Good Supply Practices

Supply by Design for the 21st Century
Starting with the End in Mind

Inspiring collaboration. Leading innovation. Making a difference.
The Powerful Strategic Question

• 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

Quality by Design

Competing Priorities

- Time
- Quality
- $
GSP Value

Quality by Design

Supply by Design

Integrated Risk Reduction

Product in Development

Product on Market
GSP Value

**Today: Common Model**

Cross-Functional Hand-offs → Supplier Selection → Product on the Market → Supplier Performance Review

- Corrective Actions
- Failure/Poor Performance

**GSP Work: Right First Time**

Cross-Functional Alignment → Supplier Engagement → Supplier Selection → Product on the Market → Supplier Engagement

- Preventative Actions
- Improvement Ideas

GSP Work: Right First Time
Inherent Product Risk
Risk Exposure
Supplier Risk
Inherent Material Risk

Pre - Supply by Design

Post - Supply by Design

Risk Prevention
Relationship Risk
Inherent Material Risk
Self Risk
Holistic Supplier Risk

GSP Value
With the End in Mind

Increase Product Confidence
Supply by Design Guidance

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
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

Inspiring collaboration. Leading innovation. Making a difference.
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
Supply Chain Development Gaps

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
Supply Chain Management Gaps

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”
Paradigm Shift

Our Suppliers 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

We are Causing Problems

Key Takeaway
Disciplined process will focus on true root cause
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

**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

Which Supplier? – show of hands
More information on Supplier B

• **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.
More information on Supplier B

- **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?
## Cross-Functional Involvement

<table>
<thead>
<tr>
<th>Functional Area</th>
<th>Examples of what is needed from the supplier by the functional area</th>
<th>Examples of what can be contributed to the supplier selection process by the functional area</th>
<th>Does the functional group feel their involvement has been missed, or not at the right time?</th>
<th>Score likelihood of involving each cross-functional member going forward</th>
</tr>
</thead>
</table>
| **EH&S**        | • Supplier’s capabilities  
                   • Supplier’s compliance  
                   • Impact of material and supplier  
                   • Supplier’s Risk Profile  
                   • Carbon footprint  
                   • Safety Data Sheets | • 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 | | |
Initial Supplier Selection Process

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
### Initial Supplier Selection

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples of Criteria to Assess</th>
<th>Relative Importance</th>
<th>Does Supplier Fit Your Need</th>
</tr>
</thead>
</table>
| **Supplier Business Capability** | • 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 |                     |                             |

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# Communication Strategy

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

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>A  Our process control ranges and product specification ranges are supported by data and/or have scientifically sound justification.</td>
<td></td>
</tr>
<tr>
<td>B  Our technical transfer for process and/or analytical/test methods meet predetermined protocol requirements first time.</td>
<td></td>
</tr>
<tr>
<td>C  Our product is manufactured during commercial production without failures related to product and/or process development inadequacies.</td>
<td></td>
</tr>
<tr>
<td>D  Our products have no complaints in the field related to product and/or process development inadequacies.</td>
<td></td>
</tr>
</tbody>
</table>

**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
Mitigation – Trigger Action!

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.
Relationship Mapping

Supplier Qualification

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

Self Qualification

Compliance, Resources, Stability of Workforce, Product Knowledge, Forecast Accuracy, Internal Alignment
Spider Diagram for Relationship

Overall Scores

Technical Competency

Forecast Ability vs. Supplier Flexibility

Forecast Growth vs. Supplier Capacity

Supplier Score

Self Score
Spider Diagram for Relationship

- Overall Scores
- Technical Competency
- Forecast Ability vs. Supplier Flexibility
- Forecast Growth vs. Supplier Capacity

- Supplier 1 Score
- Supplier 2 Score
- Self Score
Pulling it All Together

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Reactions and Ideas?

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