WHEN IT COMES TO SUPPLY CHAINS, THE RISKS ARE INEVITABLE. HERE'S HOW TO BE BEST PREPARED.

The importance and complexity of global supply chains have increased over the past 25 years in many industry sectors, including those involving the Life Sciences sector, such as medical device manufacturing, pharmaceuticals, nutraceuticals, biological products and research and testing laboratories, to name a few. The explosive growth of development and dependence on increasingly diverse supply chains during this period was initially sparked by the need to find less expensive sources of raw materials, components and APIs manufacturing, as well as the desire to expand the footprint for end-point processors to enhance market share in other countries.

Many enterprises in the manufacturing, retail, consumer goods, pharmaceutical, food and beverage sectors and others are moderately to highly dependent on just-in-time fulfillment through these supply chains to continue their normal operations. Further, elevated dependence upon logistics entities has developed as more nodes exist where disruptions can occur, many of which are co-located with other tier suppliers.

In today's world, supply chains can consist of hundreds to thousands of multiple-tier suppliers located in multiple countries around the world. They have brought a great variety and diversity of raw materials, components and parts, while reducing the cost and time to process and manufacture finished goods and enhance efficiency compared to how goods were produced just three decades ago. By their nature, however, they are quite complex and vulnerable to "shocks" in the supply networks from man-made, natural hazard, cyber and other disruptive events.

In 2020, the COVID-19 pandemic event underscored significant disruptions can be created in a wide variety of supply chains, requiring enhanced preparation and business continuity planning to assure businesses can mitigate this type of risk and continue operations.

This paper will not only focus on the sources of disruption in the Life Sciences supply chain, but will additionally provide a collection of best practices which can assist in preparing for and mitigating significant risk to operations resulting from these disruptions.

continued

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SOURCES OF SUPPLY CHAIN VULNERABILITY

While there are many existing potential sources of vulnerability to supply chain risk events, the most significant for the Life Sciences industries includes the following:

- **Geo-Location Sources** – Raw materials and intermediates for pharmaceuticals, biologic and medical device manufacturing usually originate in Asia. China houses some of the major manufacturing hubs of critical medical equipment and also accounts for a huge share of intermediates (APIs) used in the pharmaceutical and nutraceutical market. Many of the raw materials for these sectors are sourced in India, Vietnam, Indonesia and other areas which ship these materials to China where they are processed into intermediate products for eventual shipment to North America and Europe for final production. Estimates indicate 75% to 80% of natural product raw materials used in dietary supplements are sourced from China. India contributes 20% of the global generics supply used in both of these markets.

  The lithium-ion battery is an essential component in the manufacture of a range of medical devices, with a significant share of the lithium-ion battery production existing in China. Regional resiliency in many of these areas is low and may not be well supported by government agencies or may be ineffective in responding and restoring from a major event – this is true of man-made and natural hazard exposures such as floods, typhoons and earthquakes. In many areas, medical and health network resiliency is not as robust as in the United States and preparedness for an outbreak like COVID-19 is sporadic or non-existent.

- **Regional Tier Supplier Convergence** – This occurs from the practice of multiple suppliers co-locating in the same region or even the same industrial park which might create significant disruptions as firms may depend upon multiple suppliers of both same and different components from suppliers that are exposed to the same event risk. While this phenomenon is found in many areas of the world, it is prolific in China and Southeast Asia where a single industrial park can house over 10,000 manufacturers, many which are feeding tiers at the next several levels located in the same park. Significant supply chain losses were incurred during the Tohoku earthquake and tsunami and the catastrophic flooding in Thailand in 2011, resulting from the co-location of multiple tier suppliers supporting the electronics, automotive and medical device markets.

  Regional convergence issues have been exacerbated during COVID-19 through the actions of sourcing countries restricting export of 26 highly active nutraceutical and pharma ingredients which account for nearly 10% of their export capacity. Likewise, the diagnostic testing market has been affected as logistics have seen some impacts on the shipment of components due to country shutdowns or restrictions.

- **Logistics and Transportation Chokepoints** – Global dispersion of supply chains in today's world is highly dependent upon a strong and efficient logistics and transportation network to provide and enable enterprises to achieve their just-in-time and lean manufacturing business models. These supply chains depend upon regional ports, trucking, ocean cargo and air shipment support to keep the supply chain in operation at full capacity.

When area or regional impacts disrupt or shut down one or more of these nodes, re-routing becomes necessary which creates delays in moving goods to final destinations or bringing raw materials or intermediate components to the affected area, further depressing capacity. These transportation nodes and logistics hubs can be highly vulnerable to a natural disaster or pandemic event, especially as they act as a hub into which many firms move products for shipment to the next or final destination.

TOP EXPOSED CARGO PORTS - ASIA*	TOP EXPOSED CARGO PORTS – U.S.*	TOP EXPOSED CARGO AIRPORTS*
Kaohsiung, Taiwan	New Orleans, Louisiana	Hong Kong, China
Hong Kong, China	Houston, Texas	Shanghai Pudong, China
Shenzhen, China	Mobile, Alabama	Incheon, South Korea
Guangzhou, China	Savannah, Georgia	Taoyuan, Taiwan
Xiamen, China	Jacksonville, Florida	Tokyo Narita, Japan
Busan, South Korea		Changi, Singapore
Ningbo-Zhoushan, China		Miami, Florida
Shanghai, China		Guangzhou Bai Yun, China
Colombu, Sri Lanka		Tokyo Haneda, Japan
Laem Chagang, Thailand		Shenzhen, China

***Riskpulse**

A recent study of the most critical cargo ports and cargo airports exposed to tropical cyclones in Asia and the U.S. were developed by Riskpulse (www.riskpulse.com), a global supply chain risk organization. They reviewed locations based upon their throughput tonnage, supported trade markets and their location risks to typhoons/hurricanes. The top riskiest cargo ports and cargo airports are shown in the table above.

PANDEMIC CREATES SUPPLY CHAIN DISRUPTION

The COVID-19 outbreak triggered a supply chain disruption which did not fully materialize for several months. This event has proved to be a significant impact to many supply chains in key industry sectors, including entities in the Life Sciences sector, due to the location of the origination of the event. Industrial China, the origination country, represents critical manufacturing of a wide variety of components, parts and materials, and supplies hundreds of thousands of intermediate and end-point processors, manufacturers and retailers in the United States, Europe and other highly developed markets. China has a direct and

indirect impact on market economies with over 15% of the world's GDP as of 2017, and making up over 21% of the imports of the U.S. in 2018, making this disruptive event as significant on market economies as much as it will on public health.

The pandemic created shutdowns and major disruptions to manufacturing in critical regions of China, and also significant disruptions in transportation and logistics both inbound and outbound from China, depressing the flow of finished products developed prior to the shutdown, to next tier suppliers and end customers. According to Maersk, many logistics and transportation capacities used in China to get materials into the manufacturing locations, and to route completed parts and components out to the global manufacturing system, are much reduced still months into the pandemic. This resulted from a combination of quarantined and sick workers creating an inadequate number of workers to move containers around, inadequate number of truck drivers and no one to receive them at the outbound ports.

Cargo ship traffic was significantly impacted with many laying idle in Asia during the first few months, due to the cancellation of many loadings out of China. At one point, over 45% of scheduled departures on the major Asia to North European route were cancelled for many weeks. Container volume dropped 2.7% at American ports mostly due to the outbreak in China. These logistic disruptions to inbound and outbound air cargo shipments, trucking and rail cargo services as well as heavy port congestion for vessels along the Yangtze River near Wuhan continued in the early months of the event.

In the medical devices industry, clinical trial requirements (pre- and post-market) for Class 3 devices are being hampered by healthcare facility reduction due to capacity demand for COVID-19 patients – making it difficult for manufacturers to make informed decisions about their products, supply chains and regulatory obligations. About 13% of U.S. medical products are manufactured in China which have been significantly curtailed by the pandemic. Markets impacted from COVID-19 include aortic and coronary stent grafts, aesthetical injectables, implants, bariatric surgery and cosmetic procedures.

In the U.S. pharmaceutical sector, about 72% of APIs supplying the domestic market are foreign sourced. India accounts for about 18% of the U.S. imports in this sector which have been constrained due to COVID-19. India and China account for about 90% of the medicines distributed in the U.S. India supplies approximately 40% of over the counter and generic prescription drugs to the U.S., and it depends on China for about 80% of APIs and chemical intermediates essential for production.

Production of APIs in China resumed to about 35% of capacity in March. Sourcing alternatives are critical for pharma as capacity from China will require additional time before resumption to normal levels. Clinical trial impacts due to shutdowns and stoppages in China has slowed down trials and follow-on FDA approvals

and subsequent release to the market. Demand for COVID-19 testing created a race of firms in the pharma, biotech and medical device industries resulting in a shift in the pipeline of IVD (in vitro diagnostic) products.

China ranks first among countries that export medical devices to the U.S. by import line – creating vulnerability in the supply of medical products in the U.S. Labor shortages due to quarantines in China plus diversion/reallocation of certain antiviral drugs to in-country (China) has reduced availability to manufacturers in the U.S.

In the medical device market, it is believed that reductions in demand will appear over the next 12 months as cash flow issues, therefore limiting operational freedom. Some lower-tier suppliers may disappear reducing supply capacity in the future when the market returns. For this reason, future focus on supply chains will include supplier survivability.

BEST PRACTICES TO WEATHER A SUPPLY CHAIN IMPACT

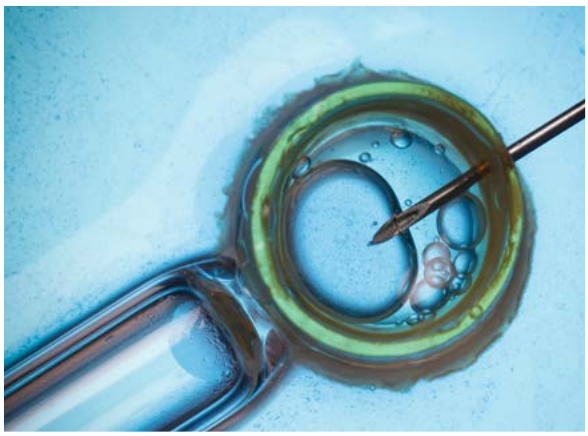
The best defense against significant disruption during an infectious outbreak or due to a regional natural disaster is a strong and comprehensive supply chain business continuity plan that is developed in line with a focus on the largest peril event occurrences and visibility into an insured's supply chain configuration. This would encompass an effort to identify the critical suppliers and tier level structure in the supply chain, identify and quantify the risk from a group of credible scenarios, and a business continuity plan which is created based upon these findings. The following best practices have been identified to be effective in reducing risk due to supply chain disruptions from a variety of perils, including pandemics.

- **Develop a Components Taxonomy** – This process involves development of a listing and hierarchy of all parts, materials and components used in or sold as key products by the enterprise; the listing should identify which parts/components are critical to the product line and which could create financial hardship if discontinued on short notice.
- **Identify Sources of Components and Materials** – This challenging effort involves "mapping" out the supply chain that supports the firm's key products or offerings, identifying suppliers and the parts or components they provide into your firm's supply chain; the firm should attempt to identify as many tier levels as possible and any interconnections with other tier level suppliers. This effort should initiate with the firm's Tier 1 suppliers (those suppliers from whom the firm purchases directly) to inquire about the various suppliers from whom they acquire parts and components from. The inquiry should explore the level of redundancy that your Tier 1 suppliers incorporate into their supply chain, and any suppliers that they utilize for which they have knowledge of higher risk for shortages or temporary discontinuation.
- **Determine Location of Sources** – Once the enterprise has prepared a "map" of their supply chain, they should next initiate the task of determining the geographic location of each tier supplier identified to determine potential risk to each from outbreak quarantines, shutdown of production plants and shutdown or disruptions at logistics hubs; additionally, identify interconnections between individual tier suppliers to better understand interdependencies and possible reduction in fulfillment to your supply chain in deference to other supplier markets. This effort to identify and map the locations and identities of each tier supplier can be used to compare the "map" against known higher risk locations from not only pandemics but also natural hazards such as flood, typhoon, earthquake and others.

- **Identify any Single or Sole Source Suppliers** – Use the tier supplier map to try and identify any single or sole-source suppliers within the firm's supply chain that may present elevated risk due to the lack of alternative suppliers for the same part, component or material. This will require inquiries into your Tier 1 and below suppliers to assist in determining the existence of single or sole sources,

but will help identify potential "chokepoints" that could disrupt or shut down your supply chain should those single or sole-sourced suppliers be located in regions affected by pandemic risk.

- **Identify Potential Alternative Producers** – Aligned with the supply chain map, the enterprise should



identify potential alternative producers or suppliers that are not located in high risk areas, but which can provide the same or similar component or material to meet the firm's specifications. This inquiry should not only focus on the quality, cost and specification, but also the capacity in terms of product requirements as well as the "lag" time required to ramp up production for your firm's supply chains. This effort is most successful if it is a joint approach with your firm's Tier 1 and below suppliers who may already have information on alternatives.

- **Distinguish Potential Logistics Chokepoints** – Using the supply chain map created with the listing of suppliers, ask identified suppliers about their routes of transport of their goods that are being fulfilled to your supply chain as well as key logistics hubs that are depended upon. Map those transport routes and logistics hubs against reported delays and shutdowns at those hubs to better understand potential disruption of parts and components as well as the anticipated delay and lag time for those disruptions so the firm can plan accordingly.
- **Detect any Internal Production Capacity for Replacement** – This practice may not be available for many firms, but those who maintain or comprise some level of processing or production, determine if any identified parts or components at higher risk can be replaced in part or whole by the firm's own capacity. This may require some re-tooling and some effort to get production in place using existing production lines or equipment, so the cost to implement vs the identified delay in components will need to be weighed against the firm's customer demands and needs, and potential for market share or other financial impact.
- **Expand Purchasing Relationships** – Where "bottlenecks" have been identified in your supply chain either through impacted suppliers, single-source suppliers or impacted logistics, the firm should be reaching out to potential alternative supply chains and suppliers to develop business relationships and expanding some purchasing for similar or like parts and components to meet the firm's production or service demands. As mentioned, this effort may be more successful if it is a joint approach with your firm's Tier 1 and below suppliers who may already have information on alternative suppliers.
- **Expand Buffer Stocks of Materials and Components** – Where possible, the identified critical parts, components and materials in earlier steps should lead to an increase in "safety" stocks above that normally maintained, so as to increase the inventory duration for the firm's production or servicing to navigate beyond the anticipated "peak" period of this supply chain disruption. This would include any replenishment of these critical components from identified alternative suppliers.
- **Relax Just-In-Time Criteria** – Working with your internal supply chain management, production teams and suppliers, temporarily relax just-in-time criteria which drives the fulfillment process of parts, components and materials. This is related to the practice above in the expansion of buffer stocks and is designed to extend the timeframe between fulfillments during this supply chain disruption to attempt to reduce significant impact to the firm and your customer base.

- **Establish Multiple Locations for Buffer Stocks** – In cases where critical inventories are maintained in a single location, consider moving some portion of the supply stocks of parts and components to a sister facility or location to avoid potential loss of all of your buffer stocks due to a peril event at the main stored location.
- **Identify and Implement Alternate Logistics Routes** – Conduct a review of all transportation methods, routes and logistics hub locations to identify any that may present disruption risk from an expanding pandemic due to civil authority shutdown, or impact to worker populations due to sickness and quarantine. Where high risk is identified from potential or existing disruption, identify alternative logistics support and transportation routes that are not likely to be impacted by the event, and develop new logistics relationships as necessary to mitigate and avoid shutdown or disruption to goods and suppliers that your firm is dependent upon to continue operations.
- **Develop a Supply Chain Business Continuity Plan** – As with other threats to business processes and operational continuity following significant loss events and disruptions, your firm should be developing business continuity plans which address the supply chain risk potential from a variety of existential threats including pandemic outbreaks, natural disasters and cyber risk. Many of the steps listed above and other best practices would be used to develop a comprehensive Supply Chain Business Continuity Plan and should be integrated into the firm's existing business continuity planning process. Similar to a business continuity plan, a Supply Chain Business Continuity Plan should be tested using a desktop or scenario testing approach on some frequency such as annually, or even semi-annually, dependent upon the level and magnitude of change in the firm's supply chain over the course of a year.

Additional best practices for the Life Sciences Sector:

BIO-TESTING MARKET

- **Improve Visibility into Testing Capacity** – Create information nerve centers that collect data on local capacity and match with demand on a daily basis.
- **Maximize Existing Laboratory Capacity** – Develop a full inventory of the installed testing equipment base, distinguishing between open and closed systems, then calculating the maximum theoretical laboratory capacity, given the installed base. This would allow companies to locate and address bottlenecks, be it by establishing new workflows, hiring additional personnel, or finding alternative suppliers of reagents if open-source systems are used.
- **Create New Laboratory Capacity** – Increasing the amount of equipment existing laboratories and establish new, high-capacity laboratories. Collaboration among governments, public-health organizations, equipment manufacturers, and private laboratories can accelerate such efforts. Establish a centralized repository which comprises information on the performance of various kits and their components which can assist in speeding the validation and approval processes. Additionally, prioritizing the validation of suppliers with high capacity would likely grant faster access to additional manufacturing capacity.
- **Scale-up Production of Closed System Cartridges and Proprietary Reagents** – OEMs should ramp up their production volumes to enable the utilization of these systems closer to their theoretical maximum capacity.
- **Consider Alternative Testing Protocols** – Where FDA approval can be obtained, utilizing alternative protocols and curve shifting technologies for sample collection and testing can assist in increasing testing capacity and alleviate shortages of particular components, and some of these protocols have already been validated by various authorities. The use of sample pooling can help decrease the quantities of reagents needed which have been in demand and shortage of supply during the early days of the pandemic.

PHARMACEUTICAL AND NUTRACEUTICAL MARKETS

- **Relocating Available Inventory** – To enhance inventory duration, consider re-locating available inventory to areas outside of known or potential quarantine zones and near ports where it can be easier accessed for shipping.
- **Securing Capacity and Delivery Status** – To reinforce supply and inventory requirements of raw materials and intermediates, identify and secure Tier-2 and Tier-3 suppliers and allocated supplies and overtime assembly capacity where possible.
- **Buying Ahead** – To procure future estimated inventory and raw material demand that are in short supply in impacted areas, establish a program to purchase materials in advance from alternative suppliers to assure adequate inventory duration of raw materials into the future. Increase the traditional inventory purchase to compensate for expected shortages and reduce future lag time.
- **Securing Future Air Transportation** – To reduce extended shipment times during a shortage of necessary raw materials and intermediates, consider transferring and securement logistics support by air transportation as supply and capacity become available. This will assist in shortening ocean freight-based lead times.
- **Activating Pre-approved Materials** – Where a primary supplier is impacted from a disruption event but available alternative suppliers are not, arrange to more rapidly approve parts or raw-material substitutions.
- **Activating Product Redesign** – Conduct product redesign or revise material certification resources where reliable second sources of parts or raw material are not already available.

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