Session: Sustainability Throughout the Supply Chain: FDA Perspectives

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COVID-19 Medical Device Shortages

Testing Supplies and Consumables


Swabs & Transport Media


Blood Collection Tubes


Pipettes


Laboratory Testing Supplies


Laboratory Reagents

Test Kits

Personal Protective Devices & Ventilation


Ventilators


Respirators


Gloves

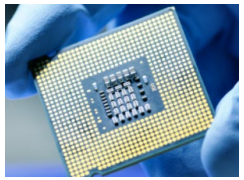

Surgical Gowns


Surgical Masks


Examination Gown

Cross-Cutting Examples


Resin


Semiconductors


Ethylene Oxide


Paper (e.g., labels)


Silicone

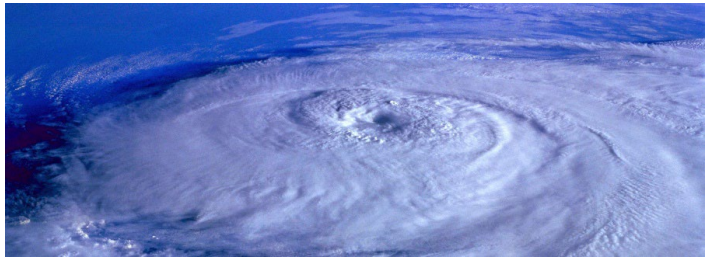
Today's Supply Chain Complexities

Supply chain disruptions pre-date COVID and will continue in the future

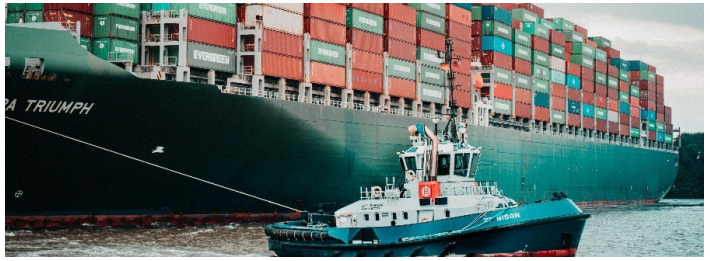
Just in Time Delivery
Minimizing inventory costs + increasing risk from disruption

Sole-Source Suppliers
Supply base consolidation

Labor + Logistics
Shortage of workers + transportation bottlenecks



Climate Change
More frequent weather disruptions + natural disasters



Geopolitical Competition
Increased trade disruption + competition for resources

Demand Shocks
Increased demand due to pandemic or post-pandemic illnesses

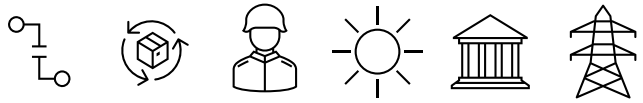
Healthcare is Critical Infrastructure

Innovation and partnership is needed to ensure medical device availability as threats are increasingly cross-cutting and systemic.

Supply Chain Pressures

1 Global Supply Chain Pressures

Supply chain pressures: Geopolitical; Climate Change; Sole Source; Regulatory; Transportation; Energy

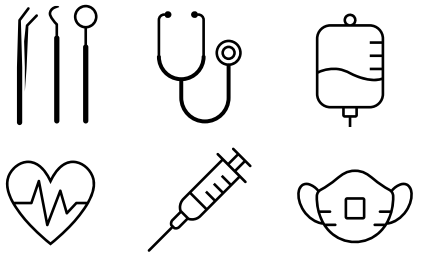


2 Medical Tech Industry vs. Overall Market

Small resource needs relative to other industries; suppliers tend to favor larger purchasers

3 Broad Impacts

Supply chain pressures impacting multiple devices and device types



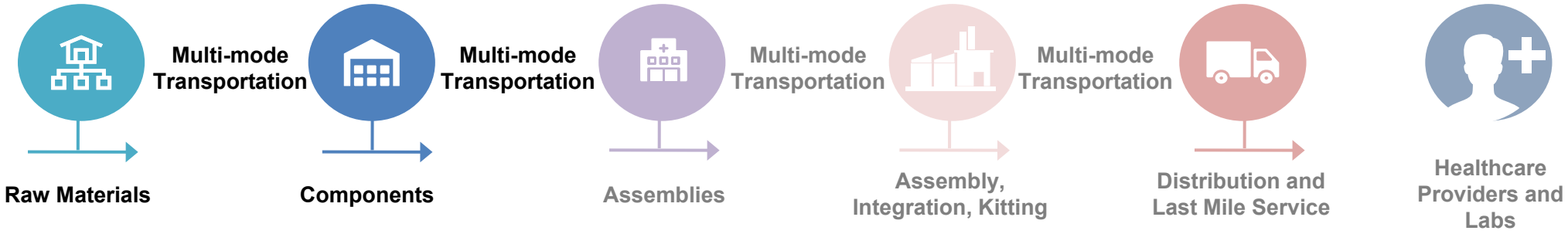
Resilient Supply Chain Program (RSCP)

Our Mission: Strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities to prevent shortages of medical devices

Protecting patients and providers means strengthening the end-to-end supply chain for critical medical devices

Raw materials ♦ Suppliers ♦ Manufacturers ♦ GPOs ♦ Distributors ♦ Transportation + Logistics ♦ Patients + Providers

Raw Materials/Components



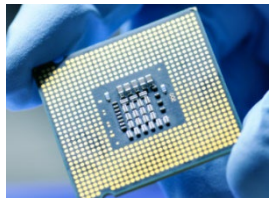
Root Causes

- Sole Source Suppliers
- Geopolitical
- Natural Disasters
- Uyghur Forced Labor Prevention Act (UFLPA)
- Market Concentration
- Labor

Supply Chain Impacts

- Resin
- Silicone
- Semiconductors
- Paper
- Cotton


Resin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Silicone

Case Study: Resin

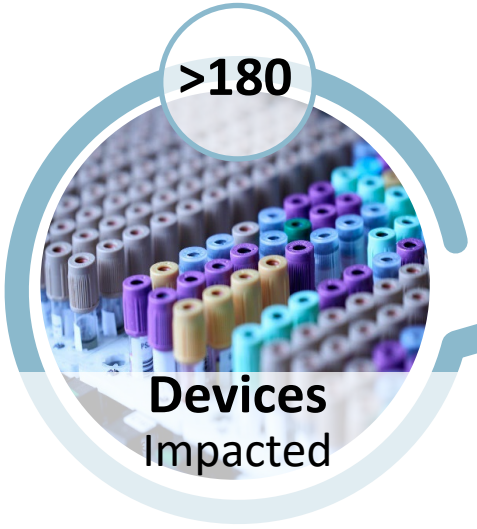
2020	Feb 2021	March 2021
Hurricanes Hanna and Laura	Winter Storm Uri	Force Majeure

FDA CDRH Response
Coordinated, Targeted Actions

Outcomes

- Impact Assessments
- Increased Allocations to MedTech
- Priority Ratings

Manufacturers
Affected



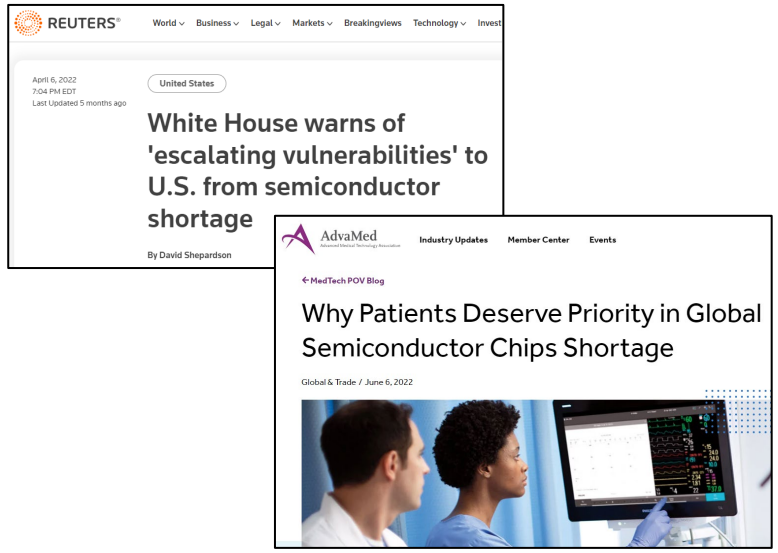
Devices
Impacted

Patients
Vulnerable Populations Exposed

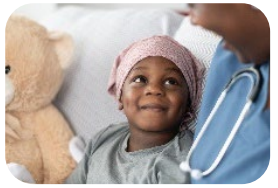
Case Study: Semiconductors

Signal	Actions
Manufacturers	Outreach, Advocate, Coordinate, Illuminate

FDA CDRH Response
Coordinated, Targeted Actions



Supply Chain Analysis and Illumination



Patient Impact Assessments

Industry Engagement

Escalation to DoC, ASPR, White House

Outcomes

- Priority Request Letters
- DPA Priority Rating
- Medical Device Advocacy
- DoC and CEO Roundtable-Awareness

Case Study: Packaging

May 2022	July/August 2022
Signals: Allocations, Converter Communication, Manufacturers)	Outreach, Coordination

FDA CDRH Response
Industry and Interagency Coordination, Analytical Insights

Outcomes

- ASPR DPA and WH COVID WG Engagement
- USG Encouraged Transparency
- Advocate-Prioritization of MedTech Industry

Stakeholder Outreach

Impact Assessments
Inform USG actions

Supply Chain Visualization
Manufacturers, Suppliers, Converters

USG Coordination
ASPR DPA Office; WH COVID Working Group

Sterilization

FDA's Role: Assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices

- FDA regulates devices which need to demonstrate adequate sterilization using method chosen by manufacturer
- Cross government coordination on sterilization issues and regulations (EPA, ASPR, White House)

EPA Action on April 11th, 2023:

- Released proposed rule regulating ethylene oxide (EtO) sterilizers of medical technology and other commercial uses through the National Emission Standards for Hazardous Air Pollutants (NESHAP) under the Clean Air Act.
- Released proposed updated of EtO registration as a sterilant under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

FDA Communications & Actions

Communications

- April 11th: Announcement of Radiation Sterilization Master File Pilot Program
- Updating FDA webpages
- CDRH Center Director Statement
  - FDA Continues Efforts to Support Innovation in Medical Device Sterilization (August 2022)

Actions

- Launched Radiation Master File Pilot Program
- Maintain 2 EtO Innovation Challenges
- Maintain the PMA Master File Pilot Program
- Launched the 510(k) EtO Master File Pilot Program
- Continued Shortage Assessments
- Continued Stakeholder Engagement

Radiation Master File Pilot Program

- Voluntary program for sterilization providers that **terminally sterilize single-use PMA approved medical devices** and **use gamma radiation or ethylene oxide (EtO)**.
  - In response to global supply chain constraints and supports sterilization supply chain resiliency
  - Sterilizers may submit Master File(s) when making **certain** changes to **sterilization sites**, **methods**, or **processes** under the specific conditions outlined in the notice
  - Help companies advance alternative and innovative ways to sterilize approved medical devices, including changing radiation sources, ***in a least burdensome regulatory approach***
- PMA holders with a right of reference by a sterilization provider may include references to Master File(s) accepted into the Pilot in **post-approval reports** describing the particular changes noted above (changes to **sterilization sites, methods, or processes** of Class III devices).

Our Role as the FDA

- Bird's Eye View
  - Interdependencies and Vulnerabilities
  - Prevent Shortages
  - Mitigate Challenges
- Alternative Suppliers
- Advocate
  - USG; Suppliers
  - Medical market allocations
- Impact Assessments

RESILIENCE BUILDING + INNOVATION

- Supply Chain Transparency
  - Data and best practices
  - Convener
- Supply Chain Master File pilots
- Alternative supplier-qualification
- Innovative regulatory mitigations
- Innovation challenges

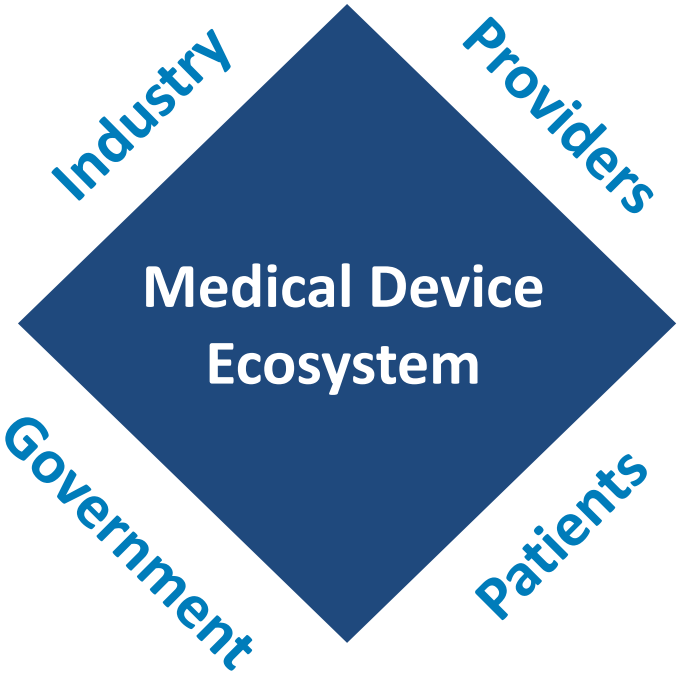
Collaboration Is Essential

No single entity can resolve these issues on its own. We must work collaboratively to proactively identify and address vulnerabilities

Shared vulnerabilities

Coordinated actions

Mutual outcomes



Trade Associations | Professional Organizations | Academia | Advocacy Organizations

How to Share Shortage Signals

Help us get ahead of potential shortages and raise awareness early

- Manufacturers can submit voluntary 506J notifications by:
  - Submitting a 506J notification via the web portal: https://fdaprod.force.com/shortages
  - Emailing: CDRHManufacturerShortage@fda.hhs.gov

- Other medical device stakeholders can submit shortages by:
  - Emailing: deviceshortages@fda.hhs.gov

We take confidentiality seriously!

Any information provided to the FDA that is trade secret or confidential information will be treated as such, consistent with 5 USC 552(b)(4), 18 USC 1905, and other applicable laws.

MEDCON

Sustainability Through the Supply Chain: Industry Perspective

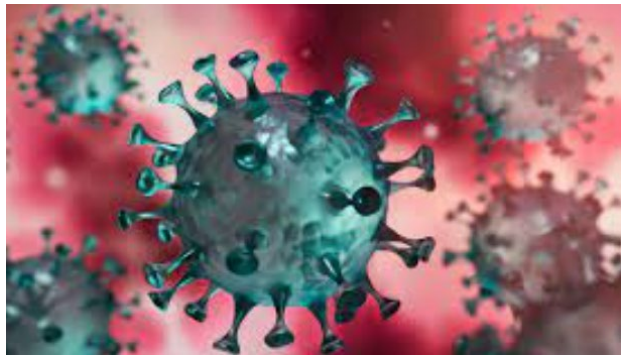
26 | April | 2023

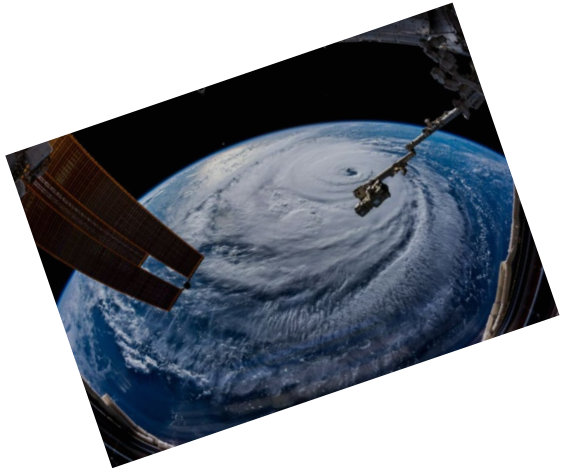
AARON BERNSTEIN – DIVISIONAL VICE PRESIDENT, PROCUREMENT - ABBOTT

MEERA BHATIA – DIVISIONAL VICE PRESIDENT, QUALITY - ABBOTT

Supply Challenges Continue to Evolve

- Supplier health and quality
- Labor shortages
- Geopolitical landscape
- Severe weather conditions
- Sole sourced materials
- Evolving regulatory environment
- Cyber threats





Pandemic Launched a Crisis in Global Supply Chains

How the World Ran Out of Everything

Global shortages of many goods reflect the disruption of the pandemic combined with decades of companies limiting their inventories.

Auto Makers Warn Chip Shortage Will Continue to Impact Vehicle Production

GM idles truck plants again, Jeep maker Stellantis sees lack of semiconductors hurting its operations

Price Hikes and Shortages: Production Uncertainty for Electronic Parts in 2021

Electronic industry expects increased prices and lead times for electronic parts due to shortages and uncertainty.

ARTICLE BY CHASE CORRELL
Updated June 16, 2021 - 5 Min Read

'It's a Roller-Coaster Ride': Global Chip Shortage Is Making Industries Sweat

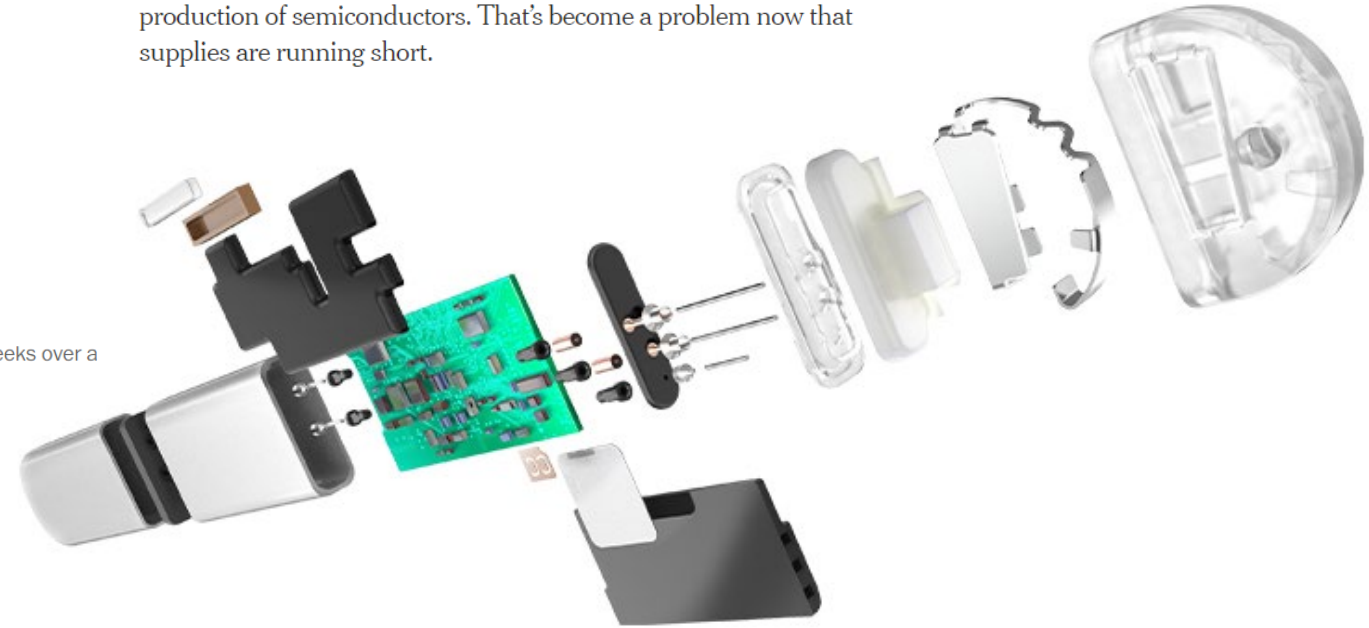
The internet-connected world is completely dependent on the production of semiconductors. That's become a problem now that supplies are running short.

'Perfect storm' creates electronic component supply chain shortages

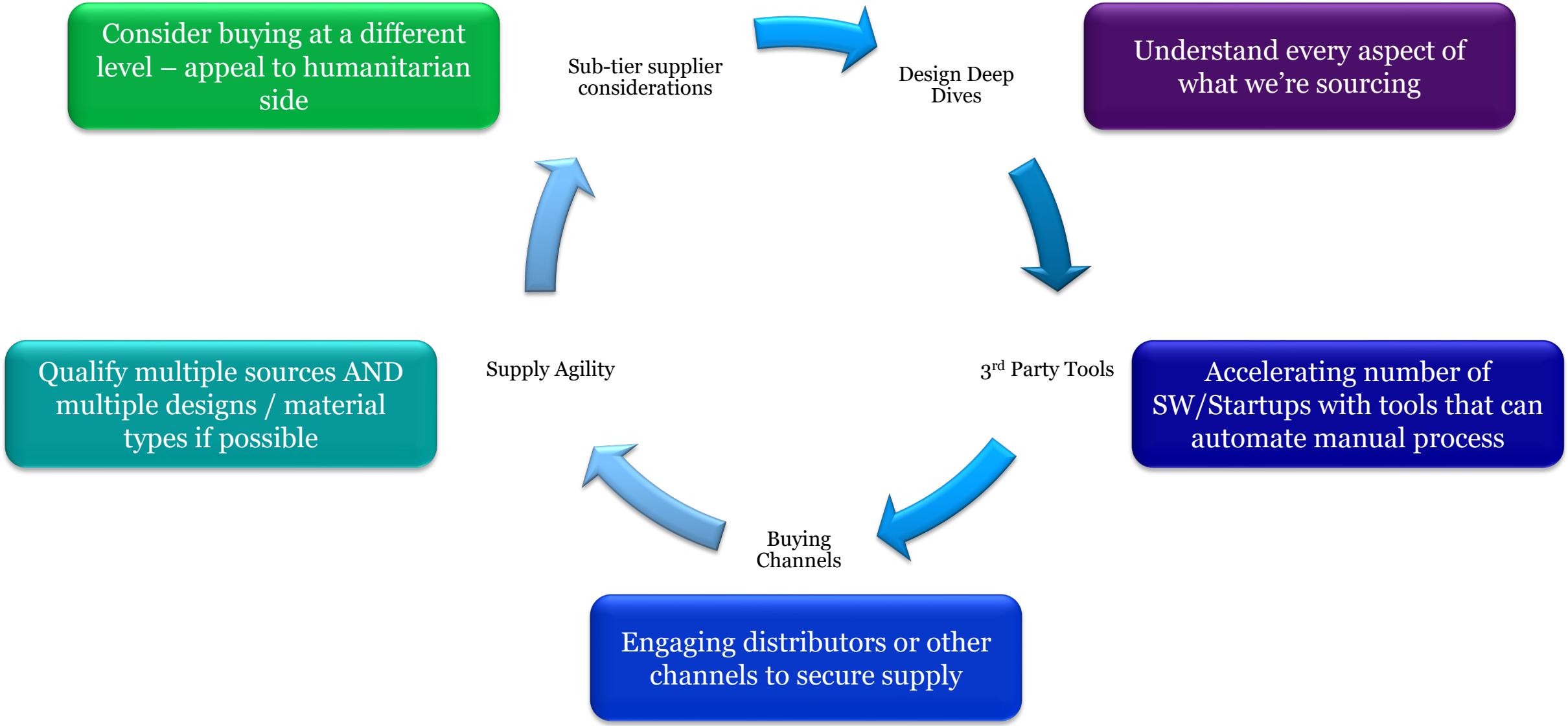
Semiconductor shortage hammering automakers, costing billions in lost production and sales

Nearly 20 auto factories in North America and Europe have cut back in recent weeks over a lack of parts.

20th April 2021
Digi-Key
Joe Bush



Securing supply when we're a small buyer



Single Sourcing – Swab Story

2019

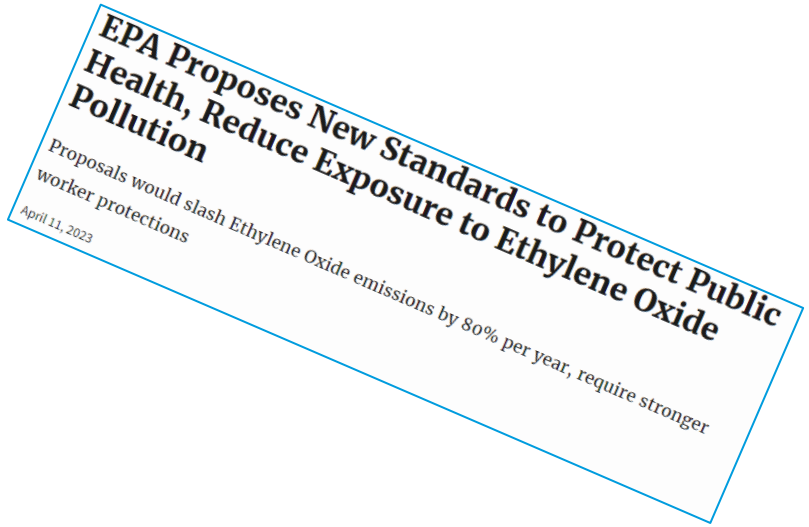
- Single Sourced Swab for Flu test
- Low volume forecasted

2020

- Leveraged existing platform to develop Covid-19 test
- Assisted on single source volume ramp up
- Qualification of additional suppliers
- Expedited all aspects of supply chain

Sterilization Challenges of Medical Devices – Ethylene Oxide

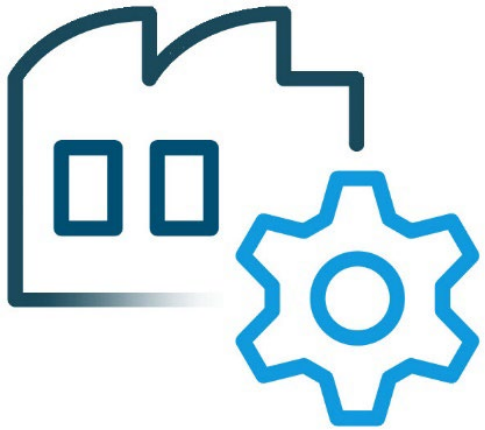
- Evolving regulations has impacted the availability of EtO Sterilization suppliers
  - Affects the output of existing sterilizers
- Feasibility, validation and ultimate product approval of alternative modalities is a multi-year process
  - Many products will not tolerate sterilization modalities
  - Evaluate alternative materials / components which will tolerate alternative modalities during design
- Partnership with FDA through multiple forums has been positive (Resilient Supply Chain Program, CDRH, Master File Pilot for changes)
- Industry groups have formed recognizing the importance on establishing and harmonizing sterilization standards and development of sustainable sterilization methods


EPA Proposes New Standards to Protect Public Health, Reduce Exposure to Ethylene Oxide Pollution

Proposals would slash Ethylene Oxide emissions by 80% per year, require stronger worker protections

April 11, 2023

Ongoing Considerations



Vertical Integration

- Allows manufacturers more supply chain control and agility
- Presents a different set of complexities for manufacturers

Design Philosophy

- Enhanced supply chain consideration in development
- Introduce greater flexibility down stream (more platforms, software and speed)

Sustainability

- Rapidly evolving landscape
- Creates supply chain risk, but also opportunity

QUESTIONS