XAVIER HEALTH

Increasing Supply Chain Reliability – Shifting Paradigms

MedCon

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Inspiring Collaboration Leading Innovation Making a Difference

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

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**.

Governance Team

Name	Title	Company
Helge Batz	Director Materials Management	Boston Scientific
Peter Beckerman	Deputy Associate General Counsel for Program Review	FDA
Dale Carter	Global Director of Quality	Huber
Bill Dempsey	Head of Procurement	Shire
Dale Huff	Exec. Director, Supplier Development & Performance Management	Merck & Co.
Al Kentrup	Worldwide Director, Corporate Quality Assurance.	Procter & Gamble
Mike King	Director, Supplier Quality	J&J - Ethicon
Michael Landberg	Strategic Global Sourcing	Boston Scientific
Hank Llamas	VP of Supplier Quality	J&J
David Lowndes	SVP Supply Chain and Quality	Shire
Will Mitchell	Corporate Quality Assurance External Liaison	Procter & Gamble
Gwyn Murdoch	Director, QA-Procurement, Global Quality Auditing and Compliance	Eli Lilly and Co.
Mark Paviglianiti	Director, Supplier Development & Performance Management	Merck & Co.
Marla Phillips	Director	Xavier University
Susan Rolih	EVP, Regulatory Affairs and Quality Assurance	Meridian Bioscience
Michelle Smith	Senior Director, Regulatory Affairs and Design Assurance	Meridian Bioscience
Steve Solomon	Deputy Associate Commissioner for Regulatory Affairs (acting)	FDA
Rafiqah Williams	Vice President Global Quality Auditing and Compliance	Eli Lilly and Co.

Our Data

Cause/Effect and Pareto

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 don’t follow our own supplier selection process
4. We are not able to detect changes or deficiencies in in-coming material
5. We do not have a feedback loop for specification effectiveness
6. We do not have a robust change management system in place
7. We are not involved in selecting our supplier’s suppliers

Cause/Effect and Pareto

8. Our supplier approval process is not robust
9. We are unable to verify GMPs with a certain base of our suppliers
10. We have no real understanding of how the supply chain is managed beyond Tier 1
11. We lack leverage with a certain base of our suppliers
12. We do not have enough resources to monitor entire supply chain
13. We do not adequately share information with our suppliers
14. We do not engage cross-functional colleagues in the process, or not at the right time

Cause/Effect and Pareto

15. We do not have vendor agreements with every supplier
16. We do not include social/branding/environmental components in our agreements and contracts
17. We do not have visibility to a database of good suppliers
18. We are not involved in setting the specifications beyond Tier 1
19. Our Supplier Agreements conflict with other agreements we put into place

Notice the "We"

Paradigm Shift #1

"Our Suppliers Are Causing Problems"

We are Causing Problems

August 2012 — **July 2013**

- August 2012: we wanted to focus on Food's GFSI model
- January 2013: we wanted to focus on certification of our suppliers
- May 2013: top data is pointing to ourselves as the root cause

Key Takeaway

Disciplined process will focus on true root cause

Supplier Input

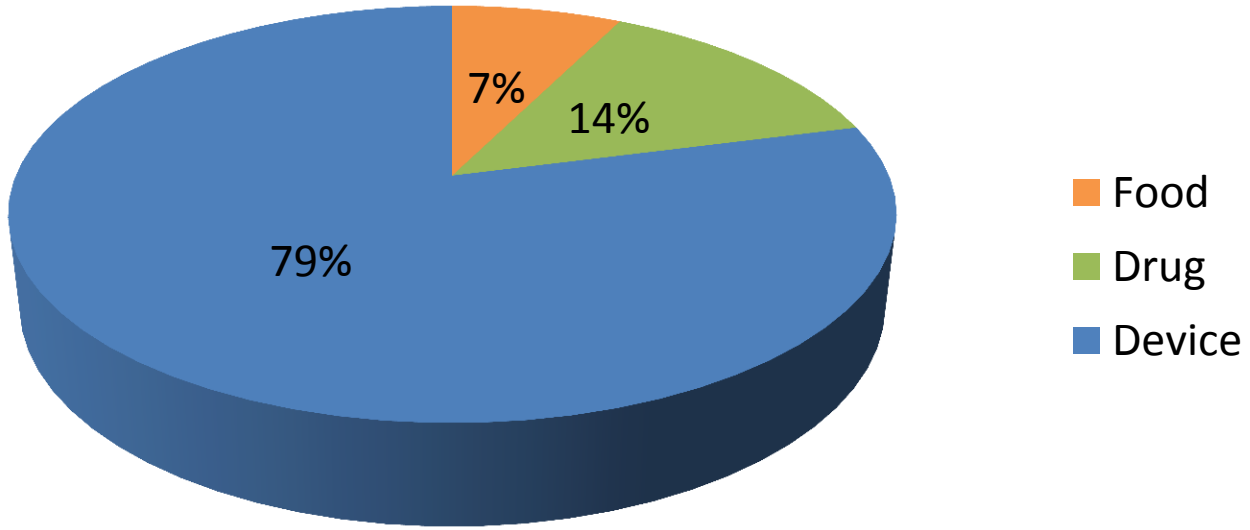
Total Respondents

Food	Drug	Device
12	22	128

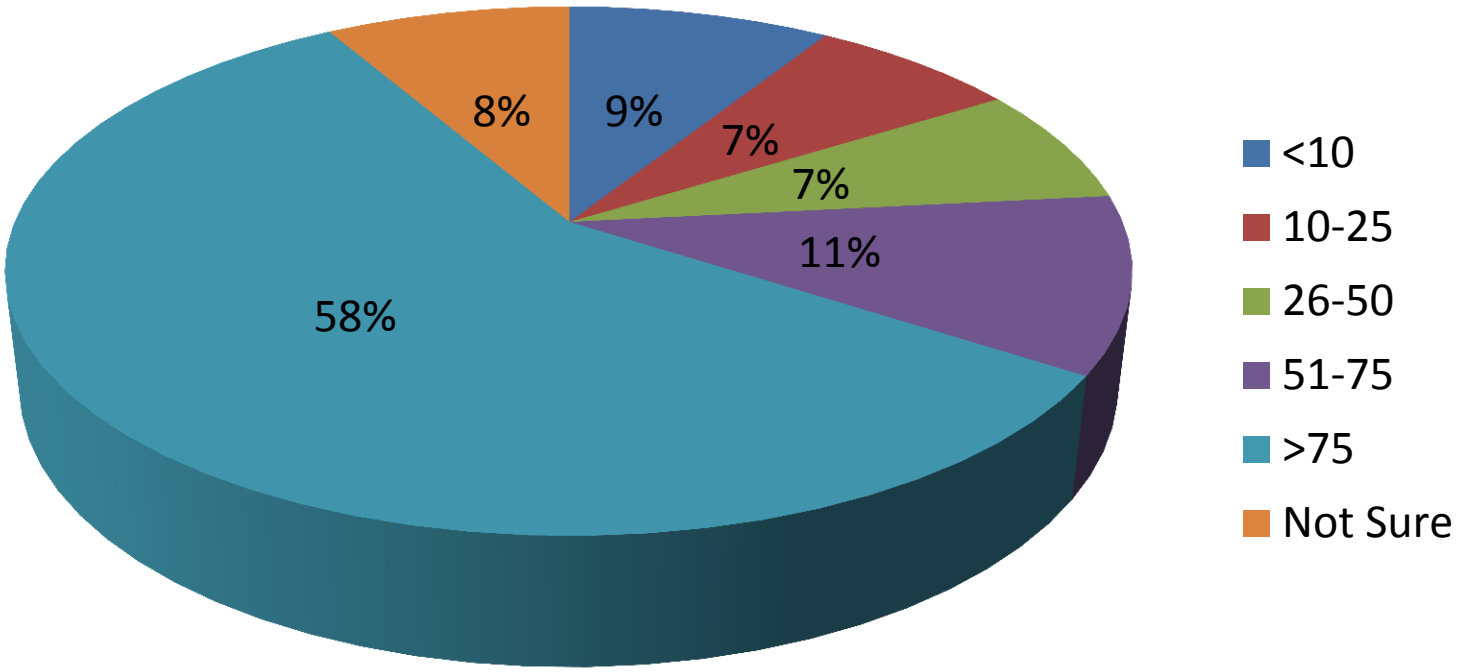
Respondents: Mixture of functional background

Suppliers responding:

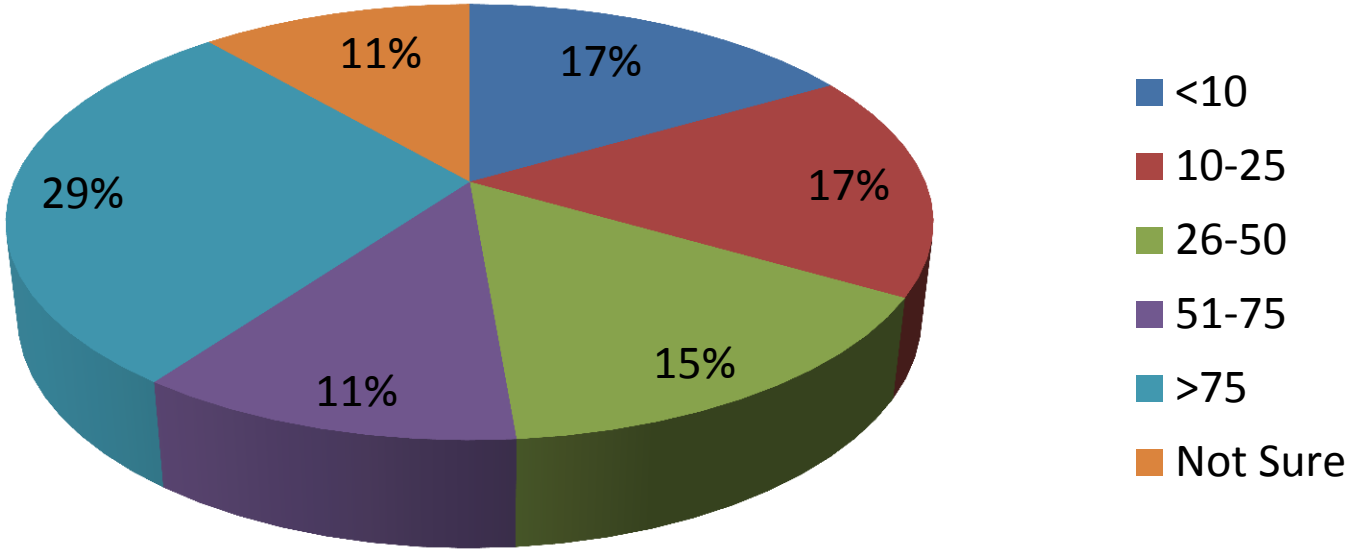
- Many products manufactured – volume and type
- Industries served outside of FDA industries
- Large percentage of Specialty products



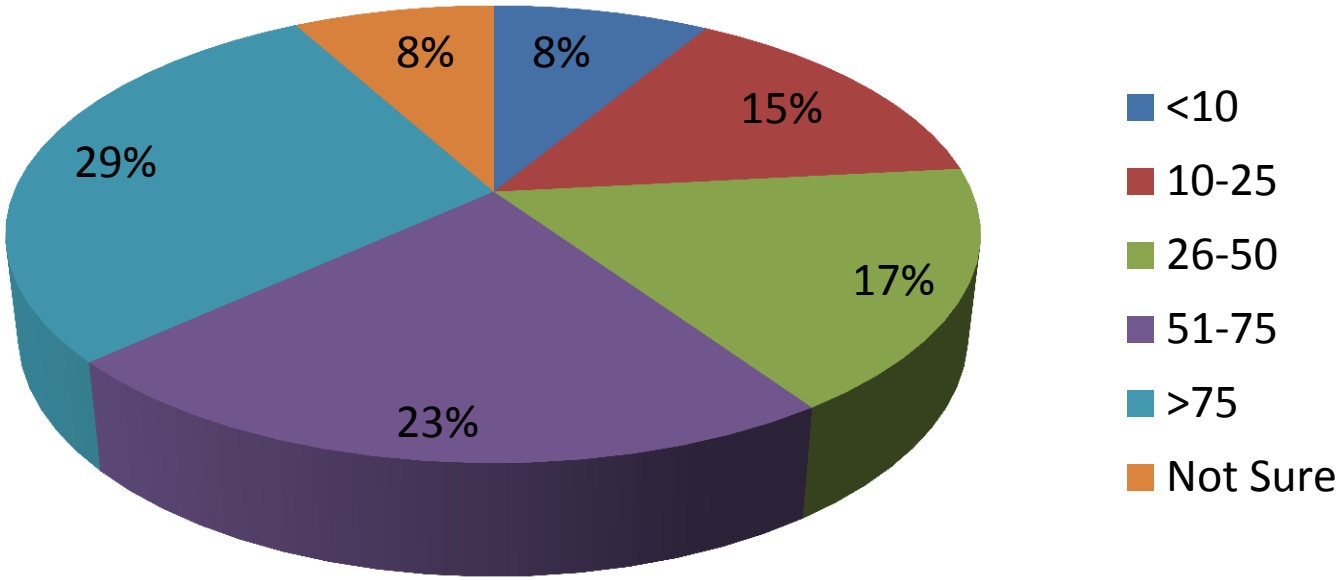
% of time it is critical to know the intended-use of your product/material



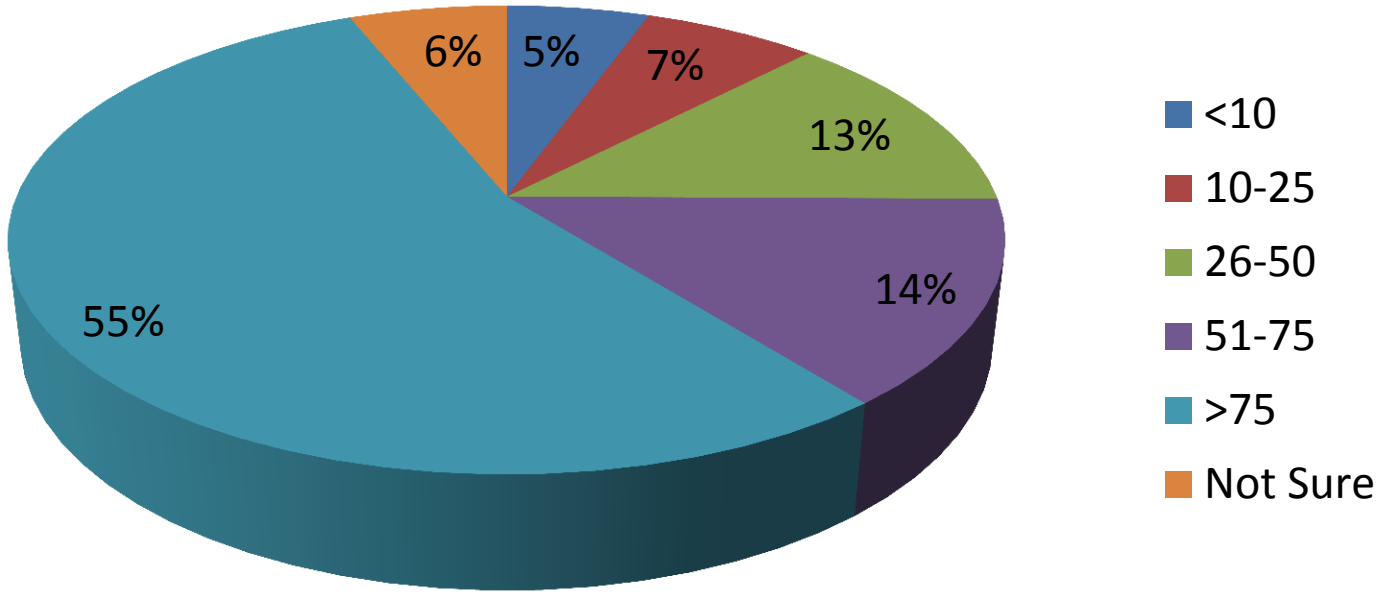
% of customers who ask to see your process capability data and/or composition of material information



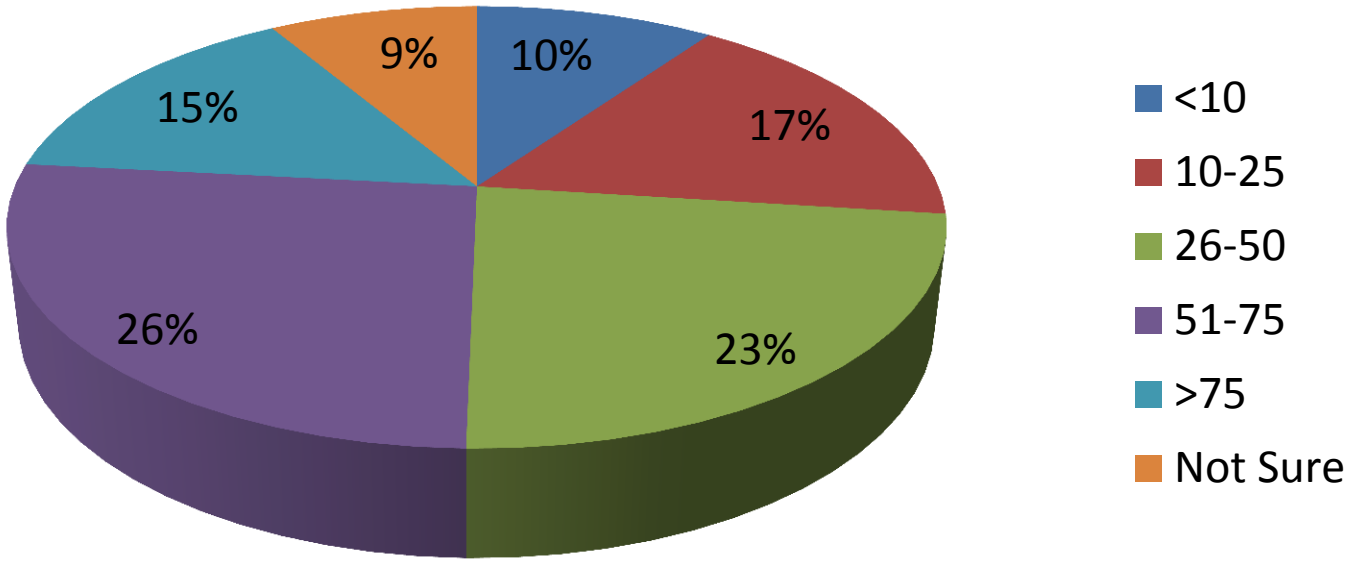
% of customers ask for your input on specifications for your product/material



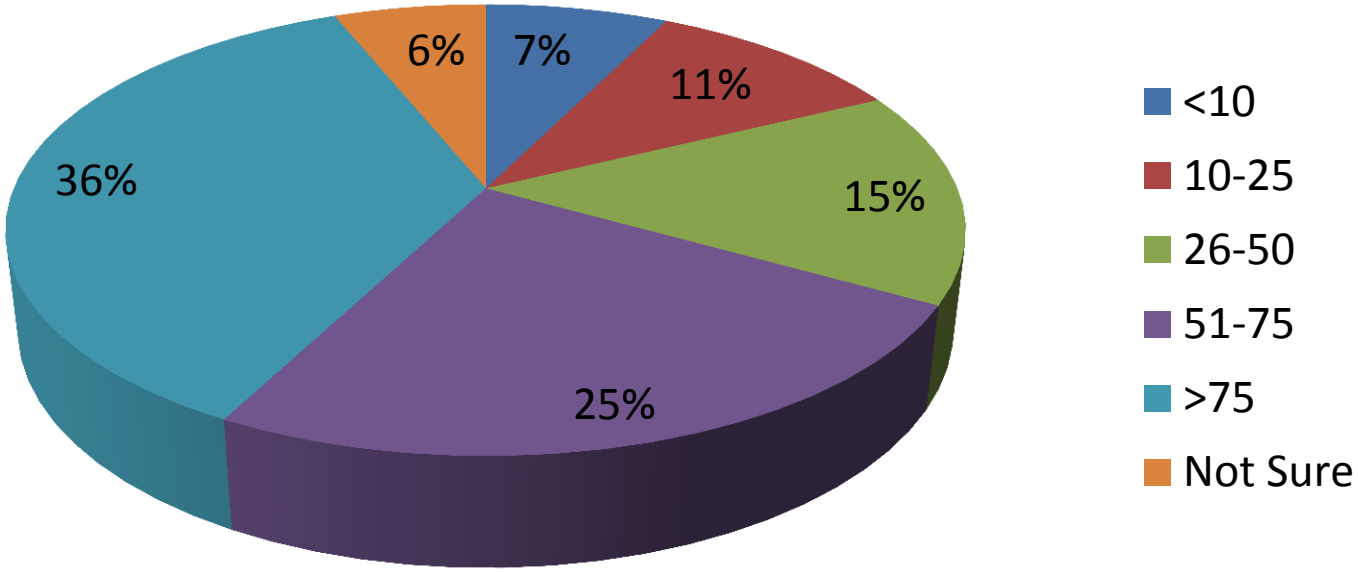
% of time you have enough info about customer needs and process to know when it is important to report changes



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



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



Good Supply Practices (GSPs)

End Goal

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

Three over-arching themes

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

Your Next Steps?

Focus improvement efforts on:

- Yourself first
- Then your suppliers