

Manufacturing Supply Chain Resiliency

PhRMA member companies are dedicated to researching, developing, and delivering lifesaving and quality-of-life enhancing innovations for patients. There are a range of ways PhRMA member companies work to bolster manufacturing supply chain resiliency including managing risk and event preparedness, maintaining global and diverse vendor networks, and applying technologies and processes to assure inventory continuity.

Understanding Manufacturing Supply Chain Resiliency:

Supply chain resiliency refers to the ability of a biopharmaceutical company and its suppliers to adapt to unexpected events, continue to function throughout disruptions, prepare for future disruptions, and quickly return to pre-disruption operational capacity. Examples of activities to encourage supply chain resiliency include integrating end-to-end, data-driven controls; preparing for disruptions before they occur through extensive scenario planning; developing redundancies (e.g., emergency stockpiles, safety stocks); diversifying suppliers; and collaborating with private and public supply chain stakeholders.

Over decades, biopharmaceutical manufacturers have carefully built robust global supply chains to help ensure patients in the United States and around the world have ongoing access to medicines. PhRMA member companies are focused on ensuring high-quality reliably sourced materials are used in the manufacturing process to ensure the availability of a highly skilled labor force with the ability to manufacture products; and to maintain the critical quality control and testing systems needed to protect patients. To encourage supply chain resiliency, PhRMA members are constantly managing potential risks, including preparing for a range of scenarios that could disrupt supply chains, maintaining global and diverse vendor networks, and applying technologies and processes to assure robust business continuity plans.

The Importance and Objectives of Manufacturing Supply Chain Resiliency:

A high-level scan of PhRMA member company websites and publications found examples from 29 PhRMA members related to the application of new digital tools and solutions to bolster supply chain resiliency, including leveraging AI/digital tools for real-time tracking, or enabling an expansive modeling/real time data intelligence regarding global supply chains to facilitate rapid decision-making and adjustments (e.g., modes of transport).

Faster adaptability to changes: By encouraging resiliency, biopharmaceutical companies can quickly adapt to changes in their supply chains in the event of potential shocks and stressors. By investing in digital tools to help understand and modify their supply chains, this increased understanding allows PhRMA member companies to develop and enact proactive responses to these disruptions and diversify their supply chains as needed.

Improved supplier trust and reliability: Positive, flexible, and dependable working partnerships between biopharmaceutical manufacturers and their suppliers are an essential goal of and benefit to resiliency.

Reduced supply-chain uncertainty: A key advantage of encouraging resiliency is the ability to reduce uncertainty within the supply chain. From managing numerous global supplier relationships to navigating foreign regulations, resilient supply chains are able to overcome uncertainty and maintain product safety.

Fewer backorders and supply shortages: Resilient supply chains are less likely to experience challenges related to product backorders or supply shortages, which can be extremely costly and can lengthen time to market.

Manufacturing Supply Chain Resiliency: Examples of PhRMA Members in Action

Notable examples of PhRMA member companies working to encourage supply chain resilience are highlighted below:

THE PHARMACEUTICAL SUPPLY CHAIN INITIATIVE (PSCI)

There are 19 PhRMA member companies participating in the Pharmaceutical Supply Chain Initiative (PSCI). Full members include Boehringer Ingelheim, GSK, Johnson & Johnson, Eli Lilly and Company, Merck, Novartis, Novo Nordisk, Pfizer, Sanofi, Takeda, and UCB. Associate members include Amgen, Biogen, CSL, Eisai, and Gilead.¹ The vision of the PSCI is for excellence in safety, environmental, and social outcomes for the whole of the global biopharmaceutical and healthcare supply chain. The initiative brings together members to define, establish, and promote responsible supply chain practices, human rights, environmental sustainability, and responsible business. Members and their suppliers abide by PSCI's Five Principles for Responsible Supply Chain Management, and all members are expected to support and incorporate the principles into their key supplier documents and agreements.

- **Ethics:** Suppliers shall conduct their business ethically and act with integrity.
- **Human Rights and Labor:** Suppliers shall be committed to uphold the human and employment rights of workers and to treat them with dignity and respect.
- **Environment:** Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle.
- **Health and Safety:** Suppliers shall provide a safe and healthy working environment, including—where applicable—any company-provided living quarters. Health and Safety measures shall extend to contractors and subcontractors on supplier sites.
- **Management Systems:** Suppliers shall use management systems to maintain business continuity, facilitate continual improvement and compliance with the expectations of these principles.



INTERNATIONAL PHARMACEUTICAL SUPPLY CHAIN CONSORTIUM

There are 14 PhRMA member companies participating in the International Pharmaceutical Supply Chain Consortium (Rx360), a community focused on building strong partnerships between biopharmaceutical manufacturers and suppliers by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of its materials.² Participating companies include: Amgen, Bayer, Biogen, Boehringer Ingelheim, CSL Behring, Daiichi Sankyo, Eli Lilly & Co., EMD Serono, Genentech, GSK, Johnson & Johnson, Merck, Pfizer, and Takeda. Rx360 focuses its activities on facilitating auditing programs for companies and suppliers and conducting working/discussion groups across topics such as supply chain security, data integrity, and supplier quality.

CLINICAL SUPPLY BLOCKCHAIN WORKING GROUP

Pfizer, Biogen, Merck, and GlaxoSmithKline are among the companies leading the Clinical Supply Blockchain Working Group (CSBWG), which recently developed the KitChain App – a Blockchain-powered iPhone app that assists with biopharmaceutical clinical supply chain management by creating an immutable record for shipping and event tracking.³ While the biopharmaceutical clinical supply chain currently relies on paperwork to record the movement of packaged medicine involved in clinical trials, KitChain uses a blockchain-based solution to track shipments of packaged medicines which are sent by the biopharmaceutical companies. All parties can see when the delivery is both sent and received. This allows for a method that is faster, more efficient, and more secure than traditional paper methods, because senders and receivers have control over who can see the details of a particular shipment and any third-party viewers are unable to change any of these details.

FIGHTING COUNTERFEITING

Boehringer Ingelheim is working across the biopharmaceutical value chain to fight drug counterfeiting by piloting a mobile app that helps U.S. law enforcement agencies spot counterfeit drugs before they reach patients.⁴ The app was developed using a cloud-based network solution that helps organizations comply with provisions of the US Drug Supply Chain Security Act (DSCSA). The app checks whether medications are authentic and allows wholesalers to verify saleable returns for medications already shipped to pharmacies. The latest update is designed to expand the app's anti-counterfeiting capabilities beyond DSCSA requirements, allowing law enforcement agencies to exchange drug serialization information more securely and easily.

STRATEGIC PARTNERSHIPS

CSL is implementing strategic partnerships with contract manufacturers to establish services that increase capacity and mitigate risks.⁵ New partnerships have enabled CSL to spread single-sourced product supply over multiple manufacturers, while others are in various stages of the technology transfer process and when delivered will further increase supply reliability and resilience of CSL's most important products. CSL is using digital tools in its supply chain to assess vendor risk, and is rolling out DisasterAware, a digital platform that provides early indication warnings to CSL's procurement team of natural and human-induced risks based on the physical location of its vendors.

GLOBAL SUPPLY NETWORK

Merck is continuing to work toward an uninterrupted, unconstrained, highest-quality global supply network.⁶ Through digitally enabled “end-to-end supply planning,” Merck is digitizing its manufacturing facilities and conducting efficient and balanced planning decisions to maximize business results and deliver medicines and vaccines to customers, which include hospitals, retail outlets and patients, when and where they need them. With both an environmentally and socially conscious mindset, these facilities, along with Merck’s external contractors, suppliers and partners, make up an integrated, interdependent global manufacturing network.

LEVERAGING DATA SCIENCE

Johnson & Johnson is leveraging data science and utilizing complex algorithms to ensure resilience.⁷ For example, J&J monitors typical order patterns and flags significant deviation, and when an algorithm detects an unusual pattern, it alerts supply chain professionals to investigate. J&J also uses track-and-trace sensors that leverage GPS technology and travel with a shipment, allowing for “end-to-end” visibility. In some instances, track-and-trace technology is also paired with intelligent automation, which uses data to automatically trigger subsequent production steps and supply chain streams.

PROMOTING DIGITAL TECHNOLOGIES

Daichi Sankyo is promoting the use of digital technology in all aspects of procurement, production, and logistics.⁸ Under the 5-year Business Plan, the Supply Chain Unit’s vision is to “contribute to maximizing the value of ADC*1 products and to realize Smart Supply Chain.” By “Smart Supply Chain”, they refer to both the promotion of DX (digital transformation) at their plants, such as job automation and the realization and expansion of increased remote or automatic control, but also the use of digital technologies in all aspects of the supply chain. This includes procurement, supply and demand planning, and logistics, as well as the visualization and integration of data. Daichi Sankyo are currently working on building a new database that will enable them to centralize up-to-date information from all locations. At its plants, the company is also actively working to predict when equipment will fail by introducing digital technology and improving inspection accuracy by using image processing technology.

1 Pharmaceutical Supply Chain Initiative (PSCI), “building Responsible Supply Chains in the Pharmaceutical Industry.” See: <https://pscinitiative.org/home>
2 Rx-360, “The International Pharmaceutical Supply Chain Consortium.” See: <https://rx-360.org/>
3 Clinical Supply Blockchain Working Group (CSBWG), “Transforming Pharmaceutical Clinical Supply Messaging with Blockchain.” See: <https://static1.squarespace.com/static/5b819b5b45776e48dcfb5df2/t/5d5336523effc200016ecf03/1565734487554/CSBWG-transforming-clinical-supply-1.8.pdf>
4 Forbes, “Connected Data Is Lifesaving Breakthrough in Trusted Drug Supply Chains.” See: <https://www.forbes.com/sites/sap/2022/04/26/connected-data-is-lifesaving-breakthrough-in-trusted-drug-supply-chains/?sh=6f40822b562e>
5 CSL, “Annual Report 2022.” See: <https://investors.csl.com/annualreport/2022>
6 Merck, “Environmental, Social & Governance (ESG) Progress Report 2020/2021.” See: <https://www.merck.com/wp-content/uploads/sites/5/2021/09/Merck-ESG-Report.pdf>
7 Johnson & Johnson, “High-Tech Tools Johnson & Johnson Is Using to Get Products to You During the Pandemic.” See: <https://www.jnj.com/innovation/johnson-johnson-supply-chain-technology-during-coronavirus>
8 Daiichi Sankyo, “Developing a Resilient and Genuinely “Smart” Supply Chain.” See: https://www.daiichisankyo.com/our_stories/detail/index_4223.html