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Increasing Supply Chain Reliability – Shifting Paradigms

AFDO Conference

June 22, 2015



Inspiring Collaboration Leading Innovation Making a Difference



Xavier Health

Medical Device Industry

- FDA/Xavier University MedCon Conference
- QARA Institute (professional development and certification)
- Support for CDRH “Case for Quality”

Pharmaceutical Industry

- FDA/Xavier University PharmaLink Conference
- Xavier/PwC Metrics Initiative

Cross-Industry Initiatives

- Integrity of Supply
 - Good Supply Practices (GSP)



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Patient Safety **Risks**

Inconsistent

Recalls

Complaints
Field Alerts

Complex
Supply Chain

Ineffect.
Warning Letters

Repeat
Deviations

Contaminated
Product

Adverse Events

Limited R&D
Studies

Product
Failures

High Turn-
Over Rate



GMP

GSP

Increase
Product
Confidence

GIP

GDP



Governance Team

Helge Batz Director Boston Scientific	Al Kentrup WW Director P&G	Gwyn Murdoch Director Eli Lilly	Rafiqah Williams VP Eli Lilly
Gretel Benavides VP Perrigo	Mike King Director J&J	Mark Paviglianiti Director Merck	Steve Wolfgang Acting Assoc. Director CDER
Dale Carter Global Director Huber	Michael Landberg Global Sourcing Boston Scientific	Marla Phillips Director Xavier University	
Steve Greer QA External Engagement P&G	Hank Llamas VP J&J	Susan Rolih EVP Meridian Bioscience	
Dale Huff Exec. Director Merck	David Lowndes SVP Shire	Michelle Smith Sr. Director Meridian Bioscience	



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Integrity of Supply GSP

Where did we Start?



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Problem Statement

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



Natural Tendencies

“If”

We are unable to reliably and consistently ensure the supply of incoming materials

“and”

We need greater assurance that suppliers can reliably and consistently supply safe and quality materials/products

“Then obviously”

Our Suppliers are causing the Problems

“So of course that means”

We need to “fix” our Suppliers



WHEW!



Mission Statement

To determine the **source of dysfunction** affecting the Integrity of Supply, and to implement **sustainable solutions** that can be tied to **Return on Investment** - such as increased safety, improved quality and enhanced reliability – **commensurate with the need.**





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Integrity of Supply GSP

Our Data

Product and Process Theme

1. We are not setting the right specifications to begin with
2. We rely on compendial testing rather than determine if other tests are needed for our product and process
3. We are not able to detect changes or deficiencies in in-coming material
4. We do not have a feedback loop for specification effectiveness
5. We do not have a robust change management system in place
6. We are not involved in setting the specifications beyond Tier 1

Supply chain Theme

1. We are unable to verify GMPs with a certain base of our suppliers
2. We have no real understanding of how the supply chain is managed beyond Tier 1
3. We do not have enough resources to monitor entire supply chain
4. We are not involved in selecting our supplier's suppliers
5. We lack leverage with a certain base of our suppliers



Behaviors Theme

1. Our supplier approval process is not robust
2. We do not adequately share information with our suppliers
3. We do not engage cross-functional colleagues in the process, or not at the right time
4. We don't follow our own supplier selection process

Notice the "We"

**“Our Suppliers
Are Causing
Problems”**



**August
2012**

**July
2013**

**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



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Action-Provoking!



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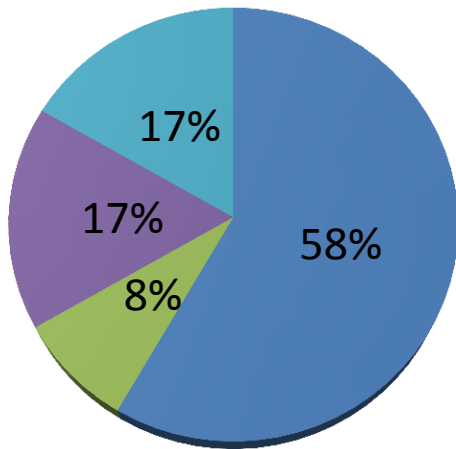
Integrity of Supply GSP

Supplier Input

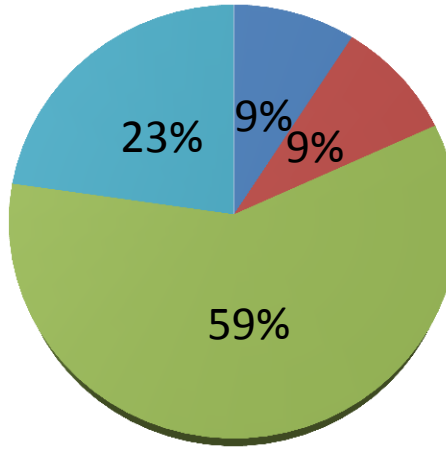


Functional Background

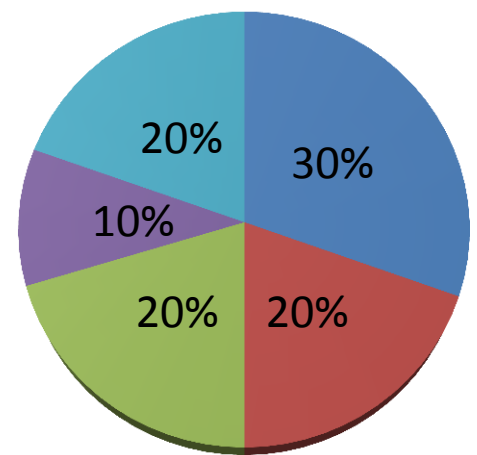
Food



Drug



Device

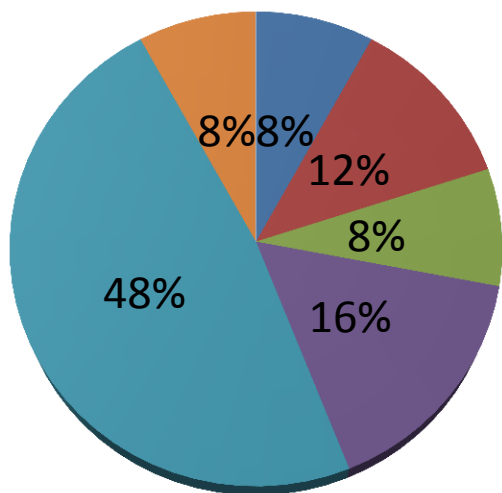


- Business Development
- Customer Service
- Quality Operations/Assurance
- Technical Operations
- Other

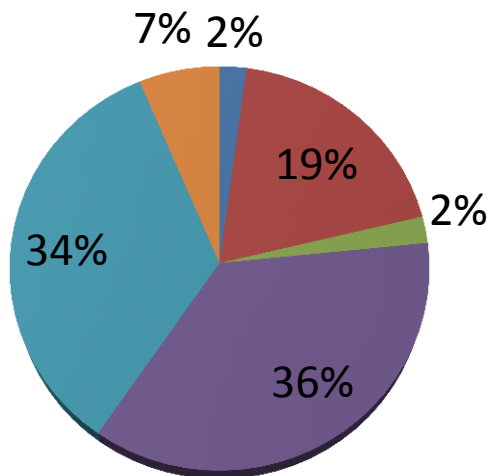


Location of manufacturing facilities

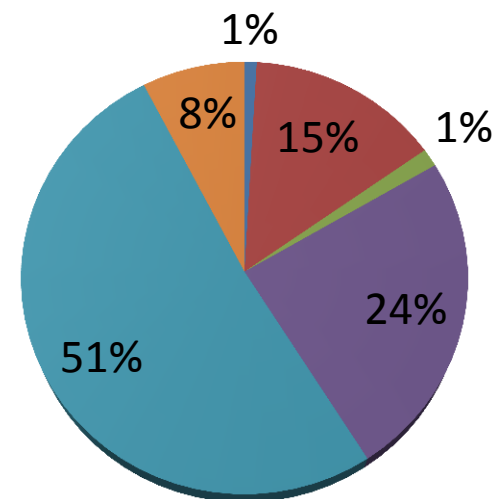
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Drug

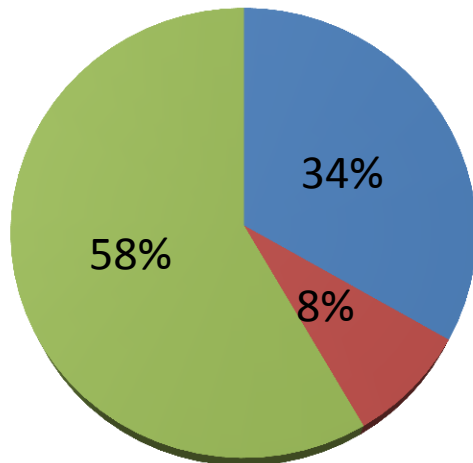


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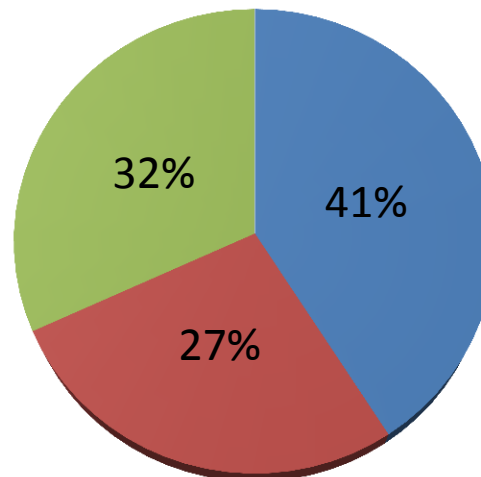


of different “types” of products/materials

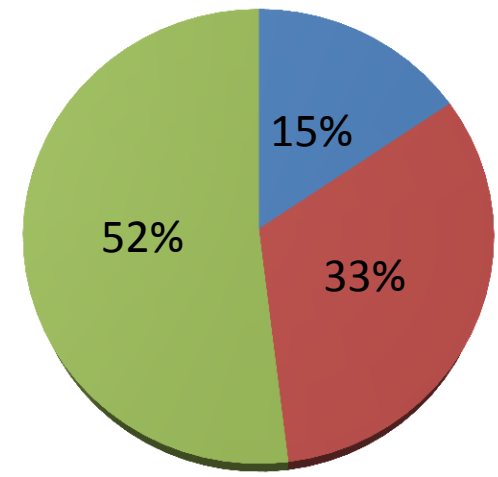
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Drug



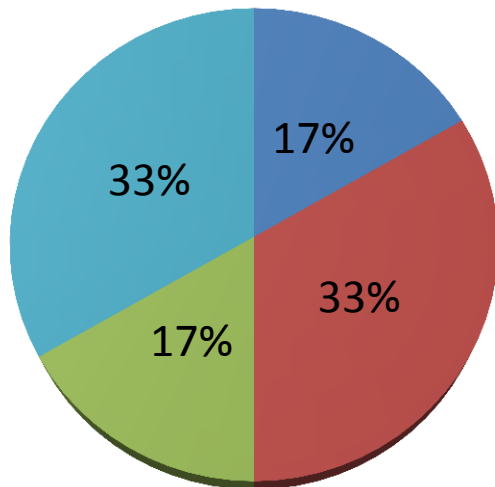
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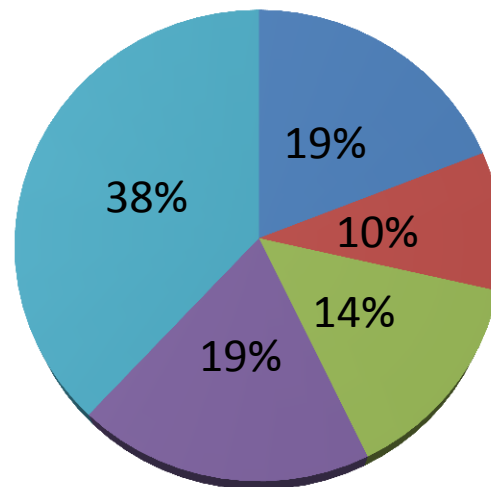
■ <10 ■ 10-50 ■ >50

% of supplier's product/material is specialty

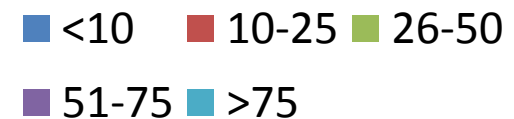
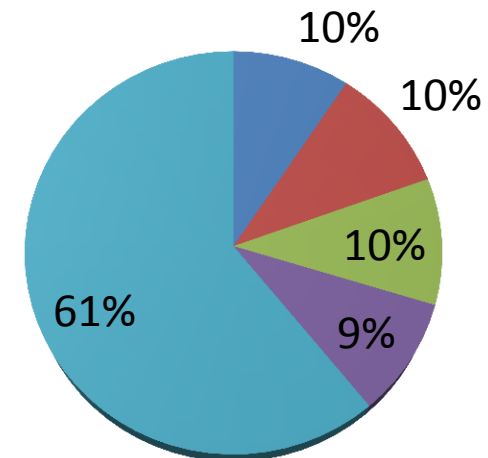
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Drug



Device





Total Respondents

Food

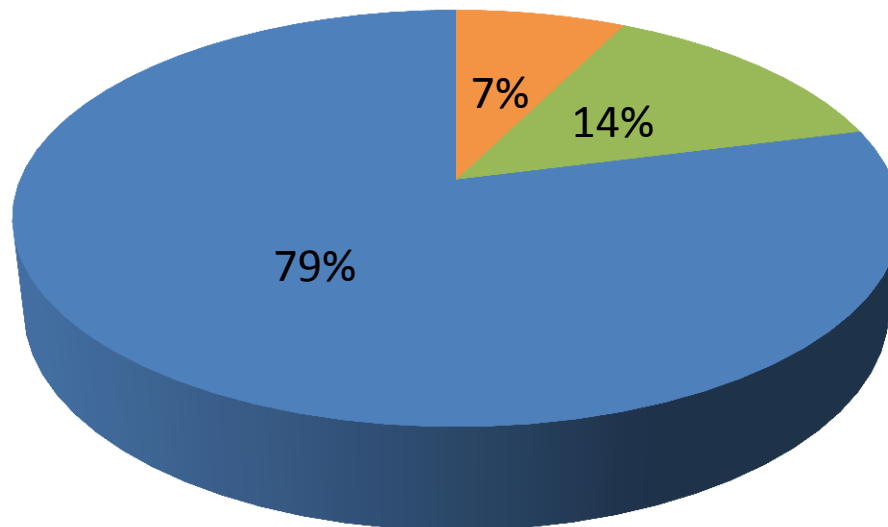
12

Drug

22

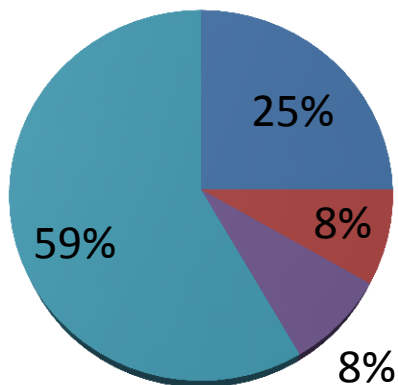
Device

128

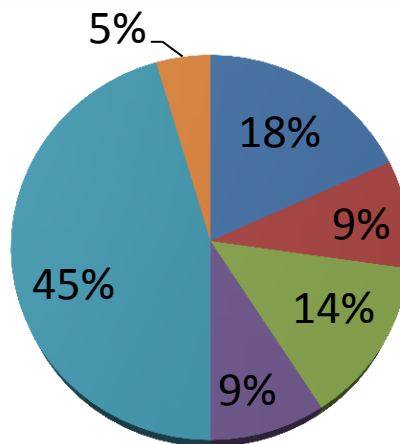


% of time willing to share **process capability** data and/or composition of material with customers

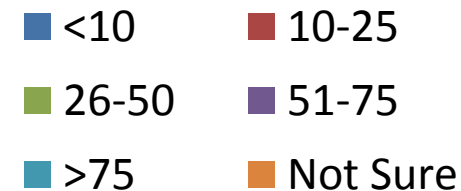
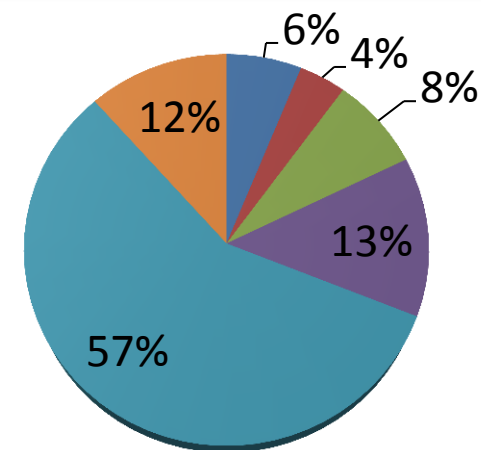
Food



Drug

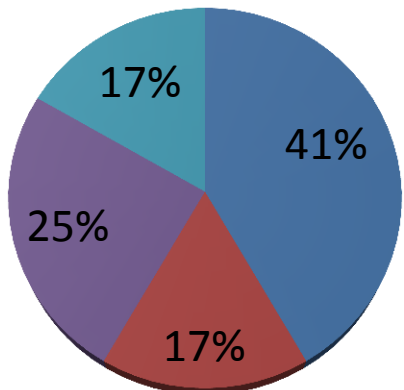


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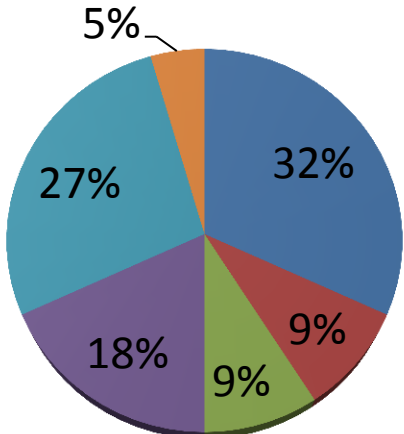


% of customers who ask to see your **process capability** data and/or composition of material information

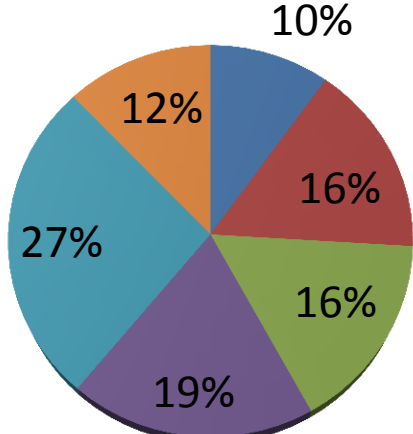
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Drug



Device

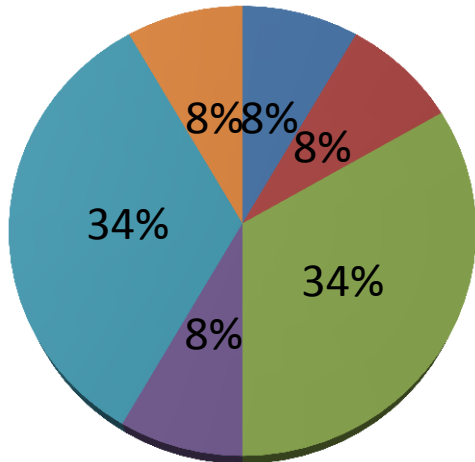


- <10
- 10-25
- 26-50
- 51-75
- >75
- Not Sure

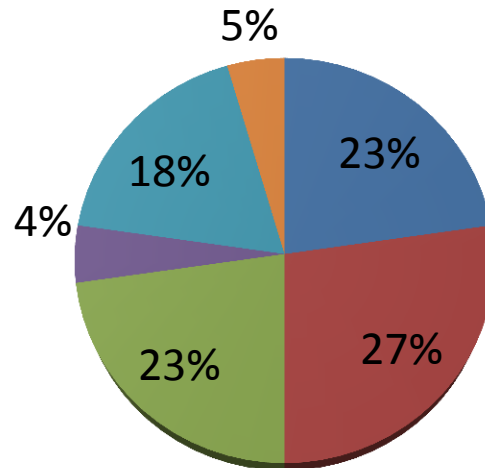


% of customers ask for your **input on specifications** for your product/material

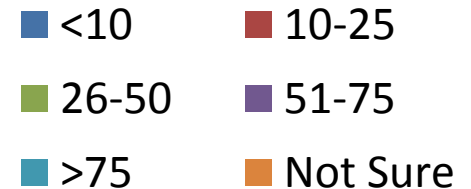
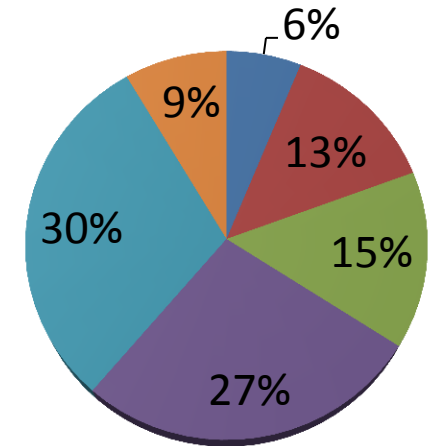
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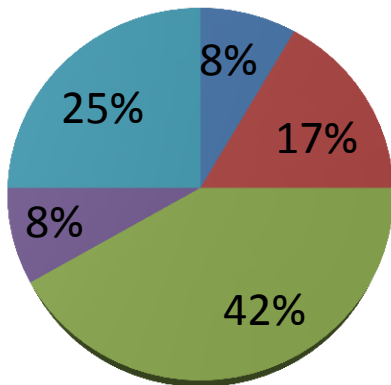


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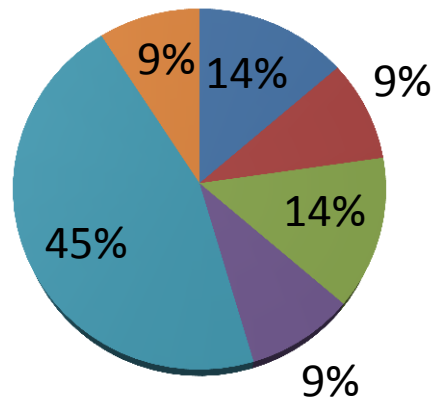


% of time you have **enough info** about customer needs and process to know when it is important to **report changes**

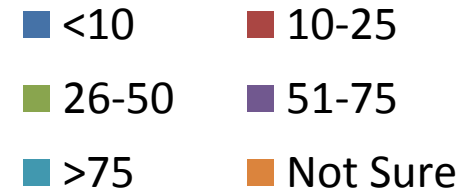
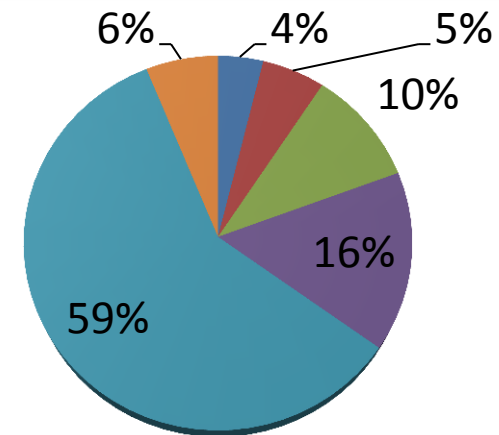
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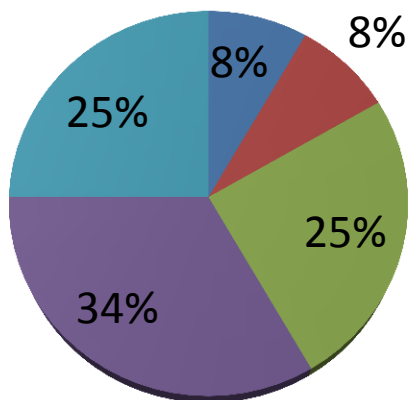


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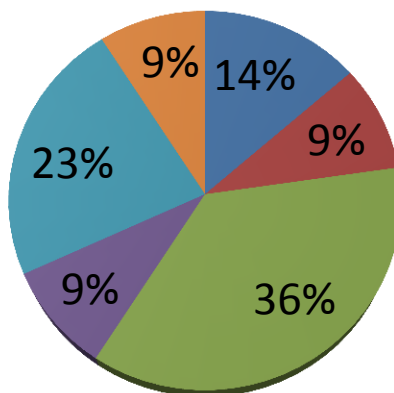


% of time given **access to representatives** from your customers who have the responsibility, competency, and authority to make decisions

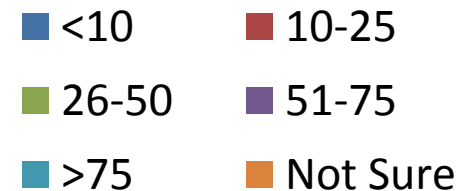
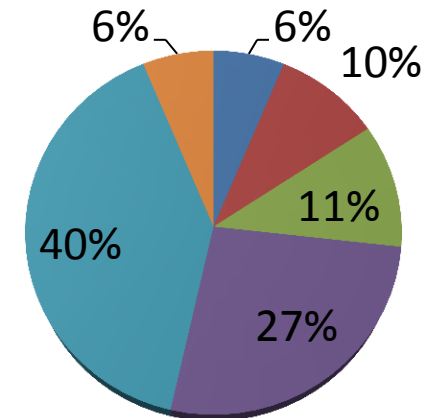
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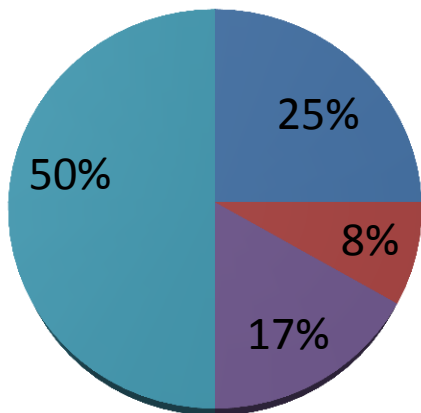


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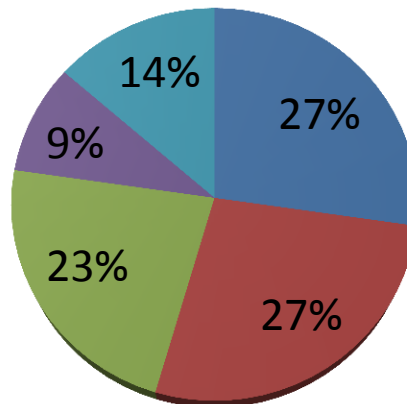


Quality Agreement in place with what % of customers

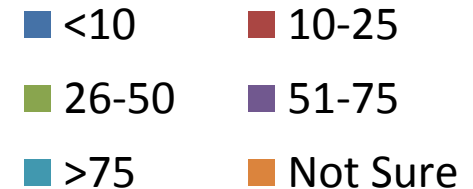
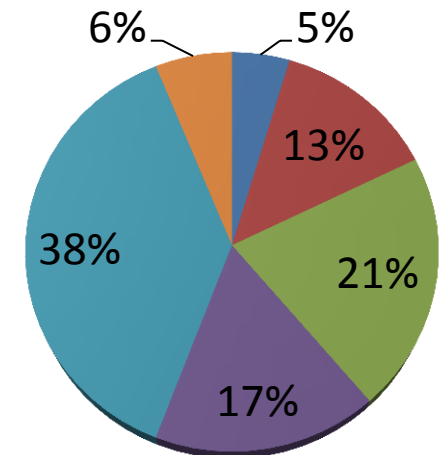
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Drug

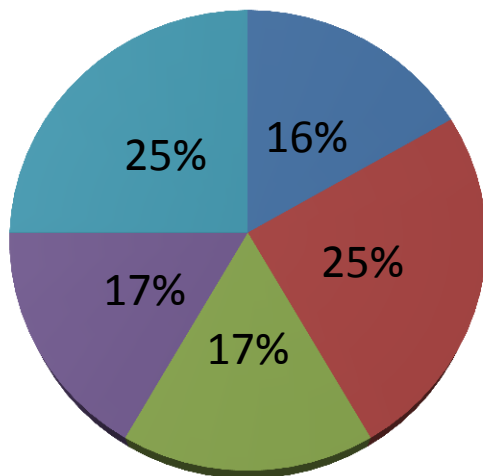


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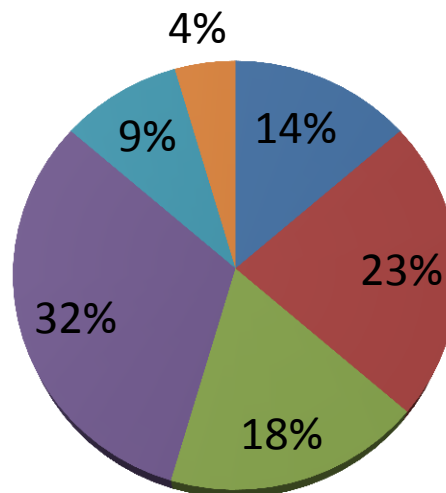


% of customers who involve cross-functional representatives in the **due diligence** process

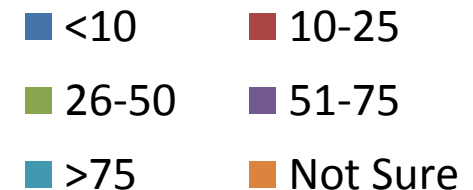
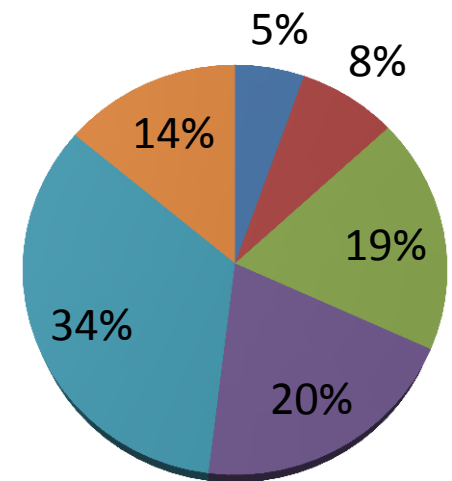
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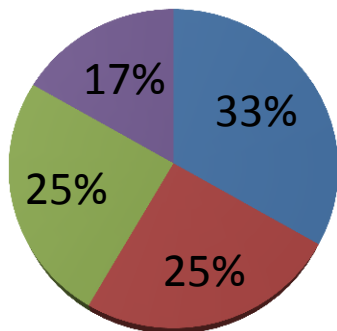


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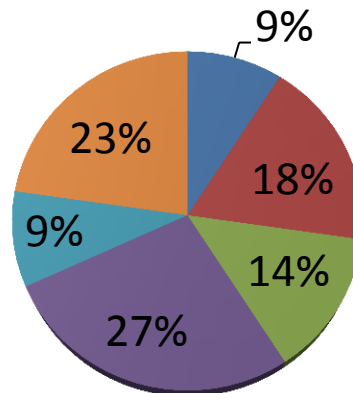


% of time changes in **scheduling** from your customer communicated w/ enough notice and with regard to the commitments you have with other customers

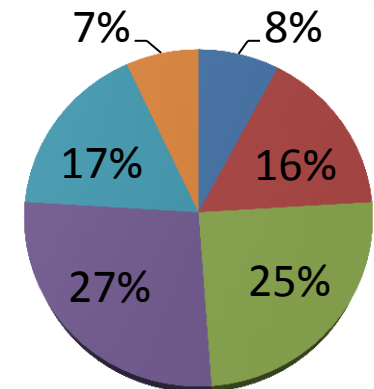
Food



Drug



Device



Paradigm Shift #2

**Suppliers
are
Suppliers**



**Suppliers
are
Customers First**

- **Suppliers = Customer:** our specifications, requirements and expectations are the “products” we deliver to our suppliers
- **Suppliers = Suppliers:** the incoming material is the product we then receive from our suppliers

Suppliers ≠ “Lesser” Entities



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Action-Provoking!



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Integrity of Supply GSP

Solution Phase



Three over-arching themes

1. Product and Process Knowledge and Development
2. Supply Chain Development and Management
3. Driving Ideal Behaviors

End Goal

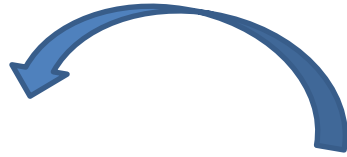
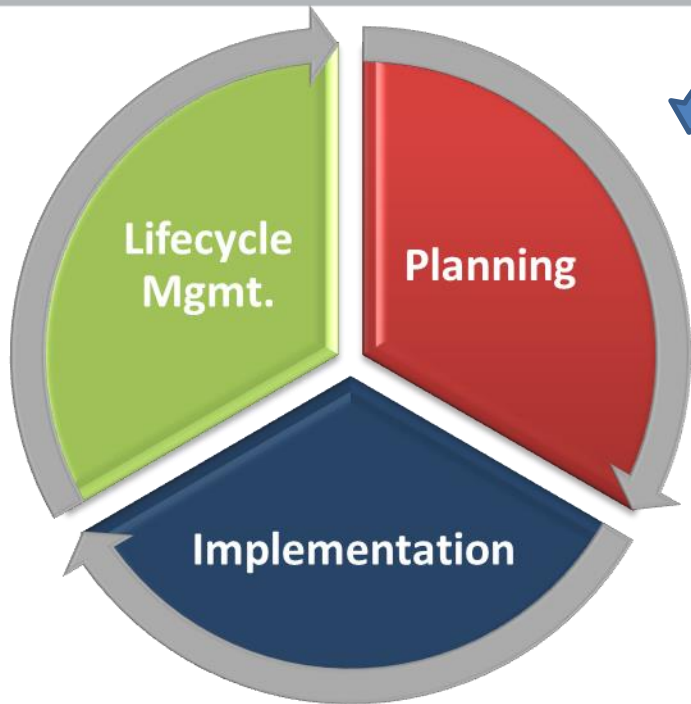


business smart!

Development and implementation of pragmatic Good Supply Practices (GSPs) related to the three over-arching themes that include standardized practices based on cross-industry best practices



Anchor to SCM Process



Group GSPs under Supply Chain Management Phases



Link to process-specific steps

Planning	Implementation		Lifecycle Management
Requirements and Risk	Supplier Identification	Qualification	Monitor/ Feedback



Matrix of Input

Team	Planning	Implementation		Lifecycle Management
	Requirements and Risk	Supplier Identification	Qualification	Monitor/ Feedback
Product and Process				
Supply Chain				
Ideal Behaviors				

Product and Process Knowledge and Development

First	Last	Title	Company
Christopher	Claeboe	Product Manager	Albemarle
Matthew	Deacon	Director - API Manufacturing	Eli Lilly
Elaine	Jai	Supply Chain and Procurement	Eli Lilly
Siek Meng	Khor	QA Director	Teleflex
Viliam	Kovac	Head of Global Compliance	Roche
Glenn	Muldoon	Manager, materials procurement	Shire
Mike	Oleksa	Senior Director	Steris
Stelios	Tsinontides	Sr. Director, Mfg. Sci & Technology	Shire
Sherry	Warren	President	WLS Enterprises



Supply Chain Development and Management

First	Last	Title	Company
M.	Bhupathy	Senior Director	Shire
Hanna	Edstrom-Valsinger	Sourcing Process Leader	GE Healthcare
Paul	Nelson	Exec. Dir., Supply Chain	Auxilium
Shonte	Pettiford	Quality Program Manager	Abbott
David	Rothenberger	Consultant - QA Procurement	Eli Lilly
Gerard	Sheehan	Quality/ Regulatory Affairs Director	Tornier
Jack	Solomon	Practice Leader, Supply Chain	Core Risks Ltd
Ken	Stopar	Director Supplier Quality	Baxter
Andre	Warren	Vice President	WLS Enterprises
Jean Pierre	Zajac	General Mgr., Sourcing EMEA	GE Healthcare
Don	Zgoda	CQA Supplier Quality Management	P&G



Driving Ideal Behaviors

First	Last	Title	Company
Dave	Gault	Sr. Manager Risk, Compliance & Security	CPKelco
Harry	Gill	Vice President	Patheon
Christine	Gladwell	Quality Director - Global Supply Chain	Baxter
Patrick	Henry	Director of Business Development	Puritan Products
Tim	Johnson	Sr. Director, Quality	J&J
Stephanie	Leonardos	President & CEO	Amerikam
Diana	Lewis	Senior Specialist – Quality	Merck
Ben	Locwin	Director	Biogen Idec
Kristen	Lyons	Quality Engineer	Cook
Geert	Van Acker	VP of Purchasing	Baxter



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Swim Lanes



R&D

Quality

Supply
Chain

Reg
Affairs

Suppliers

Step 1. Internal Risk Based Assessment

Step 2. Development of Product and Process

Step 3. Finalization of Requirements



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Action Provoking!



- Understanding our Product/Process
- Developing our Supply Chain
- Establishing Ideal Behaviors

Increased Product Confidence



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Action Provoking!



Transparency actually builds trust, inspires creative problem solving, and engenders ownership of outcomes

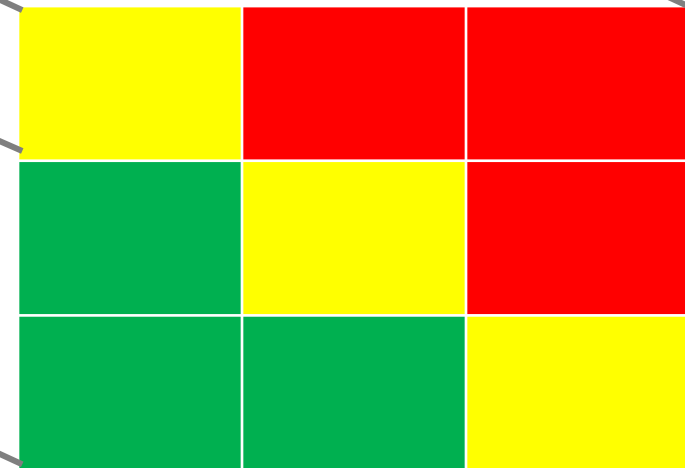
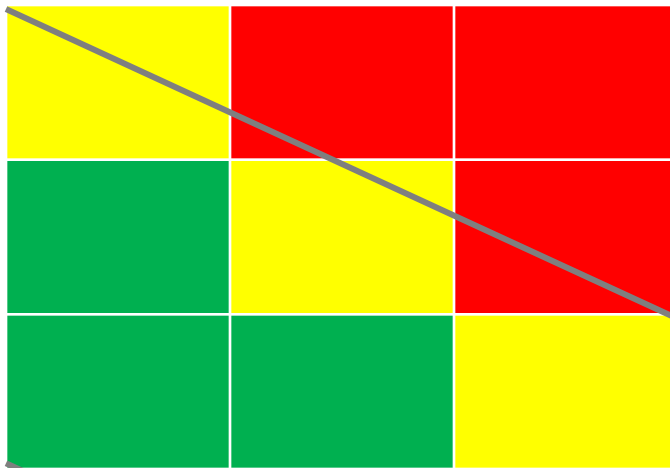


Accurate forecasting and harmonizing (“I’ll take a #1”) reduces risk of error



Supplier Qualification

Capacity, Location, Risk of Material
Compliance, History



Compliance, Resources,
Stability, Product Knowledge
Forecasting Ability, Internal Alignment

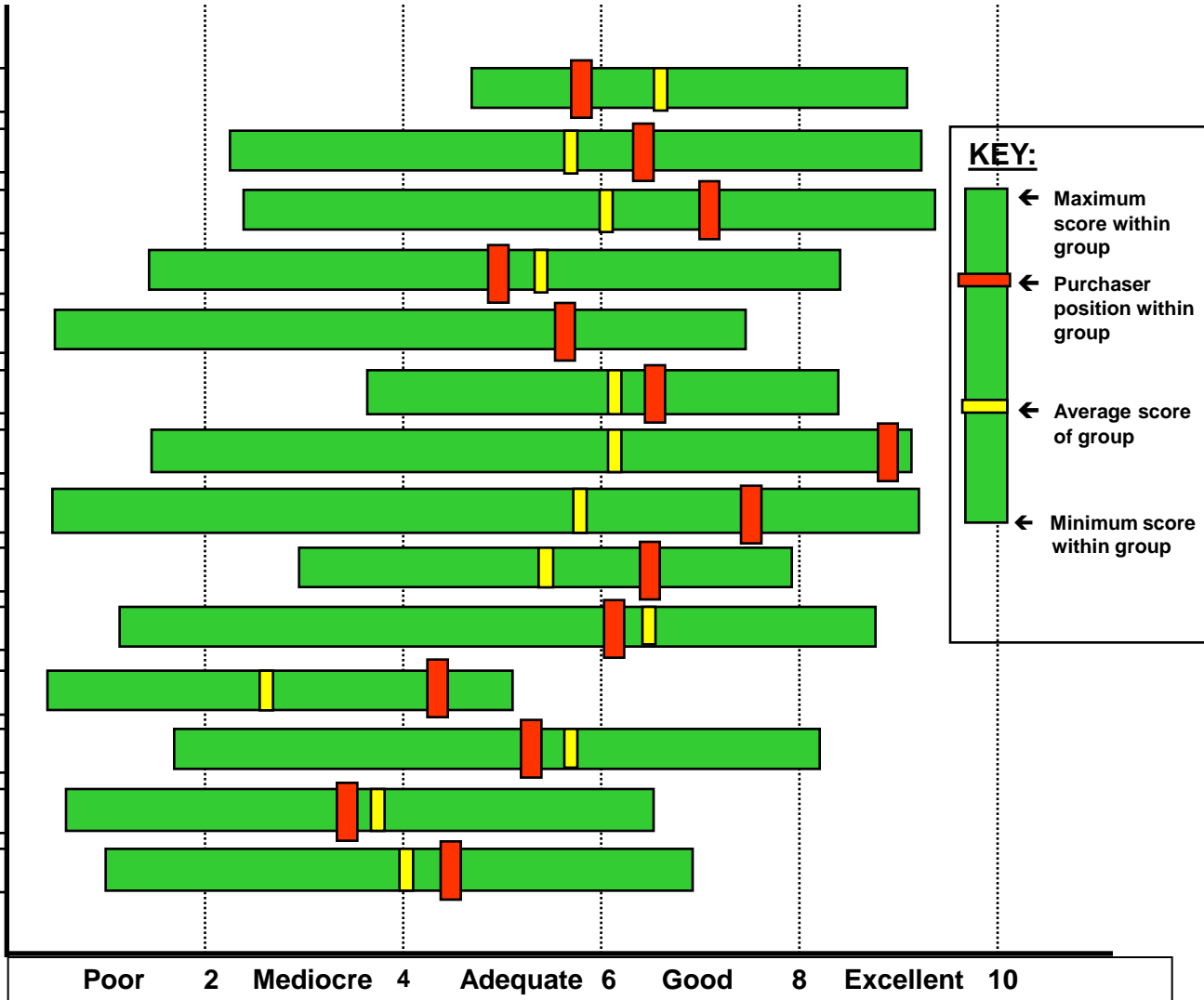
Self Qualification



Suppliers Rate Clients



25	650	Specification
25	670	Tender Process
18	650	Bid Clarification
20	672	Purchase Order / Contract Docs
16	623	Communications
12	261	Manufacturing/Service Supprt
24	692	Quality Control
25	590	Change Control
25	594	Documentation
23	630	Delivery
21	629	Commercial Management
14	300	Interfaces with Client Systems
12	220	Post Delivery Experience
18	614	Co-operation & Relationships





GMP

GSP

Increase
Product
Confidence

GIP

GDP



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Integrity of Supply GSP

Questions...Ideas



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Director

Xavier Health

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