

Good Supply Practices

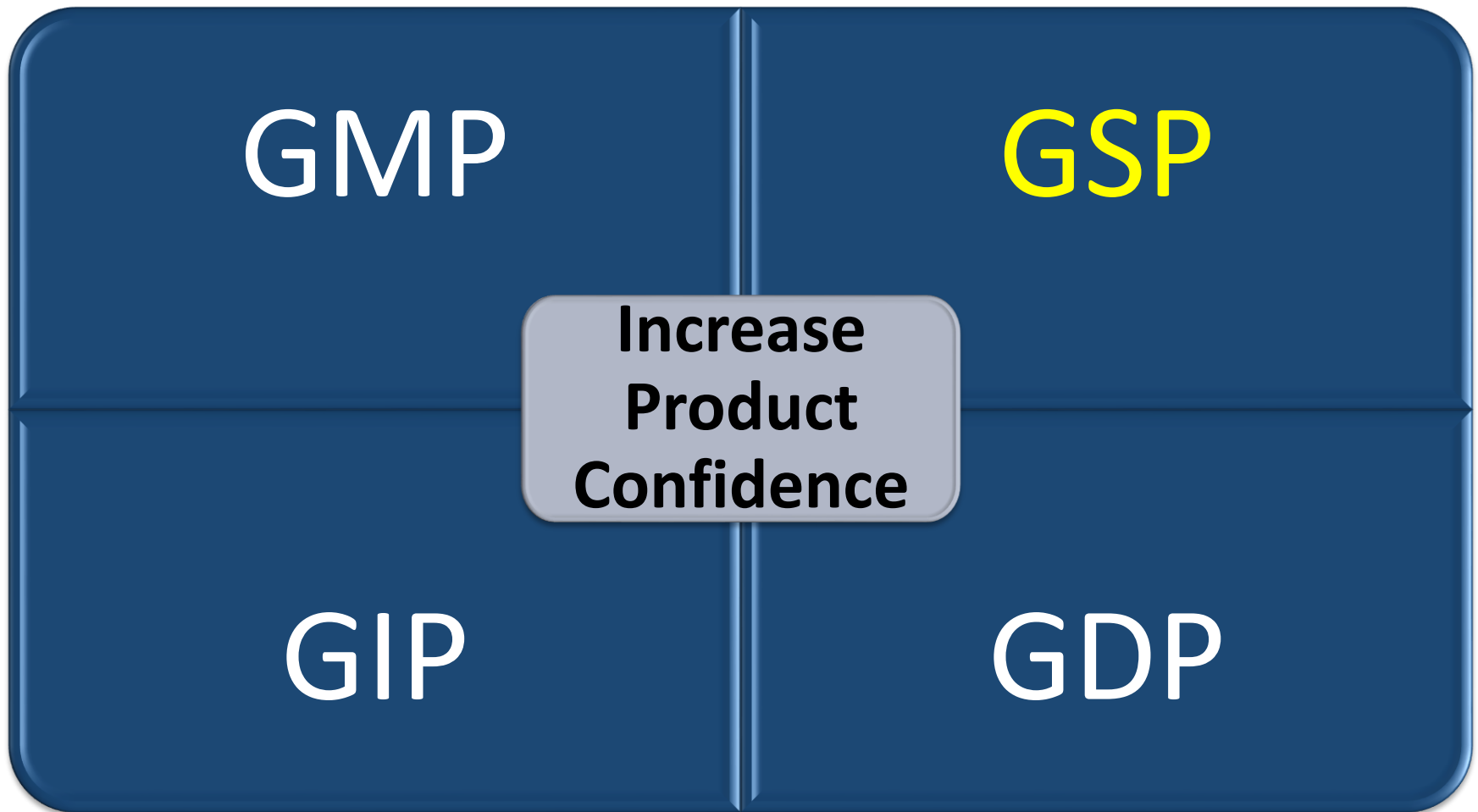


How Qualified Are You
to be Part of Your Own
Supply Chain?

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Good Supply Practices

- USP and Xavier partner on the development of a new general information chapter on the GSPs
- Xavier approached USP with the GSP work from the FDA/Industry team
- Through USPs public standard setting process, this work will have a global platform for the benefit of all industries





5 countries

39 companies

162 key suppliers

2 industries + FDA

4 New Key Concepts

1 Major Paradigm Shift

11 Practical Solution Tools

4 New Concepts

1. Supply by Design
2. Cross-Functional Alignment
3. Self-Qualification
4. Relationship Risk Mapping



Key Differentiator!

1. Setting the Foundation

- ✓ a. Cross-Functional Team Formation
- ✓ b. Self-Qualification
- c. Knowledge Management (and supply chain intelligence repository)
- d. Supply Chain Risk Management Triage

2. Internal Alignment

- a. Internal Alignment on Material Requirements
- ✓ b. Internal Alignment on Supplier Requirements
 - Single Source vs. Multi-Source
- c. Communication Strategy

3. External Alignment

- a. Supplier Engagement
- b. Holistic Supplier Qualification
- ✓ c. Relationship Risk Mapping

4. Lifecycle Management

✓ = What we will cover

Understanding the “why” behind the Good Supply Practices

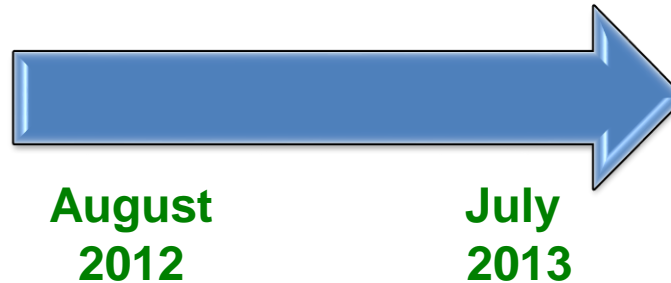
We are unable to reliably and consistently ensure the supply of incoming materials used in products to serve the Pharmaceutical and Medical Device industries

Therefore, we need greater assurance that **suppliers** can reliably and consistently supply safe and quality materials/products to limit adverse impact on end-user safety and brand equity

1. We do not understand our own product and process
2. Our systems are not robust
3. We do not behave in a way that engenders trust

Notice the “We”

**Our Suppliers
Are Causing
Problems**



**We are
Causing
Problems**

August 2012: we wanted to focus on certifying our suppliers

July 2013: top data is pointing to ourselves as the root cause

Action Provoking!

Insanity: doing the same thing over and over again and expecting different results.

~ Albert Einstein

Supplier Input – Voice of the Customer

Total Respondents

Food

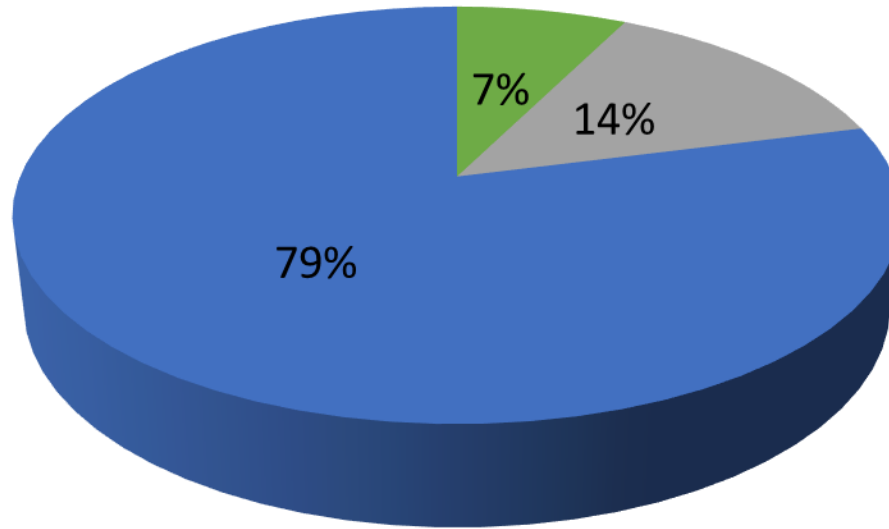
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Drug

22

Device

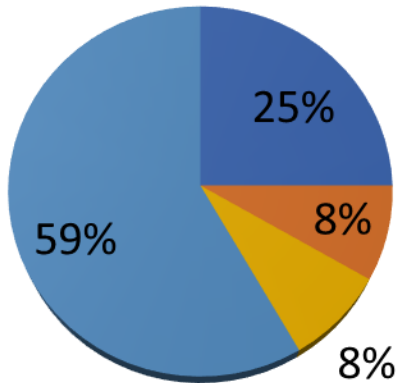
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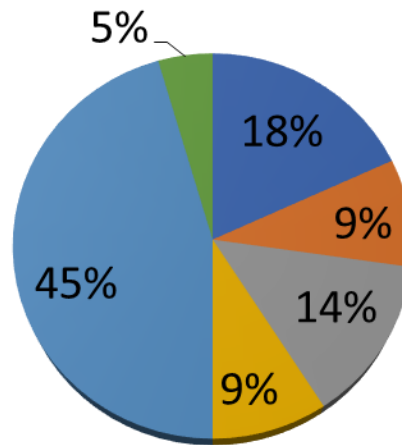
- Food
- Drug
- Device

% of time willing to share **process capability** data and/or composition of material with customers

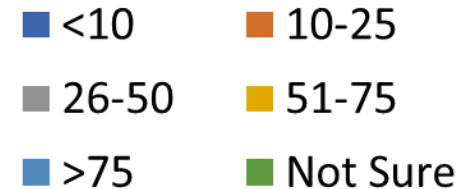
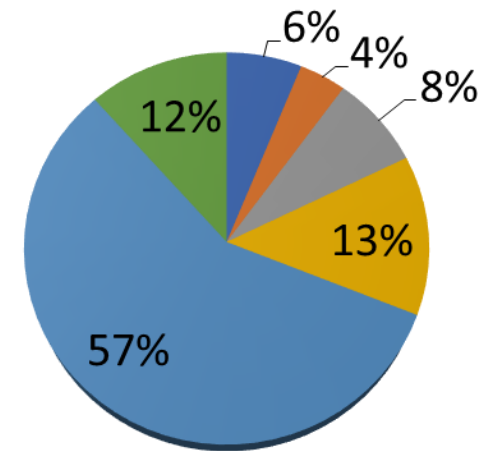
Food



Drug

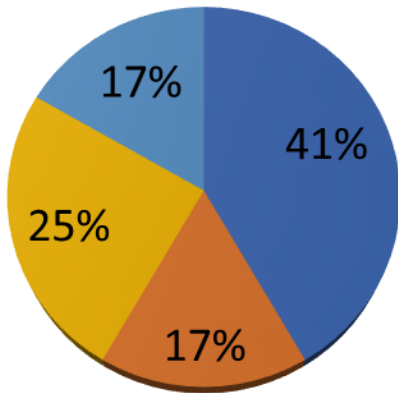


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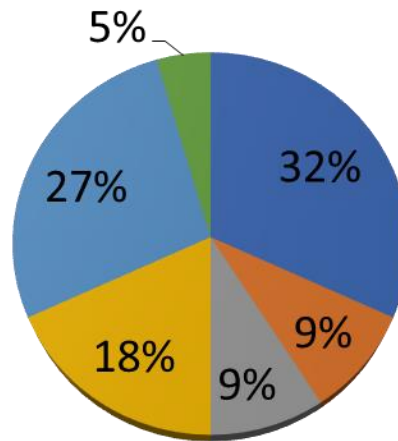


% of customers who ask to see your **process capability** data and/or composition of material information

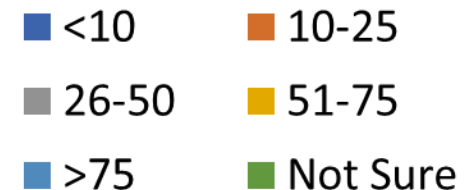
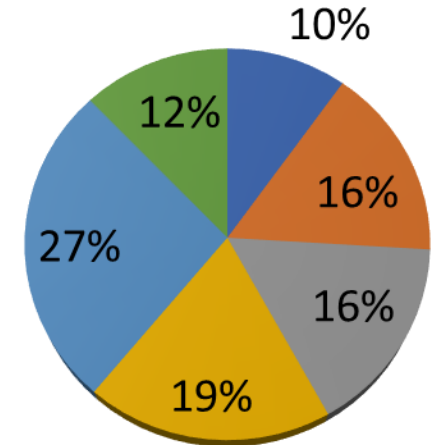
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Drug

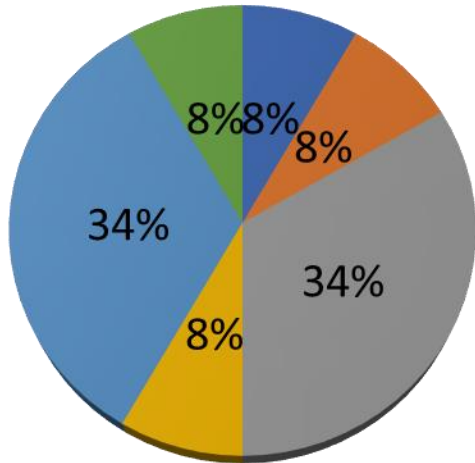


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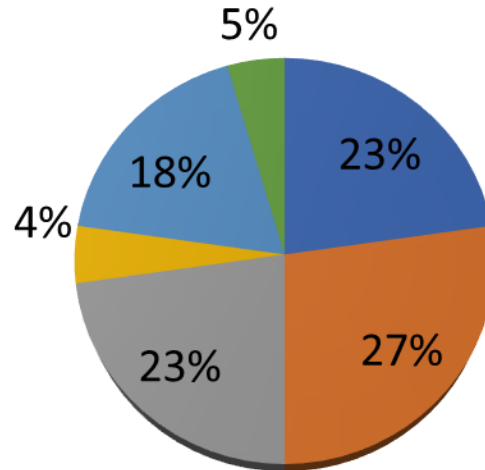


% of customers ask for your **input on specifications** for your product/material

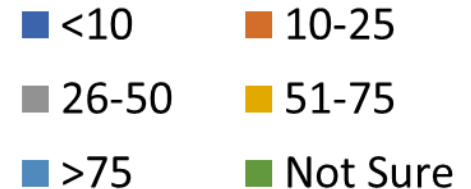
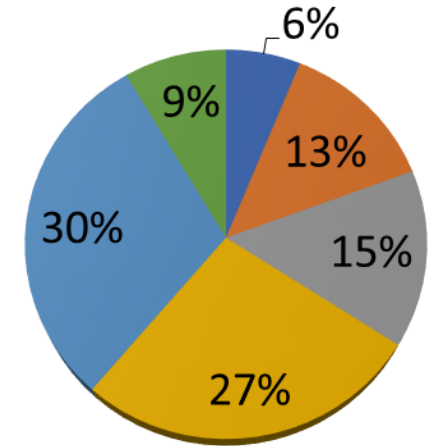
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Drug

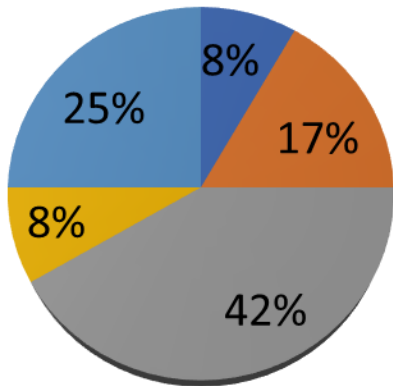


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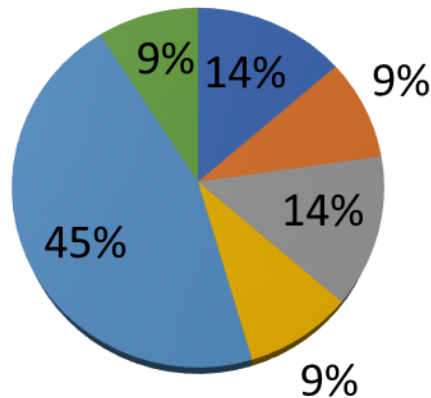


% of time you have **enough info** about customer needs and process to know when it is important to **report changes**

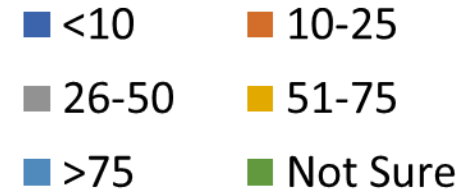
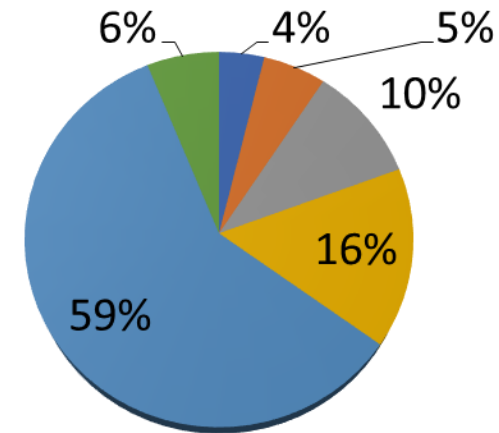
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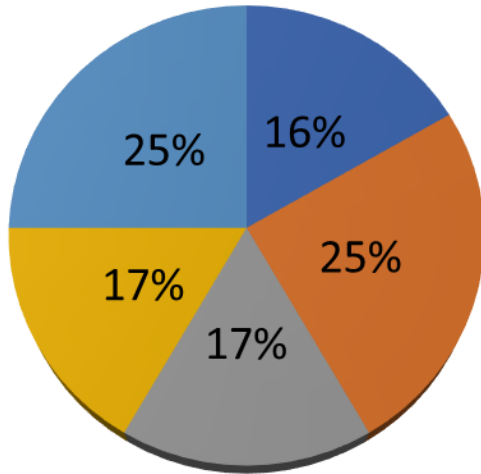


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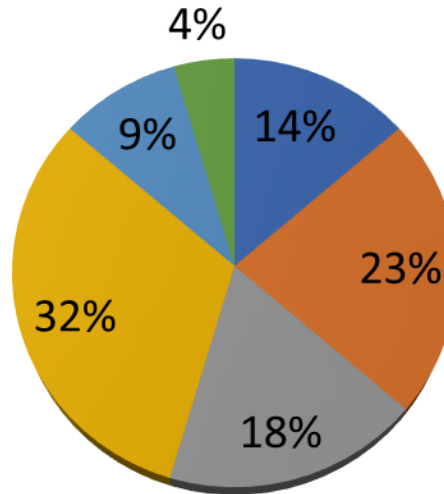


% of customers who involve **cross-functional representatives** in the due diligence process

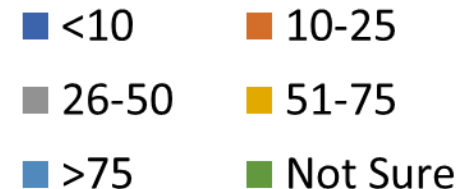
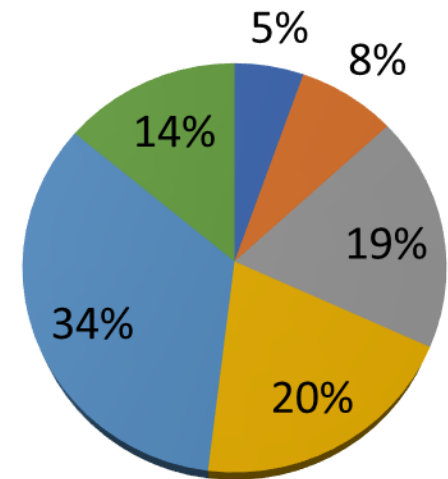
Food



Drug



Device



Cross-Functional Team Formation

For the Environmental, Health and Safety Group, determine:

1. Group 1: Examples of what is needed from the supplier by the functional area
2. Group 2: Examples of what can be contributed to the supplier selection process by the functional area

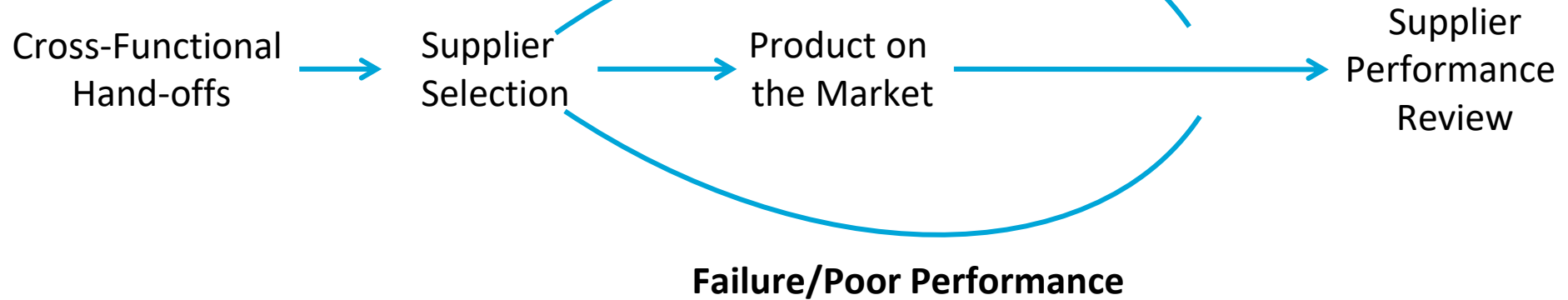
Example: Cross-Functional Team Formation

Functional Area	Examples of what is needed from the supplier by the functional area	Examples of what can be contributed to the supplier selection process by the functional area
EH&S	<ul style="list-style-type: none">● Supplier's capabilities● Supplier's compliance● Impact of material and supplier● Supplier's Risk Profile● Carbon footprint● Safety Data Sheets	<ul style="list-style-type: none">● Identify regulatory requirements● Assurance of Supplier's compliance● Audit supplier● Supplier/material impact on Company, e.g., Waste disposal, hazards, Risk class● Environmental impact● Historical experience with suppliers

Alignment is the Foundation!!

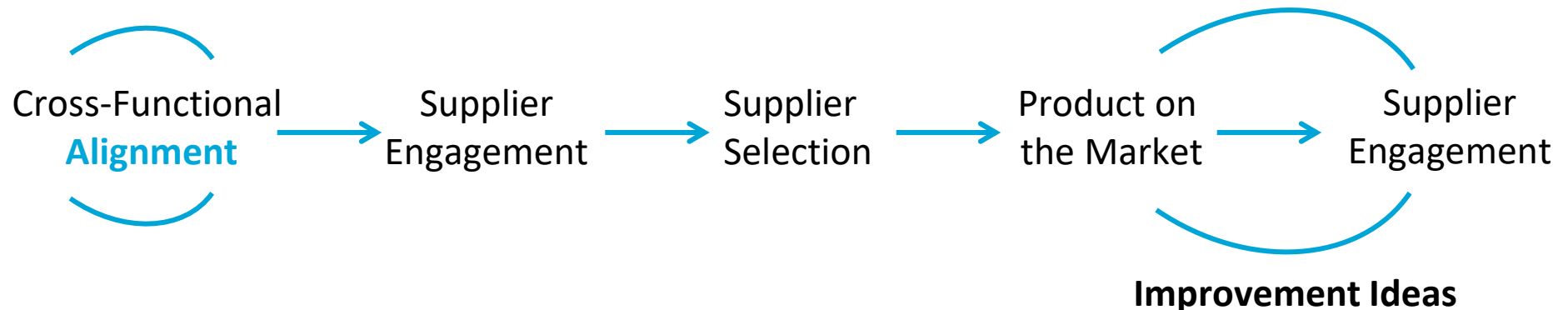
Common Model

Corrective Actions



GSP Model: Right First Time

Preventative Actions



Internal Alignment on Supplier Requirements

Supplier Requirement Alignment – 4 Categories



1. Operating Systems and Business Capability

- Able to support speed to market
- Flexibility to respond to changes in demand and/or specifications, e.g., facility, labor
- Long-term operational and financial viability – low debt, profitability, diversity of clientele, multi-year business plan, investment in operations
- Supplier has acceptable systems and practices to manage Enterprise Risk Management (ERM), including Business Continuity, Disaster Recovery, Cyber Security and Supplier Risk management.

2. Relationship Alignment

- The supplier is willing to share information we need regarding quality and compliance.
- Direct access to technical staff is given to us
- Social responsibility practices are acceptable, e.g., Sustainability, diversity
- Meets the Strategic need for: Company Culture, Commitment, Trust, Confidentiality/values, Transparency

Supplier Requirement Alignment – 4 Categories (cont'd)



3. Quality and Regulatory Compliance

- Quality System Compliance Information meets our requirements.
- Complaint with non-FDA requirements, such as REACH, RoHS, Controlled Substances, EHS, Ethics and Labor, etc.
- The Supplier has acceptable Quality & Compliance systems to control their supplier selection practices
- The Supplier has acceptable systems to ensure validation of methods, process and facility

Supplier Requirement Alignment

Category 4	Examples of Criteria to Assess	1 Relative Importance? (0, 3, 7 10)	2 Does Supplier fit your need?
Supplier Product & Process Technical Capability	Possesses specific technical expertise, process capabilities and experience		
	Suppliers have demonstrated process improvements to afford future economies of scale to support price negotiation opportunities for ongoing win-win		
	Packaging type meets the business needs (amount of material needed, type of package needed)		
	Ability to handle hazardous material		
	We have familiarity with the equipment used by the supplier		

Self-Qualification

1. Operating Systems and Business Capability

- We maintain the Quality Agreement with our Key Suppliers as a living document that we have agreed upon with the supplier, reference throughout the year, discuss during meetings, and assess for needed changes.
- The type of relationship needed with this supplier has been agreed upon by a cross-functional team, and this relationship can be achieved.
- We respect the frozen period of our suppliers related to scheduling changes.
- We communicate a steady, realistic order forecast with our suppliers.
- We pay our suppliers on-time and in accordance with agreements made with the supplier in order to support their business needs.

2. Relationship Alignment

- We have active discussions with our Key Suppliers regarding “intended use” and have documented their feedback regarding the appropriateness of our use of their material.
- We ensure our suppliers have direct access to the appropriate cross-functional representatives from our business.
- We respect the business of our Key Suppliers by understanding the profit margin they need in order to maintain their business (e.g., through should-cost analyses or similar methodologies), and are able to articulate the benefit(s) of our business to them.

3. Quality and Regulatory Compliance

- We have systems in place to ensure our Supplier's **technological capability** is acceptable and sufficient to support our business based on the supplier selection requirements we established.
- We have systems in place to ensure our Supplier's **quality and regulatory compliance** is acceptable and sufficient to support our business based on the supplier selection requirements we established
- We have systems in place to ensure our Supplier's **business capability** is acceptable and sufficient to support our business based on the supplier selection requirements we established.
- We have systems in place to ensure our Supplier's **operational capability** is acceptable and sufficient to support our business based on the supplier selection requirements we established.
- We have systems in place to ensure our Supplier's **social responsibility** is acceptable and in alignment with our expectations based on the supplier selection requirements we established.

3. Quality and Regulatory Compliance (cont'd)

- Our supplier selections are approved through an established process that involves cross-functional team alignment.
- We have the resources necessary to execute our supplier audit schedule as planned.
- We implement knowledge management practices in a way that provides access to employees across our organization to historical and real-time decisions made, rationale used, studies conducted, and failures that occurred.
- We have shared objectives across functional groups that enables our organization to work together collaboratively for the common good of the patients/customers we serve, and for our business.

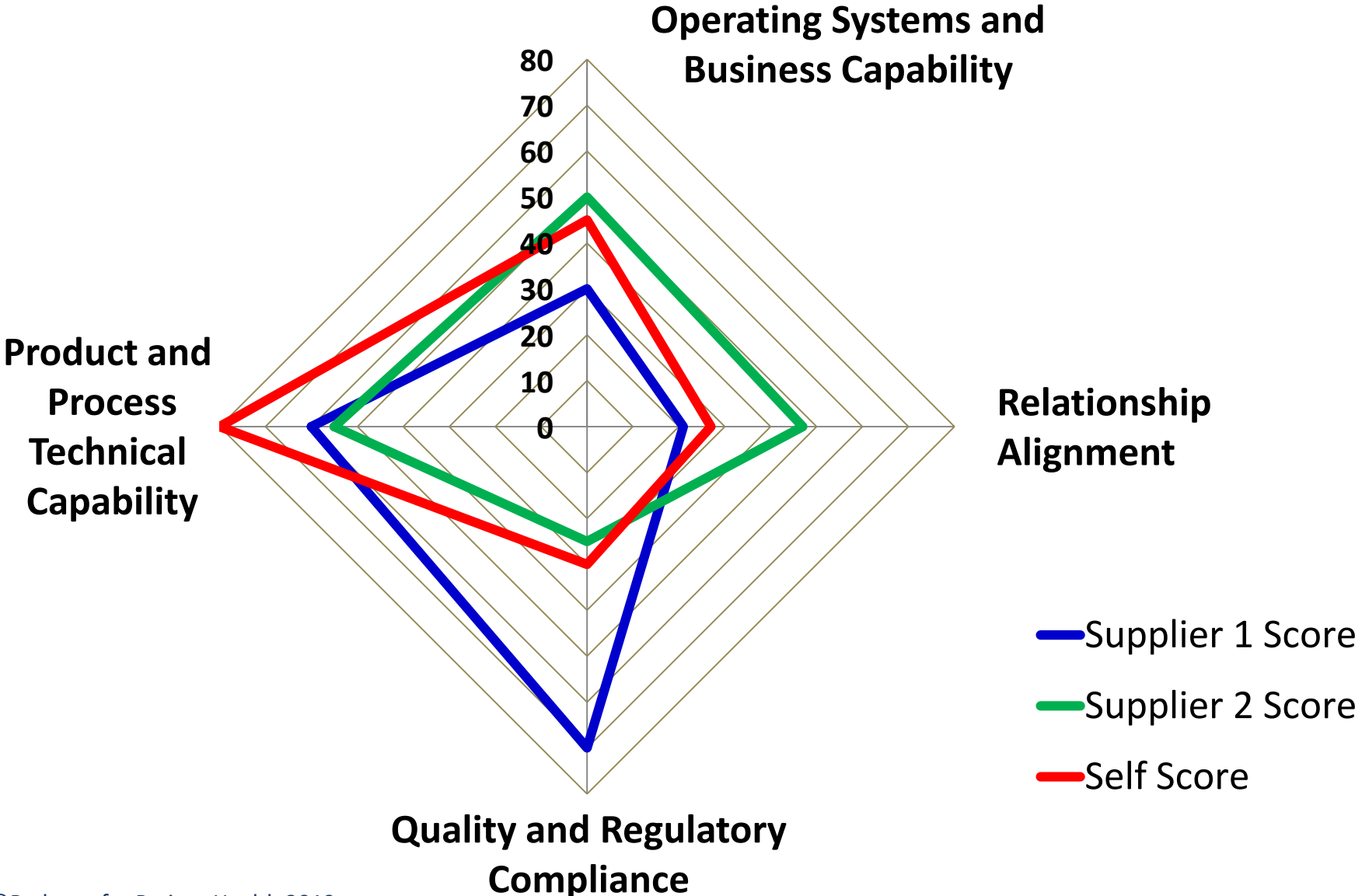
Self-Qualification Scoring

Category 4: Product and Process Technical Capability		Score (0, 3, 7, 10)
1	Our process control ranges and product specification ranges are supported by data and/or have scientifically sound justification.	
2	Our technical transfer for process and/or analytical/test methods meet predetermined protocol requirements first time.	
3	We understand the process capability of our key suppliers for their manufacturing process, and have action limits around that process capability.	
4	We discuss with our Key Suppliers the appropriate specifications to have in place for their material, and have documentation to demonstrate the suppliers' agreement with those specifications.	

Tie to mitigation

Relationship Risk Mapping

Relationship Risk Mapping Example



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Reactions

Thoughts

Questions

???

