

Strategic supply chain leadership: Driving biopharma growth

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In today's evolving and, at times, volatile biomanufacturing market, drug sponsors must prioritize strategic sourcing and quality-focused distribution to safeguard their processes and raw material supply. With certain chemicals often taking up to 3x longer to source than pre-pandemic, even the smallest supply chain vulnerabilities can place operations at risk. Each manufacturing process has unique requirements and raw material needs that add complexity and potentially limit sourcing options. These challenges are often compounded by regional limitations and geopolitical factors that restrict access to critical raw materials. Strategic sourcing now extends beyond procurement, becoming essential for operational continuity, consistent site performance, regulatory compliance, and market delivery.

How to determine your raw material selection criteria

Raw materials play an important, foundational role in bioprocessing and may influence overall product performance. When evaluating a raw material manufacturer's or supplier's quality control and performance capabilities, the following considerations may be helpful:

- **Chemical grade:** Is the chemical grade appropriate for the intended stage of regulated drug development and manufacturing? Materials aligned with recognized pharmacopeial standards (i.e., ACS, USP, EP, JP, etc.) can help support consistency with published specifications. Regulatory bodies typically review documentation demonstrating adherence to applicable standards during clinical and commercial review.
- **Supply chain reliability:** Is the manufacturer/supplier able to support consistent availability of the raw material? Regulatory and industry publications increasingly emphasize the consideration of supply risk mitigation strategies within quality systems, informed by program needs and risk assessments.
- **Consistency:** Does the manufacturer/supplier demonstrate an approach to managing lot-to-lot variability? Variations in raw materials may affect process performance, and consistency measures can help support process control efforts.

- **Product history:** Does the material have an established history of use or prior application to implementation in similar contexts? Materials with prior usage experience may help inform validation efforts and development planning.
- **Quality documentation:** Does the manufacturer/supplier offer quality documentation appropriate to the biologics' development stage? As programs progress toward clinical trials and commercialization, more extensive documentation, manufacturing information, and traceability are common.
- **Scalability:** Can the manufacturer/supplier support changes in volume as development progresses and potential demand evolves? Maintaining material consistency across development and manufacturing stages may help reduce the need for additional process changes or revalidation.

The relative importance of each of these considerations may evolve as your biologic progresses from research through commercialization. In early-stage research, material selection is often guided by technical specifications, cost considerations, and source consistency, typically at laboratory scale and with an emphasis on minimizing variability. As programs advance into

clinical development and commercial manufacturing, evaluation criteria commonly expand to place greater emphasis on quality-related factors as part of broader risk management efforts.

At later stages, scaling processes may involve selecting raw materials that can support consistent performance while seeking to manage operational and capital expenditures where feasible. Supply interruptions during clinical trials or commercial manufacturing have the potential to impact production timelines and market readiness, depending on the specific circumstances.

RUO versus GMP: the key differences

Developing an effective sourcing strategy for your product also requires a clear understanding between the two grades of raw material in biologic manufacturing: Research Use Only (RUO) and Good Manufacturing Practice (GMP)-compliant. RUO and GMP serve distinct purposes in life sciences, with RUO products intended for research and GMP products adhering to strict regulatory standards for human use. Figure 1 provides a comparison between these classifications.



Figure 1. RUO and cGMP materials differ not only in intended use, but in depth of quality systems, documentation, and supply chain controls required to support regulated manufacturing

Documentation type	Research Use Only (RUO)	Current Good Manufacturing Practices (CGMP)
Standard operating procedures (SOPs)	General guidelines; less detailed	Detailed written instructions for all processes; regularly updated
Batch records	Basic records of production processes	Comprehensive records for each batch; includes raw materials, processes, and QC results
Quality control records	Basic documentation of QC tests	Detailed documentation of all QC tests; equipment calibration and validation records
Validation protocols and reports	Minimal or no validation documentation	Detailed plans and results for validating processes, equipment, and systems
Training records	General records of employee training	Extensive records of staff training programs and individual qualifications
Deviation and incident reports	Basic documentation of incidents; less detailed investigations	Detailed records of deviations; includes investigations and CAPA
Change control records	Basic documentation of major changes	Comprehensive documentation of changes; includes justifications and impact assessments
Audit reports	Minimal or no audit documentation	Detailed internal and external audit findings and follow-up actions
Supplier qualification records	Basic supplier information; less rigorous	Extensive documentation of supplier assessments and ongoing monitoring
Environmental monitoring records	General environmental monitoring	Detailed data on environmental conditions in manufacturing areas

Figure 2. Documentation practices for RUO versus cGMP materials.

RUO suppliers often maintain quality systems focused on research reproducibility rather than regulatory compliance. While these suppliers provide basic stability data and documentation, their quality standards differ significantly. In contrast, cGMP-compliant suppliers typically deliver comprehensive stability data, documentation, validation, and change control protocols alongside supply chain transparency.

Documentation practices — as shown in Figure 2 — are one of the most marked differences between RUO and cGMP materials, and they can impact your ability to satisfy regulatory requirements, demonstrate process control, and mitigate risk. RUO documentation typically entails general guidelines with limited detail, which is sufficient for research reproducibility but lacks the procedural specificity needed for regulated manufacturing. Understanding these documentation differences is important when evaluating suppliers and planning your transition from research to clinical development.

Another consideration is the cost differential between RUO and cGMP-manufactured materials (Figure 3). Industry sources have described that cGMP chemicals may be priced higher than RUO materials, reflecting a range of factors related to regulated manufacturing environments.²⁻⁶ While the specific drivers vary by material and application, industry publications and professionals indicate that the chemical itself typically represents only one component of the overall cost structure.

Additional cost considerations commonly cited include quality-related activities such as documentation, compliance processes, regulatory readiness, and quality testing systems, as well as investments in specialized facilities and personnel training. As development programs progress, organizations may place increased emphasis on the quality systems and infrastructure associated with materials intended for clinical or regulated use, compared with those used in early-stage research.

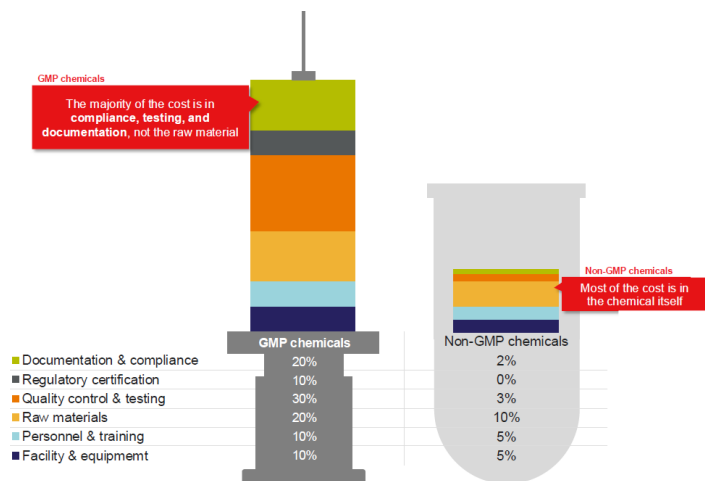


Figure 3. Example comparison of costs for cGMP chemicals and RUO chemicals.

By beginning with the end in mind and planning ahead, you can help streamline your drug's transition from RUO to cGMP materials and minimize quality risks while maintaining development momentum. Unfortunately, this switch comes with significant hidden costs (Figure 4). The difference in purchasing price between RUO and cGMP raw materials may be transparent, but many implications are lurking beneath the waterline, primarily: risks, operational inefficiencies, and financial burdens.

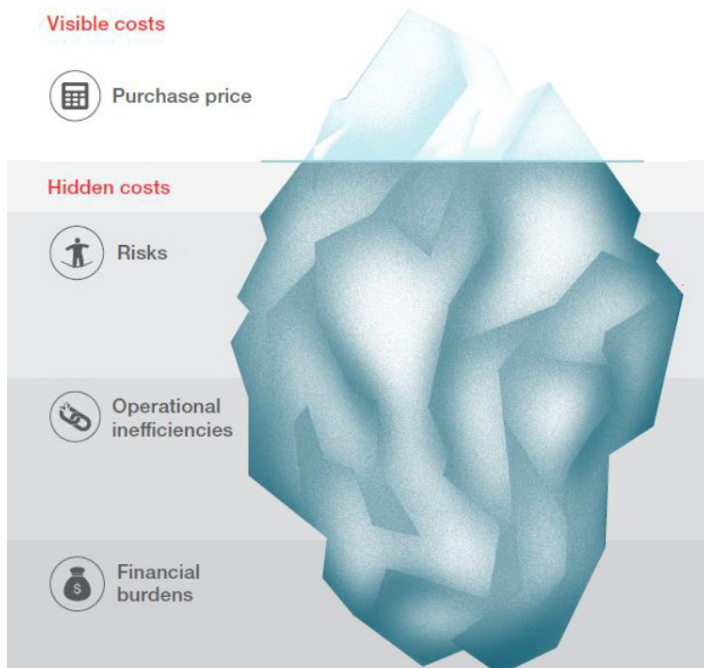


Figure 4. The iceberg of visible and hidden raw material costs.

Costly risks include unplanned supply disruptions or change notifications that impact product consistency. Without rigorous change control, changes may become apparent only after performance variations are observed, often resulting in batch failures and production delays. In terms of operational inefficiencies, sponsors must navigate the different quality systems and potential documentation inconsistencies among RUO versus cGMP suppliers, as well as shifting lead times. Financial burdens include method validation, comparability testing, stability studies, and the cost of holding raw material inventory and safety stock. To account for the costs, scientific, manufacturing, supply chain, and business teams may want to closely collaborate to adapt their strategy and maintain competitive advantages.

Evaluating suppliers

A strong bioprocessing supplier balances price, quality, and service to provide optimal value. Choosing the lowest material cost may help meet budget constraints, but it could lead to poor quality and significant expenses downstream. As the sponsor, it is important to maintain control over critical quality attributes (CQAs) to facilitate product safety, efficacy, and compliance. This includes assessing a supplier's ability to provide consistency and quality control for animal-origin and animal-origin-free raw materials.

Prioritize working with suppliers that drive continuous improvement, embrace feedback, and design quality systems that mature alongside products. Furthermore, look for partners that have conducted thorough capacity and contingency planning as well as risk mitigation to protect supply chains and continuity. In your evaluation, strive to understand a supplier's quality system and the integration of each function.

To vet the depth and effectiveness of their procedures, consider the following questions:

- How do you handle contamination control?
- What facilities, technologies, and equipment do you use throughout your processes?
- What are the components of your quality management system (QMS)?
- Do you perform appropriate in-process and release testing?
- Do you provide all necessary regulatory documentation, manufacturing records, analytical methods, and change control procedures and histories?
- Do you maintain appropriate regulatory certifications and allow customer and regulatory audits?
- What are your storage and manufacturing requirements?
- How do you approach personnel training?
- How do you manage and communicate change control and corrective and preventative actions?
- What is your approach to getting it right the first time?

Beyond these questions, examine whether they have implemented comprehensive facility segregation, validated cleaning procedures, and risk-based monitoring. Determine whether they incorporate risk management and continuous improvement into change management, maintaining transparent change control with appropriate notification periods and impact assessments and validation prior to implementation.

Strong suppliers demonstrate high levels of communication and commitment to quality by design (QbD), robust validation, and comprehensive cGMP training programs. Their investment into their teams, facilities, and quality systems can directly impact your supply chain reliability and should therefore be factored into your risk assessment and evaluation. Suppliers with dedicated cGMP facilities, trained personnel, and appropriate equipment redundancies help deliver more consistent supply performance.

Creating your raw material sourcing strategy

One powerful approach to protect your supply chain is in-region, for-region sourcing, which enables reduced costs and lead times by sourcing raw materials that are manufactured within your region. Closer proximity between manufacturers, suppliers, and production sites can shorten delivery cycles compared to long-distance sourcing, helping sponsors meet competitive milestones without excessive safety stock. This approach can lower transportation costs and reduce handling events, which can limit the risk of damage, temperature excursions, and quality incidents during transit.

Most importantly, regional sourcing can improve supply chain resilience. With supply chains vulnerable to port congestion and geopolitical tension, sourcing within your manufacturing region allows you to bypass global bottlenecks and establish more predictable supply patterns. Ultimately, strategic risk diversification balances global capabilities with localized security. For organizations with global manufacturing footprints, regional sourcing hubs in North America and Europe create natural redundancies, allowing materials to flow between regions as necessary while maintaining regional efficiency during normal operations.

Beyond the regional component, there is also the choice between single sourcing, dual sourcing, and multi-sourcing. While single sourcing — sourcing a chemical from one supplier — comes with weak supply reliability which can result in a high risk of production delay, multi-sourcing — sourcing a chemical from three or more suppliers — can provide high supply reliability and a low risk of production delay. However, multi-sourcing entails significant operational complexity, which can sometimes lead to inefficiencies.

To provide balance between these two approaches, sourcing a chemical from two suppliers, or dual sourcing, has rapidly become an approach among biologics manufacturers. This strategy involves establishing qualification and supply relationships with two suppliers for each critical raw material, creating immediate redundancy without excessive complexity. The key is planning early and maintaining procurement splits, i.e., 60/40, 70/30, or 80/20, to keep both vendors engaged and to prevent overdependence. When disruptions occur, you can

rapidly shift your volumes between suppliers without qualifying a new source. Although the initial investment in supplier qualification may be higher, these costs are less compared to supply chain disruptions for critical raw materials.

The impact of supply chain collaborations

Collaborations can enable access to critical cGMP-manufactured raw materials, supported by comprehensive solutions designed to help enhance operational continuity and mitigate the effects of supply chain volatility. Consider the following benefits of Thermo Fisher Scientific support:

- **Reduce costs:** The Alternate Sourcing Savings Program allows [sourcing and procurement](#) specialists to identify more affordably priced cGMP chemical equivalents without compromising quality, reducing expenses. As a result, customers may have stronger purchasing power and increased supply availability. They also offer up to 90 days of [storage](#) at no additional cost when cGMP chemicals, process liquids and buffers are purchased through them, reducing OPEX and CAPEX in warehousing.
- **Access a diverse vendor catalogue:** Thermo Fisher offers an extensive [multi-compendial chemical network](#) of qualified manufacturers, suppliers, and brands, creating built-in redundancies for critical raw materials. Customers can implement dual sourcing and regional procurement strategies with access to a breadth of chemicals supported by comprehensive quality documentation to streamline qualification and regulatory submissions.
- **Leverage a robust quality system:** QMS is supported by harmonized procedures and ISO 9001 certification across facilities. A highly trained team addresses issues prior to impact via their proactive risk management protocols. Network laboratories accommodate [quality release](#) and specialized testing needs, and quality agreements and change notification processes streamline supplier onboarding.
- **Increase productivity and mitigate risk:** Redundant procedures empower supply continuity while the chemical selection team identifies materials with stable supply profiles and consistent performance. By leveraging this approach, their team can provide real-time sourcing insights based on their extensive experience in [chemical supply chain management](#).
- **Shorten lead times:** The [chemical stocking program](#) uses a vendor-managed inventory model maintains inventory levels of commonly used materials in scalable volumes and a just-in-time delivery schedule to support with production timelines, reducing inventory holding costs.
- **Enable material traceability:** Customers receive comprehensive material traceability, visibility into quality management, and real-time status updates. Materials arrive with documentation, ready for use.

- **Maintain reliable supply:** Over the last 12 months, Thermo Fisher has achieved $\geq 97\%^*$ on-time shipment of stocked items, offering customers personalized stocking and [inventory management](#) plans.
- **Auditing capabilities:** Flexible auditing options (i.e., desktop, virtual, or onsite) can be used to verify Thermo Fisher systems.

In addition to these benefits, Thermo Fisher offers flexible shipment and delivery options for cGMP chemicals, process liquids, and buffers to support diverse operational needs. These options can be tailored to align with specific constraints and production timelines, allowing customers to optimize supply chain efficiency and maximize overall value by selecting different approaches for various materials or production stages.

An example of cost reduction in action through dual sourcing**

The following example is a hypothetical, intended to demonstrate how dual sourcing strategies may support cost optimization.

Consider a modeled scenario where a biopharma organization with more than 14 molecules in development is evaluating opportunities to reduce costs associated with its 30 most frequently used chemical

stock keeping units (SKUs), representing an estimated \$18 million in annual spend. As part of an Alternate Sourcing Savings Program assessment, analysis assumes the incumbent supplier operates as a repackaging manufacturer rather than a source manufacturer, presenting a potential opportunity for material cost optimization.

To explore this opportunity, a network of source manufacturers can be evaluated to identify specification-equivalent chemical alternatives for commonly used SKUs. In this illustrative analysis (Figure 5, potential material cost reductions of approximately 60% to 85% per SKU are identified, potentially resulting in a modeled overall cost reduction of approximately 50% across the 30 cGMP SKUs evaluated. These projected outcomes assume maintained quality standards and no required changes to existing manufacturing processes.

Conclusion: Finalize your sourcing strategy

To optimize your raw material management strategy, consider prioritizing quality and traceability at every stage. Strategic implementation of regional and dual sourcing can help mitigate risk and build a more resilient and agile supply chain. Finally, choose a collaborator to help reduce raw material spending while maintaining quality standards.

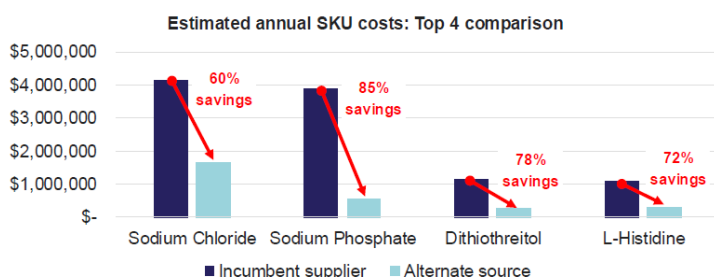


Figure 5. Modeled savings impact via the Alternate Sourcing Savings Program.

* Derived from Thermo Fisher Scientific Production Chemicals and Services business annual performance reports from the past 12-month period.

** This model reflects a potential bioprocessing scenario but is not an actual customer experience.

About the authors

Alyssa Colón is Senior Manager of Quality, Cell and Gene Therapy at Thermo Fisher Scientific. She has over 20 years of experience in the pharmaceutical and life sciences industries and is actively involved in professional organizations like Biophorum. Alyssa holds a B.A. in Cell Biology and Neuroscience from Rutgers University and an MBA in Management from Centenary College. Throughout her career, Alyssa has held quality-centric leadership positions at organizations including Glenmark Pharmaceuticals, Hoffmann-La Roche, Celgene Corporation, and Schering-Plough. Her experience spans diverse product forms including cell and gene therapies, injectables, oral solid dosages, and drug/device combinations. Alyssa supports quality-focused initiatives within the healthcare and life sciences space, with an emphasis on regulatory awareness and industry standards.

Shefali Mitra is a seasoned supply chain leader with experience in supply assurance, production chemicals, and end-to-end supply chain management in highly regulated environments. She serves as Supply Chain Manager for Production Chemicals and Services at Thermo Fisher Scientific, where she enables continuity of supply for critical materials that support life sciences and advanced customer manufacturing operations. With a strong background in supplier collaboration, inventory optimization, and risk mitigation, she has led cross-functional initiatives to strengthen supply resilience during periods of disruption, including shortage response strategies and global supplier alignment. Shefali is known for her pragmatic, data-driven approach, balancing analytical rigor with speed and adaptability, and holds a degree in Mechanical Engineering from the Georgia Institute of Technology.

References

1. Breidenbach, K., Wang, J., Schnellbacher, W., Dolya, A., Agarwal, S., & Capucci, L. (2025, August 12). Acting decisively as global sourcing shifts. BCG Global [bcg.com/publications/2025/acting-decisively-global-sourcing-shifts](https://www.bcg.com/publications/2025/acting-decisively-global-sourcing-shifts)
2. "Key Considerations for cGMP Raw Materials Compliance." Pharma Manufacturing, Endeavor Business Media, www.pharmamanufacturing.com/home/article/33012744/key-considerations-for-cgmp-raw-materials-compliance. Accessed 21 Jan. 2026.
3. "The Cost of GMP Compliance." SupplySide Journal, Informa Markets, www.supplysidesj.com/manufacturing/the-cost-of-gmp-compliance. Accessed 21 Jan. 2026.
4. "The Cost of Goods Estimation: Balancing Efficiency and Budget in Drug Product Manufacturing." DS InPharmatics, www.dsinpharmatics.com/the-cost-of-goods-estimation-balancing-efficiency-and-budget-in-drug-product-manufacturing. Accessed 21 Jan. 2026.
5. "Supplier Qualification Program for Key Raw Materials." Pharmaceutical Engineering, ISPE, www.ispe.org/pharmaceutical-engineering/march-april-2022/supplier-qualification-program-key-raw-materials. Accessed 21 Jan. 2026.
6. "Current Good Manufacturing Practice (cGMP) Regulations." FDA, www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations. Accessed 21 Jan. 2026.

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