

# Supply Chain Risk Management: A Supplier Perspective

## Biotech Supply Chain Academy

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# Agenda

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- **About SAFC Biosciences**
- **Katrina and Risk Management : Process**
- **Melamine and Supply Chain Transparency: Project**
- **Collaboration for Risk Management and Transparency**

# Focus Points

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- **Importance of data transparency**
- **Improve supply chain surveillance**
- **People are more important than technology**

# Sigma-Aldrich

- 2008 Sales: \$2.2B
- 38 Production Sites in 10 Countries
- 1,000,000 customers
- 7,900 employees
- 130,000 products listed
- Manufacture over 46,000 products
- Network of over 10,000 suppliers
- 34 years of continuous growth (Sales & EPS)



*Financially stable with 50 consecutive years of growth*

# SAFC within Sigma-Aldrich

**SIGMA-ALDRICH®**

**Research**

**Development**

**Manufacturing**



**SAFC** Supply Solutions™  
Inspiring Science

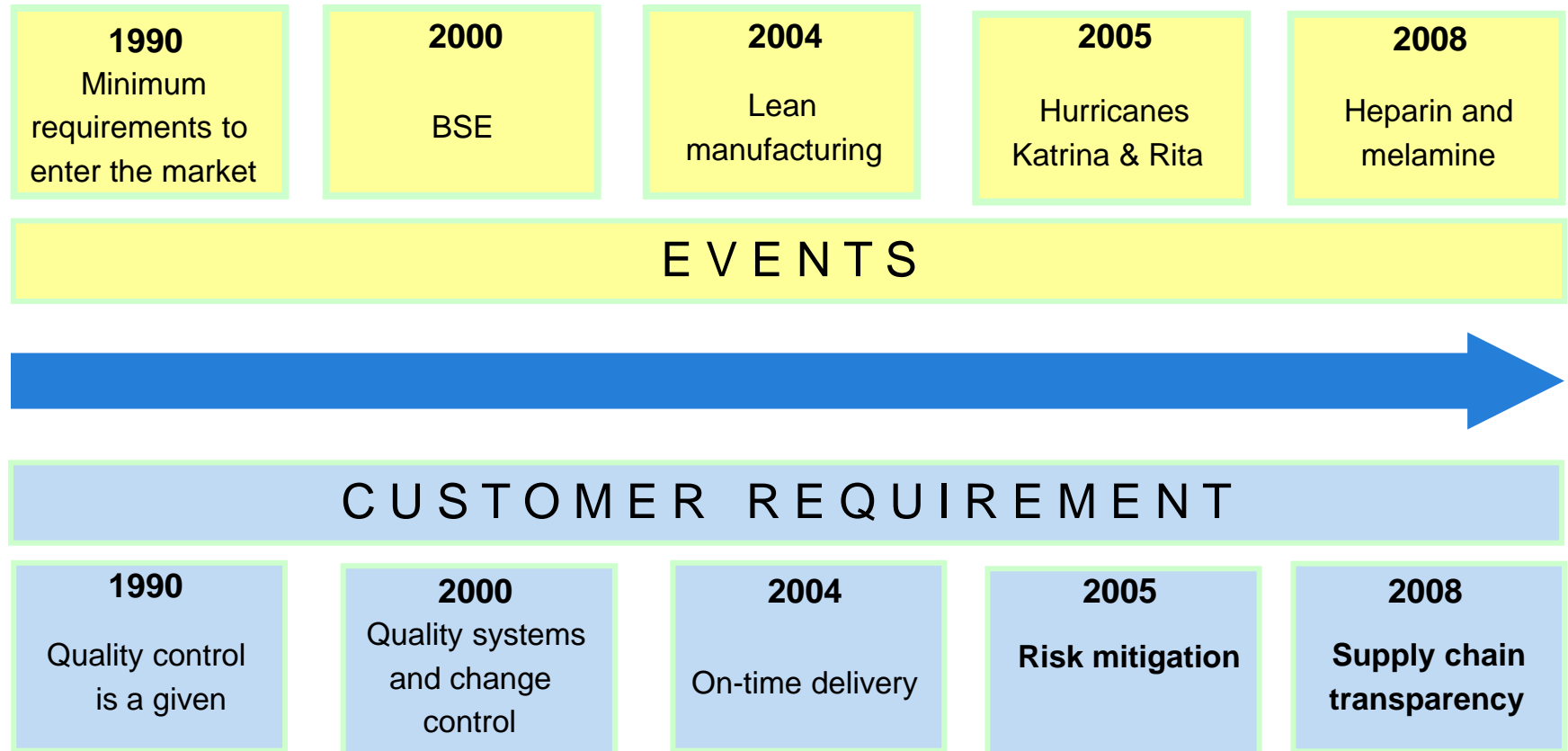
**SAFC** Pharma™  
Inspiring Science

**SAFC** Biosciences™  
Accelerate Success™

**SAFC** Hitech™  
Enabling Technology

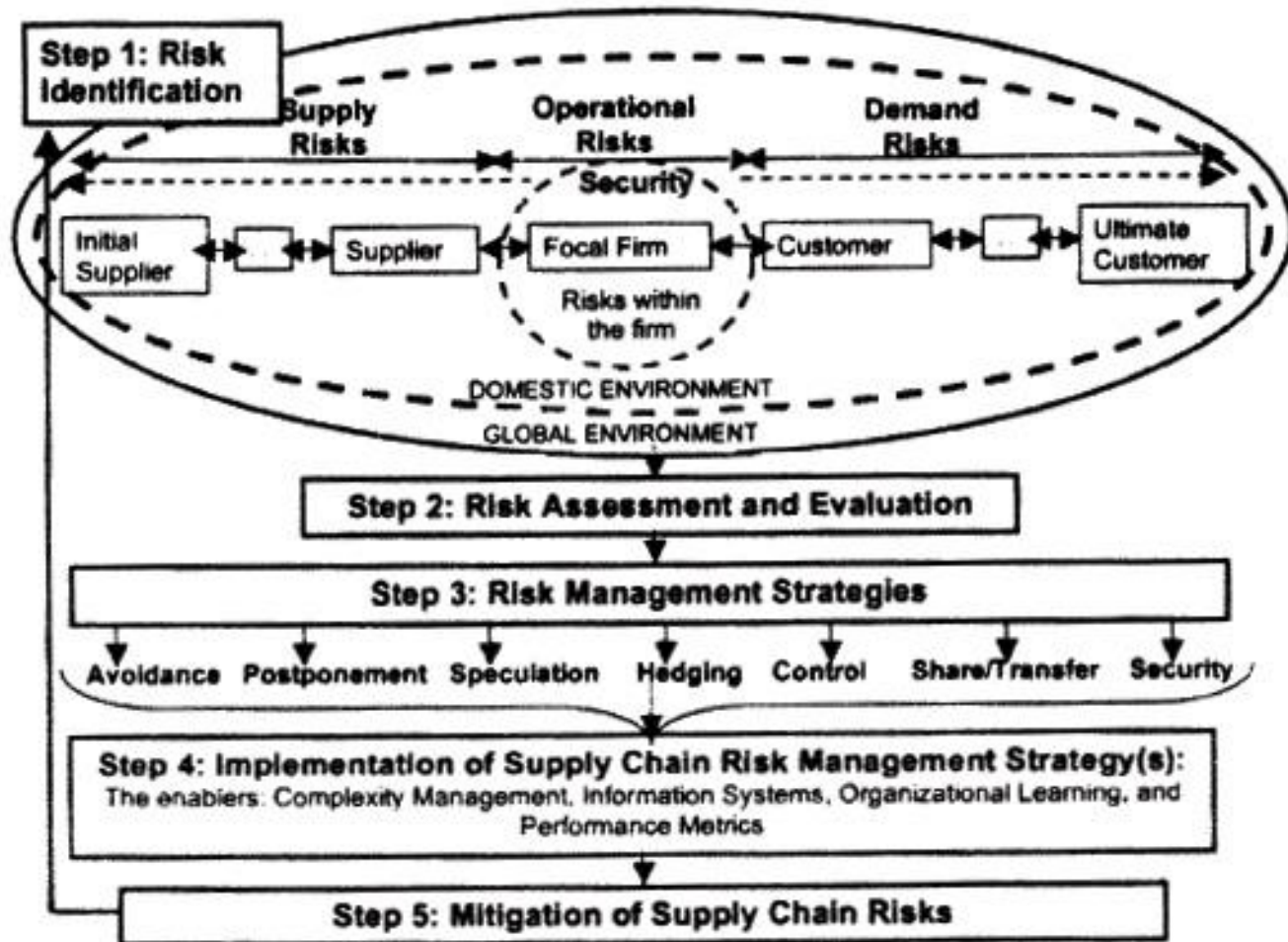
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# Global Events Have Increased Customer Requirements



*Upstream Supply Chain Transparency is Required*

# Risk Management Model



# Types of Risk

- **Supply Risks**
  - disruption of supply, inventory and schedules
- **Operational Risks**
  - breakdown of operations, changes in technology
- **Demand Risks**
  - variations in demand
- **Security Risks**
  - theft, **sabotage**, terrorism, **counterfeiting**, infrastructure breakdown
- **Macro Risks**
  - economic shifts, recession, hike in wages, variation in exchange rates
- **Policy Risks**
  - actions and sanctions of governments, shifts in legislation
- **Competitive Risks**
  - uncertainty about competitors' moves and actions
- **Resource Risks**
  - uncertainty about resource availability

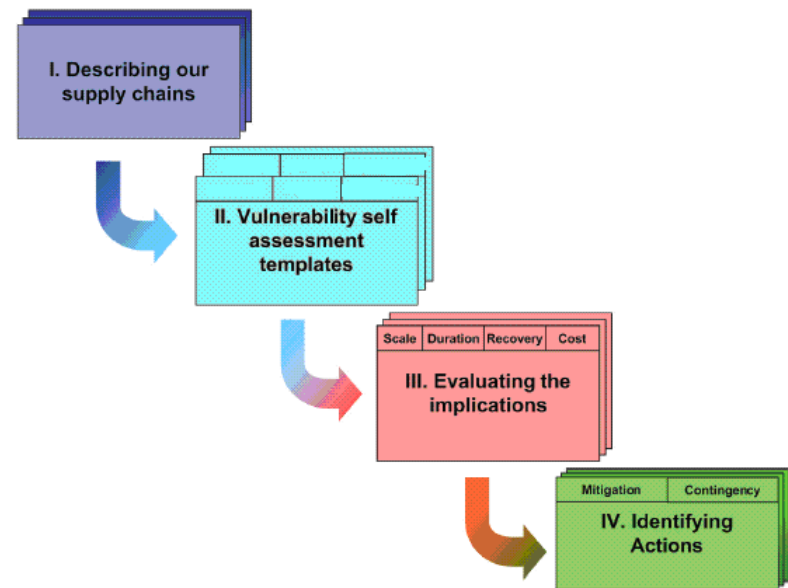
# Risk Management Strategies

- **Avoidance**
  - exiting a market (or product) or delay entering a market (or product)
- **Postponement**
  - delay commitment of resources to maintain utmost flexibility
- **Speculation**
  - assuming risk to gain competitive advantage
- **Hedging**
  - globally dispersing your portfolio of suppliers, customers and facilities
- **Control**
  - vertical and lateral integration of suppliers and business partners
- **Transferring/sharing risk**
  - outsourcing, off shoring, contracting
- **Security**
  - identifying unusual movements and protecting against unwanted penetration

# Supply Chain Risk Factor Analysis

## The Process

- Identify and describe your supply chains
- Identify risk factors and potential vulnerabilities
- Rank exposure to each risk factor
- Document the results and identify potential risk-reduction actions



# The China Syndrome

WORLD BRIEFING | AFRICA

**Nigeria: Contaminated Medicine Blamed for Deaths**

**Tainted cough syrup kills 21 in Panama**

CDC investigation traces mysterious deaths to industrial chemical

## The New York Times

Heparin Contamination May Have Been Deliberate, F.D.A. Says

### Melamine in pet food may not be accidental

Updated 4/20/2007 10:16 AM | Comments 06 | Recommend 54 | E-mail | Save | Print | Reprints & Permissions | RSS

**CNN.com /US**

updated 9:51 p.m. EST, Fri November 28, 2008

**FDA sets 'safe' levels for melamine in baby formula**

INTERNATIONAL  
**Herald Tribune** | Asia & Pacific  
THE GLOBAL EDITION OF THE NEW YORK TIMES

### China recalls infant formula

By Keith Bradsher

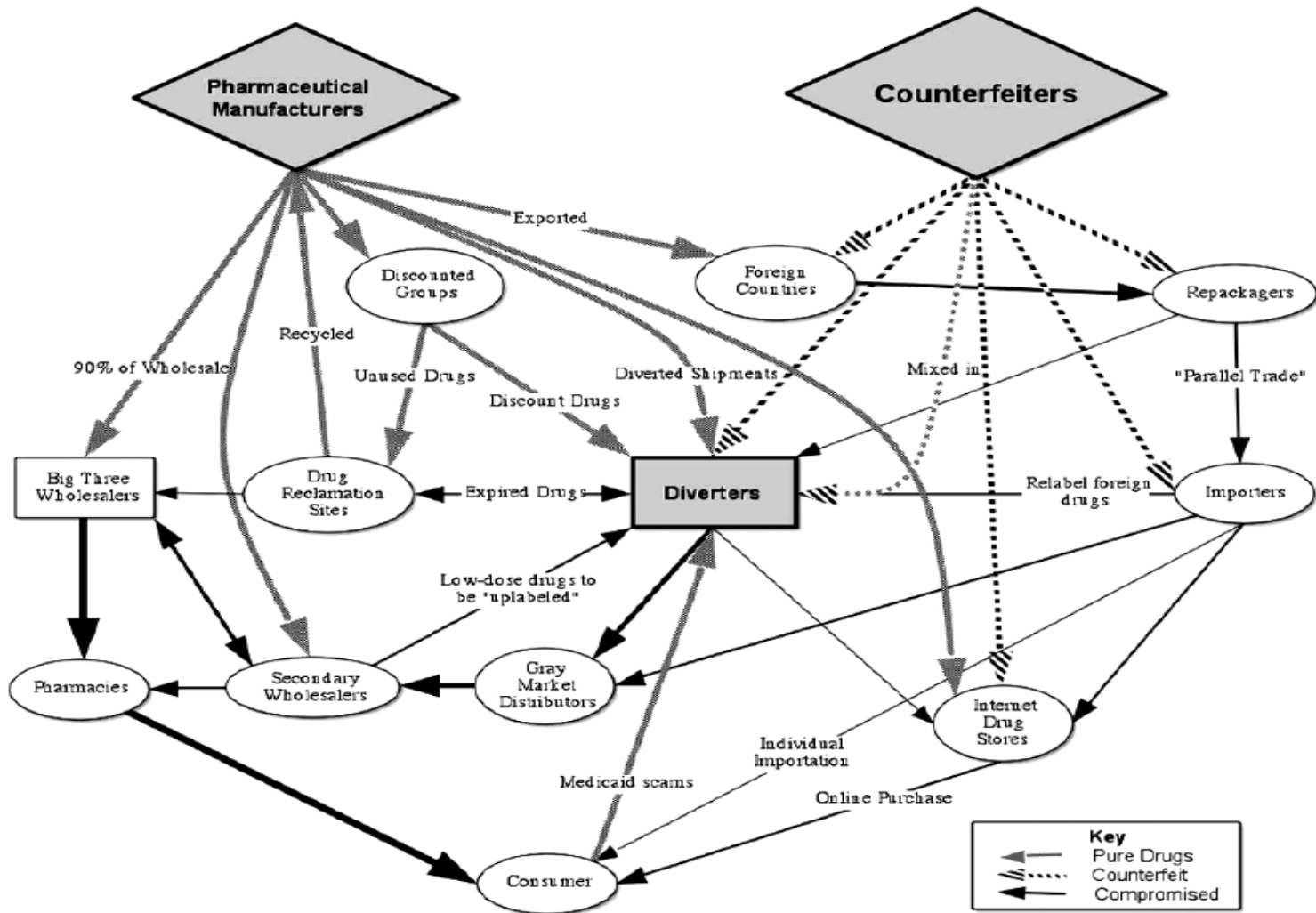
Published: September 12, 2008

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# Therapeutic Supply Chain

## Complex and Not Secure



Wyatt Yankus - ACSH - 2006

# Actions

- **FDA: “You can’t outsource responsibility!”**
- **Customer A: “We want full supply chain visibility for all items we buy from you. Through all supply chain levels. Yesterday.”**
- **Customer B: “Tell us the country of origin of all components, and give us your audit reports for all the Chinese manufacturers.”**
- **Customer C: “We don’t want any Chinese origin materials in our products. But don’t delay my orders.”**
- **Customer D: “We’ve been using that component from China for years without a problem. Don’t convert to another supplier just because they aren’t Chinese. By the way, we consider Eastern Europe, Asia except Japan and Singapore, Africa and South America as high risk.”**
- **Customer E: “Melamine?”**

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***“Have a bias toward action –let's see something happen now. You can break that big plan into small steps and take the first step right away.”***

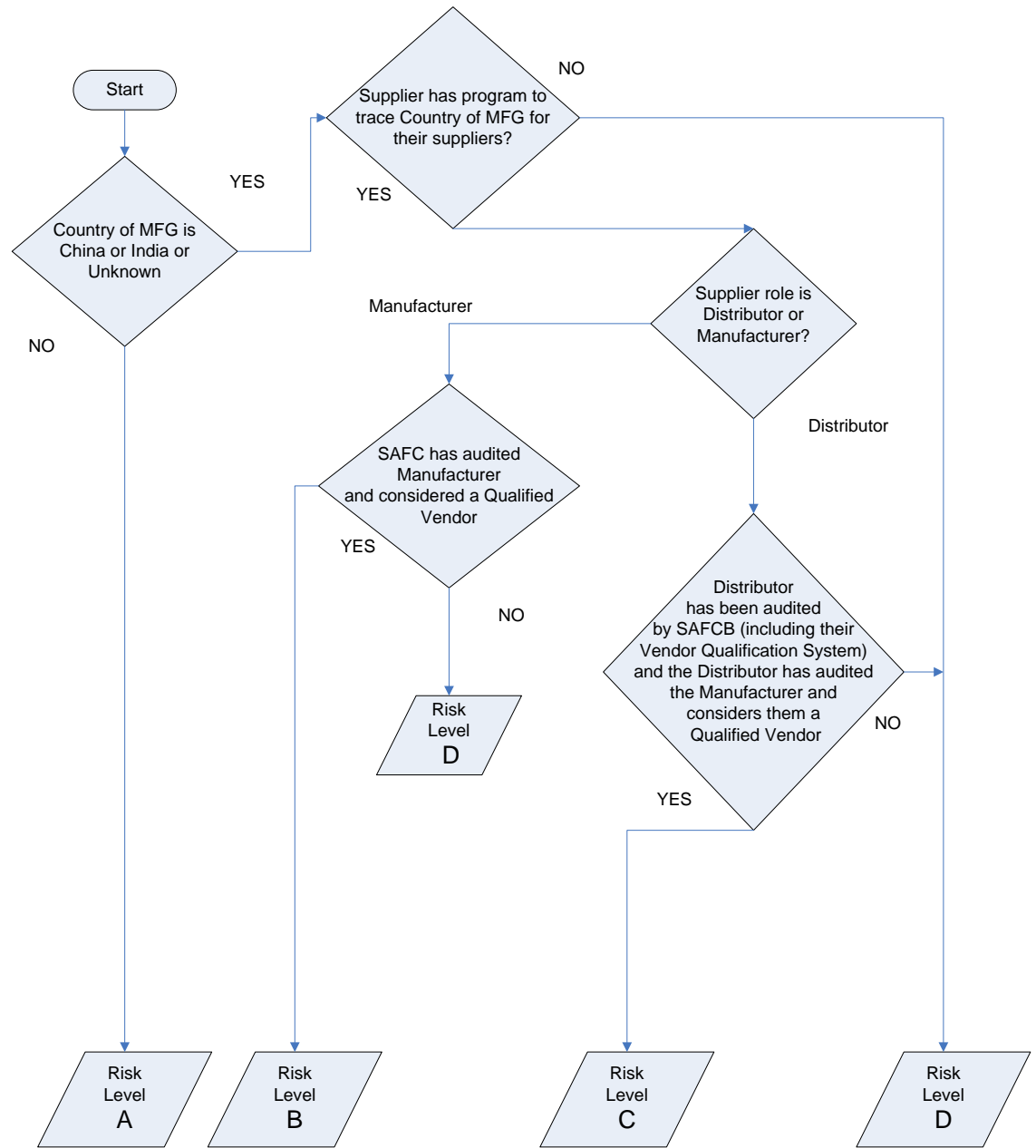
**-Indira Gandhi**

# Project scope

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- **Obtain country of manufacturing origin (N-1) data for each component/ source combination.**
- **Develop risk assessment process aligned with strategic customers.**
- **Identify and implement risk management actions**
- **Communicate pro-actively to internal and external stakeholders.**

# Risk assessment decision tree



# Risk Management Action Summary

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- **Continue to source in China, but reduce risk and increase supply chain visibility**
- **Qualify alternate sources for those customers that desire to eliminate China origin material**

# Mitigating Actions

- **Level D (Highest Risk)**
  - Collaboratively assisting the vendor to fill out missing or incomplete raw material questionnaire
  - Prioritized SAFCB quality on-site audits of Manufacturers
  - Request the Distributor physically audit their Manufacturer
  - Start CDA process if vendor says the manufacturing information is proprietary
  - Require the vendor to provide additional information (examples: testing to CoA, require testing to compendia)
  - Identify and qualify new source of material if no Level A, B or C exists
  - Additional testing at SAFCB for qualification/release for use
  - Request Country of Origin's Seal of GMP for raw material at that manufacturing site

# Mitigating Actions

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## Level C

- Identify and qualify new source of material if no Level A or B exists
- SAFCB audit of Distributor's manufacturer
- Execute quality agreement with Manufacturer/Distributor

## Level B

- Identify and qualify new source of material if no Level A exists

## Level A (lowest risk)

- Follow standard SAFCB supplier quality management actions

# Collaborative Actions

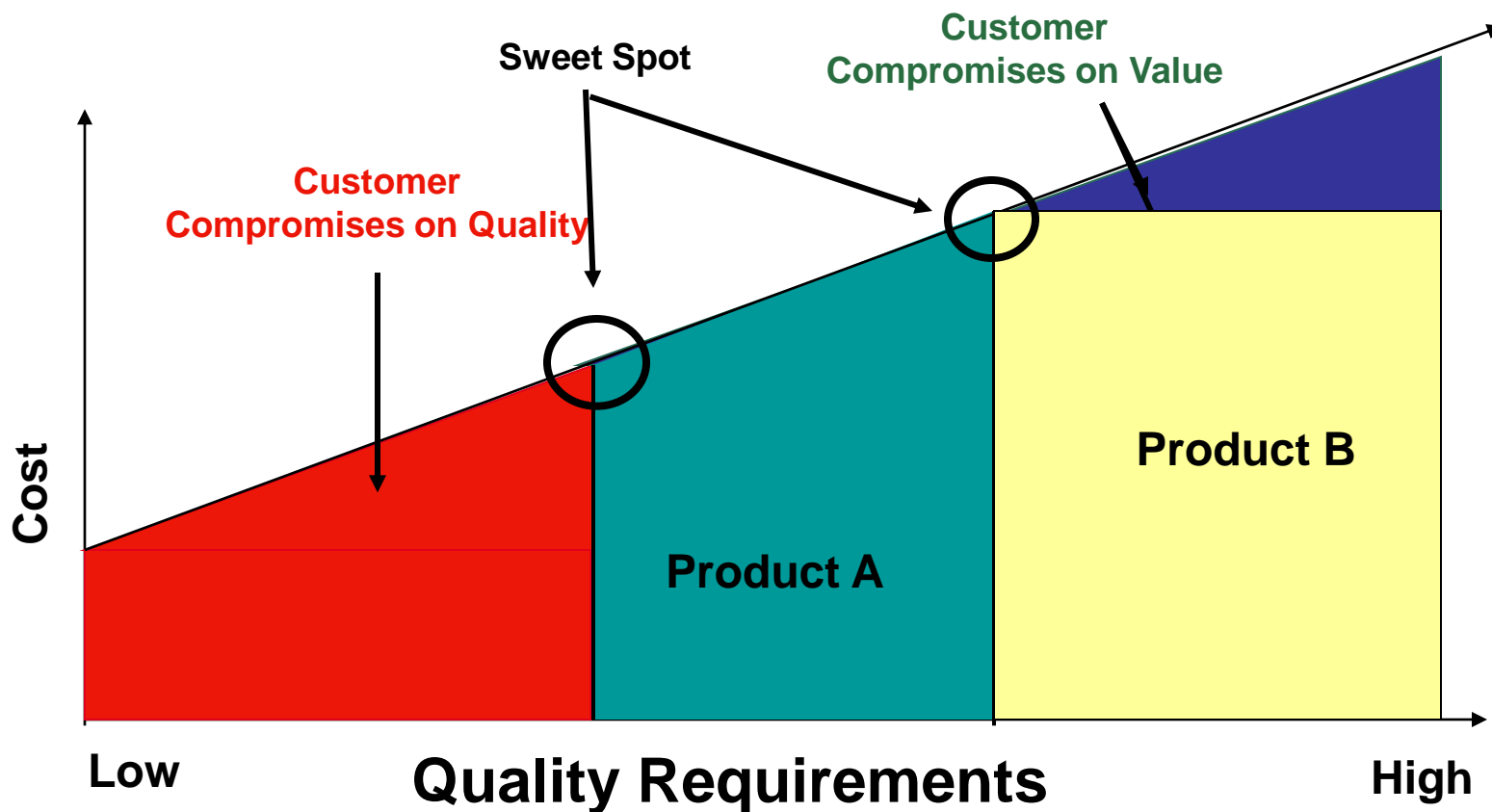
- **Customers**
  - Aligned project and decision tree with strategic customers
  - Provided detailed output of findings with intended action plans to all customer inquiries
  - Jointly developed risk management action plans with strategic accounts
  - Implemented customized action plans for strategic customers
- **Suppliers**
  - Worked with distributors to prioritize audits
  - Assisted manufacturers in completing questionnaires
  - Developed paths to meet distributor commercial concerns regarding manufacturer identity while gaining access

# Learnings

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- **Collaboration yields better results**
  - For us and the customer
- **Communications plans are essential**
- **We ♥ project scope**
  - Remember Indira's quote
- **Some Sigma- Aldrich materials were being used in unintended ways**
- **We needed to move our supplier quality system to a risk based approach**

# The Dilemma



The "sweet spot" is product-specific.

# Enhanced Quality Profile (EQP)

Value-Added Activities	Standard	Premium	Elite	GMP/Compendia
Certificate of Analysis CCN-STANDARD				
Specification				
Certificate of Origin				
Expiry or Retest Date				
Vendor Management CCN-PREMIUM				
Critical Control Parameter (CCP)				
QA batch review				
Lot Sample Retained CCN-ELITE				
Validation				

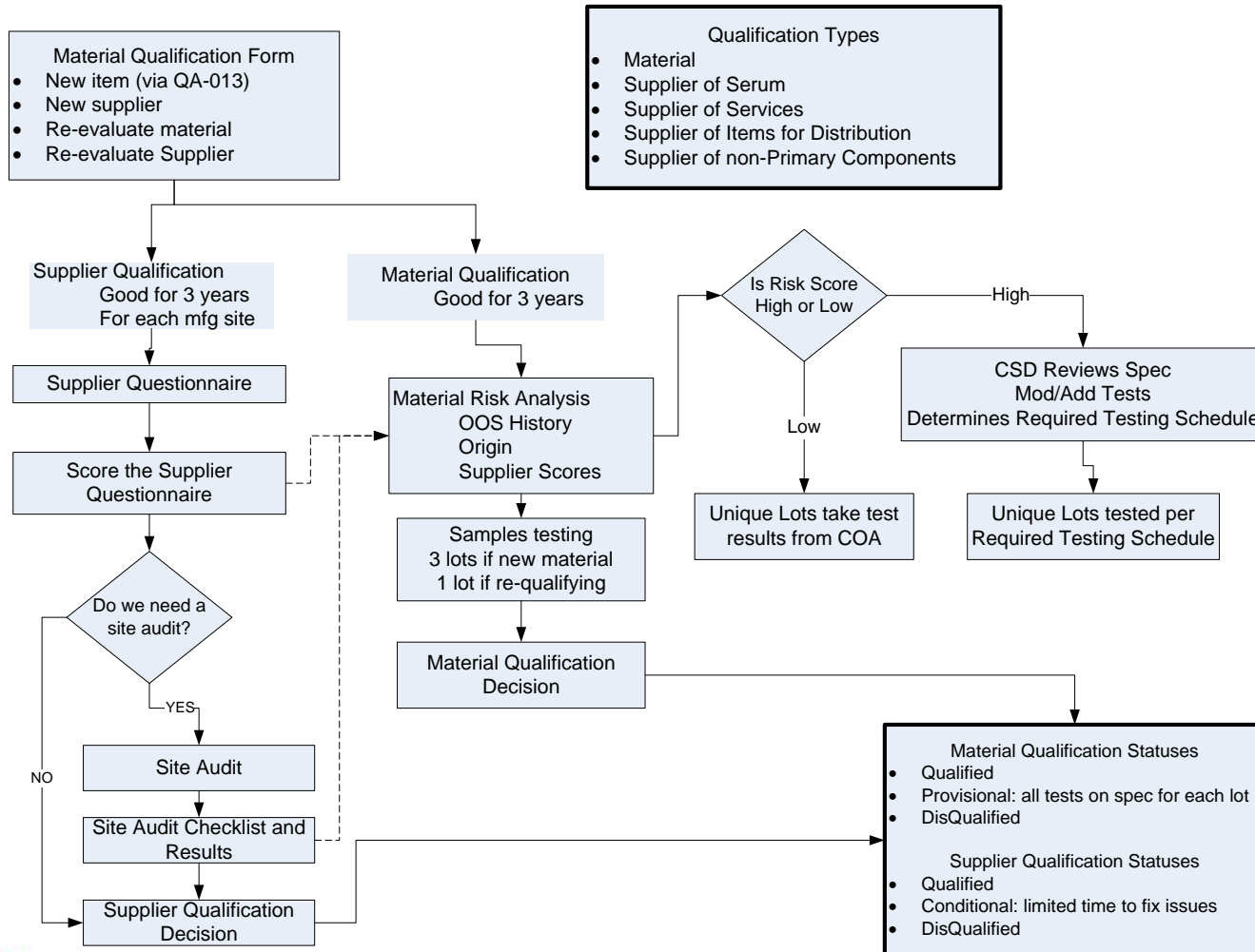
Increased suitability in regulated applications



# Supplier Quality Program

- **Initiated risk based Supplier Quality project Sept. 2008**
- **Updated OP's implemented June 2009**
- **Passed first customer audit July 2009**
- **ISO recertification August 2009**
- **Improved material characterization and specification analysis**
- **Elevated testing for critical components or at risk suppliers**
- **Improved supply chain transparency**

# Supplier & Material Qualification Flow



# Industry Collaboration

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- **Common standards**
- **Perfection is the enemy of the good**
- **Reign in drive for competitive advantage**
- **Common surveillance**
- **Eliminate redundant audits**
- **Voice for industry with regulators**

# Take Aways

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- **Importance of data transparency**
  - If it can impact your business, you need visibility
- **Improve supply chain risk management**
  - Reduce the unknown unknowns
  - Reduce response time to events
  - Trust but verify
- **People are more important than technology**
  - Person to person collaboration
  - Common frameworks- consortia

# Conclusion

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- **Collaboration**

# Thank you

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