

Impact of Globalization on Supply and Supplier Management

By: Vinay Goyal

Disclaimer

- This presentation has nothing to do with my present or previous employers and their internal practices
 - All the companies I worked for or with, were successful companies in their respective fields
- This presentation is based on presenter's own interpretation and experience
 - This is a general presentation
 - Please seek advise/opinion from a professional/legal counsel, if any of the contents are currently or potentially applicable to you (your organization)

Brief Introduction

- As a Quality and Regulatory (Q&RA) associate, I have been working with Supply Chain Management (SCM) team(s)
 - Most procurements (except few emergency supplies) and contractors agreement were finalized and communicated through SCM team
 - SCM professionals are the primary focal point (liaison)
 - Industry Types:
 - Military, Aerospace, Medical, Commercial, Hardware (Electronics, non-electronics- sheet metals, hardware, etc.), Chemicals (substances and products)
 - Thousand of parts
 - Customers: Most global companies (directly or indirectly)
 - Defining requirements, audits, feedback, training, resolving issues, documentation etc.

Quick Survey

- Please raise your hand
 - How many of you are in
 - Quality?
 - Regulatory? Or
 - Not in Quality and Regulatory
 - How many of you think that Globalization and/or Technology have/has caused a major impact on Supply, and Supply Chain and Supplier Management?
 - There is no right or wrong answer or reason to agree or disagree
 - I am here to share from my perspective

US Food and Drug Administration

- FDA is a US Regulatory Agency
 - Now has
 - 223 field offices and
 - 13 laboratories
 - located throughout the 50 states, the United States Virgin Islands, and Puerto Rico
- **In 2008, the FDA began to post employees in foreign countries, including**
 - China, India, Costa Rica, Chile, Belgium, and the United Kingdom
 - I would not be surprised to see many more...

Today's Presentation Abstract

- The performance of Supply Management (SM) department's professionals is commonly measured in terms of amount of money saved and mitigating risk of non-timely-availability of the parts

Today's Presentation Abstract

- In today's complex competitive global business world, constantly changing technology, regulations and standards; have encompassed additional responsibility in ensuring higher efficiency and effectiveness

Today's Presentation Abstract

- This presentation will highlight some of the challenges that may directly or indirectly impact the roles, responsibility and relationship of the SM management professionals with suppliers as well as internal cross functional team, critical for an organization's survival and growth
 - **Especially related to Quality and Regulatory professionals**
 - **That means opportunities**

Key Definitions

- Supply:
 - Typically refers to:
 - The amount of a resource that is available
 - Material
 - Parts/Products
 - Something that is required to do a certain task or accomplish something
- Supplier:
 - Typically refers to
 - Someone who either creates or coordinates to create and provide the resources
 - Contractor

Key Definitions

- Supplier:
 - Can be
 - Raw Material –
Manufacturer/Miner/Smelter/Refiner
 - Someone who creates a substance or product
(hardware or chemical)
 - Original Equipment Manufacturer (OEM)
 - Third Party Manufacturer (or Contract
Manufacturer)

ASQ

- **ASQ has added a **NEW** certification - “Certified Supplier Quality Professional”**
 - The Certified Supplier Quality Professional
 - Works with an organization's supply chain and suppliers to continuously improve performance of key system components (increase lifecycle, reduce scrap, improve repair processes) by implementing process controls and developing quality assurance plans
 - Tracks data, identifies improvement projects, and manages cross functional implementation to improve performance of key components and suppliers
 - Testing Windows:
 - **September 1 - October 15, 2016: Application deadline August 15, 2016**
 - **January 6 - 22, 2017: Application deadline December 9, 2016**

Growth of PS/PEC Requirements

New Medical Device Regulation

- Product Stewardship Requirements
 - EU Medical Device Regulation
 - Change from directive to regulation
 - Changes include CMR disclosure
 - Carcinogenic, Mutagenic and Reproductive Toxins
 - If applicable, disclosure and labeling
 - Stay tuned for more details
 - Effective
 - 2020 for medical devices
 - 2022 for IVD
 - Will impact on Quality, Regulatory and Product Environmental functions
 - CE Marking → Notified Body Certification → ISO13485

What is Supply Chain

SUPPLY CHAIN
MANAGEMENT - SCM

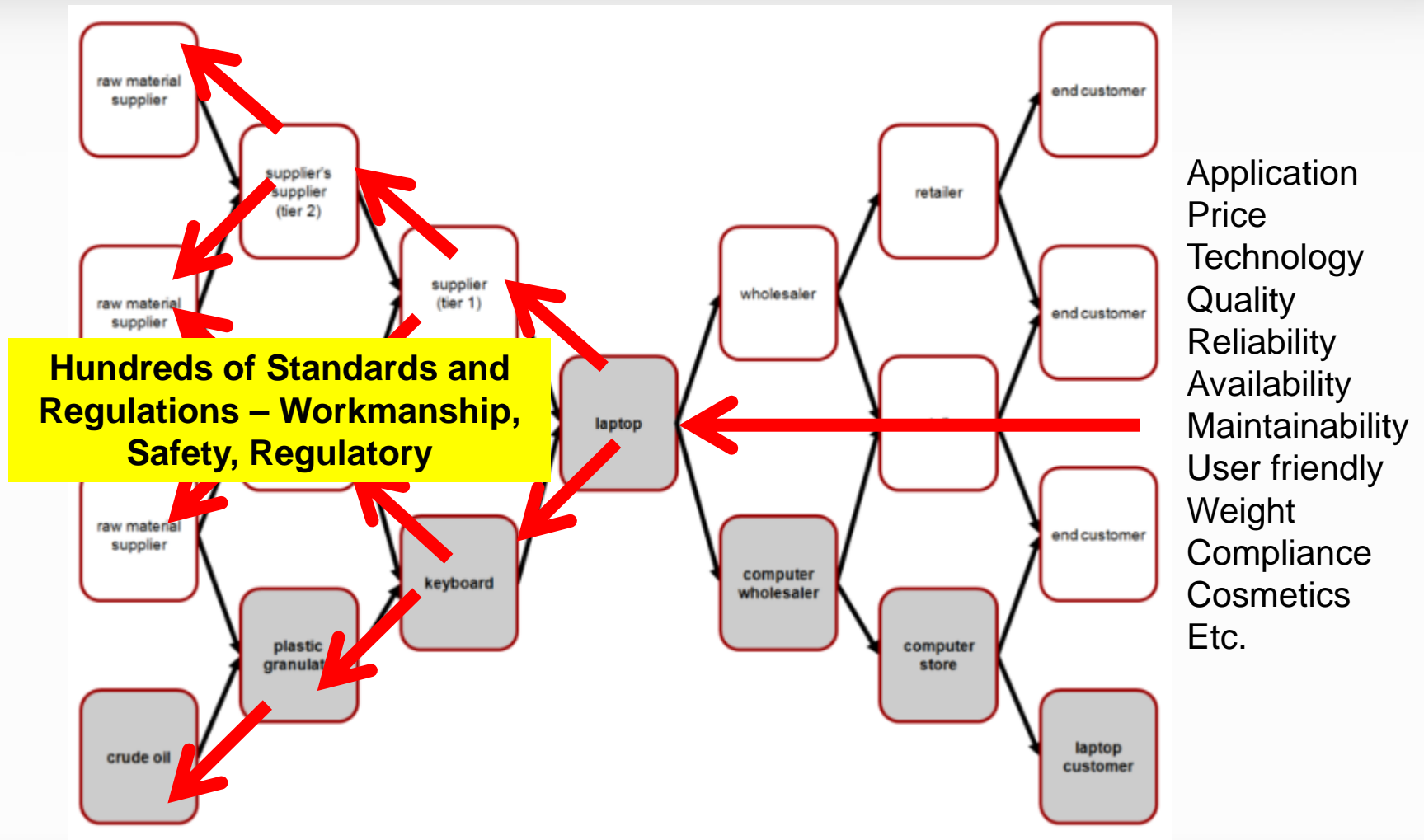
Key Definitions

- A **supply chain** is a system of
 - Organizations,
 - People,
 - Activities,
 - Information, and
 - Resources

involved in moving a product or service from supplier to customer

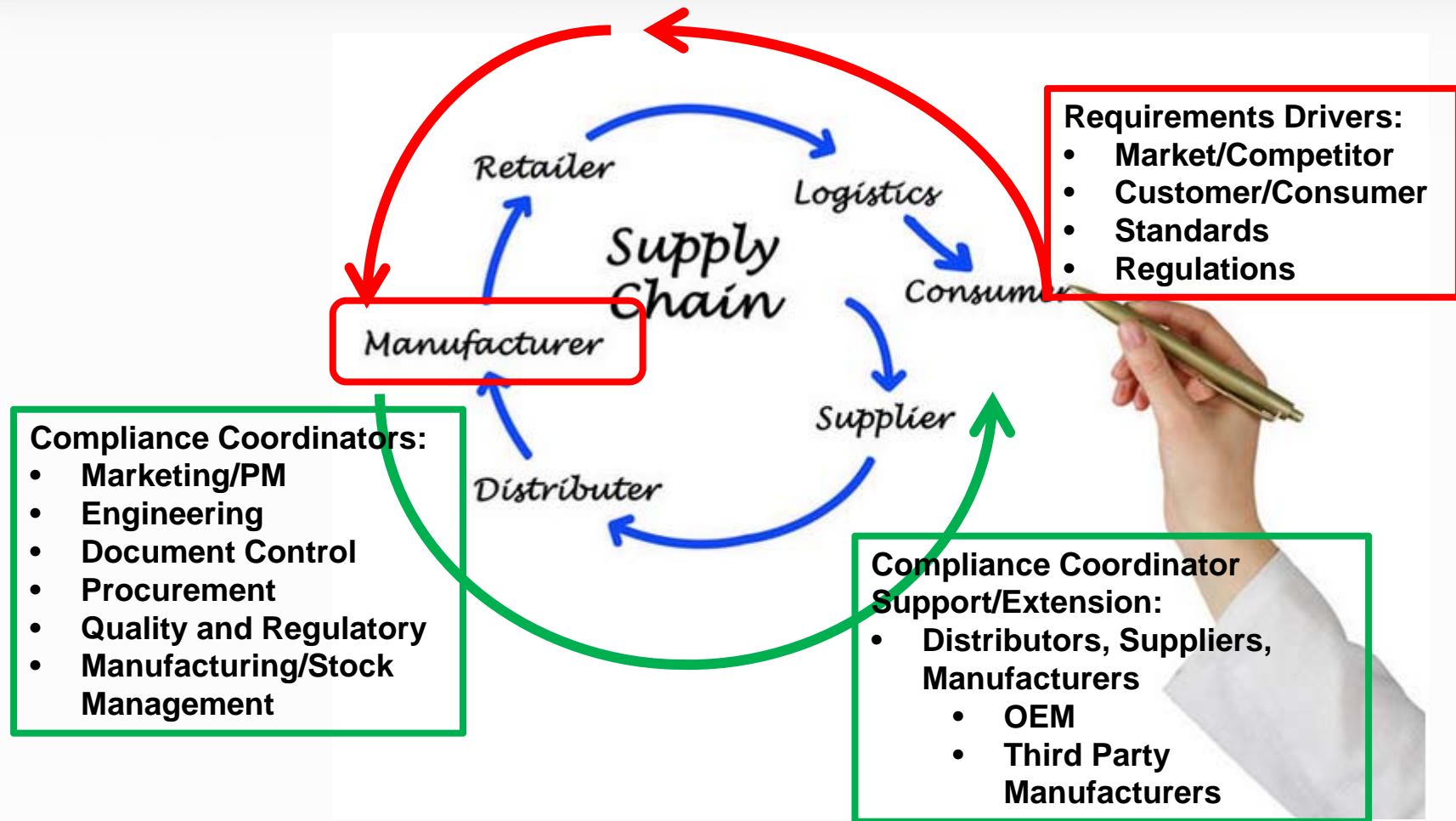
https://en.wikipedia.org/wiki/Supply_chain

Simplified Complex Picture of SCM



https://en.wikipedia.org/wiki/Supply_chain

Supply Chain Management - SCM



Picture: <http://www.businessnewsdaily.com/4804-supply-chain-management.html>

Supply Chain Management - SCM



- ✓ Treat suppliers as an extension/part of your operation
- ✓ Supplier is not limited to material, part, sub-assembly or assembly supplier,
- ✓ A Supplier can be a short or long term contractor working at your facility or remotely

Challenges

1. Cost (**always # 1 Goal**)

- Globalization
 - Global competition
 - Demand and Supply

2. Growth in

- Technology
 - Innovation
- Compliance
 - Regulations
 - Standards

Globalization Trend

- Global Competition
 - From WWII to 60's economic growth was very stable, mostly domestic
 - Innovation
 - Manufacturing
 - Cyclic since 70's
 - Japan and Taiwan (90's)
 - China, India and many other countries (90's)

Globalization Trend

- Global Competition
 - Until 83 most companies used to have captive operations
 - Most operations e.g. PCB, PCBA, wiring, machine shop, silk screening, Manufacturing etc. were done in-house
- Outsourcing
 - 80's Growth in domestic Contract Manufacturing
 - Parts, Sub-assemblies, Completed Products
 - Distribution and Customer Service
 - 2000's International Outsourcing

Globalization Trend

- Misconception/Clarification:
 1. We sell in the US only, and not in the affected market, so we do not need to comply with the requirements
 - You may not be selling in the affected markets but
 - Your customer may be incorporating your part into its final product, and placing on the affected markets
 - So they have to ensure the product is compliant
 - Indirectly impacting your part/product
 - Your competitor may be compliant

Globalization Trend

- Misconception/Clarification:
 2. Regulations apply only to person/organization responsible for placing on the local market e.g.
 - Local manufacturer
 - Importers
 - **Exception** if manufactured or imported for *export purposes*
- Since your direct or indirect customers may be impacted, and if you are not compliant, they may decide not to buy yours without telling you

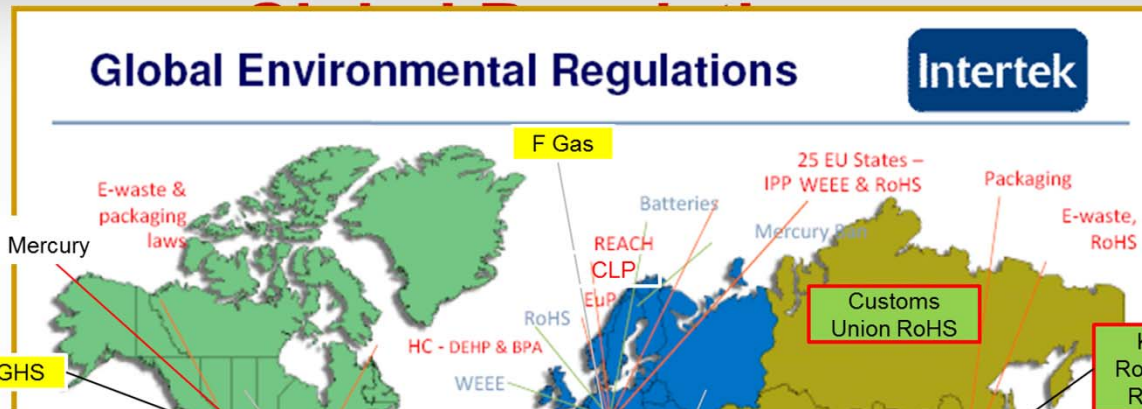
Growth - Technology

- Most products are electronics dependent
 - Cannot think a life without being a computer (smart phone) literate
 - Average life of a computer and peripheral products
 - In 60"s: 10-15 years
 - (one computer per organization)
 - In 80's: Less than 5 years
 - (One per department)
 - In 2000's: Less than 2 years
 - One per employee

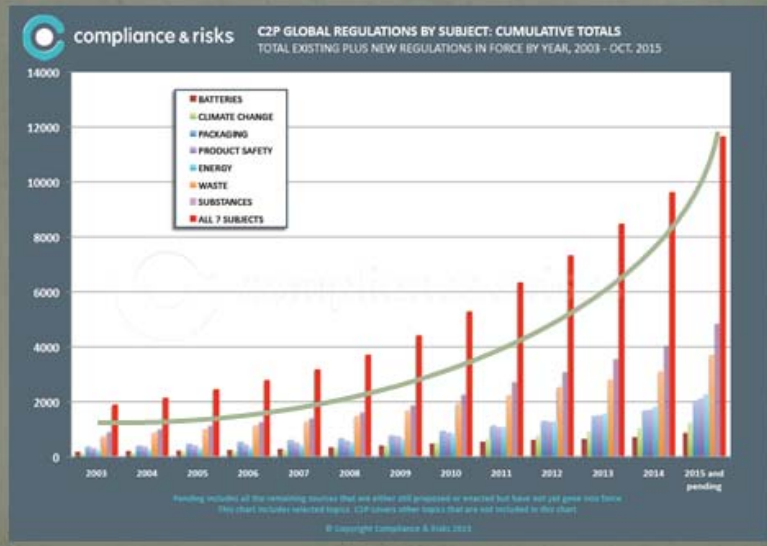
Growth - Technology

- Most products are electronics dependent
 - Software upgrade forces to
 - Buy new software
 - Buy new hardware too
- Market Pressure for Faster, Better and Cheaper solutions
 - Constant changes – may be from batch to batch
 - Hardware and Software upgrades
- Information Technology
 - Instant good or bad press
 - Global visibility

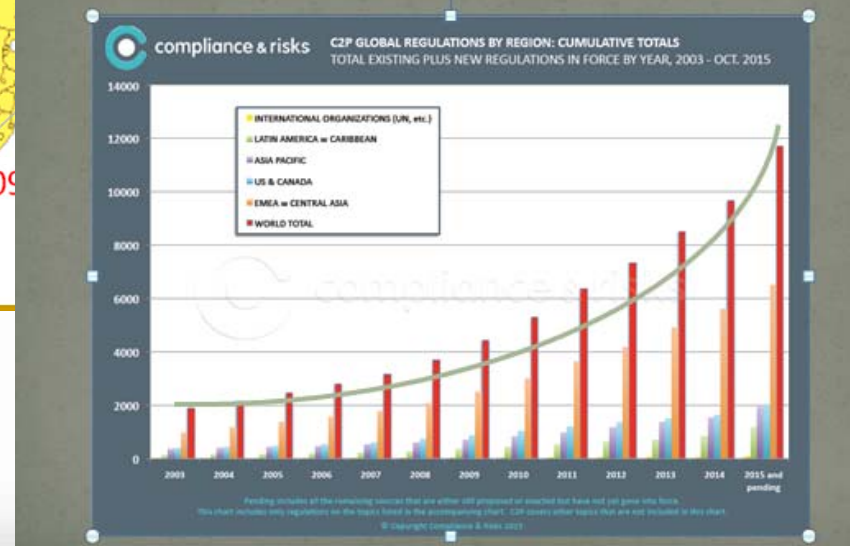
Growth Environmental Regulations



Growth of Product Environmental Regulations (By the Subject)



Growth of Product Environmental Regulations (By the Region)



Challenges

- Encompassing in addition of:
 - Keeping the Cost low and
 - Mitigating timely availability risks
- To ensure effectively and efficiently meeting
 - Compliance to changing regulations and standards
 - Standards not applicable to Military, Aerospace etc.
 - Constant monitoring of
 - Internal demand and constant change in forecast
 - External supply and prices
 - Supplier relationship
 - Two way Open communication

Supplier Relationship

- Understanding the internal requirements based on the strategic planning
- Supplier selection
 - Communicating the requirements
 - Standard
 - Unique/Special
 - Capacity
 - Capability
 - Surveys, Audits
 - Approval
 - Constant monitoring

Supply Chain Management - SCM

Translating Consumer requirements in to Product Life Cycle Management

Supply Chain Management - SCM

Communicating them to upstream material and part manufacturers

Challenges

- Cost
 - Globalization
- Compliance
 - Regulations
 - Standards

Understanding additional market forces

Growth - Technology

- Most products are electronics dependent

Cannot think a life without being a computer (smart)

Proactively keeping abreast with technological changes and communicating to right team(s)

Globalization Trend

- Global Competition
 - Until 83 most companies used to have captive manufacturing
- Out
- 8
- 2

Proactively benchmarking and adjusting your priorities

Globalization Trend

- Global Competition
 - From WWII to 60's economic growth was very stable
 - Innovation

Constant monitoring with change due to globalization

Growth Environmental Regulations

Global Environmental Regulations Intertek

New: Product Environmental Compliance and related disclosures requirements

Challenges

- Encompassing in addition of:
 - Keeping the Cost low and
- T
- Supplier relationship
 - Two way Open communication

Extensive task: Irrespective of small, Medium or Large Organization

Supplier Relationship

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Q&RA: one of the key members of SCM in defining, training, enforcing & auditing requirements related to PLC management

Complexity

- Compare the complexities in just buying something for your household to
 - A small group
 - Small Organization
 - Large Organization
 - Very Large Organization
 - Global Organization
 - Dealing with thousands of people, suppliers and parts/products – adding, deleting
 - On going changes
 - Part/product change notification
 - » Obsolete, newer, faster, parts, last time buy

Q&RA Support in Supplier Management

- Supplier selection
 - Communicating the requirements
 - Standard
 - Unique/Special
 - Capacity
 - Capability
 - Surveys, Audits
 - Approval
 - Constant monitoring

Supplier Selection

- Communicating the requirements
 - Standard
 - Each raw material/part/sub part/assembly has:
 - Hundreds of applicable standards and regulations
 - Existing and upcoming global and local
 - » e.g.: FDA, ASTM, IEC, IEEE, UL, RoHS, REACH, Safety, EMC, Counterfeit Parts, Conflict Minerals etc.
 - Unique/Special
 - Consumer specific, e.g. color, delivery dates, special agreements e.g. disclosures, performance, audits, CAPA etc.

Supplier Selection

- Communication Methods
 - Specification, Drawing Notes, Contracts, Purchase Orders, Webinars, Face to face meetings etc.
 - Documentation
 - User training program
 - Executives
 - Users
 - Web and Software tools
 - Post/update requirement information
 - Supplier email or upload their compliance statement periodically in acceptable formats

Supplier Selection

- Capacity, Capability, Audits, Surveys
 - One time, On-going (depending on the risk) and as required
 - Remotely:
 - Surveys, On-line Reviews, Certifications, Declarations, virtual audits
 - On-site:
 - Audits, meetings etc.

Supplier Selection

- Approval and Constant Monitoring
 - On-going (depending on the risk) and as required
 - Supplier Rating
 - Based on Quality, On-time delivery
 - Response to inquiries
 - Support
- Communication:
 - Performance (Supplier Rating) Reviews
 - Awards
 - If feasible, provide necessary assistance
- **Keep looking for alternates**

Documentation

- Supplier Management Procedure
 - Constant update
 - Incorporate recommendations
 - On-Going training for everyone in SCM
 - Instructor led
 - Recorded on demand
 - Periodic meetings
 - Online
 - Face to face
 - Document and distribute to all associates (as applicable)

Summary

- Globalization has introduced many challenges
 - Opportunities are global in nature
 - Right product will get immediate attention and demand
 - Increased Competition
 - Reduced monopoly
 - Increased accountability
 - Reviews, good or bad press, Price comparison, Quality, Reliability, etc.
 - Pressure to keep yourself abreast with upcoming changes
 - Coordination:
 - Planning, Documentation, Communication, Supplier and Supply Management, Design Control (Planning, Input, Output, Review, Verification and Validation, Change Control, Transfer) and all related activities

Q&A

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