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Pharmaceutical Services

PUTTING POST-PANDEMIC SUPPLY CHAINS TO THE TEST

In this article, John Swift, Head of Supply Chain at Owen Mumford, discusses the need for medtech companies to undertake a reappraisal of their supply chains in light of covid-19, taking into consideration how the pandemic has exposed vulnerabilities that have previously gone unnoticed or ignored.

The pandemic has forced many medical technology businesses to re-assess their supply chain in a short space of time. As companies struggled to address both peaks and troughs in product demand, it is likely that they identified stress points and vulnerabilities in supply chain infrastructure and operations. Throughout this pandemic, changing stress points have put companies under severe pressure, bringing supply chain risks to their attention, which could have caused issues at a future date.

It is now imperative to troubleshoot faults detected in supplier networks to ensure that businesses are protected from additional waves of the pandemic – or any other unexpected shocks in the supply chain. The pandemic has disrupted market dynamics, increased risks to long supply chains, reprioritised patient treatments and set up a forthcoming explosion of pent-up demand for postponed elective procedures. Failure in the medical device supply chain simply cannot be an option, as a lack of supply may impact the scheduling of future treatments and, ultimately, put lives in danger.

Any business continuity policy should comprehensively plan for operational continuity, disaster prevention and business recovery, in order to minimise the impact of disruptions on product supply. Within this framework, assessing supply chain risks must be an iterative process, where risks are mitigated as much as reasonably practicable within the agreed cost constraints of the business. It is true that, by definition, supply chain models come with risks. For instance, while the just-in-time model offers major benefits, such as reduced storage fees and much greater flexibility in inventory management, there is a very slim margin of error. A fresh look at the risks involved is well overdue.

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MANUFACTURING PLANTS

First, risk must be reassessed within manufacturing plants. There must be clear schedules and guidelines in place to check that manufacturing controls are working as expected. This could include a review of engineering spares policies, usage for all equipment and assets, and checking that service level agreements are in place where needed.

Each key process in the manufacture of medical devices must be reviewed in light of recent pandemic experiences. Are they still fit for purpose given what we have learned? Have risk parameters changed? Are new risk mitigation strategies required? Once this analysis is complete, the business needs to ensure that they are agile and flexible enough to respond to changes in customer demand. Additional investment may be needed here, for example in moulding or assembly capabilities across alternative or multiple sites, or in alternatively sourced materials.

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NEW PRODUCTS

Next, it is advisable to take a fresh look at products in development. The production and distribution model has to be built with initial launch requirements and subsequent scaling according to demand in mind. This will vary according to product; one scenario might be planning for a bespoke device design for individual customers (such as an autoinjector), while another case may be a platform design for multiple customers (such as a safety device for prefilled syringes) with an initially low volume but a forecasted growth to high volume. The business will therefore need to identify any potential risks to ongoing supply from initial launch, through product growth and into the projected demand. A sound scale-up strategy in line with forecasted demand will allow the business to make appropriate decisions related to tool investment, tool cavitation, assembly investment or transitions from low-volume engineered fixtures to full automation.

VULNERABILITIES

One survey of supply chain professionals in the medtech industry identified supply shortages (15%), lack of alternatives (12%) and delays in production (12%) as key post-pandemic concerns.[1] The polymer industry has not yet recovered from the effects of the pandemic, and downstream markets that use polymers (such as the medical device market) are experiencing longer lead times from suppliers and extended door-to-door shipping times for multiple routes and shipping lanes.[2] There are various reasons for these delays, including a surge in demand for plastic products (such as appliances), a global shortage of shipping containers and interruptions in production schedules.

Companies will need a broader and more rigorous tracking and management process to improve the quality of information about their supply chain, and to ensure that this information is as up to date as possible. The earlier they receive information on potential disruption to supply, the quicker they can implement mitigation activities to avoid or minimise impacts.

There may be further vulnerabilities among suppliers that are not yet known. Based on their re-analysis of their supply chain, businesses may need to make some bold decisions to mitigate these issues. To avoid missing any weak areas, they must cover the following points in their review:

- Manufacturing suppliers' site changes, mergers, acquisitions, market volatility
- Regulatory compliance (current and future trends)
- Product lifecycle reduction, such as the obsolescence of raw materials
- Supplier constraints, such as capacity, capability, low-volume challenges and logistical risks
- Supplier solvency and financial health
- Risks due to supplier reliance on raw materials and concentration in countries likely to be impacted by climate change
- Supply chain disclosure aligned with appropriate policies, such as commitment to low carbon emissions
- Reliance on single-sourced key strategic items
- Supplier material/process changes and notification of change
- Uncertainty in and level of understanding of the supply chain, role of distributors, upstream manufacturers, complex supplier networks, complete processes and supplier maps
- Pre-screening and auditing of supplier quality:
  - Organisation quality process assets
  - Manufacturing/processing equipment
  - Potential internal process failures.

SUPPLY CHAIN MAPPING

All this data can be used to draw up a supply chain map to provide a clear overview for consistent, effective risk scoring and assessment (Box 1). This is a vital tool, both in today's post-pandemic reappraisal, and then on an ongoing and regular basis going forward. Mapping out the process will support regulatory activities, such as tracking economic operator compliance under the EU Medical Device Regulation, which makes manufacturers, importers and authorised representatives jointly and severally liable for nonconformities. For all key purchased and manufactured items, armed with the product's bill of materials, the procurement path of tier one and sub-tier suppliers can demonstrate:

- Single source relative supply chain risk score
- Material demand chain: material type, processes, distribution, sub-tier suppliers (first level)
- Supplier names, sites and geographical locations
- Dual-source alternatives and preferences for primary and secondary sourcing

BOX 1: ASSESSING SUPPLIERS

Owen Mumford assesses the following across all platforms within the supply chain using quantifiable weighted criteria:

- Quality performance of the supplier
  - Delivered product
  - Certification
  - Audit performance
  - Quality improvement
  - Supplier-related complaints and non-conformance report responses.
- Commercial aspects
  - Supplier dependency
  - Supply chain risk
  - Ability to deliver performance
  - Strategic importance
  - Frequency of orders
  - Financial health.
- Supplier features
  - Market changes
  - Quality management systems
  - Quality organised strength
  - Sub-contracting.
- Manufacturing risk
  - Criticality to process
  - Multi-code per supplier
  - Single-source or multi-site
  - Qualification lead time.
- Geographical risk
  - Natural disasters.

- Strategic and generic procurement supplier agreements, including robust, active notification of change processes and aligned safety stock policies
- Validation level information and recovery time objectives
- Commercial engagement splits for dual-sourced fully validated supply chains.

Every medical device manufacturer will discover different patterns of how risks have morphed as a result of covid-19, and must therefore carry out a deep and urgent reappraisal of their supply chain as they are likely to consistently encounter the danger of commercial damage if they fail to do so. Some of the changes we are now experiencing are likely to be permanent, and the pandemic has alerted businesses, governments and regulators alike to risks in the medtech supply chain that were previously under-recognised, or not even recognised at all. Those that begin their reappraisal soon are likely to be well prepared and more capable of weathering the storms of the future; such capability will rapidly become a significant source of competitive advantage.

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ABOUT THE AUTHOR

John Swift is Head of Supply Chain at Owen Mumford. He is an experienced operations programme manager with a successful track record working throughout the supply chain, covering procurement, supplier management, invention, development and manufacture, as well as promotion, sales and distribution. Mr Swift has experience in applying and adapting skills across both large corporations and SMEs, and has worked in multiple industries, including medical device, aerospace and defence, rail, chemical, automotive and printing.

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2. *Williams SC, "Plastics Shortage Hits Plastic Parts Supply Chain". ISM Blog, Apr 2021.*

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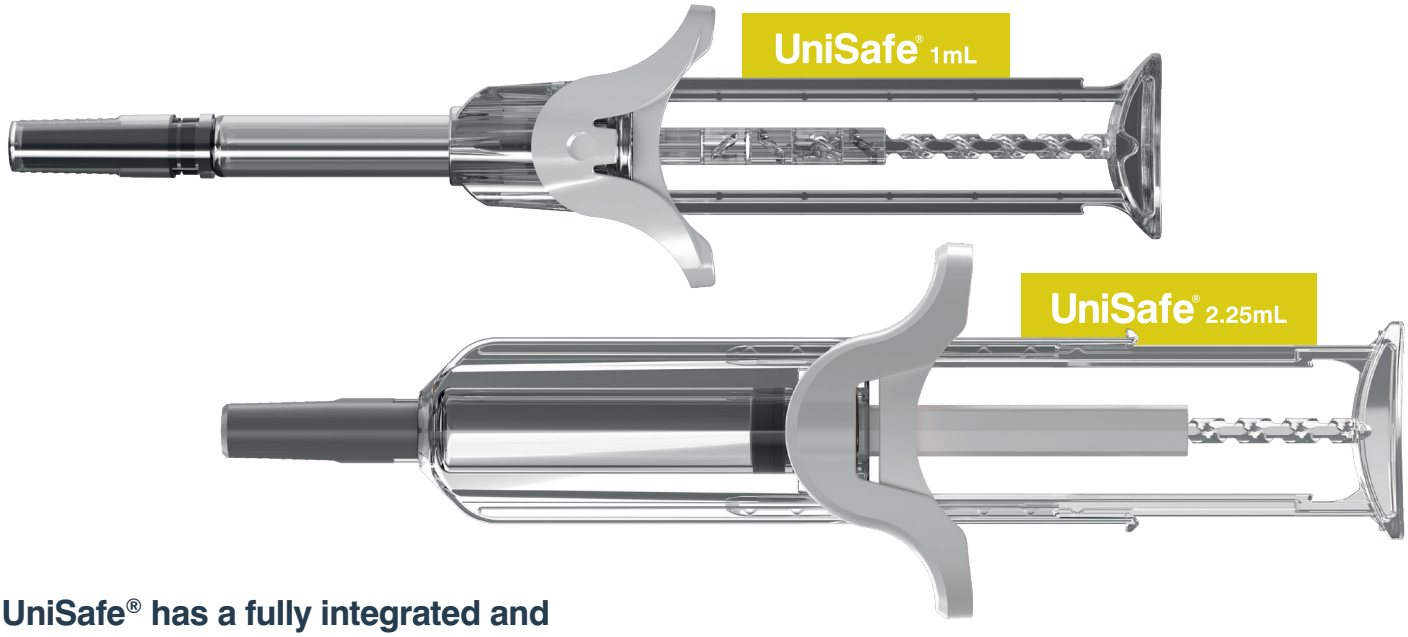

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