

Purchasing Controls

(case studies)

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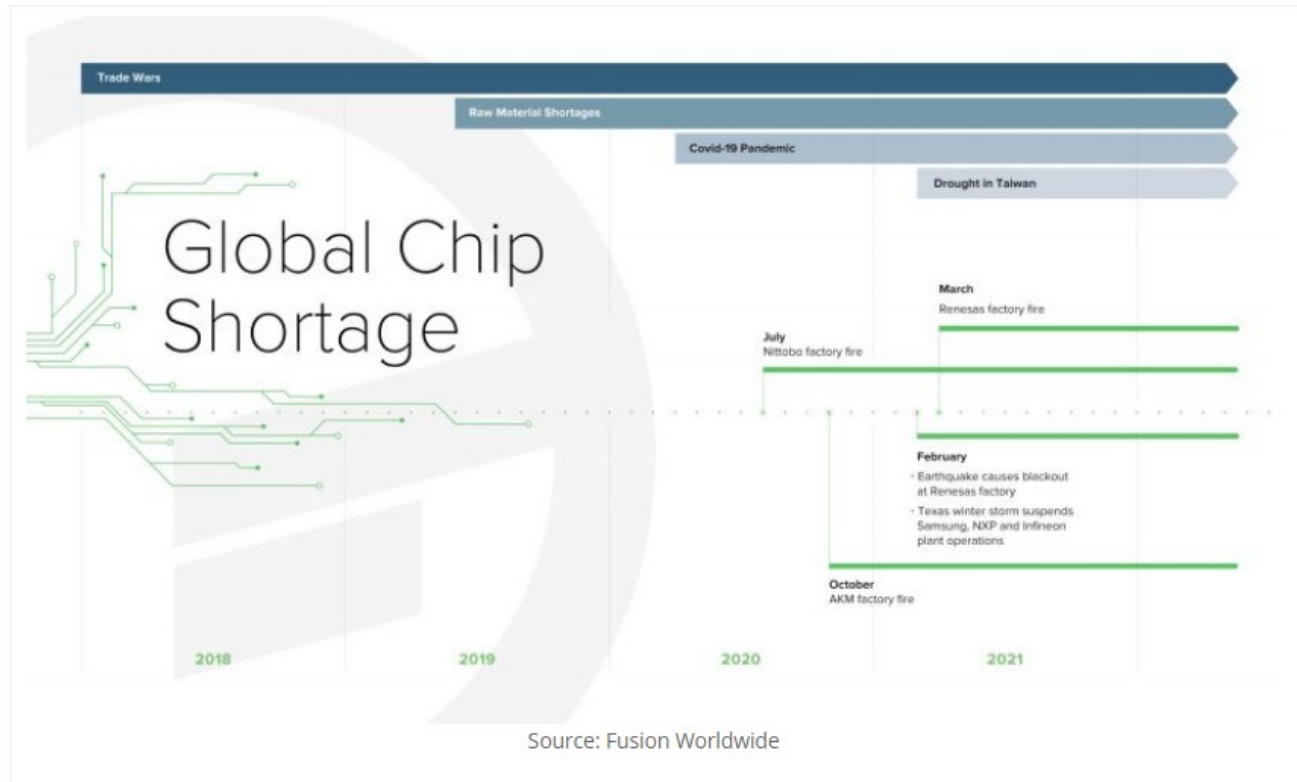
Supply-Chain Snags Create Shortages Of Lifesaving Medical Supplies In U.S.

“There are probably hundreds of outages of items that we order that do not come in...”

“With just-in-time ordering, the health system relies on distributors to deliver supplies quickly rather than hospitals keeping them in stock. “Many of those things on a daily basis don’t show up...””

Global Chip Shortage's Latest Worry: Too Few Chips for Chip-Making

<https://www.wsj.com/articles/global-chip-shortages-latest-worry-too-few-chips-for-chip-making-11651575601>



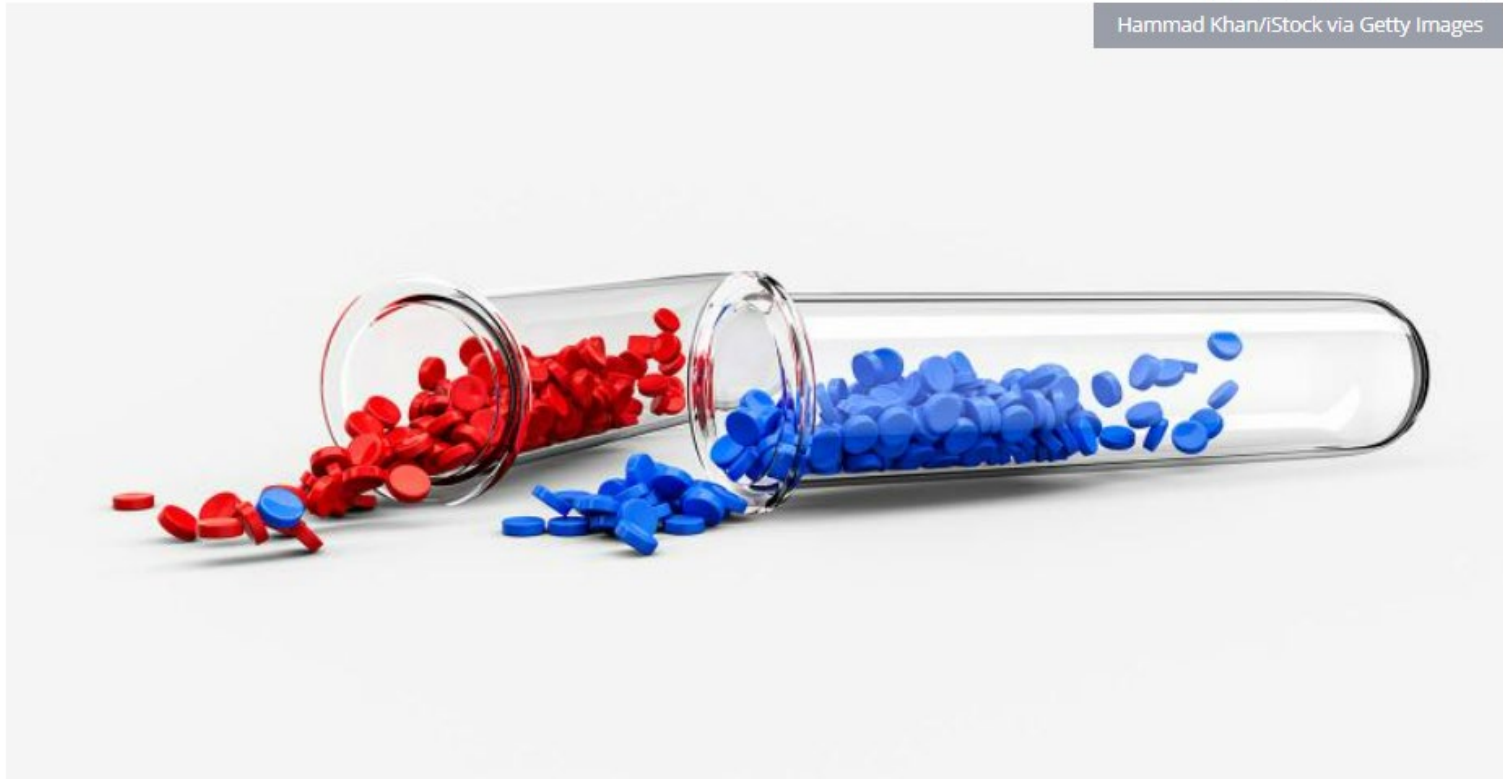
<https://www.ept.ca/features/global-chip-shortage-a-timeline-of-unfortunate-events/>



Resin Price Report: Soaring Monomer Costs Push Up Polypropylene Prices



Hammad Khan/iStock via Getty Images



Challenges in polymer-grade propylene production limit critical monomer availability.

Posted by Staff | Mar 13, 2023





What if your supplier gets a WL?

- Your supplier may get some sort of regulatory action that requires significant remediation and they need some down time to fix the issues



What do we do about it?

- “just-in-time” systems pose challenges
- Trade wars, natural disasters, factory accidents, etc. are continued possibilities, if not certainties, that must be planned for.
- So... How do we build resiliency into our systems?

Heart Pump (LVAD) Ventricular Assist Bypass



Product Code DSQ, Class III



Used with individuals with advanced heart failure who meet certain criteria



Example: patients being considered for a heart transplant may need to have an LVAD implanted if they are unlikely to survive until a donor heart becomes available



Implantable pump designed to help the heart pump blood



Mechanical circulatory support pump used for advanced heart failure patients needing short- or long-term mechanical circulatory support



Includes a system controller and batteries

Case Study 1: Building Resiliency

- You are a heart pump (LVAD) manufacturer and have encountered shortage of a critical component for your medical device. You cannot get batteries from your qualified supplier based on shortage in the market.

Case Study 1: Shortage of Critical Component

- In light of these events, discuss the following questions and consider what actions you should take...

Case Study 1: Shortage of Critical Component

- Question 1:

What are some of the things you must consider in **planning** and who at your firm needs to be involved in this decision-making and what are their functions?

Case Study 1: Shortage of Critical Component

- Question 2:

What **criteria** will you use to evaluate new suppliers for this critical component?

Case Study 1: Shortage of Critical Component

- Question 3:

What **actions** must you take to **evaluate** the supplier and the component itself?

Case Study 1: Shortage of Critical Component

- Question 4:

What types of **controls** will you put in place at the component manufacturer and at your facility? What caveats must you consider?



FDA & Industry Perspective

Consider Requirements

21 CFR 820.50

Establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements

21 CFR 820.50(a)

1. Evaluate based on ability to meet specified requirements
2. Define type and extent of control
3. Records of acceptable suppliers

21 CFR 820.50(b)

- Establish and maintain data for specified requirements
- Change control agreements
- Approved per 820.40

How do we build resiliency?

GHTF/SG3/N17:2008



FINAL DOCUMENT

Title:

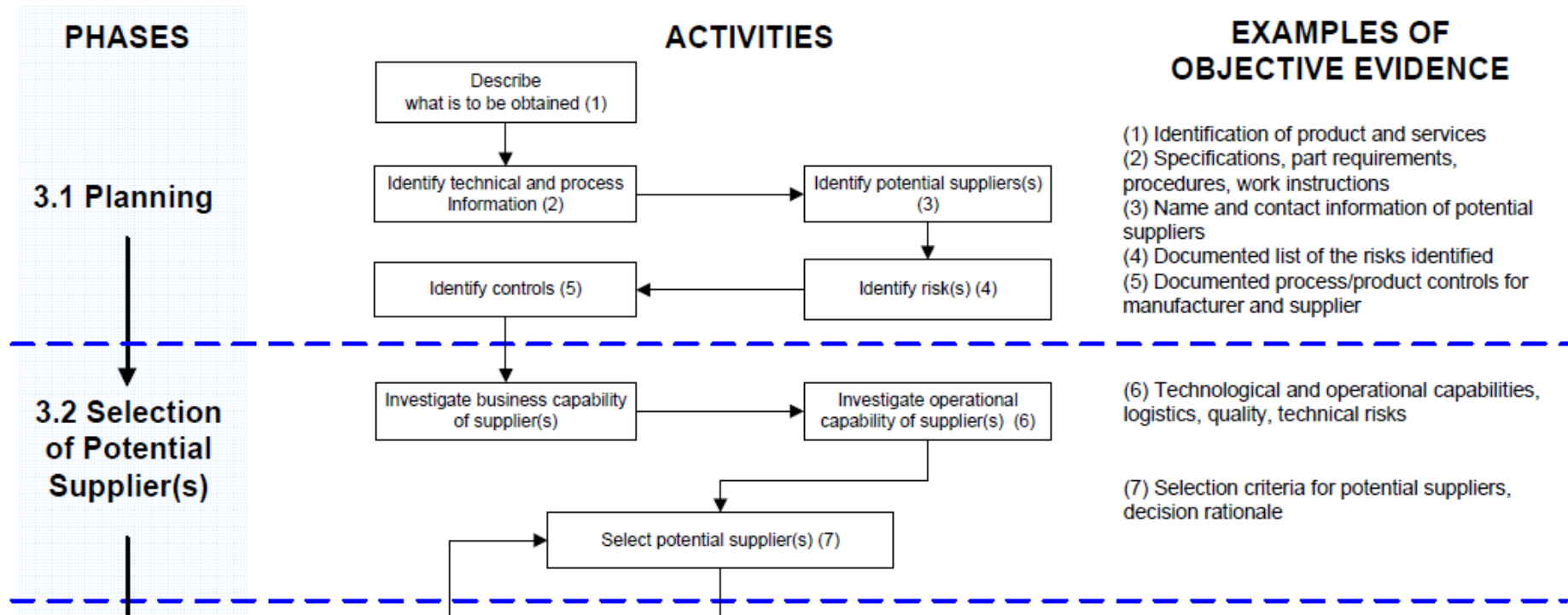
Quality Management System – Medical Devices –
Guidance on the Control of Products and Services
Obtained from Suppliers

How do we build resiliency?



Guidance on the control of products and services obtained from suppliers.

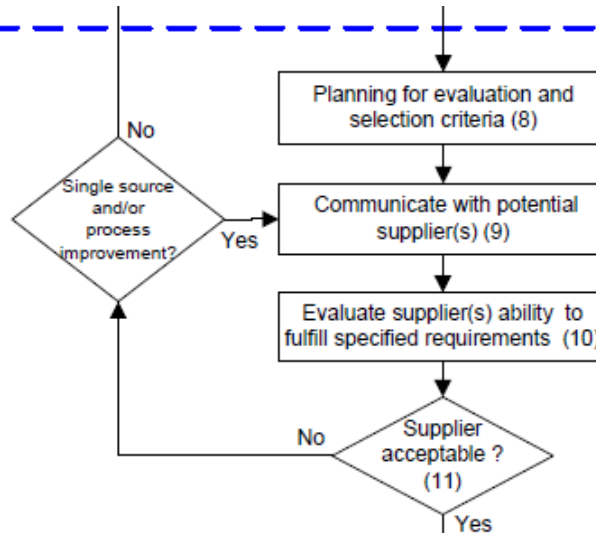
GHTF/SG3/N17R9:2008



How do we build resiliency?

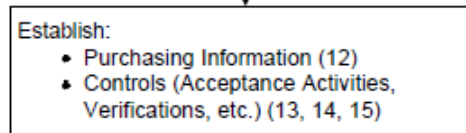


3.3 Supplier Evaluation and Acceptance



- (8) Documented evaluation and selection criteria
- (9) Documented initial agreement(s)
- (10) Documents and records
- (11) Documented decision and rationale

3.4 Finalization of Controls



- (12) Contracts, purchase orders, etc.
- (13) Acceptance procedures; purchasing requirements
- (14) Specifications and requirements
- (15) Records of review and acceptance



Case Study 2

Contract Manufacturer Issued a WL

You have just been informed that the contract manufacturer of your spinal implants has been issued a Warning Letter.

Case Study 2

Question 1:

Who (i.e. responsibility and expertise) in your company should be on the team that you assemble to address this warning letter?

Case Study 2

Question 2:

What would you review at your company (OEM)? At the contract manufacturer?
What actions would you take?



FDA & Industry Perspective

Questions



