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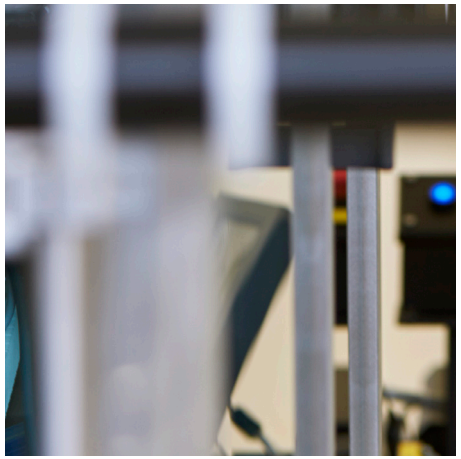
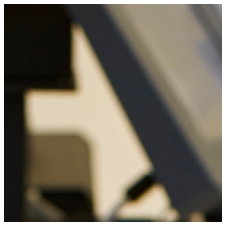
New Links in the Chain?

A report on fresh post-pandemic approaches to supply chain risk management

By John Swift





Owen Mumford
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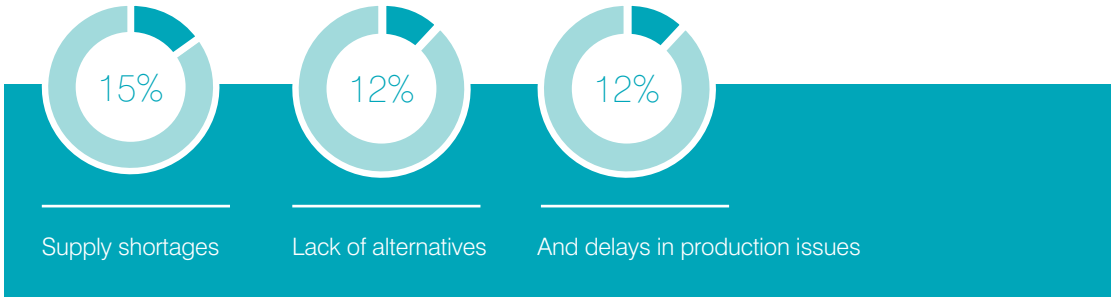
Medical supply chains
– where are we today?

The global pandemic put healthcare systems across the globe under very visible pressure, and that pressure in turn raised major challenges for a medtech industry struggling to meet unprecedented peaks (and troughs) in demand for its products. As a result of this experience, medtech companies have learned a great deal about their supply chains, with the pandemic exposing stress points and vulnerable stages in both supply-chain infrastructure and its underlying operational robustness.
Many companies have found that without the pandemic stress test, they would have unwittingly carried on bearing supply chain risks which they were simply not previously aware of. Now that these vulnerabilities have been brought to the surface, it is absolutely imperative that they are addressed. Failing to fix the flaws that have been exposed in 2020 and 2021 would leave the same supply chains at risk not only in future waves of the pandemic, but also susceptible to other supply-chain shocks[i].

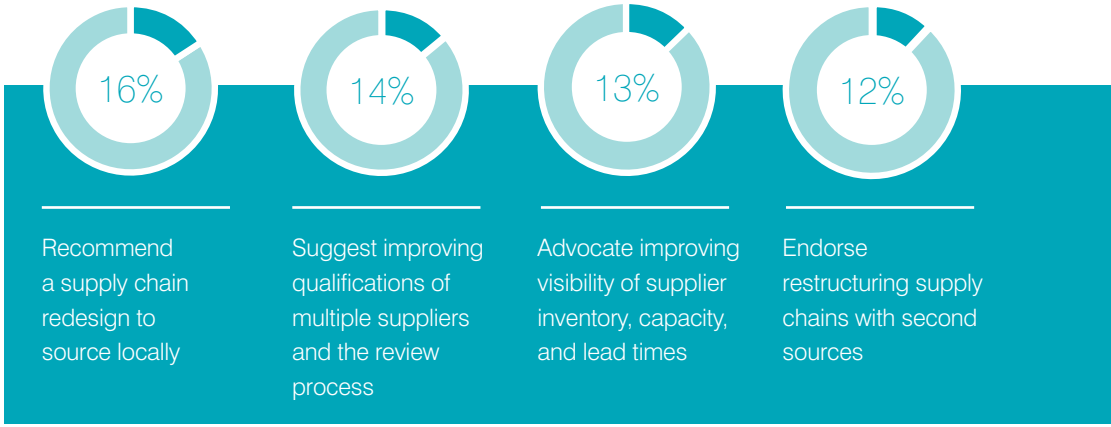
By definition, supply chain models have risks, and the just-in-time (JIT) model operates by its nature within very slim margins of error. A just-in-time approach offers major benefits, such as reduced storage fees, and much greater flexibility in inventory management. Yet the pandemic has shown a fresh look at those risks is overdue. In the case of medical devices, supply chain failure is simply not an option – where failure to supply may make planning of medical procedures and treatments increasingly difficult and ultimately put lives under threat[ii].

One commentator grappling with pandemic-induced supply chain disruption poignantly noted, "Probably the main challenge is just growing capacity throughout the world with our supply base. As you go down into the lower tiers of suppliers too, we didn't have a relationship with them so we were contacting them for the first time, introducing ourselves and asking them to increase capacity by five times the norm[iii]."

One survey[iv] identified the top medtech supply chain risks to be:

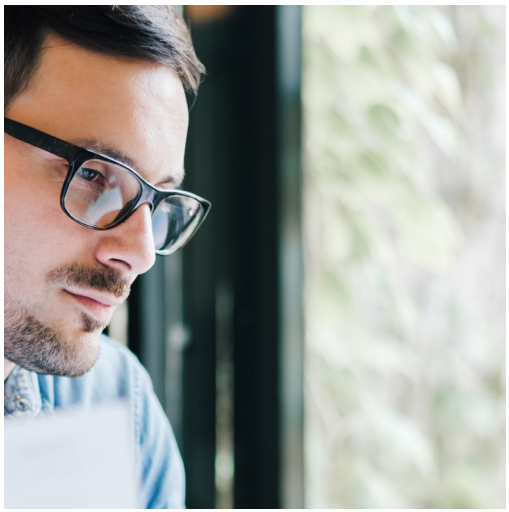


To prepare for the next pandemic or natural disaster, the same survey found:



This short paper draws on Owen Mumford's pandemic experience to reveal current thinking about medical device supply chain resilience. The authors of the paper would welcome input and comment from peers and experts who have gone through the same process.

Supply chain risk management
– first principles



It's probably best to start with a re-statement of first principles for supply chain management in the medical device sector.

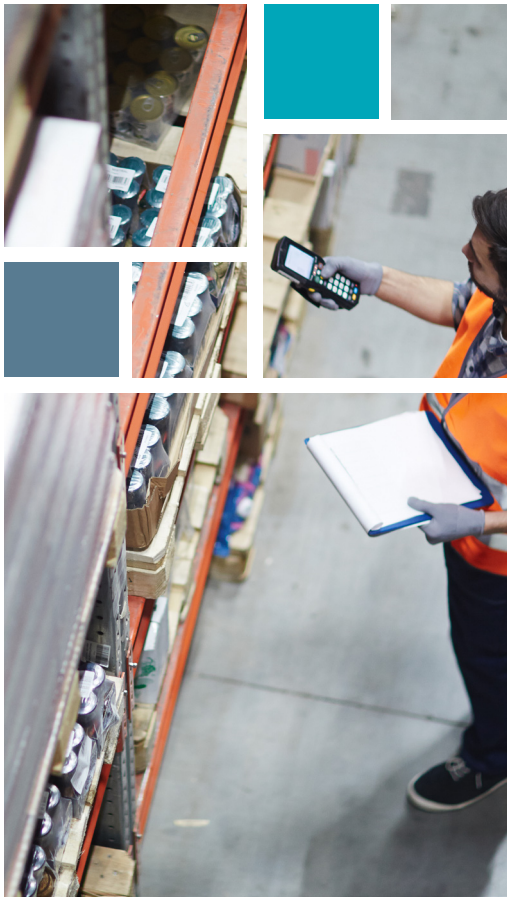
Any business continuity policy should set out a comprehensive program for operational continuity, disaster prevention and business recovery. The purpose is to provide consistent availability of quality products, maintain operations in a safe and environmentally responsible manner and protect employee and visitor access to company manufacturing and commercial sites. The objectives are to have an efficient and logical recovery of the business, minimise impact and ensure communication is effective, so that business can continue as usual, as far as possible.

An additional assurance of supply is a risk mitigation strategy developed to minimise the impact of business disruption which may be caused by either supplier, network, customer events within manufacturing sites across the globe. The mitigation of supply chain risks to as low as reasonably practicable within agreed/approved cost constraints is an iterative risk assessment process and key to uninterrupted supply.

Key risk management processes – examples

Based on these key principles, risk must first be reassessed within manufacturing plants. Risk control requires schedules and forums, as well as generally defined governance oversight to check that controls are working as expected. For example, this could include:-

- A review of engineering spares policy and usage for all equipment and assets
- What are the critical utilities supporting the processes?
- Checking of service level agreements (are they in place where needed and are they of the appropriate depth and frequency?)
- What is the lifecycle stage for key assets such as tooling, injection moulding machines, assembly equipment, calibration, test and release equipment?
- Is there appropriate capacity to support the product lifecycle and an operational strategy to support this?



For these key processes in the manufacture of medical devices, it is important to review each in the light of recent pandemic experience. Are they still fit for purpose given what we have learned? Have risk parameters changed? Are new risk mitigation strategies required? Once the analysis is complete, the business needs to make the necessary investments to ensure that the appropriate level of flexibility and agility exists in order to respond to changes in customer demand. This may include multiple site capability for moulding and assembly and site centres of excellence across various geographies.

Risk management protocols for new product launches

Next, a fresh look at emerging product developments is advisable. New products are, by definition, dynamic – and require an alignment between operational strategy and business/product strategy. This frequently requires an independent supply chain establishment process to run in parallel to product development/R&D activity. As part of that process a scale-up strategy map needs to be defined in line with forecasted demand. This will vary according to product. In one scenario you might be planning for a bespoke design for an auto-injector, for individual customers. In another case, you might have a platform design – such as a safety device for pre-filled syringes – for multiple customers, with a low volume introduction and a forecasted growth to high volume.

The production and distribution model has to be built mindful of initial launch/scale-up requirements and key triggers points driven by dates, demand volumes, capacity and lead times. This identifies any potential risks to ongoing supply through the product growth and into established demand. Clearly, the pandemic has disrupted such market dynamics – in terms of long supply chain risks, immediate reprioritising of patient treatments, and the forthcoming explosion of pent-up demand for postponed elective procedures. That picture will re-appraise events such as timing for tool investment, decisions on tool cavitation, assembly investment, transitions from low volume engineered fixtures, and semi-automation through to full automation. At all times, to reduce risk of supply, available capacity should be aligned – but ahead of forecasted demand. An effective ongoing Sales and Operation process (S&Op) ensures alignment between customer forecasted demand and available capacity.

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A fresh look at supply chain vulnerabilities – key areas to cover

We have noted that the pandemic has revealed weaknesses in extended supply chains, requiring a robust reanalysis and tough – possibly radical – decisions based on that data. In our view, that reanalysis would cover all the following points across all platforms within the supply chain using quantifiable weighted criteria.

- Manufacturing suppliers site changes, mergers, acquisitions, market volatility
- Regulatory compliance (current and any trends)
- Product lifecycle reduction i.e. obsolescence of raw materials
- Supplier constraints i.e. capacity, capability, low volume challenges and logistical risks
- Supplier solvency and financial health
- Bespoke specification requirements and demands/reliance on single sourced key strategic items
- Supplier material/process changes and notification of change (NOC)
- Uncertainty and level of understanding of the supply chain, role of distributors, upstream manufacturers, complex supplier networks, complete processes and supplier map
- Supplier quality – pre-screening and auditing
  - Organisation quality process assets
  - Manufacturing/processing equipment
  - State-of art health check
  - Potential internal process failures

Assessing Suppliers

When reviewing each individual supplier, the following framework maps key assessment points.

- Quality Performance of the supplier
  - Delivered product
  - Certification
  - Audit performance
  - Quality improvement
  - Supplier related complaints and NCR responses
- Commercial aspects
  - Suppler dependency
  - Supply chain risk
  - Deliver performance (OTIF)
  - Strategic importance
  - Frequency of orders
  - Financial Health
- Supplier features
  - Market changes
  - Quality management systems
  - Quality organised strength
  - Sub-contracting
- Manufacturing Risk / Supply Chain Centric
  - Criticality to Process
  - Multi Code per supplier
  - Single Source / Multi site
  - Qualification Lead Time
- Geographical Risk
  - Natural disaster
  - Business

A coherent view
– supply chain mapping

Finally, all this data will be used to draw up a supply chain map. A supply chain map is a graphical or tabular representation of the procurement path of tier one and sub-tier suppliers for all key purchased and manufactured items. The supply chain structure is derived from the product Bill of Materials (BOM).

The supply chain map demonstrates:

- 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
- Strategic and generic procurement and supplier agreement information like NOC (National Occupational Classification) and safety stock
- Validation level and information and recovery time objectives
- Commercial engagement splits for dual sourced fully validated supply chains

This is vital operational framework to support consistent, effective risk scoring and risk assessment within the supply chain, both in today's post-pandemic reappraisal, and then on an ongoing and regular basis.

Conclusions

The world has changed; and some of those changes will be permanent. The pandemic has exposed risks in the medtech supply chain which had previously either been under-recognised or even not recognised at all. Every medical device manufacturer will discover a different pattern of how risks have morphed as a result of COVID-19; but any manufacturers not conducting a deep and urgent re-appraisal of their supply chain are likely to encounter a consistent challenge – commercial damage. This short paper has aimed to set out – for general management in the industry – the key factors that this urgent re-appraisal should cover.

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Footnotes

i. McKinsey & Company, The resilience imperative for medtech supply chains, 18 December 2020

ii. Med-Tech Innovation, Vulnerability in the medical supply chain - time for a shake up, 29 March 2021

iii. MedTech Dive, How COVID-19 is challenging and changing medtech supply chain management, 27 July 2020

iv. Managed Healthcare Executive, Study Reveals Path to Recovery in the Global Medical Device Supply Chain, 11 November 2020

OMPS/events/rep/ob/0321/7

John Swift

John Swift is Head of Supply Chain at Owen Mumford Ltd. He is an experienced operations program 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. He is experienced 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.