

Good Supply Practices



**Supply by Design
for the 21st Century**



Starting with the End in Mind

Inspiring collaboration. Leading innovation. Making a difference.



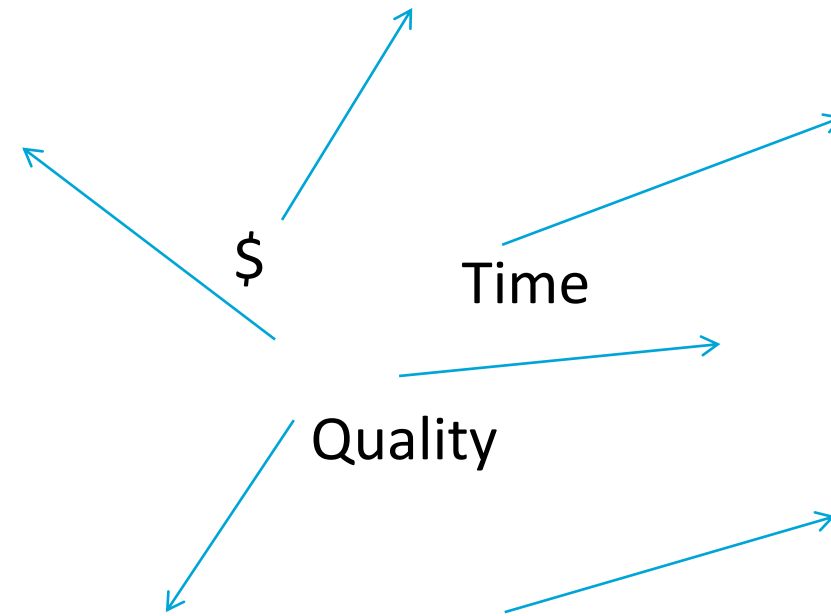
- **Why are we still vulnerable?**
 - Heparin, baby formula, pet food
 - Delays, investigations, lost opportunities
 - Waste, hassle
- **When we have these in place:**
 - Quality by Design
 - FDA Regulations
 - Operational Excellence
 - SRM: Supplier Relationship Management
- **Introducing the GSP Difference:**
 - Every Person. Every Product. Every Time.
 - Intentional holistic alignment for true Supply-by-Design
 - Business-smart and commensurate with the need



A Typical Day in the Supply Chain



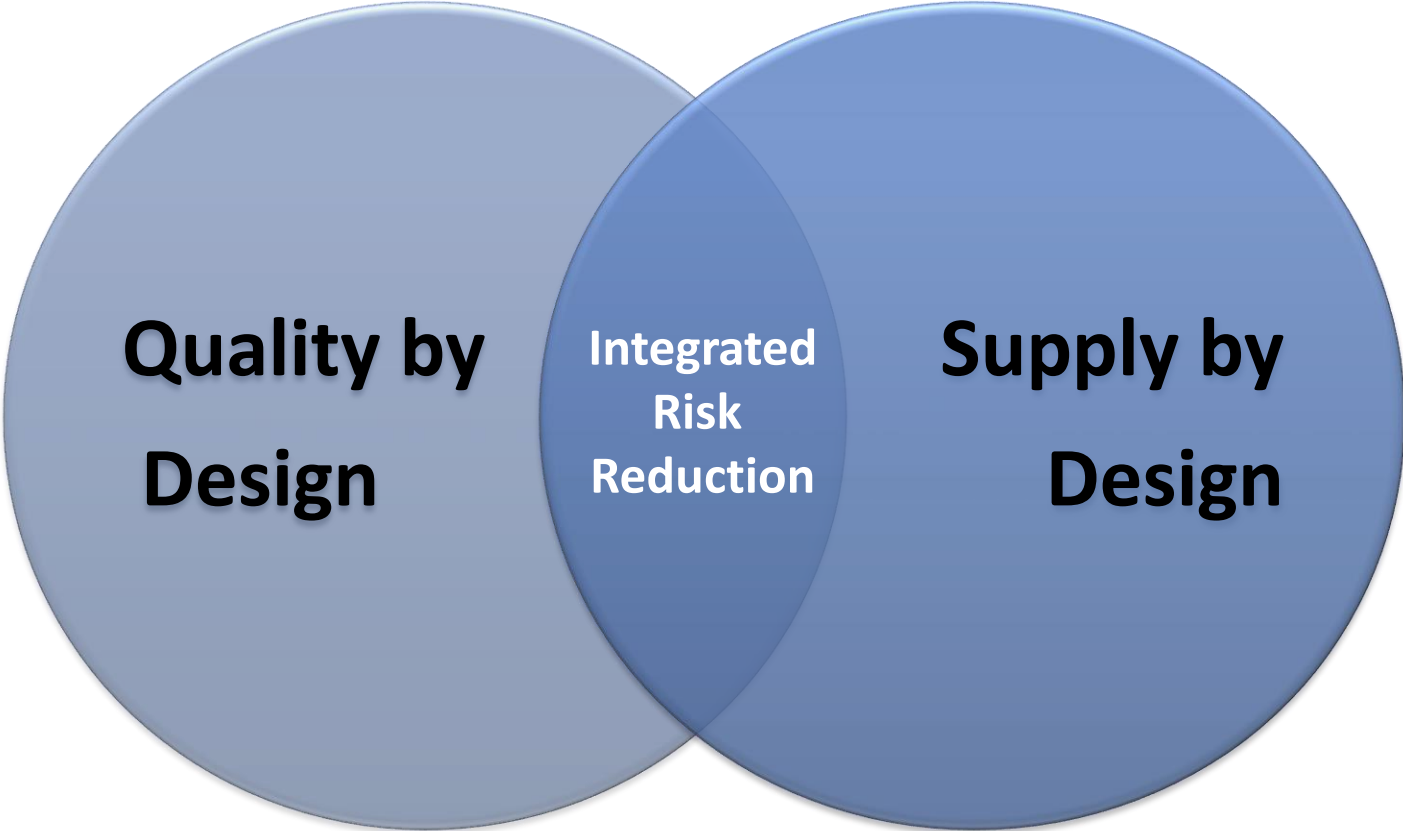
Competing Priorities



**Product
in Development**



**Product
on Market**

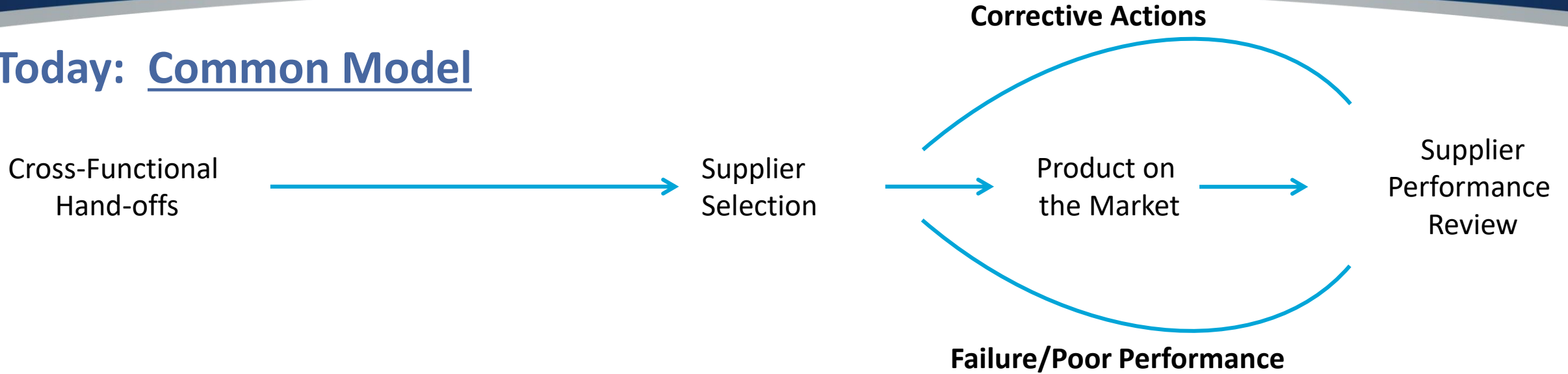


**Product
in Development**

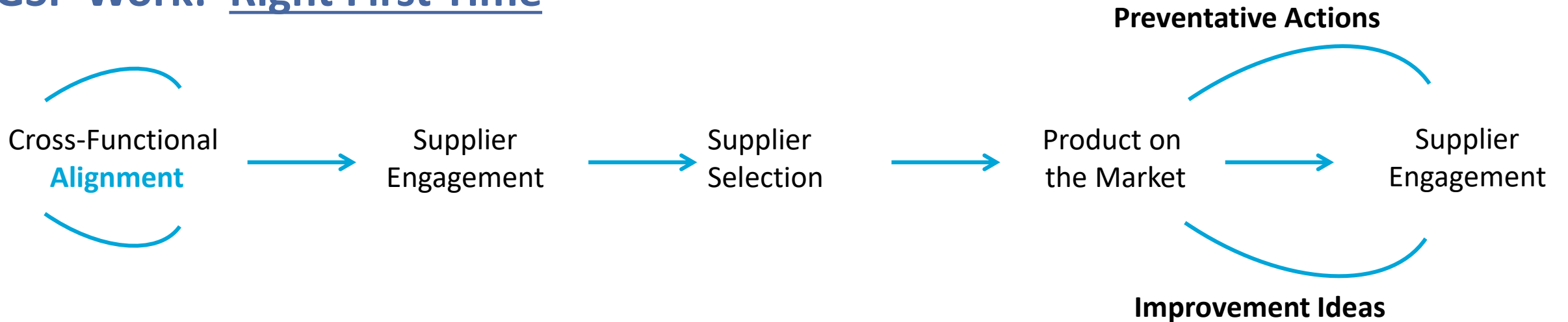


**Product
on Market**

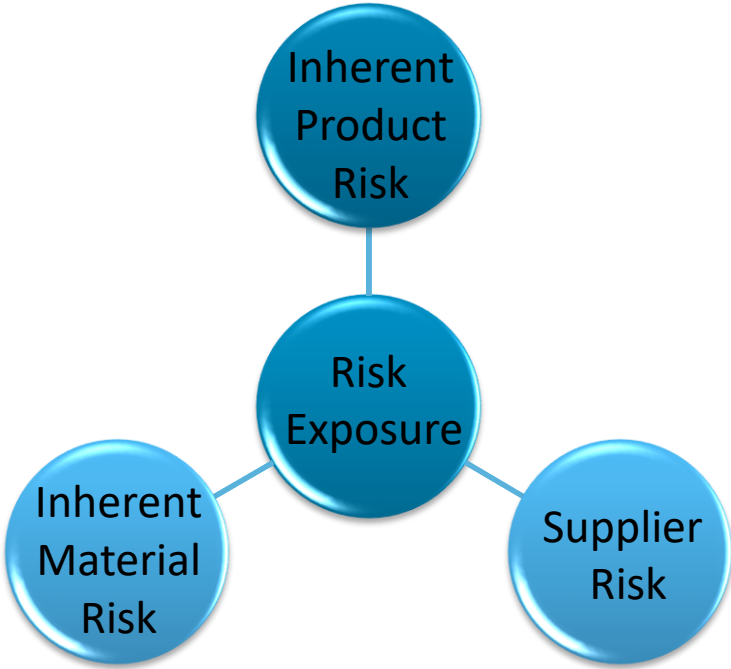
Today: Common Model



GSP Work: Right First Time



Pre - Supply by Design



Post - Supply by Design



GMP

GSP

**Increase Product
Confidence**

GIP

GDP

1. Setting the Foundation

- a. Self-Qualification
- b. Knowledge Management
- c. Supply Chain Risk Management

2. Internal Alignment

- a. Cross Functional Team Formation
- b. Material Requirement
- c. Initial Selection Criteria
 - Single Source vs. Multi-Source
- d. Communication Strategy

3. External Alignment

- a. Supplier Engagement
- b. Holistic Qualification
- c. Overall Relationship Risk

4. Lifecycle Management

Our Work

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Team Member Demographics

Co-Leaders: Troy Fugate, Compliance Insight
Marla Phillips, Xavier University
Jack Solomon, Core Risks Ltd.

Number of Members: 40

Number of Countries: 4 (DE, IE, SE, US)

Number of Companies: 23

Types of Companies:

- Pharma, Device, Consumer Goods
- FDA and Notified Bodies
- Manufacturers (Innovator, Contractor, Virtual)
- Suppliers and Consultants
- Large, Medium, Small



Gap Analysis

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We do not understand our own product and process well enough to:

1. Set the right specifications to begin with, and there is no feedback loop for effectiveness
2. Understand the impact of incoming material variability and specifications needed
3. Identify proper incoming material testing – rely on compendial testing
4. Detect changes in incoming material and the resulting impact on the final product

Our Systems are not Robust:

1. We select suppliers prior to gaining cross-functional alignment on requirements and needs
2. We do not view our suppliers as valued experts
3. We are not transparent with our suppliers
4. We qualify suppliers against a limited set of risk elements
5. We do not have quality agreements in place with a large percentage of suppliers

We do not behave in a way that engenders trust:

1. We do not assess the amount of risk we are inducing into the process – are we “qualified”?
2. We do not engage suppliers at all, or if so, not at the right times – and not on an ongoing basis
3. We do not have a robust change management system in place
4. We do not respect the business of our suppliers
5. Our order-forecast is constantly changing

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

Key Takeaway

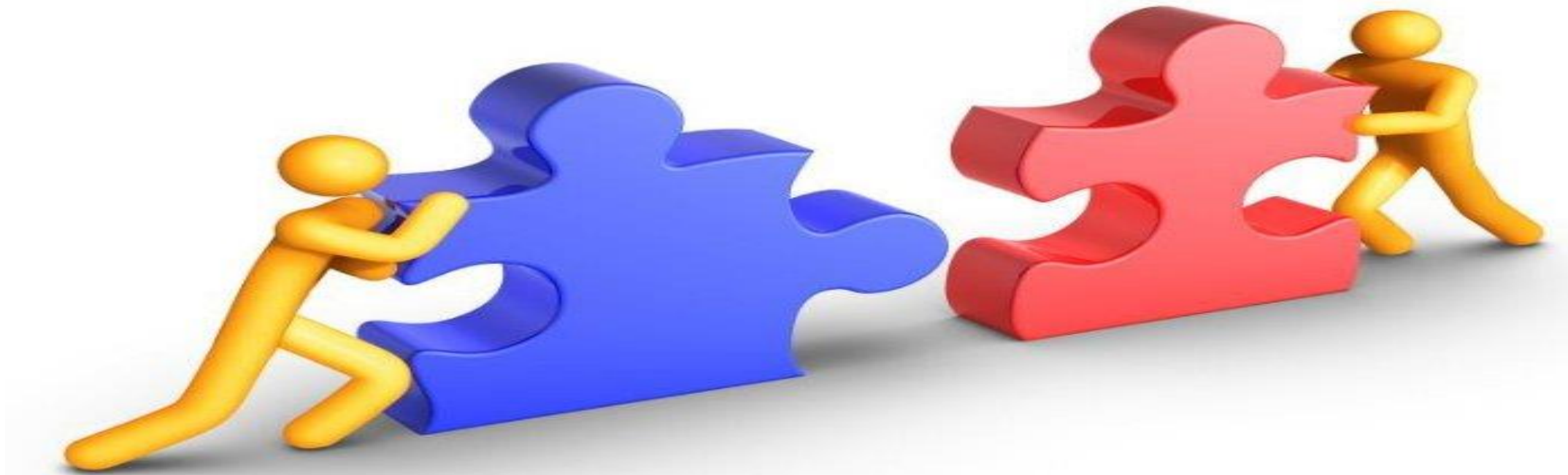
Disciplined process will focus on true root cause

Solutions

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Initial Supplier Selection – Table Discussion



Develop the following 2 lists at your table:

1. Typical risk criteria to assess for initial supplier selection
2. Functional groups to involve in the supplier selection process

Which Supplier would You Choose?

Supplier A

- Lowest cost
- No direct experience with this supplier
- Used by major pharma companies
- Compliance track record seems acceptable
- Located in China

Which Supplier? – show of hands

Supplier B

- 10% more cost than Supplier A
- You use Supplier B for different material
- Used by major pharma companies
- Largest business sector is with this material
- Passed cGMP audits
- On-time delivery is acceptable
- Located in England

- **Financial Stability:** The supplier's funding source is not stable.
- **Senior Management:** although we have worked with Supplier B, the supplier went through a complete overhaul of senior leadership this year.
- **Material Stability/Reliability:** the supplier has very limited material stability information on a recent change they made to the process.
- **Health:** the supplier manufactures health sensitive materials and does not have appropriate HVAC system controls to avoid cross-contamination and exposure to our people (in addition to their people)
- **Process Controls:** the supplier does not track process capability.

- **Culture:** the supplier is not willing to sign a Quality Agreement.
- **Supply Demand:** supplier lead time does not meet market demands.
- **Capacity:** the supplier has limited capacity for growth.
- **Environmental Requirements:** the supplier has a history of violating stack emission requirements.
- **Safety:** Public OSHA audits reveal a history of government action due to safety violations.

Would you change
your vote?

How can you determine what is important for the Initial Supplier Selection?

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Cross-Functional Involvement

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	Does the functional group feel their involvement has been missed, or not at the right time?	Score likelihood of involving each cross-functional member going forward
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 		

1. Assess the Following Supplier Selection Categories:

- Supplier Technological Capability
- Supplier Quality and Regulatory Compliance
- Supplier Business Capability and Alignment
- Supplier Operational Capability
- Supplier Social Responsibility
- Transparency
- Agreements required
- Target relationship



2. Align on the Relative Importance

3. Provide rationale for Inclusion or Exclusion of the Criteria

Category	Examples of Criteria to Assess	Relative Importance	Does Supplier Fit Your Need
Supplier Business Capability	<ul style="list-style-type: none">• Ability to respond to changes in demand• Breadth of product line to supply different materials – potential for partnership alliance• Able and willing to support speed to market• Suppliers have demonstrated process improvements to afford future economies of scale• Financial viability – low debt, profitability, diversity of clientele, 5-year business plan, investment in operations, etc.• Effective, timely and business smart transparent communications• Not a competitor		

Communication Strategy

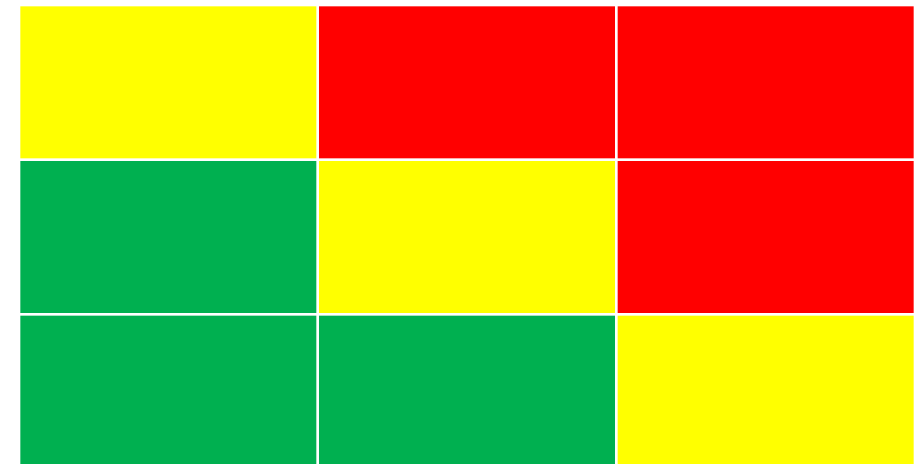


What information are companies concerned about sharing?	Why would the suppliers need to know this information?	What is the risk of sharing this information?	What is the benefit of sharing this information?	We currently share this information?	Probability of sharing this going forward
Actual flexibility in shipping/production schedules	To understand demands and work collaboratively to meet needs	supplier may take greater risk Supply may delay manufacturing if extra time is allowed	improve availability of supply from synergies of treating supply chain as a single system Supplier may be able to adjust their schedule		
Function of supplier's product in formulation/device	To assist in choosing correct product to supply for given function	IP concerns May raise cost	Get the best product for the application		
Cost/profit margin	To come to an agreement on price that is fair for supplier and manufacturer	Supplier increase their price	Long term benefit of relationship building Assists supplier with improving efficiencies		

How qualified are we to be in any supplier relationships?

Self Risk Assessment:

- Do we know our own compliance level
- Product and process understanding
- Level of cross-functional internal alignment
- Adequacy of Resource
- Stability of our workforce
- Accuracy of order-forecast for our suppliers



Section 1: How well do we understand our own product and process to begin with?

	Assessment	Score
A	Our process control ranges and product specification ranges are supported by data and/or have scientifically sound justification.	
B	Our technical transfer for process and/or analytical/test methods meet predetermined protocol requirements first time.	
C	Our product is manufactured during commercial production without failures related to product and/or process development inadequacies.	
D	Our products have no complaints in the field related to product and/or process development inadequacies.	
Total Raw Score for Section 1 (out of 40):		

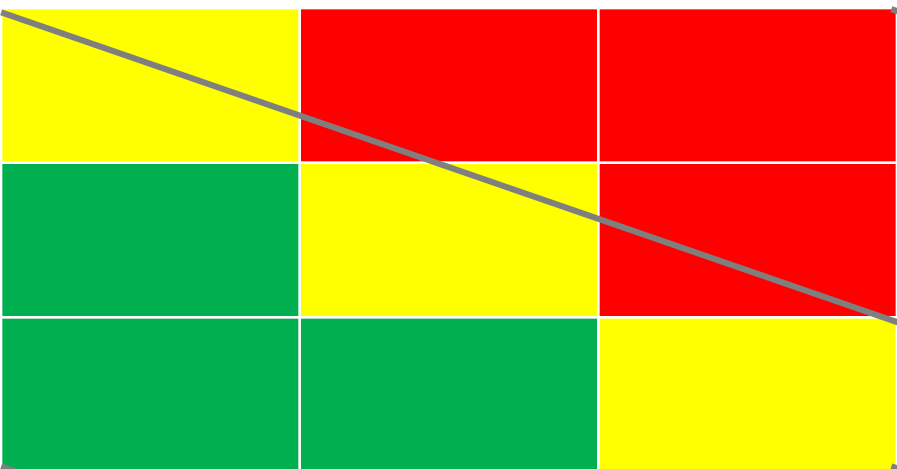
Scoring System:

- 10 90 – 100% of the time
- 7 51 – 89% of the time
- 3 11 – 50% of the time
- 0 0 – 10% of the time

Section 1 Formula: $A + B + C + D \leq 40$

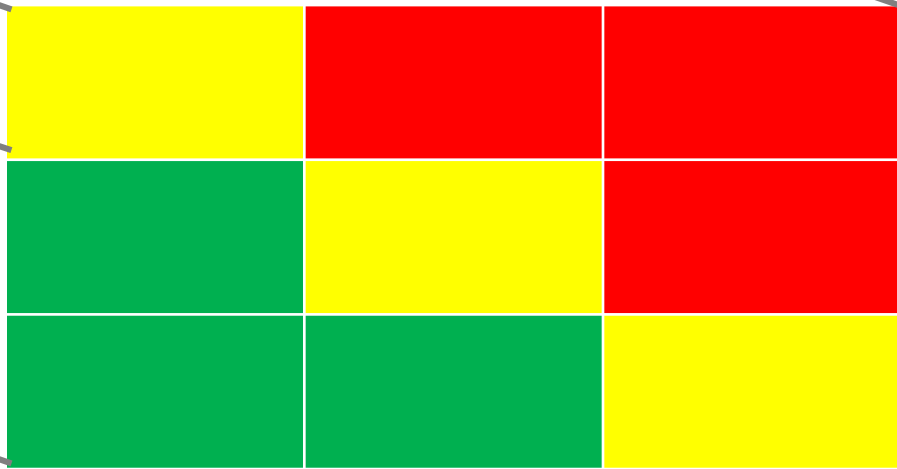
- **35 - 40: No action required, assuming all responses are 7 or higher.**
- **26 - 34: Cross-functional awareness escalation and development of mitigation strategies.**
- **0 – 25: Immediate Cross-functional action plan development, implementation and mitigation.**

Supplier Qualification



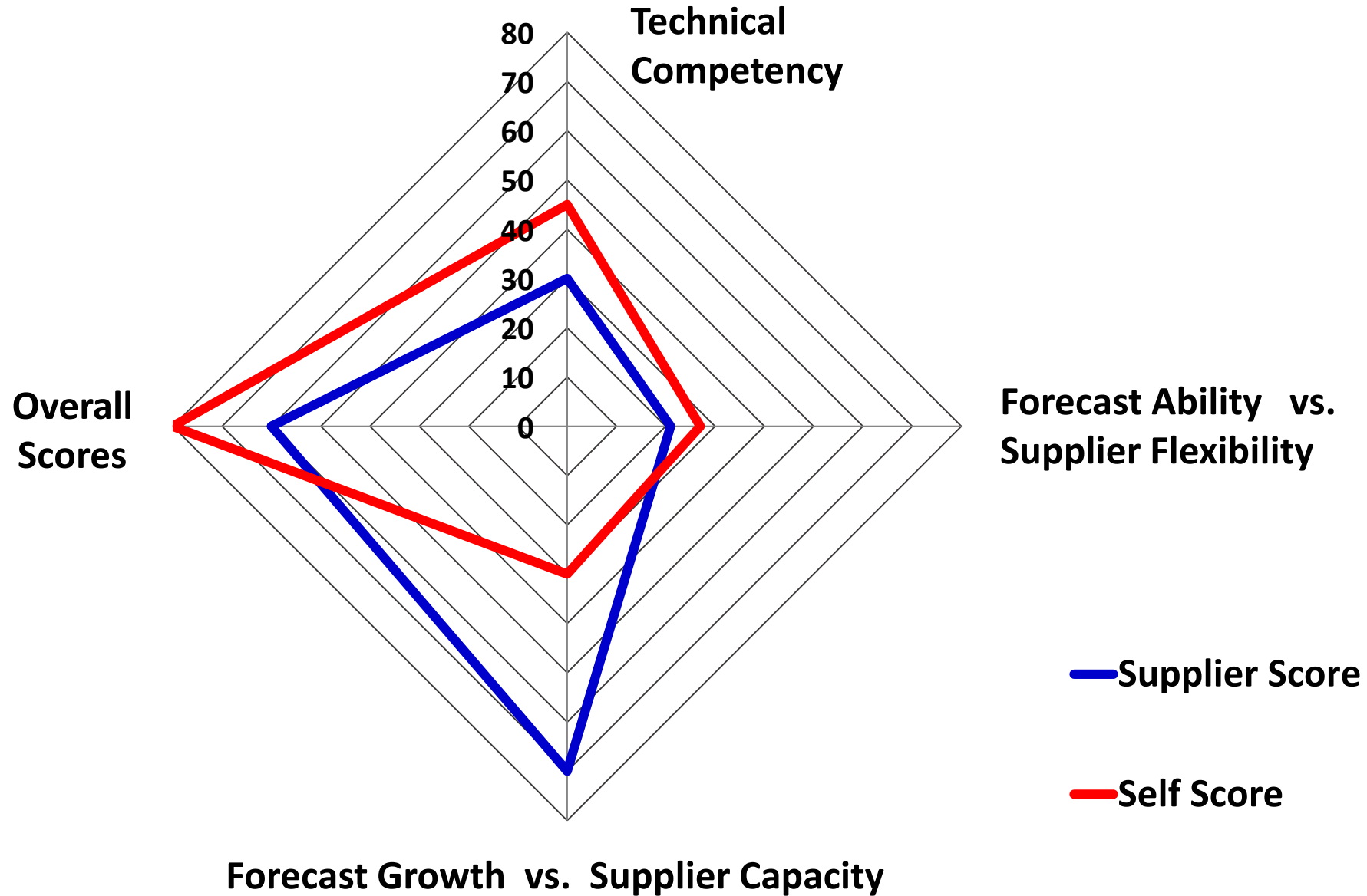
Capacity, Location, Risk of Material
Capability, Compliance, History
Financial Stability

Compliance, Resources,
Stability of Workforce,
Product Knowledge, Forecast
Accuracy, Internal Alignment

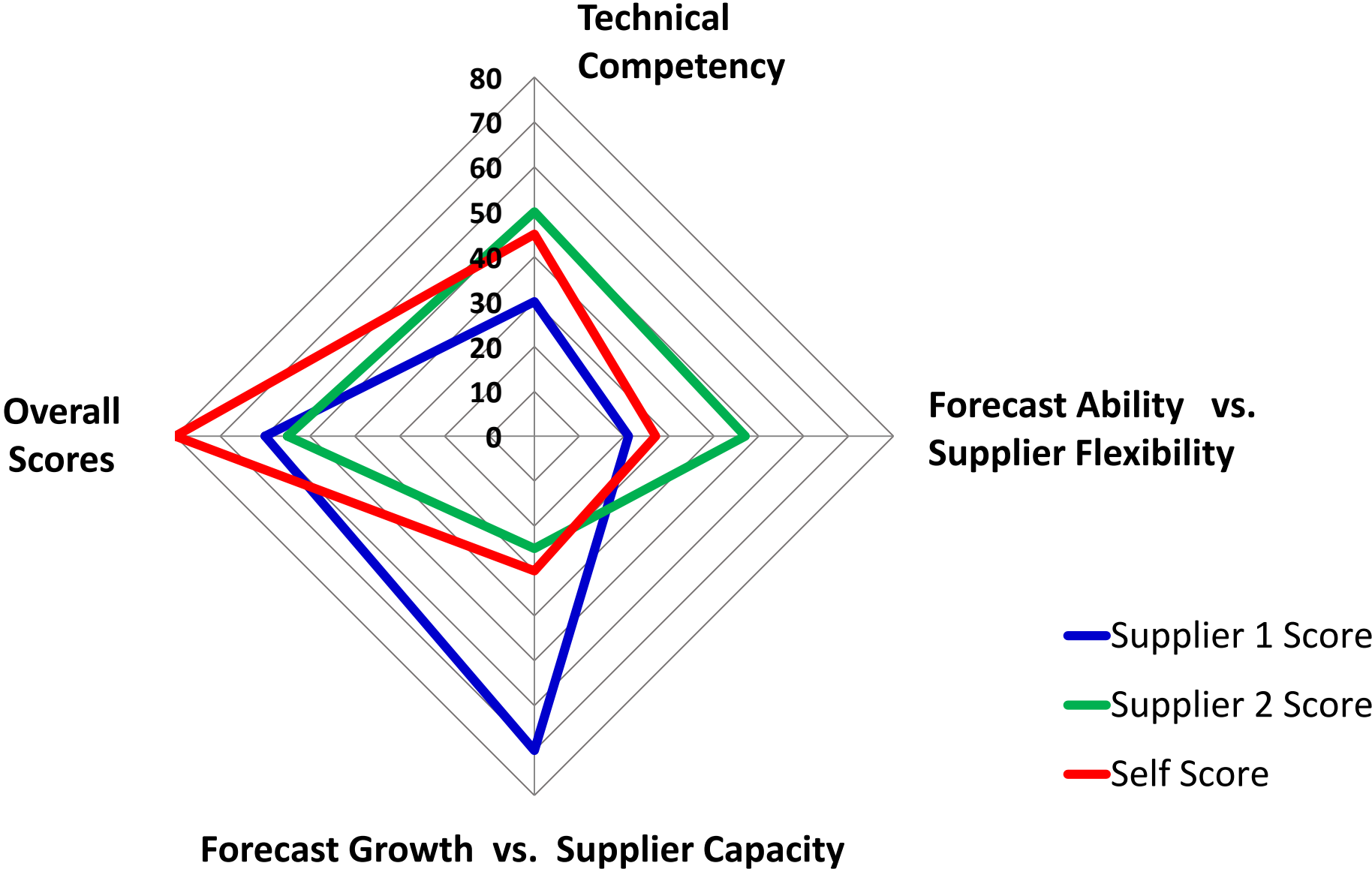


Self Qualification

Spider Diagram for Relationship



Spider Diagram for Relationship



Pulling it All Together



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Reactions and Ideas?

Marla Phillips

Director, Xavier Health
Xavier University
phillipsm4@xavier.edu
513-745-3073

