AMGEN
Pioneering science delivers vital medicines™

Enhancing The Relationship Between the Drug Firm and Its Suppliers

David Cady

Director, Global Strategic Sourcing

Objectives – Best Practices?

- Supply continuity strategy
- Key focus areas – overview
- Raw material focus
- Org structure
- Supplier management
- Supply chain transparency

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We are Committed to Delivering… Every Patient, Every Time

- **Ensuring dependable supply is at the heart of Amgen's social architecture**
- **Effective mitigation of risk to product supply requires a holistic and multifaceted risk management strategy**
- **The commitment to uninterrupted product supply starts with the Board of Directors and CEO and involves everyone in Operations**

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Amgen Has Implemented a Comprehensive Approach for Mitigating Risk to Supply

Prevention

- Compliance with CGMP and a robust quality management system
- Operational Excellence
- Supply Chain security
- Infrastructure investments
- Business continuity planning

Technology

- Enhance product and process robustness
- Greater focus on characterization
- Investment in technology
  - Nuclear magnetic resonance
  - HTST (High Temperature Short Time) sterilization
  - Isolators

Inventory

- Quantity of material
- Stage of manufacturing
- Storage location

Diversification

- Implement backup manufacturing capabilities (diversification)
- Enhance existing contract manufacturing capabilities

These four levers are not mutually exclusive and each has an impact on risk, cost, and flexibility

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There Are Five Key Elements in Amgen's Strategy to Prevent Supply Interruption

GMP Compliance	Quality Management System provides a systematic approach to identify, measure, control, and improve quality
Operational Excellence	Culture that promotes a mindset of continuous improvement, Right First Time, and high reliability performance
Supply Chain Security	Management of supply chain security risk throughout the end-to-end product lifecycle
Infrastructure Investments	Enhancements made to existing facilities to improve the resilience of structures, equipment, and processes
Business Continuity Planning	Documented plans for critical business processes to improve emergency responsiveness

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External Risks to Supply Are Being Addressed by Our Global Product Protection Program

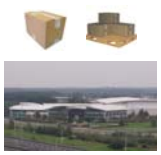
1 Raw Materials and Devices

- Second-sourcing of raw materials
- Supplier Relationship Excellence program

2 Product Authentication

- Implementation of serialization
- Overt and covert security feature implementation

3 Warehouse Security



- Building security systems
- Distributor/LSP security audits

4 Cargo Security

- Cargo security at pallet, truck, and carrier level
- Cargo tracking technology

5 Market Surveillance

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→ Customer

- Counterfeit monitoring
- Test buys and authentication

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Fundamental Reasons for Understanding the Risks Posed by Raw Materials

- **Classical raw material issues**
  - Variability introduced by packaging, media, component traces & residues
  - Extraneous matter (process or reagents residues, particles), breakage
  - Single sourced materials
- **Increment in the complexity of the supply chain**
  - Globalization or production centralization in supplier's operations
  - Introduction of new technologies
  - Implementation of cost reduction initiatives
- **Increase of regulatory expectations and scrutiny**
  - Combo product and Device regs
  - Supplier accountability & quality agreements
  - Raw material monitoring prior & after Process Validation

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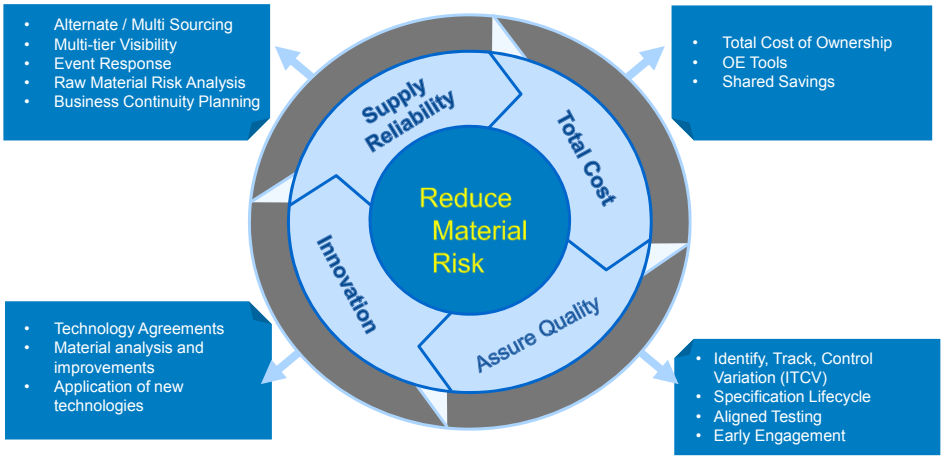
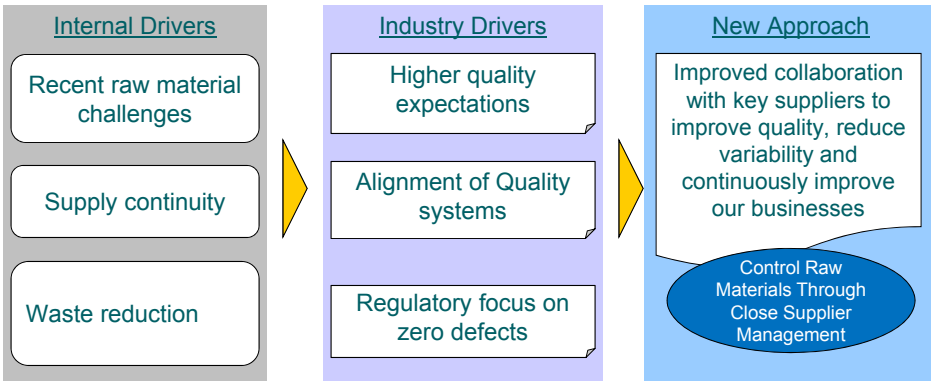
Raw Material Strategies Utilize Defense in Depth Principles to Understand and Mitigate Risk



Ensure reliable supply of quality materials at best total cost of ownership

Internal and Industry Drivers Necessitate a Holistic Approach with Raw Materials



Raw Material and Device Team created to expand the Amgen OpEx mindset to our key suppliers

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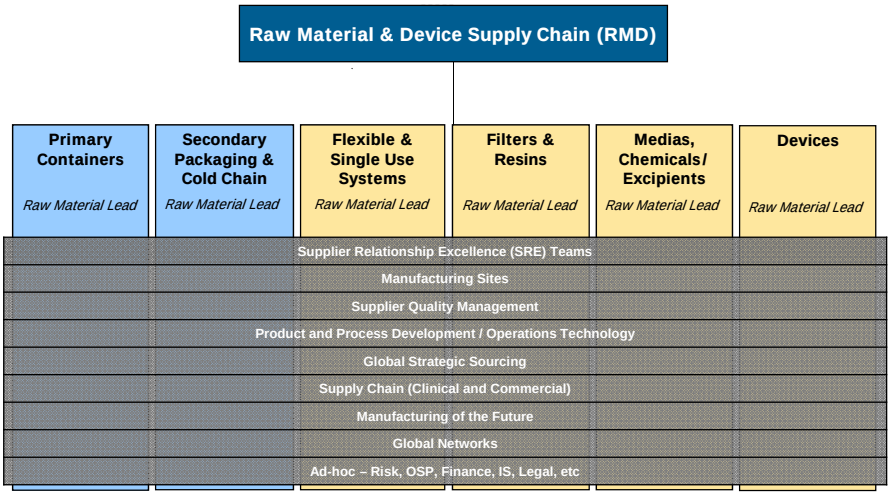
Org Strategy: Dedicated Function In Place With Direct or Dotted Line Accountability of Subject Matter Experts



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The Raw Materials Team is Focused On Key Elements For Success

Mission

- **To assure quality & supply reliability for Raw Materials and Devices across our clinical and commercial programs to se**

Vision

- Manage External Supply Chain in order to proactively reduce material and supplier risk
  - Eliminate quality issues through control of variability **Identify, Track, and Control Variability (ITCV)**
  - Ensure reliable supply of all materials and components with intense focus on risk reduction
  - Improved collaboration with suppliers through **Supplier Relationship Excellence (SRE)** and proactively addressing future problems leveraging their expertise
  - Understand **Total Cost of Ownership (TCO)** and utilize **OE tools** to reduce COGM
  - Capture value -self funded investment

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SRE Focusses on Key Suppliers Within Amgen's Supplier Management Program

- Strategic relationships
- Continuous intense engagement
- Shared investment and value
- Open two way feedback

Supplier Relationship Management is not a new concept but aspects of our program are new to this industry

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The SRE Program Built on Three Pillars With Defined Objectives

1 Intense Technical Engagement	2 Supply Chain Optimization	3 Robust Relationships
Deep and holistic mutual technical understanding of key raw materials, their manufacture, use, and interactions	**Complete transparency and synchronization of supply chain**	**Collaboration with well defined teams and continued focus at the executive level**
Outputs: - Raw material and process characterization - Clear, critical attributes and specifications - Improved manufacturing in-process controls - Aligned Quality systems	**Outputs:** - Line of sight to OEMs - Lot definition and traceability - Optimized inventory and lead-times - Consistent, quality and reliable supply	**Outputs** - Joint goals / progress ensured via regular & frequent executive meetings - Clear communication channels - Two way feedback - Joint understanding of the challenges & sharing of benefits

Operational Excellence is Pursued in All Three Pillars to Create Value

ITCV and MVA	SC Transparency	Total Cost of Ownership

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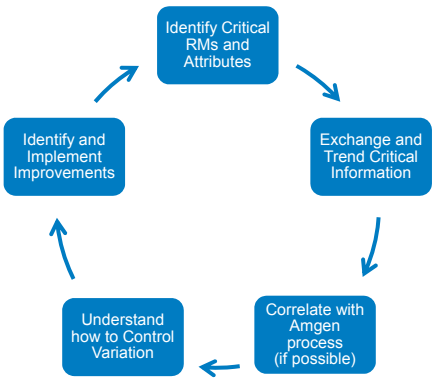
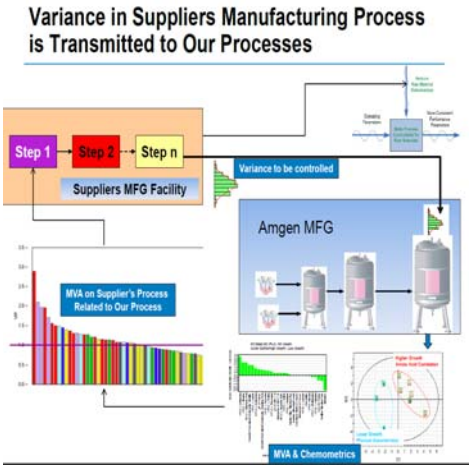
A Large Part of Technical Engagement Involves ITCV (Identify, Track and Control Variation)





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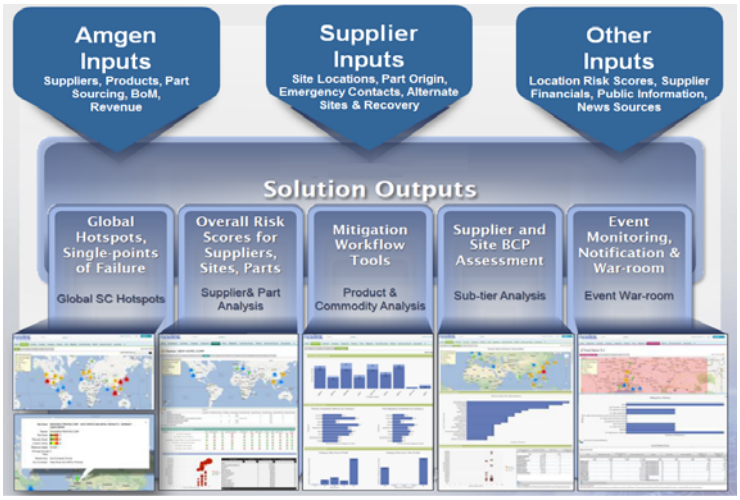
Amgen's Raw Material Transparency Focus Is On Total Understanding of Our Supply Chain

Definitions

"Tier 1" suppliers	Direct supplier of goods or services to Amgen
"T2,3,X" suppliers	Provides goods or services to Tier 1 suppliers or their suppliers
Node	Each supplier's site associated with a given supplier 1 supplier can have multiple sites (nodes) associated with the materials provided

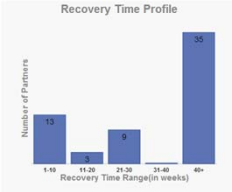
Challenge - Introducing this new concept to the BioPharma Industry

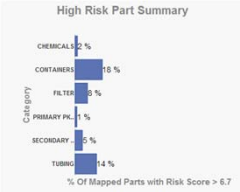
Solution Selected Delivers a Comprehensive Suite of Functionality and Features



Non-Amgen Sample Data

Central Repository for Storage, Monitoring, and Analysis of Supply Chain Intelligence

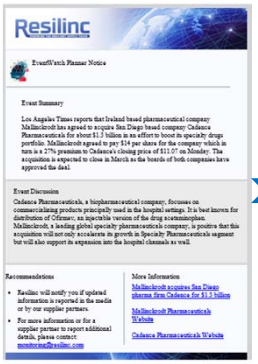


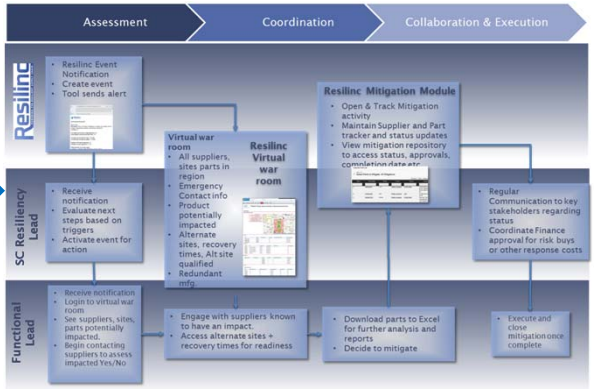


Non-Amgen Sample Data

Finger on the Pulse of Global Events with Potential to Impact our Supply Chain

Sense **Respond**





(Notification) **(Actions)**

We Are Getting Traction…

- Reduction in non conformances, scrap
- Variation correlation and process improvements
- Reduction in TCO
- Improved approaches to process development
- New innovation adoption
- Targeted innovation pipeline
- Robust agreements that reward success
- Improved engagement for new raw material sourcing

…..but careful targeting of resources is essential

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Acknowledgements

- Rod MacLea, Director, Global Supply Chain
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Thank You!

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