OPTIMISING THE PHARMACEUTICAL PACKAGING SUPPLY CHAIN WITH DUAL SOURCING

Report 2025

DATWYLER

INTRODUCTION

It is well known in the pharmaceutical injectables industry that "packaging" is not as simple as choosing a well-designed box or label for a given drug product. Materials which interact directly with a drug product for an extended period of time – including the glass and rubber components which contain the drug product – must undergo rigorous evaluation prior to approval. The work does not stop once a packaging component has been chosen; rather, decisions will follow the drug product throughout its lifecycle. Disruption in the supply chain of one seemingly small piece of the packaging puzzle can cause delays, financial losses, and even shortages. For this reason, engaging only a single supplier for any packaging component can expose a product to unnecessary risk, while leaving value on the table.

In an industry heavily affected by global volatility and regulatory changes, single-sourcing creates a single point of failure upon which an entire pharmaceutical product gambles. The result is an unstable supply chain with unacceptable vulnerabilities; delays related to a single component can lead to supply disruptions, increased lead times, cost spikes, shortages, and a loss of strategic agility.

In contrast, a well-planned dual sourcing approach helps to guarantee supply continuity, reduce lead times, optimize costs, and strengthen negotiation power. Drawing on insights from Datwyler's industry experts, this trend report explores how implementing a policy of dual sourcing for pharmaceutical packaging can future-proof drug life cycle management. It discusses how pharmaceutical manufacturers can build flexibility and agility into packaging portfolios, and the role of differentiated materials in managing regulatory change.

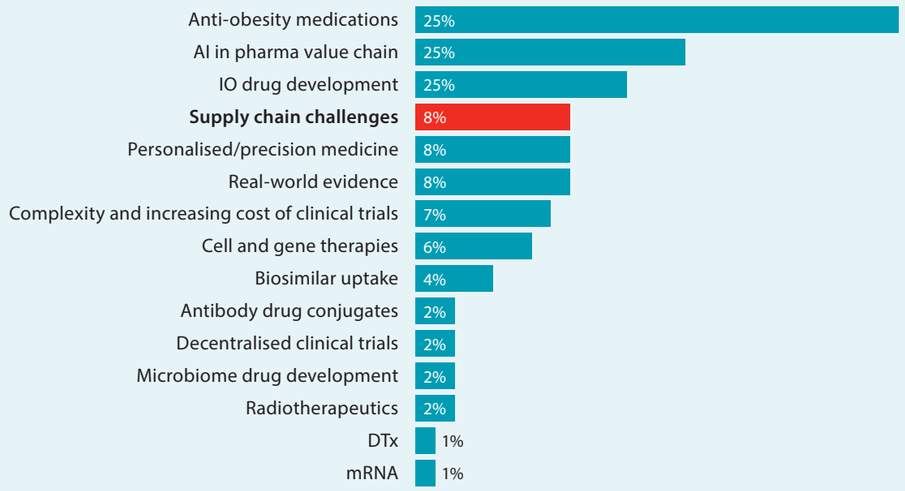
NAVIGATING AN **UNCERTAIN WORLD**

In one recent GlobalData survey, 8% of respondents voted supply chain challenges as the trend expected to have the greatest impact on the industry in 2025 – the same score received for personalized and precision medicine (see Figure 1). In addition, when ranking the negative impacts of a list of regulatory and macroeconomic trends, respondents voted geopolitical issues as having the second-most severe impact on the industry.

Pharmaceutical supply chains operate in a world marked by volatility and complexity. Events on the other side of the globe can instantly reverberate through a pharma company's operations: a trade war can impose tariffs on imported components, a geopolitical conflict can disrupt shipping lanes or raw material supply, and a pandemic can simultaneously spike demand and shut down production. Crucially, stock disruptions no longer require a single global, earth-shattering event; due to interconnected supply chains for raw materials, equipment, ingredients, and packaging, unforeseen issues anywhere can have impacts everywhere.

Relying on a single-source supplier under such conditions is a high-stakes gamble. If that sole supplier faces a strike, a quality issue, or an export restriction, a pharmaceutical company could find itself unable to package life-saving drugs. With a dual sourcing strategy, if one supplier or component is impacted by a tariff or global shortage, the approved second source can ramp up to cover the need. During the COVID-19 pandemic, many companies learned that having an alternate component qualified was the difference between maintaining production and being stuck in a costly wait. Even outside of crisis scenarios, dual sourcing provides insurance against the uncertainties of an interconnected world.

FIGURE 1: THE MOST IMPACTFUL TRENDS IN THE PHARMACEUTICAL INDUSTRY



In a recent survey, supply chain challenges were voted joint-fourth for the trend to have the greatest impact on the pharmaceutical industry in 2025. Source: GlobalData, The state of the Biopharmaceutical Industry, 2025 Edition

BUILDING FLEXIBILITY AND AGILITY **INTO PACKAGING PORTFOLIOS**

Dual sourcing can help companies hedge against disasters; importantly, it's also a pathway to greater agility in everyday operations. In the pharmaceutical world, change is constant; from scaling up production to tweaking a formulation, responding to new market trends, or facing a supplier's product discontinuation. Companies that diversify their packaging toolbox by qualifying multiple options are inherently more agile and responsive to change.

One aspect of agility is the ability to stay on top of the latest innovations and regulatory changes in pharmaceutical packaging. By virtue of working with two mainstream suppliers, drug manufacturers are kept "in the loop" as new technologies become available (and as older technologies are put to bed). With dual supply chains, pharmaceutical companies have the flexibility to test new technologies at their leisure; and, if one of their suppliers discontinues a product, they can lean on their other supplier while finding a replacement.

Datwyler has a long history of bringing new technologies to the forefront. For example, when a leading pharmaceutical company was experiencing particulate challenges with a certain combiseal, Datwyler developed DuraCoatTM technology. The company experienced a drastic reduction in particulate, leading to lower reject rates, satisfied regulatory agencies, risk mitigation, and significant cost savings.

The agility afforded by dual sourcing can help prevent disruptions when external organizations make changes that impact a company's packaging strategy. However, agility is also crucial when internal decisions are made. For example, if a change in packaging configuration from a standard bag to a Rapid Transfer Port (RTP) bag is needed, dual sourcing will allow companies to survey their suppliers' capabilities and smoothly transition on the quickest timeline either supplier can provide.

Another benefit is the cross-pollination of ideas and improvements that comes from engaging with two suppliers. Each supplier brings their own expertise; by working with two, a pharmaceutical company can learn best practices from each and apply them across their operations. This can lead to improved component designs or processes that neither supplier might have identified alone.

Crucial perspective is afforded by building relationships with suppliers across the industry. Communicating the technical needs and standards required by a given product encourages competition, and forces parenteral packagers to provide increased quality.

SAFEGUARDING AGAINST **REGULATORY CHANGES**

An often-overlooked aspect of dual sourcing is the opportunity to diversify materials and technologies in a way that shields a product from regulatory risks. Historically, companies pursuing dual sourcing have tried to keep their two options as similar as possible for seamless interchangeability. However, recent regulatory developments have shown how that approach may actually increase risk: If a material that may be regulated against is replicated exactly, then there is no longer safety in the supply chain.

A prime example of this dynamic is the ongoing global scrutiny of per- and polyfluoroalkyl substances (PFAS) in items such as pharmaceutical packaging. PFAS-based coatings have been used to create barrier films on elastomeric closures, such as vial stoppers and plungers, to reduce drug-container interactions. Some of these coatings utilise polymerization processes using fluorosurfactants. Such fluorosurfactants have been flagged for potential environmental and health risks. If a company's primary stopper has such traditional PTFE or ETFE film coating, the company's instinct for dual sourcing might be to find a very similar coated stopper from another supplier to minimise differences. In this case, should global regulations evolve to ban or restrict specific monomeric PFAS substances, both stopper options could become nonviable simultaneously. A more resilient dual sourcing strategy would pair this film-coated stopper with an alternative technology that does not carry the same risk.

Datwyler offers a spray-coated stopper as an alternative to film coatings. The spray coating is achieved using a polymerization process using non-fluorosurfactants (NFS). As such, the fluoropolymer used for spray coating, is not contaminated with fluorosurfactant residues making them more likely to remain permissible under new regulations. This means a dual sourcing strategy that pairs a film-coated closure with a functionally similar spray-coated closure provides a hedge against whichever way regulators go. If certain film coatings were banned due to restrictions on the use of fluorosurfactants, the spray-coated component would still be available and already qualified for use, thus preventing any interruption in supply or need for a rushed re-formulation. Conversely, if no ban occurs, the company still benefits from having two interchangeable solutions and all the cost, quality, and supply advantages.

The PFAS case is just one timely example. A dual sourcing strategy that incorporates differentiated solutions can ease compliance with changes such as the revised EU GMP Annex 1 requirements for sterile manufacturing or new USP 381/382 guidelines for elastomer closures. Datwyler has helped customers to comply with new regulations by offering a portfolio of solutions for all stages of the drug life cycle, providing multiple product options with different materials or sterilization technologies that all meet stringent requirements, so if one approach is favoured by a new regulation, the client already has it in hand.

DUAL SOURCING **FROM DAY ONE**

To unlock the full benefits of dual sourcing, timing is everything. The earlier in the drug development process dual sourcing is implemented, the more seamless and cost-effective it becomes. The optimal approach is to design dual sourcing into the project from the very beginning, making it a foundational element of the drug's chemistry, manufacturing, and controls (CMC) strategy. Doing so ensures that all necessary activities, including testing, validation, and regulatory filings, account for two sources from the start.

Implementing dual sourcing from day one involves a mindset shift during development and scale-up. Rather than selecting one "winner" packaging component after initial screening, the team deliberately takes forward two candidates (for example, two different stoppers or two syringe plungers). Both are then fully qualified through the necessary studies, including extractables/leachables, compatibility, stability, and machinability tests, and both are included in regulatory filings as acceptable options.

One way to achieve both consistency and dual sourcing flexibility is to leverage a product platform. In this approach, a company will pre-emptively evaluate a variety of stoppers and plungers for compatibility with vials, syringes, and cartridges. Once it is established which rubber components work with which systems, these components can be easily selected for new drug products as they come into fruition. It is ideal when this is performed with product portfolios that prioritize lifecycle; for example, Datwyler's OmniFlex stoppers use the same materials as Datwyler's NeoFlex plungers, allowing for easy transitions when going from a vial presentation to a syringe.

Some companies use a two-by-two matrix for their injection systems, in which they will qualify (for example) two different syringe barrel types and two different plungers, ensuring that each plunger is compatible with each barrel across all fill lines. This effectively gives four usable combinations and a high degree of flexibility; any one component can be swapped without halting the supply of the combination. All validation work is done upfront during development, so by the time the product launches, the company has a robust platform of interchangeable parts. Making sure that all of that is implemented as early on in a project as possible gets all those costs out of the way early and leads to not only supply chain security, but also competitive pricing in the future. This is especially financially savvy when the same matrix can later be used for subsequent projects in a similar dosage.

Real-world experience backs this up. Immediately after the COVID-19 vaccine rush, for example, most firms began evaluating dual sourcing for critical components of new projects. Many have sustained this practice. Datwyler predicts that these proactive organizations will see returns in the future if supply chains are threatened. Even if significant disruptions never occur, companies will still see returns as they have increased negotiation power and can rely on more stable pricing. On the other hand, companies that deprioritized dual sourcing after initial interest are not as well situated from a supply chain security, logistics, or negotiation perspective.

LIFE CYCLE **CONSISTENCY**

Datwyler's OmniFlex® and NeoFlex™ products exemplify the product platform concept. OmniFlex® is a line of coated vial stoppers, while NeoFlex™ refers to coated plungers for pre-filled syringes and cartridges. With the same elastomer formulation and fluoropolymer coating, these products enable easy drug product lifecycle management – from vial to syringe or cartridge. Materials compatibility data from one translates seamlessly throughout, allowing pharmaceutical companies to explore new markets and formats while minimizing costs and timelines.

This also allows for easier platforming across multiple drug products. Most pharmaceutical companies use a variety of packaging sizes and technologies – for example, a 5mL vial, a 2.25mL syringe, and a 3mL cartridge – throughout their portfolio. With OmniFlex® and NeoFlex™, the same material is available in stoppers and plungers of various shapes and sizes, built to accommodate a wide range of options.

From a regulatory standpoint, such platform consistency has major benefits. Often, a product might launch in the US, then later in Europe or Asia, possibly with local packaging preferences or requirements. A strong primary packaging platform, supported by a global supplier, means that the same high-quality components can be supplied in all regions, either from a central source or local manufacturing sites.

Datwyler operates multiple FirstLine® manufacturing facilities globally, including the US, Europe, and India, which all adhere to identical standards and produce the same formulations. This allows a "local-for-local" supply strategy: as a drug enters a new region, the company can source the identical OmniFlex® or NeoFlex™ component from the nearest Datwyler plant, rather than exporting it across the world. The product performance remains consistent, since the component is the same, but the supply chain becomes more agile and regionally optimized, as well as bypassing additional costs such as tariffs.

When dual sourcing involves two different suppliers, achieving consistency requires thoughtful component selection and thorough validation. Some companies conduct bridging studies to prove that both products work well with their drug – and their manufacturing lines. This upfront work can allow production teams to treat components from both suppliers as true equals, without needing special adjustments on their fill/finish lines.

PARTNERING WITH **A GLOBAL LEADER**

As a leading provider of primary packaging solutions for parenteral pharmaceuticals, Datwyler offers a multifaceted partnership that aligns well with dual sourcing needs, from its worldwide manufacturing footprint to its technical and regulatory expertise.

Datwyler operates FirstLine® manufacturing facilities across North America, Europe, and Asia. This allows products that meet the same standards of excellence to be shipped anywhere around the world, from sites in any given region. This global consistency gives customers confidence in the performance of the packaging components. Customers leverage this advantage by qualifying multiple sites for delivery to different locations, or for primary and secondary delivery. Such strategies dramatically increase resilience while maintaining efficiency.

Datwyler is also able to support dual sourcing through co-engineering projects. Supplying two different components for the same application can sometimes require fine-tuning manufacturing equipment or component design to optimize filling efficiency. Datwyler has cultivated relationships with major filling line manufacturers, and is able to engage in a three-way collaboration between pharmaceutical customers and machine makers. Additionally, Datwyler offers design alterations or custom components to meet specific dual sourcing needs.

To successfully manage two component sources, companies will need to navigate regulatory requirements for both. Each component and manufacturing site must be appropriately investigated, documented, and filed with relevant agencies. Datwyler's Regulatory Affairs team routinely supports customers with the necessary information, and proactively analyses new and upcoming guidelines.

STABILITY THROUGH **DUAL SOURCING**

Global trends suggest that uncertainty is here to stay. The rise of new pharmaceutical modalities, such as GLP-1s or mRNA vaccines, can create overnight demand for certain packaging components. Furthermore, geopolitical and economic shifts continue to pose risks to supply chains, and regulatory landscapes are tightening. Each of these factors will likely push more pharmaceutical manufacturers to adopt dual- or multi-sourcing strategies for critical materials. In the coming decade, regulatory bodies and quality auditors may even identify supply risk mitigation as an essential component of their evaluations, making dual sourcing a mark of a mature supply chain system.

Dual sourcing is no longer an overly cautious contingency plan; it has become a necessary way to maintain stability and achieve a competitive advantage in an ever-growing industry. Those who embrace it early will protect their supply chains, forge invaluable partnerships with packaging experts, and gain negotiation power for years to come.

The best time to implement dual sourcing was yesterday; the second best time is today.

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