*symbiosis
Pharmaceutical Services

The strategic advantage of dual-sourcing for injectable drug products

Mitigating risk and ensuring continuity with a trusted manufacturing partner

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01

Introduction

The new reality of pharmaceutical supply chains

As injectable therapies have the potential to change or even save lives, their uninterrupted availability is of vital importance, placing a great responsibility on the companies that bring them to market. However, pharmaceutical manufacturing has undergone significant transformation in recent years, exposing vulnerabilities that traditional supply chain models are ill-equipped to handle.

For many drug developers, a singular, centralised manufacturing approach is no longer sufficient. The global supply chain has become increasingly complex, with numerous potential points of failure, making it harder to manage and control, and thereby increasing the likelihood of possible issues. Recent events, including geopolitical tensions, regional conflicts, natural disasters and the unprecedented challenges posed by the COVID-19 pandemic, have highlighted the risks.

We have witnessed firsthand how a single point of failure, such as a raw material shortage, manufacturing facility disruption or logistical bottlenecks, can cascade into widespread drug shortages, impacting patient care, causing significant revenue loss, and inflicting irreparable damage to a company's reputation.

These mounting pressures require a shift in how pharmaceutical companies approach their supply chain strategies. Relying solely on a single manufacturing partner, even one with a stellar track record, is no longer a viable or responsible approach for critical injectable drug products. The need for proactive, resilient and agile supply chain models has never been more urgent.

This e-book examines the importance of dual-sourcing for sterile fill-finish manufacturing, providing a robust solution to navigate this evolving landscape and ensure uninterrupted access to essential medicines.



02 The strategic advantage of dual-sourcing

In an era defined by global complexities and rapid change, the pharmaceutical industry is actively re-evaluating its approach to supply chain management. For critical injectable drug products, the concept of dual-sourcing has evolved from a contingency plan into a fundamental component of a robust and resilient business strategy.

At its core, dual-sourcing involves strategically engaging two or more independent manufacturing partners for the commercial production of critical drug products. This isn't just about a contingency plan being in place — it is about proactively building inherent resilience into your supply chain from the outset. Crucially, this strategy focuses on clinical and commercial supply, ensuring long-term market presence and uninterrupted patient access to essential medicines. For this reason, some regulatory agencies encourage dual supply.
A key differentiator of effective dual-sourcing lies in its emphasis on geographical diversity. By partnering with facilities in different regions or even continents, companies can significantly mitigate risks associated with localised disruptions, whether from natural disasters, geopolitical instabilities or regional regulatory changes.



Why now?

Several transformative factors have underscored the urgency behind adopting a dual-sourcing strategy:

* **Lessons learned from recent crises**

  The COVID-19 pandemic served as a stark and undeniable lesson in the fragility of supply chains. We witnessed widespread logistical bottlenecks, sudden border closures that impacted material flow and policies resulting in export restrictions on vital medical supplies. Manufacturing shutdowns in one region cascaded globally, highlighting the precariousness of single-source dependencies. These experiences cemented the understanding that resilience cannot be an afterthought; it must be engineered into the supply chain.

* **Increasing market demands**

  The global demand for injectable drugs continues to surge, driven by the increasing prevalence of chronic conditions, such as cancer, in populations worldwide. Other factors responsible for this growing demand include advancements in biologics, gene therapies and other complex formulations that require specialised sterile fill-finish capabilities. This heightened demand, coupled with the inherent complexities of sterile manufacturing, places immense pressure on existing capacities, making diversified supply a strategic necessity to meet growing patient needs.

Evolving regulatory landscape

Regulatory bodies worldwide, including the U.S. Food and Drug Administration (FDA), the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA), are increasingly scrutinising the robustness and continuity of pharmaceutical supply chains. They recognise the critical importance of uninterrupted drug supply for public health. Consequently, demonstrating a resilient supply strategy, such as dual-sourcing, is rapidly becoming a de facto expectation rather than just a recommendation. Proactive compliance in this area can streamline regulatory approvals and facilitate a smoother market entry.

Competitive advantage

Beyond risk mitigation and compliance, dual-sourcing offers a distinct competitive edge. It enables companies to respond with greater agility to market fluctuations, accelerate product launches by running parallel manufacturing streams and scale production confidently to meet surging demand. In a fiercely competitive market, the ability to consistently supply pharmaceutical products when others falter can directly translate into increased market share and a stronger brand reputation.

Dual-sourcing is no longer just a defensive measure against unforeseen events. It has matured into a fundamental pillar of a robust, compliant and competitive pharmaceutical supply chain strategy, essential for ensuring patient access and securing long-term business success.





03

Considerations and benefits of dual-sourcing

Beyond mitigating potential disruptions, dual-sourcing is an investment that yields significant returns on resilience, compliance, market access and, ultimately, patient well-being.

At its core, dual-sourcing provides an immediate and robust safety net against the many challenges that can derail a single-source supply chain. If one supplier faces an unforeseen issue — be it a critical facility malfunction, a sudden raw material shortage, a labour dispute or even a temporary regulatory hold — the established secondary supplier can rapidly step in to compensate. This eliminates the "all eggs in one basket" scenario that has proven so damaging in recent years. Dual-sourcing effectively mitigates a broad spectrum of disruptive events:

Natural disasters

An earthquake in one region, a major flood impacting a specific industrial zone or extreme weather events can render a single manufacturing site inoperable. With a geographically diverse dual-sourcing strategy, production can seamlessly shift to the unaffected location.

Geopolitical instability

Trade wars, sanctions, political unrest or even shifting import/export policies can suddenly impact logistics or access to raw materials from a specific country. Having suppliers in different geopolitical environments insulates the supply chain from such shocks.

Supplier-specific issues

Beyond external factors, internal challenges at a contract manufacturing organisation (CMO) — such as quality excursions requiring remediation, unexpected equipment breakdowns or the loss of key personnel — can halt production. A secondary partner provides immediate relief and continuity.

This strategy empowers the client by significantly reducing their dependence on any single entity. It eliminates production vulnerability, safeguarding meticulously planned production schedules and, most importantly, ensuring consistent and reliable patient access to vital medicines.

A complex global landscape of regulatory compliance

Operating in the pharmaceutical sector means navigating an ever-evolving and stringent regulatory landscape. Regulatory bodies, such as the FDA, MHRA and EMA, demand not only product quality but also an unshakeable assurance of supply chain robustness [1]. Dual-sourcing directly addresses this by demonstrating a proactive and comprehensive approach to supply chain integrity.

Having diversified manufacturing partners enables companies to align more effectively with stringent, region-specific regulatory requirements.[2] For instance, a partner with extensive experience and existing Qualified Person (QP) release capabilities for European markets (EMA) can streamline distribution across the European Union. In contrast, another partner is fully compliant with FDA regulations, ensuring seamless entry into the North American market. This regional expertise facilitates not only easier market entry and access, but also faster maintenance of product registration.

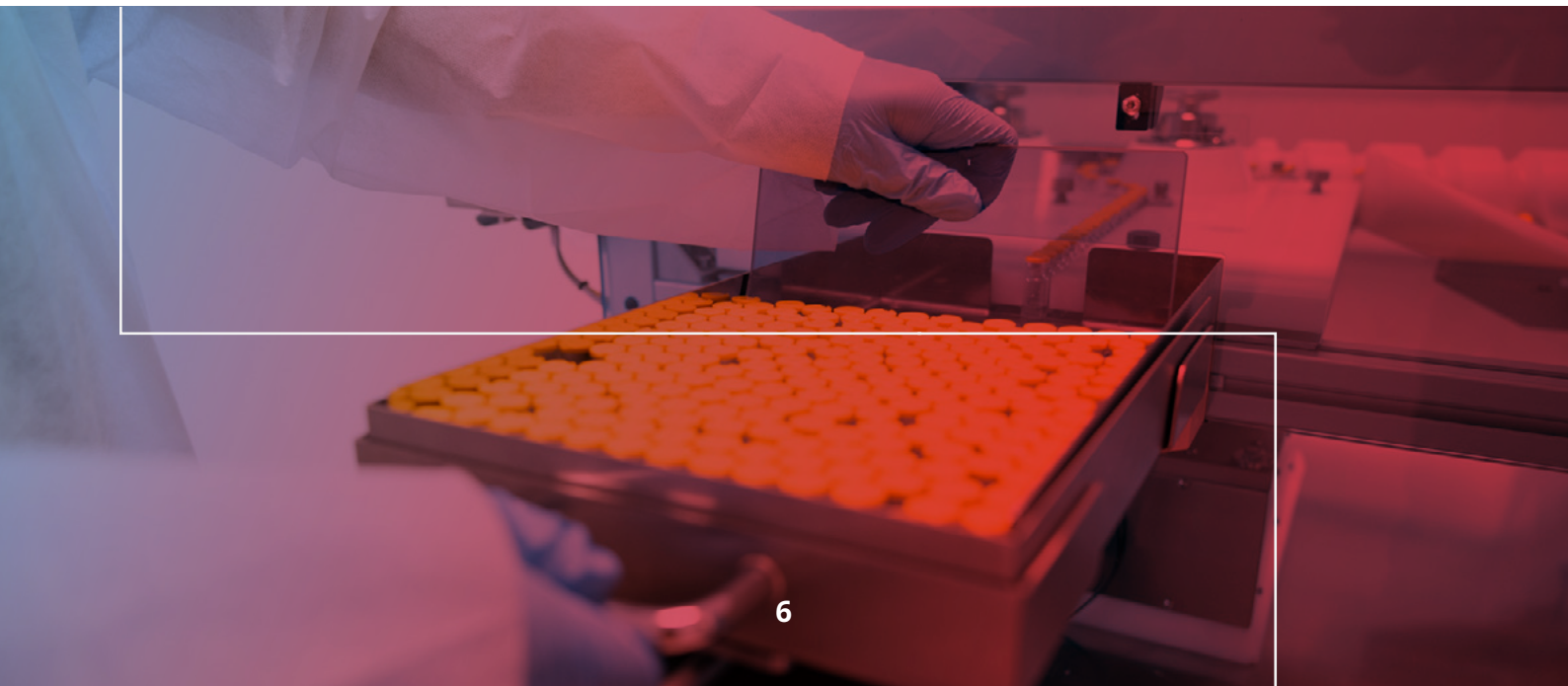
Also, maintaining two compliant sites significantly reduces overall risk during regulatory audits. It provides flexibility in presenting a robust supply chain to regulators, showcasing a commitment to continuous patient supply. While the benefits are clear, it is crucial to emphasise the importance of rigorous due diligence and the harmonisation of quality systems and specifications between partners. This ensures that regardless of the manufacturing site, the product consistently meets all required quality attributes and regulatory standards.

Adapting to evolving commercial demands

The commercial lifecycle of an injectable drug product is rarely linear. Market demands can fluctuate unpredictably, influenced by factors such as new clinical data, shifts in the competitive landscape, seasonal variations and unforeseen public health needs. Dual-sourcing provides the inherent agility necessary to adapt to these evolving commercial demands, offering both rapid scalability and critical flexibility.

Having two established manufacturing streams fundamentally accelerates market access. Companies can achieve faster initial market entry and quicker scale-up for commercial launch, potentially launching in multiple regions simultaneously. This parallel processing capability enables a more aggressive ramp-up of production, allowing companies to capture market share more rapidly than competitors reliant on a single, potentially bottlenecked source.

Additionally, dual-sourcing provides the elasticity to respond to demand fluctuations. Whether a sudden surge in patient need or a strategic decision to scale down temporarily, the ability to leverage multiple suppliers ensures that production can be adjusted efficiently without overburdening a single facility. This prevents costly stockouts during peak demand and avoids the accumulation of excessive, capital-intensive inventory during periods of low demand. With two partners, securing manufacturing slots becomes significantly less of a bottleneck, offering greater scheduling flexibility and responsiveness to urgent needs. This agility directly translates into optimised inventory management and reduced lead times.



Balancing efficiency and risk mitigation

At first glance, engaging a second supplier might appear to create an additional resources. However, this perspective overlooks the tangible economic benefits that dual-sourcing delivers by balancing upfront investment with significant risk mitigation. Framing dual-sourcing purely in terms of unit cost disregards the strategic value of an "insurance policy" for your commercial supply.

The actual costs of a supply chain disruption for a critical injectable drug product are often enormous, far exceeding the investment required to deploy a dual-sourcing strategy. These costs include:

- **Lost revenue:** Direct financial losses from inability to meet market demand.
- **Expedited shipping costs:** Exorbitant fees to rush products amid shortages.
- **Penalties for unmet contracts:** Financial repercussions from failing to fulfil supply agreements.
- **Recall costs:** If quality is compromised due to rushed or compromised production, the financial and reputational impact of a recall can be catastrophic.
- **Reputational damage:** Loss of trust from healthcare providers, patients and investors.
- **Loss of market share:** Competitors seizing opportunities created by your supply shortfalls.

Beyond avoiding these substantial costs, having alternative suppliers can provide a degree of inherent negotiating leverage, fostering competitive pricing and service levels over the long term. Also, dual-sourcing can enable more strategic inventory management. Instead of building large, expensive buffer stocks at a single location, companies can distribute inventory across two sites, potentially reducing overall holding costs while still ensuring security of supply.



Upholding product integrity across the network

A common concern with dual-sourcing is the perceived challenge of maintaining consistent product quality across multiple manufacturing sites. However, rather than diluting quality, a well-executed dual-sourcing strategy inherently reinforces it through robust quality systems.

Having two compliant partners means two sets of rigorous quality management systems (QMS) are independently overseeing your product. This provides an additional layer of scrutiny, ensuring that quality standards are consistently met. The emphasis is on maintaining identical product quality regardless of the manufacturing site. This is achieved through the meticulous harmonisation of specifications, analytical methods and comprehensive quality agreements between the client and both CMOs. Such harmonisation ensures that every batch, from either facility, adheres to the same critical quality attributes.

Moreover, dual-sourcing fosters enhanced oversight and encourages the sharing of best practices between sites and the client, ultimately driving continuous improvement in manufacturing processes across the entire supply chain and helping increase yield. This collaborative approach to quality control ensures that patient safety and product efficacy remain paramount, with built-in redundancies offering an elevated level of assurance.



04 Symbiosis: Your trusted dual-sourcing partner

When considering a dual-sourcing strategy for your critical injectable drug product, selecting the right partner is paramount. Symbiosis stands as a highly capable and reliable CMO, uniquely positioned to fulfil your CMO requirements and to act as your ideal secondary supplier for sterile fill-finish manufacturing. We are an extension of your team, dedicated to enhancing the resilience and efficiency of your supply chain.

The strategic advantages of dual-sourcing for commercial injectable drug products are undeniable in today's dynamic global landscape. By proactively implementing a dual-sourcing strategy with a trusted partner like Symbiosis, you can build a truly resilient, compliant and flexible supply chain that withstands disruption and accelerates your market success.

References

1. *https://ispe.org/pharmaceutical-engineering/ispeak/regulators-harmonization-robust-supply-chains*
2. *https://www.researchgate.net/publication/390194624_Building_Supplier_and_Manufacturing_Diversification_Strategies_to_Enhance_Resilience*

Contact Symbiosis today to discuss your specific manufacturing needs and explore how a dual-sourcing partnership with Symbiosis can be tailored to your unique requirements.

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