

If You Can't Win the Game, Change It

The global biopharma supply chain is complex. To navigate it, we must use data in a new way—not just as standalone companies, but as a united whole.

Stephen Wing, Head of Analytic & Logistical Services, MilliporeSigma
Oliver Viehmann, PhD., Leader of the Pharma and Life Sciences Practice Groups, TWS Partners

Across the biopharma industry, emerging digital technologies are helping to accelerate the R&D pipeline, optimize complex manufacturing operations, and bring new therapeutic modalities to the patients who need them. But there's one aspect of the biopharma industry where growing digital maturity has not yet yielded a consistent solution: supply and demand forecasting.

Too often, key players in the biopharma industry find themselves facing unexpected swings in market dynamics, with bottlenecks and shortages emerging as a result. Just look at the recent undersupply of prescription stimulants, for example, which has impacted millions of people who rely on these therapies to manage symptoms of attention deficit hyperactivity disorder.

It doesn't have to be this way. In the case of the stimulants shortage, the FDA points to virtual prescribing as a contributing factor, which drove an increase in demand for stimulants by up to 10% for some age groups during the COVID-19 pandemic. Early visibility into this trend could have afforded manufacturers and their suppliers the opportunity to ramp up capacity, potentially minimizing the impacts of a shortage as a result.

Variations of this situation continuously repeat themselves across the industry, always reaching the same conclusion: to respond more quickly to swings in the marketplace, companies across the biopharma supply chain need better visibility into supply and demand dynamics. And to do that, they need a solution that enables and incentivizes the exchange of electronic data (eData) across the whole manufacturing network.

This paper will suggest a pathway to that solution by drawing from economic theory and biopharma expertise in order to uncover:

- What's behind the volatility of today's biopharma supply chain?
- What role could eData play in addressing that volatility and implementing a more robust and responsive pipeline of biopharma supplies and materials?
- What can biopharma manufacturers learn from other industries about leveraging eData for greater visibility and predictability?
- What will it take for the biopharma industry to apply those lessons and move toward a future of data-enabled supply chain robustness?



Today's Biopharma Supply Chain

When demand for therapeutics fluctuates, that fluctuation swells as it moves along the supply chain. This "bullwhip effect" leads to a self-reinforcing spiral of increasing demand volatility (Figure 1). Agents over- or under-reacting to demand fluctuations (or engaging in order batching) contribute to the noisy marketplace data that characterizes today's biopharma manufacturing landscape. Capacity planning becomes difficult under these conditions, prompting suppliers to keep excess capacity on reserve and increasing the likelihood of supply disruptions—a challenge which grows progressively greater as we move up the supply chain

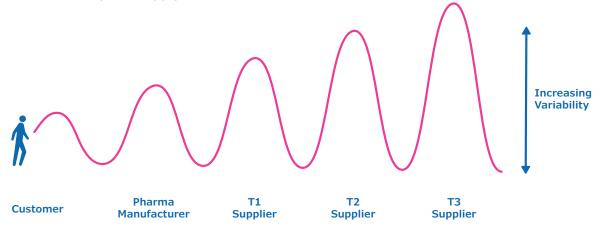


Figure 1. The bullwhip effect: a schematic.

The biopharma industry has developed some strategies to minimize the negative impacts of the bullwhip effect. Multi-sourcing is one example: by contracting two or more suppliers to deliver a critical raw material, manufacturers de-risk the possibility of a catastrophic bottleneck.

But multi-sourcing isn't a magic bullet. Certain products may only be available through a single supplier. And even if your process development team can engineer you out of that risky situation by reformulating your product using a more accessible material, you must still face the root problem of today's biopharma supply chain: it's complex, it's rife with risk, and as long as the data that flows through it remains noisy and difficult to analyze, it's going to stay that way.

Lessons From Highway Construction Industry

How suppliers in the highway construction industry collaborate to optimize their capacity planning.

In the highway construction industry, direct suppliers commission subcontractors to perform specific crafts. Those subcontractors are both competitors and collaborators, jostling for contracts but at the same time working together within their contractor's framework agreement.

To optimize capacity planning within this complex interplay of stakeholders, those subcontractors share supply- and demand-related data both horizontally (with each other) and vertically (with the direct suppliers who contract to them). This practice has grown organically within the industry as a form of risk management.

Key takeaway for the biopharma industry:

Data-sharing is possible and jointly beneficial, particularly when downstream suppliers share a pool of upstream subcontractors.

Toward Greater Supply Chain Visibility

Fortunately, there's an alternative future available to all biopharma manufacturers, CDMOs, and suppliers. That future depends on the collective power of every agent in this industry, and on our willingness to generate a more resilient and transparent supply chain by adopting a new approach—an approach that sees data not only as a competitive resource, but as a shared asset, as well.

To get there, our industry must embrace digital transformation in two key ways.

- 1. First, we need to shift from manual data collection to eData. The process of chasing unstructured supplier data and converting it from PDFs, emails, and paper records to digital data is costing manufacturers time and money all along the supply chain, and it's hampering their internal ability to mobilize that data as an input for supply chain strategizing.
 - The solution is to push for a future in which supplier data automatically arrives in your platform already formatted to meet your needs, without any manual interventions. For that to happen, you need electronic data that's standardized, structured, and suitable for analysis as part of your organization's harmonized data lake.
- 2. Next, we need to exchange eData across the biopharma supply chain. Once our industry fully embraces standardized, platform-agnostic eData, we'll have the insights we need to minimize the bullwhip effect and prepare for future demand with greater visibility and stronger preventative measures.

The keyword is "we." To unlock these benefits, a collective effort is necessary. The more manufacturers, CDMOs, and suppliers participate in the exchange of eData across the biopharma supply chain, the greater the network effect for the industry as a whole, which in turn magnifies the advantages for each business partner.

Lessons From Aerospace Industry

How the aerospace industry leverages commitment and data exchange to mitigate long lead times.

Like agents in the biopharma industry, aerospace manufacturers face extremely long lead times for critical-path equipment and materials.

To mitigate the risk of extensive delays, the aerospace industry has embraced the concept of long-term supplier commitments, which are built into their relationships all along the supply chain and backed by extensive data-sharing practices. This helps secure a predictable supply of necessary materials while affording manufacturers greater visibility into their supply chain.

Key takeaway for the biopharma industry:

Long-term relationships encourage data-sharing for two reasons. First, data sharing becomes less risky in a long-term setting. Second, the expected return on investments into data sharing is higher, which helps rationalize upfront costs.

What Would a Collective eData-Sharing Initiative Look Like?

eData sharing along the supply chain is:

A collective, industry-wide effort that's mutually beneficial.

- A multi-business partner network is key. The
- greater the number of participants, the greater the benefits for each individual company.
- This bidirectional exchange improves the planning capability of each individual partner while enhancing coordination between them.

Applicable horizontally and vertically.

- A horizontal exchange: Suppliers share their anonymized supply and demand data among each other to jointly optimize their capacity planning.
- A vertical exchange: Manufacturers share real-time demand data with suppliers, even before placing orders, which allows suppliers to accurately predict shifts in order volume and prepare their operations accordingly.

Scalable and inclusive of key relationships.

 Rather than limiting suppliers' visibility to a manufacturer's procurement data (as an example), this initiative seeks to include key manufacturer-side data from other stakeholder departments, such as marketing (from a demand perspective).

eData sharing along the supply chain is not:

- It's not about benefiting a single company or entity, but rather about working together to increase the overall strength of the supply chain in the face of global disruption.
- It does not put proprietary or otherwise sensitive data at risk. It focuses instead on anonymized supply- and demand-related data that could benefit the industry holistically.
- It is not necessarily contractually driven, but it is meaningfully incentivized. A collective willingness to design greater efficiency, resiliency, and flexibility into the way global supply chains are structured and managed is the main driver.

What Will It Take To Establish eData Sharing As An Industry Practice?

If a collective eData-sharing initiative could help the biopharma industry navigate supply chain complexity more confidently, why don't we have one already?

To answer that, we need to examine the elements that must be in place for such an initiative to work, and the barriers that have made progress difficult—until now.

Standardization

Without a universal standard for formatting and structuring data, customized solutions will continue to emerge, hampering the possibility of an industrywide exchange network.

To solve that problem and enable biopharma companies to build a meaningful and predictive map of their supply chain, we need a harmonized, platform-agnostic standard for all supply chain eData. Reaching this point will require the cooperation of key suppliers, manufacturers, and industry consortiums.

By working collaboratively towards a data standard, we can unlock several advantages for all participating companies:

- Transitioning to a data standard will allow biopharma companies to retire manual data management in favor of a rapid digital collection process.
- Data will flow securely and bidirectionally, benefiting both suppliers and manufacturers and helping to mitigate the bullwhip effect.
- The pathway to ongoing cGMP compliance will become simpler when data is reliable and traceable directly to its source.

Across the industry, a push for collaborative, data-driven solutions is underway.

BioPhorum, a global organization focused on driving progress in the biopharma industry, recently published **a visionary framework** for building more agility and resilience into the biopharma supply chain. Both data-driven decision making and industry-wide collaboration are central objectives of this framework.

With organizations like BioPhorum sounding the call for better data and stronger collaboration, an industry-wide eData exchange network may be closer than we think—which means the best time to get involved is right now.

The current state of data standardization.

Our customers at MilliporeSigma are among the pioneers pushing for industry-wide data standardization as a way to better navigate their supply chain ecosystem.

Several of those customers are currently piloting our eMERGE™ eData platform. The moment they place an order, the platform is triggered to collect, generate and deliver supplier data to the customer's secure internal data lakes. This gives the customers access to key logistical and analytical data, providing contextualized insights formatted according to industry standards.

As a result, these customers are better positioned to predict future demand, build more resilient supplier networks, and optimize their supply chain strategy for continuous success—whatever the marketplace puts in front of them.

Learn more about moving toward standard supplier data with support from the eMERGE™ eData platform here.

Security and confidentiality

Historically, the terms "share" and "exchange" haven't sat comfortably in the biopharma industry, where IP is closely guarded and manufacturers compete vigorously to reach the market first. Suppliers may also feel concerned about the risk of sharing a data signal which could impact their reputation, such as indications of missed targets or low capacity.

A collective data-sharing movement needn't compromise proprietary secrets or disclose vulnerable information to generate enormous benefits. The focus is on demand- and supply-relevant data, and any data exchange would be subject to strict confidentiality agreements. Other industries provide ample examples of how an initiative like this can deliver value without putting companies at risk—the highway construction industry, for example, approaches supply-and-demand data exchange as an industry standard.

Lessons From Freight Logistics

In the U.S., a new supply chain data exchange initiative aims to curb disruptions and material shortages.

To improve the resiliency and transparency of the U.S. supply chain and logistics industry, the White House recently introduced **the Freight Logistics Optimization Works (FLOW) initiative**. This voluntary public/private program aims to facilitate secure data-sharing across supply chains, giving manufacturers, port authorities, warehouse operators, and other stakeholders the insights they need to predict, prevent, and navigate supply disruptions more effectively.

The success of this data-sharing initiative hinges on participation. As more supply chain stakeholders voluntarily join the program, the data it collects will grow in volume and quality, leading to accelerated deliveries and reduced consumer costs. **Several dozen participants are currently involved**, ranging from retail corporations like Walmart to carriers like Union Pacific.

Key takeaway for the biopharma industry:

The FLOW initiative demonstrates how collaboration and data-sharing across a complex network of stakeholders can help all participants mitigate risk, improve supply chain visibility, and prepare to meet consumer demand with on-time, cost-managed deliveries.

Strong incentives

For an eData sharing initiative to succeed, the biopharma industry needs to agree that it's necessary—which means building consensus and support for its benefits, both from the perspective of the industry as a whole and in terms of individual contributors.

This means changing course from the old way of thinking, which incentivized each company along the supply chain to act only once a contract is signed. Instead, we need to strongly incentivize proactive action and build an ecosystem in which companies have a compelling business reason to exchange accurate, relevant data, which ultimately provides short-term incremental benefits as well as a long-term, holistic advantage for the biopharma industry.

From Supply Chain to Value Chain

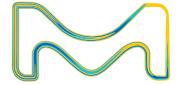
To manage the complexity and volatility of today's biopharma supply chain, manufacturers need a new strategy. That strategy must harness standardized electronic data as its compass, giving manufacturers in multi-agent, industry-wide data exchange networks the insights they need to navigate complexity and prepare in advance for shifts in customer-side demand or supplier-side capacity.

This collective data-sharing network will enable a future in which:

- Manufacturers can predict changes in demand, giving them the runway they need to adjust inventory levels, plan production volumes, and book capacity with suppliers.
- Suppliers receive early signals of new pipeline therapies, giving them an opportunity to ramp up their capacity early and thereby minimize excessive lead times.
- Suppliers work together to reduce their risks by jointly optimizing their capacity planning.
- The industry as a whole moves forward with more flexibility and resilience, ensuring that more patients will receive the therapies they depend on now and long into the future.

To join the eData movement and help define the future for the biopharma industry, visit www.EMDMillipore.com/eMERGE.

MilliporeSigma 400 Summit Drive Burlington, MA 01803



For additional information, please visit www.EMDMillipore.com/eMERGE