FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

PURCHASING CONTROLS

PRESENTED TO

ORA ANNUAL CONFERENCE 2022

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

https://www.forbes.com/sites/amyfeldman/2022/05/03/supply-chain-snags-create-shortages-of-life-saving-medical-supplies-in-us/?sh=76961ca241b0

Peace in Europe 'shattered' as Russia invades Ukraine

https://www.cnn.com/2022/02/24/europe/ukraine-russia-invasion-thursday-intl/index.html

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

Around 20% of global population under coronavirus lockdown

https://www.theguardian.com/world/2020/mar/24/nearly-20-of-global-population-under-coronavirus-lockdown

Resin buyers struggle with high prices and short supply

https://www.supplychaindive.com/news/preparation-mitigated-effects-of-hurricane-ida-but-resin-shortage-persists/607600/

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)

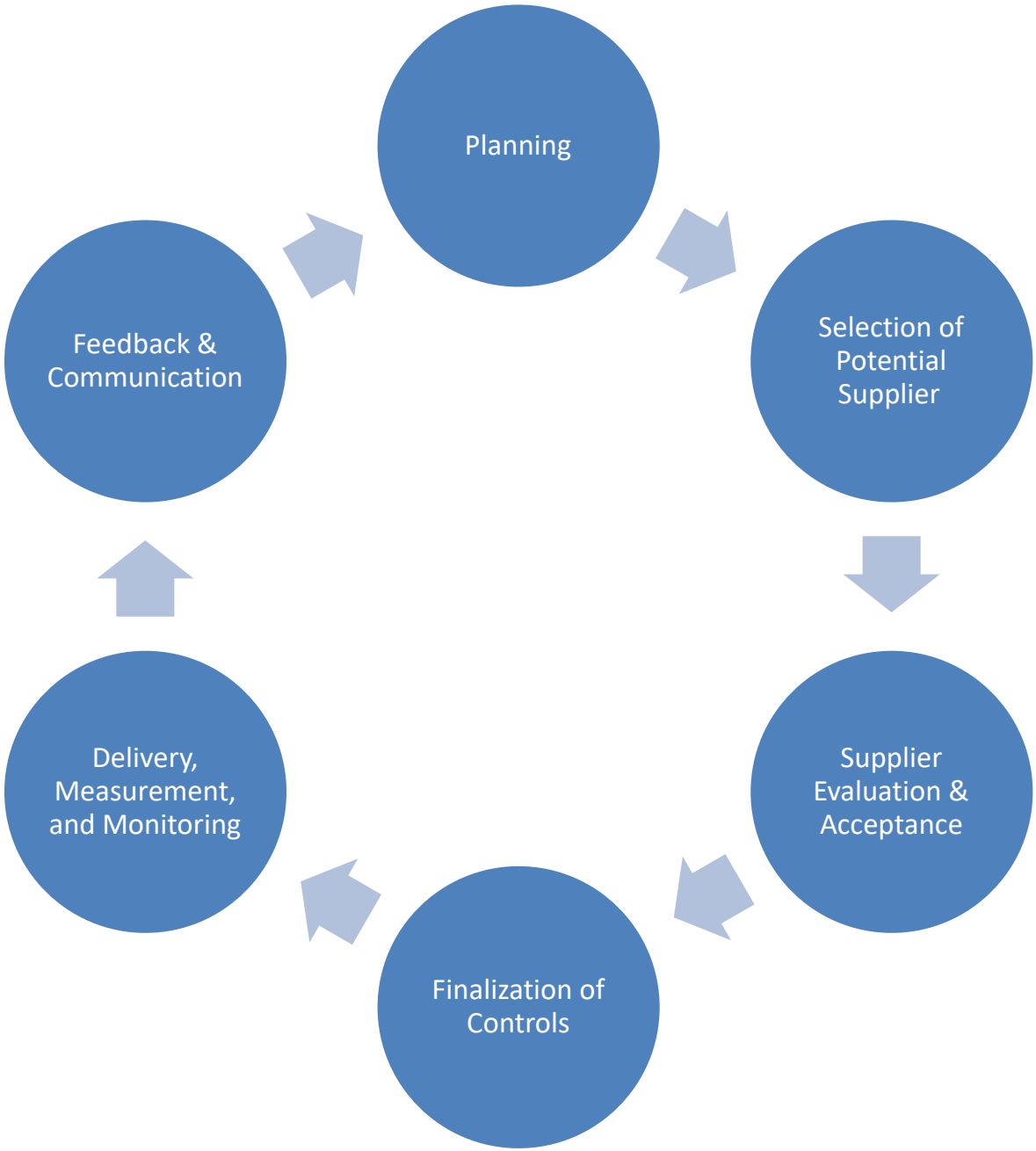
1. Evaluate based on ability to meet specified requirements
2. Define type and extent of control
3. Records of acceptable suppliers

21 CFR 820.50(b)

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

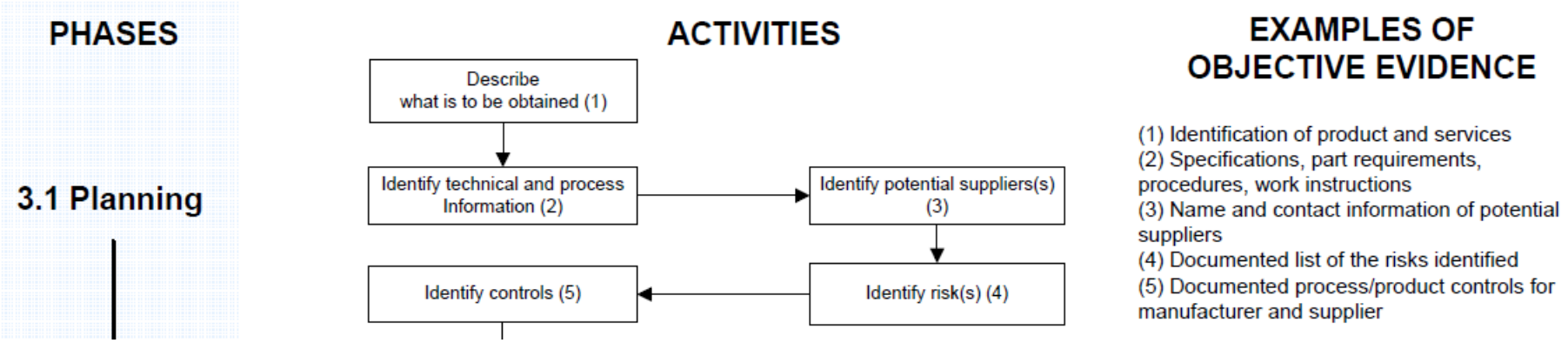
Global Harmonization Task Force(GHTF)

- Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers
- Nonbinding Guidance but developed in consultation with FDA
- Provides good framework for Purchasing Control process
- Highlights several areas of consideration which have had significant impact recently such as capacity and financial health of suppliers


Planning
Selection of Potential Supplier
Supplier Evaluation & Acceptance
Finalization of Controls
Delivery, Measurement, and Monitoring
Feedback & Communication

Planning

- Products/Services to be obtained
- Technical/Process Requirements
- Risk
- Controls



Planning
(Supply Chain Resiliency)

- Evaluation of second/sub-tier suppliers
- Planning for disaster that can be anticipated even if rare
- Stockpiling
- Multiple Suppliers
- Onshoring/Off-Shoring/Regional Supply Chains
- Integration with Suppliers

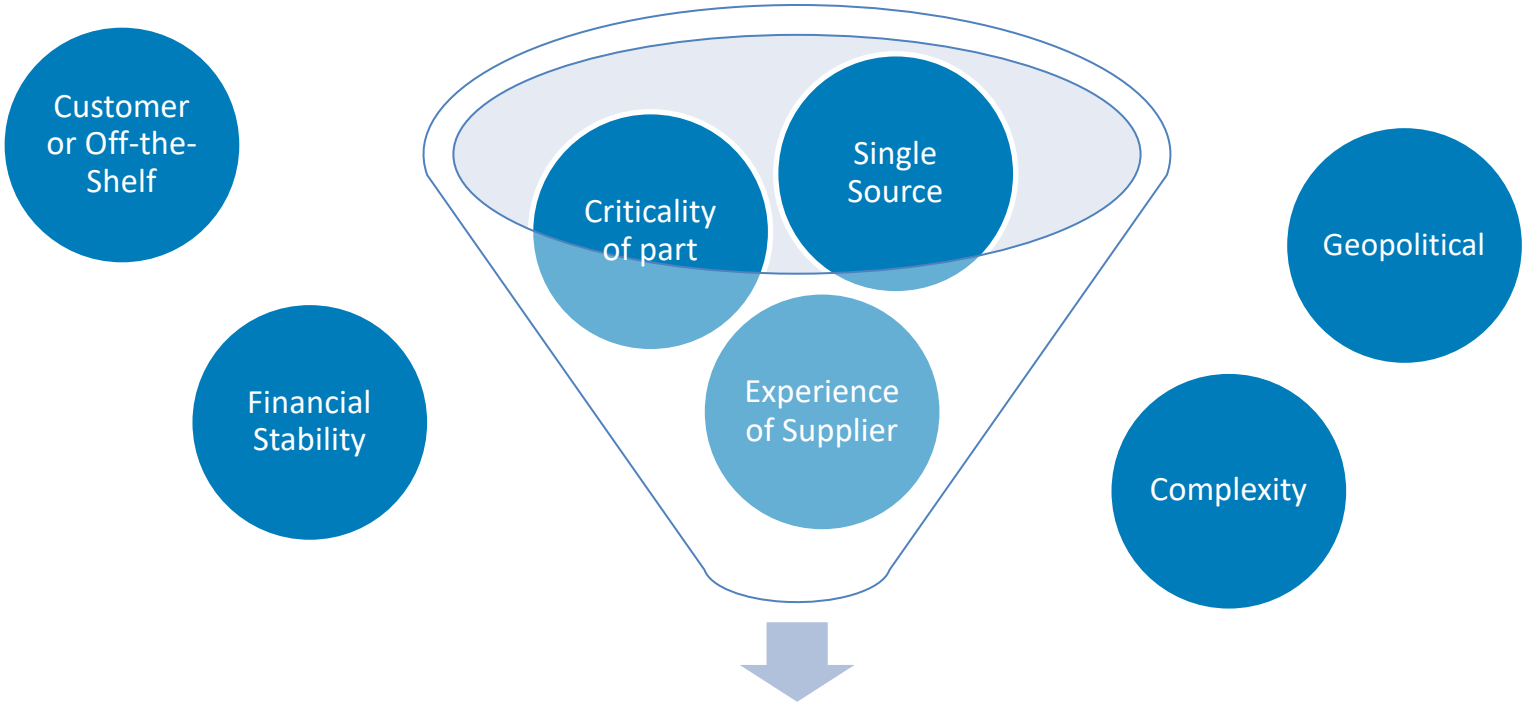
Ability to Meet Specified Requirements

820.50(a)(1) - Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

- Specifications
- Standards
- SOPs
- **Validation**
- Recordkeeping requirements
- **Capacity**
- Timeliness
- Regulatory reporting
- Expiration/Use-by Dates
- **Financial health**

Detail of Requirements

Preamble Comment 115 - The extent of the specification detail necessary to ensure that the product or service purchased meets requirements will be related to the nature of the product or service purchased, taking into account the effect the product or service may have on the safety or effectiveness of the finished device, among other factors…



Quality Requirements

Supplier will have a sampling plan as required by 21 CFR 820.250

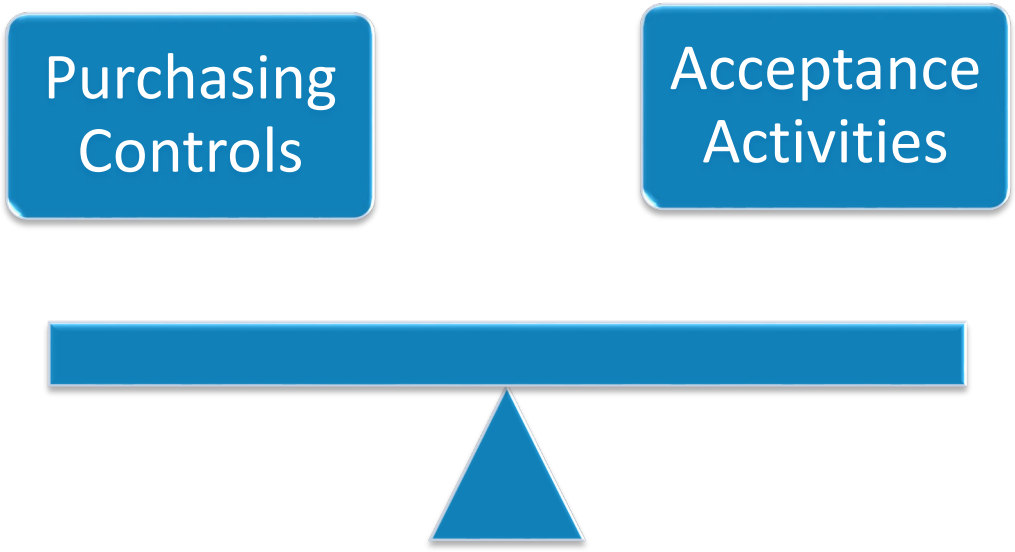
Supplier will conduct finished acceptance activities using ANSI Z1.4-2003, AQL 1.0, General Inspection II and inspect to approved design drawing.

Supplier will validate adhesive bonding process

Supplier will notify customer of all identified nonconforming products and provide results of investigation.

Type and Extent of Control

- Based on risk
- Balance of supplier control and acceptance activity
- Practicality of oversight
- Availability of cooperation



Type and Extent of Control

Common Pitfalls

- Inadequate risk assessments
- Lack of cooperative relationship
- Relying too heavily on third party audits
- Lack of clarity of reporting requirements
- Lack of routine reviews
- Lack of verification of implementation
- Failure to take advantage of resources like audit reports

506(J)

- Added under CARES Act
- Pertains to public health emergency
- Requires certain manufacturers to report potential shortage situations
- Also allows for voluntary reporting mechanism
- Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised) | FDA

Shortage Guidance

- https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage

- MITIGATING AND PREVENTING MEDICAL DEVICE SHORTAGES AND PRIORITIZING PUBLIC HEALTH

- Device Shortage List

Purchasing Control Training

- https://www.fda.gov/files/drugs/published/Purchasing-Controls---Devices.pdf

- CDRH Learn | FDA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