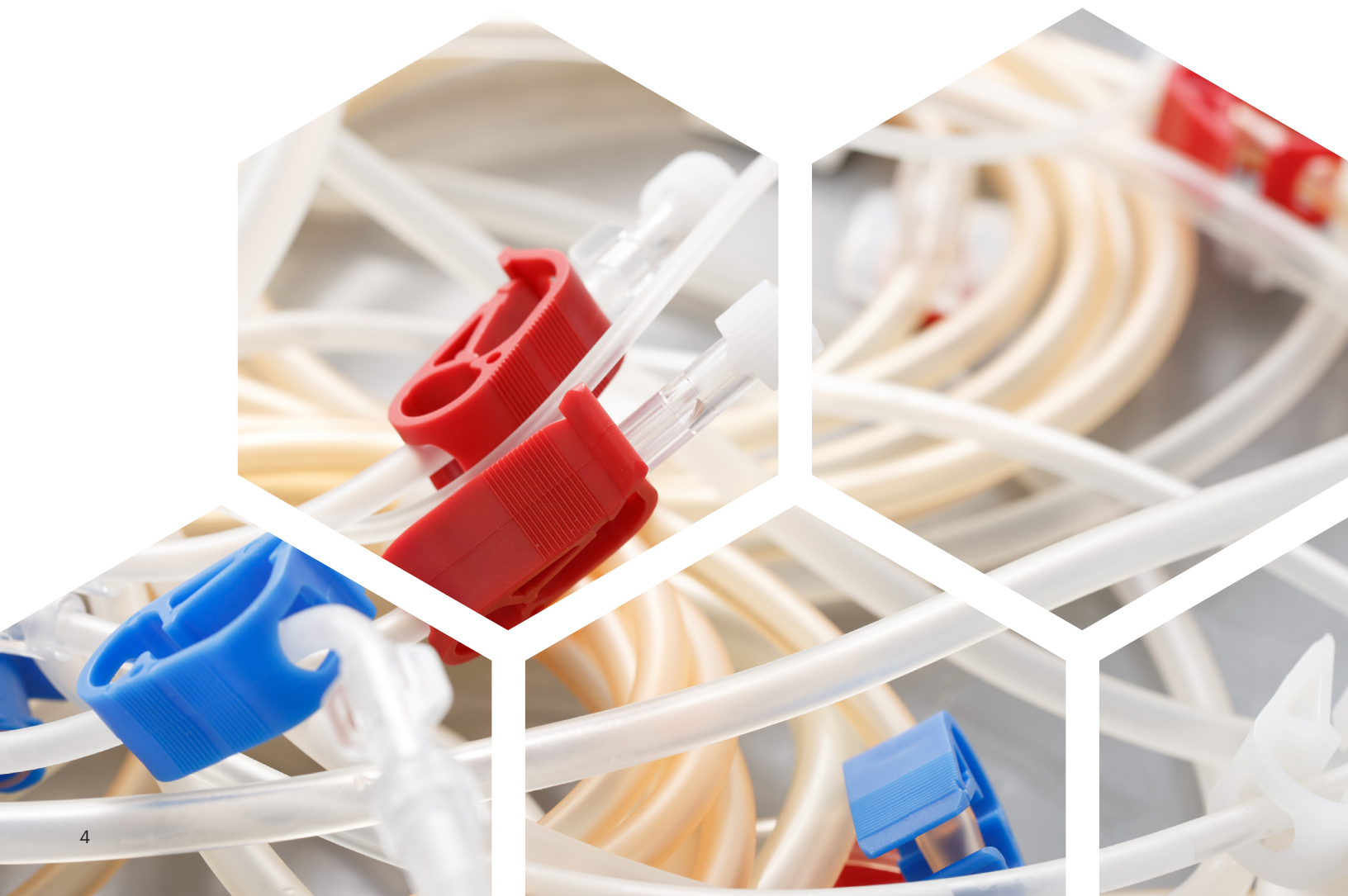
Medical device companies are being asked to innovate faster while navigating increasingly complex requirements. The challenge is not simply creating a product that works. It is creating a product that can be produced consistently, documented properly and scaled without disruption.

That is why material selection should not be isolated within product development. Material choice influences molding behavior, dimensional stability, sterilization performance and cosmetic consistency, but it also affects validation planning, quality oversight and sourcing flexibility. When viewed through that broader lens, materials become an important business decision as much as a technical one.

The stakes are even higher for medical applications because what appears to be a manageable tradeoff early in

development can become a costly obstacle later. A material may satisfy mechanical requirements but prove difficult to process at scale. It may meet core performance targets but require additional documentation or change control support that was not considered early enough. These challenges can extend timelines, complicate internal approvals and divert resources from innovation to remediation.

Medical device teams that take a more integrated approach are often better positioned to avoid those outcomes. By bringing engineering, manufacturing, quality, regulatory and sourcing perspectives into the decision earlier, companies can identify risks sooner and build a stronger path to commercialization.



Seven factors to evaluate before you lock in a material

1	End-use performance requirement	Every device begins with functional requirements. Mechanical strength, impact resistance, stiffness, clarity, flexibility, chemical resistance and long-term durability all matter, depending on the use case. But teams should define these needs in the context of the full application, not in isolation. It is not enough to know how a material performs in theory. The question is whether it will perform consistently in the real-world environment where the device will be made, sterilized, shipped and used.
2	Biocompatibility and regulatory considerations	Material evaluation should include the regulatory path from the outset. That means understanding what supporting data may be needed, what testing requirements apply and how documentation will be managed through development and commercialization. As regulatory scrutiny increases, teams benefit from thinking early about how material decisions intersect with submission readiness, traceability and change control.
3	Sterilization compatibility	A material that performs well before sterilization may behave differently afterward. Heat, radiation and chemical sterilization methods can affect mechanical properties, appearance or dimensional stability. These risks are especially important when device teams are optimizing parts for tighter tolerances or more demanding end uses. Early evaluation helps reduce the chance of discovering sterilization-related issues after critical design decisions have already been made.
4	Processability and manufacturing fit	A strong material strategy considers how the material will behave in production, not just in a lab setting. Flow characteristics, cycle time, dimensional control and ease of processing can affect yield, throughput and consistency. Materials that are difficult to process or sensitive to variation can create avoidable inefficiencies during scale-up.
5	Quality consistency	Consistency matters in regulated manufacturing. Variation in raw material properties can have downstream effects on part quality, process parameters and inspections. Device manufacturers should think not only about nominal performance but also about the consistency required to support controlled production over time. In a more disciplined quality environment, predictable performance is an operational advantage.
6	Supply continuity and continuity planning	A material is only as effective as its ability to support uninterrupted production. That means evaluating more than a data sheet. Teams should understand sourcing options, supply assurance practices, regional availability and supplier support during disruption or change. Ongoing supply chain pressures have made resilience a more visible priority for medtech manufacturers.
7	Supplier support and collaboration value	The best material decision is often supported by the right supplier. Technical insight, application development support, documentation availability and responsiveness during commercialization can help reduce friction across the product life cycle. For companies navigating tight timelines and complex requirements, supplier capability and collaboration can meaningfully influence success.

How material choices affect manufacturing outcomes

Manufacturing performance is where many material decisions reveal their full impact. A material that appears to meet application requirements in development may still create challenges in production if it introduces instability, variability or inefficiency. For manufacturers facing cost pressure and operational complexity, those issues can quickly become meaningful to the business.

Processing consistency matters because it affects more than productivity. Stable materials can help improve repeatability, reduce scrap and support better dimensional control. That can lead to more efficient validation, smoother design transfer and fewer surprises during commercialization. Conversely, materials that are more difficult to process may create additional burden for operations and quality teams that must manage deviations, investigate performance shifts or adjust process windows.

Scale-up also introduces a different set of demands than early development. Tooling changes, increased volumes and tighter production targets can expose weaknesses that were not obvious during pilot runs. When materials are selected with manufacturing realities in mind from the beginning, companies are better positioned to bridge the gap between prototype success and commercial readiness.

This is especially important as miniaturization and more complex product designs continue to shape the market. Smaller, more intricate components often leave less room for variability in both materials and process performance. That makes early alignment between engineering and manufacturing even more valuable.





Building compliance readiness into material decisions

Compliance readiness does not start at submission. It starts much earlier, with the decisions that shape how a product is designed, validated and documented. As the FDA QMSR takes effect and broader global expectations around traceability and lifecycle oversight continue to rise, medical device teams need decisions that can stand up to more structured quality and regulatory review.

Material selection plays a role in that readiness because it affects documentation, testing plans and change management requirements. If teams wait too long to engage quality and regulatory stakeholders, they may discover gaps after major decisions have already been made. Those gaps might involve missing data, a need for additional testing or uncertainty around how future changes will be managed. Each can add friction to an already compressed timeline.

A better approach is to build compliance thinking into early material evaluation. That includes understanding what documentation will be needed, whether a supplier can support U.S. or European pharmacopeia requirements where applicable, whether Drug Master File documentation is available and how retained samples, traceability and change

management will be handled over time. Companies also benefit from suppliers that use a structured medical application review process to help align proposed uses with applicable legal, regulatory and internal policy requirements.

For example, the *Purell* service concept from LyondellBasell (LYB) is built around dedicated manufacturing and quality management procedures, including established change-management and notification-of-change processes. The *Purell* service concept also supports U.S. and European pharmacopeia requirements where applicable, Drug Master File listing, long-term sample and documentation retention, and plant audits. These are practical examples of the operational and regulatory capabilities medical device manufacturers should evaluate when selecting a material supplier.

By treating compliance as part of material strategy, companies can reduce downstream rework and create a stronger foundation for commercialization. In a market where quality systems must scale with the business, that early discipline can become a meaningful competitive advantage.

Supply continuity is part of product performance

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What to look for in a material supplier

Medical device manufacturers do not just select a material. They also select the expertise and support structure that comes with it. That is why supplier selection matters.

An effective material supplier should be able to contribute more than product availability. Technical guidance, application experience, processing insight and documentation support can help device teams make better decisions sooner. This matters because early choices often determine how much rework, delay or uncertainty a company will face later.

Medical device manufacturers should look for suppliers that combine technical expertise with operational discipline. That includes support for plant audits, technical and commercial resources, a global asset base, structured change management and production controls designed to support consistency from batch to batch. In regulated applications, supplier capability can meaningfully affect commercialization readiness.

The strongest relationships are built on shared problem-solving. Medical device companies benefit when suppliers understand the pressures of regulated manufacturing, appreciate the realities of scale-up and can support cross-functional collaboration across development, quality and sourcing.

LYB illustrates what strong supplier support looks like in practice through the *Purell* portfolio and service concept. That support includes dedicated sales and technical service teams, customer-specific supply solutions, global production assets, dedicated cleaning procedures for transportation and storage equipment and access to decades of application innovation. These kinds of capabilities can create value beyond the resin itself by helping customers scale with greater confidence.

Where material strategy shows up in practice

The effects of material strategy become clearer when viewed through real healthcare applications. In prefilled syringes and assemblies, material decisions can influence dimensional stability, processability and sterilization performance. In rigid device components and labware, materials may need to balance stiffness, clarity, durability and consistency across production runs.

In healthcare packaging, the tradeoffs can be just as significant. Immediate pharmaceutical packaging, bottles, vials, blow-fill-seal containers, caps and closures all place

different demands on resins and conversion processes. Material choices may affect bottle integrity, seal performance, ease of molding, contamination control and compliance documentation.

These examples reinforce the same core point. Material selection is not a single-variable decision. It is a cross-functional choice that should reflect application requirements, manufacturing realities, regulatory expectations and long-term continuity needs.



Conclusion

Medical device companies are operating in an environment that demands speed, discipline and resilience. Innovation matters, but so does the ability to manufacture consistently, meet regulatory expectations and maintain reliable supply as products scale. In that context, material selection deserves broader attention.

Treating materials as a strategic decision rather than a late-stage technical specification can help companies reduce avoidable risk across the product life cycle. It encourages

earlier collaboration, better manufacturing alignment and a more realistic view of what commercialization success requires. It also helps organizations prepare for a market where quality systems are tightening and supply continuity is increasingly important.

Medical device teams should consider a material strategy that supports performance, compliance and continuity throughout the journey from prototype to production.

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