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Medical Device Supply Chain Council

SUPPLIER QUALITY PANEL DISCUSSION

PRTM

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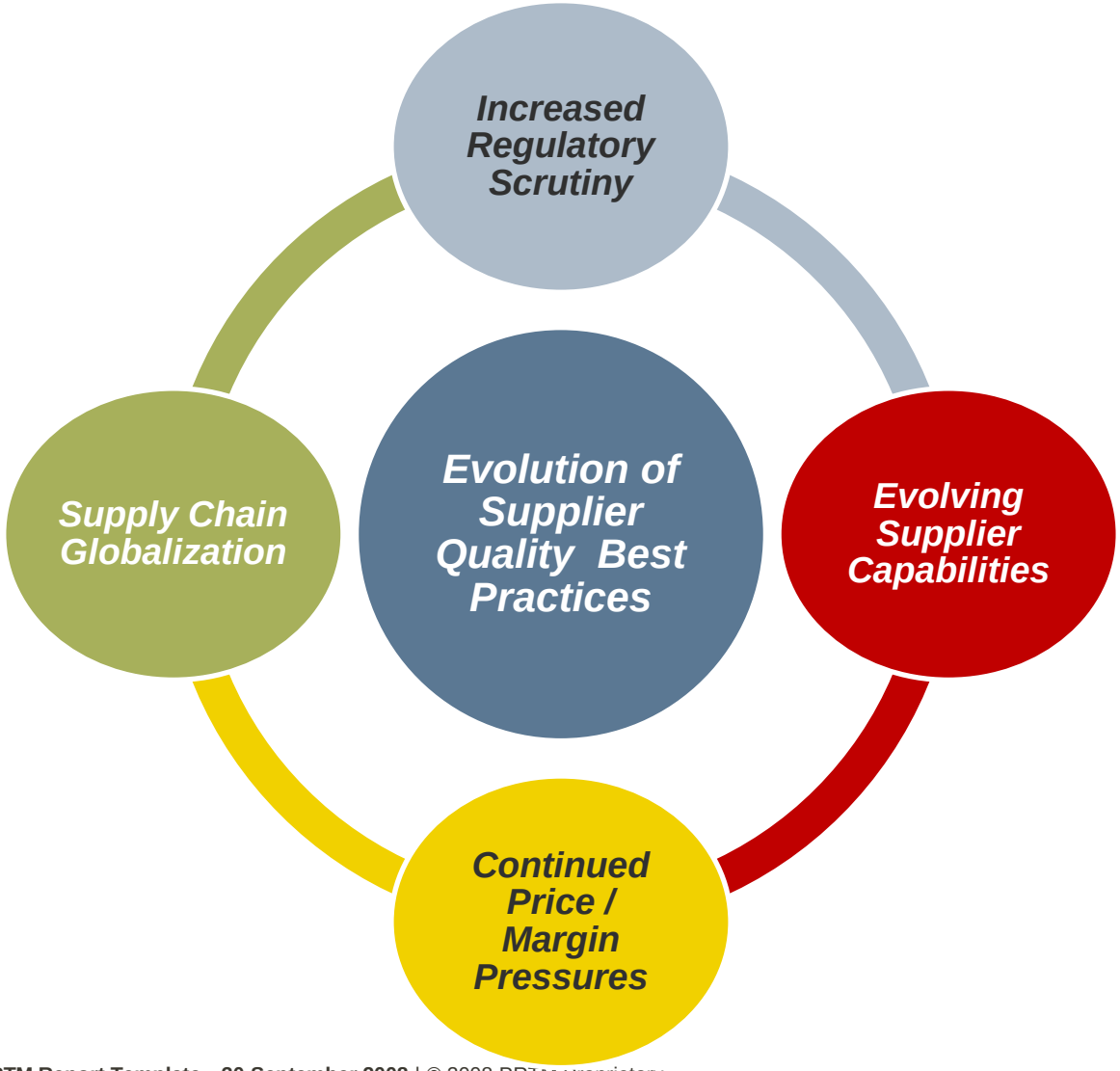
Where Innovation Operates

Medical Device Supply Chains are Facing a Rapidly Evolving External Environment



FDA has made it clear that supply chain management is a priority…

"While some companies inspect and hold their suppliers to strict U.S. standards, others don't, and they're depending on strategies that don't make a lot of sense, such as certificates of analysis."

– Michael Chappell, FDA Acting Associate Commissioner for Regulatory Affairs, July 2010

"***We're also taking steps to improve our oversight of imported products."***

– Dr. Jeffery Shuren, Director, Center for Devices and Radiological Health, May 2010

"…CDRH is focusing on increasing import safety efforts and issuing more warning letters. These efforts include going after firms who have failed to register and list their facilities in accordance with FDA regulations…"

– Tim Ulatowski, Director, Office of Compliance, CDRH, October 2009

…and has explicitly stated the "Safety and Integrity of the Global Supply Chain" as a Strategic Priority

Warning Signs:

- Contaminated Heparin
- Counterfeit Glucose Monitor Test Strips
- …

Imperatives:

- Paradigm shift – **focus on prevention** rather than control
- Require **more and better information** about product supply chains
- Regulatory standards to foster **corporate responsibility** to identify, protect and control risks
- More and better **coordination** among foreign, federal and state counterparts

Challenges Presented:

- Increasing **volume** of imported products
- Greater **complexity** in imported products
- More **foreign facilities** supplying the United States
- **Incomplete regulatory information** about supply chains
- **Patch work** of foreign, federal, and state oversight of product safety
- Greater opportunities for **economic fraud**
- **National security** threats
- **Antiquated FDA law** – relatively unchanged since 1906
- **Workload** that has outstripped FDA resources
- **Insufficient legal authorities** and enforcement tools
- **Corporations lacking accountability**

Source: *Strategic Priorities, 2011-2015*, US FDA, Draft 9/29/2010

Supplier Quality Programs Must Adapt To Meet The Challenges Posed by These Changes

The rapidly changing environment is forcing the medical device industry to up-level its approach to Supplier Quality and

- Engage the broader organization strategically
- Manage enterprise risk of the supply chain
- Redefine best practices for meeting compliance and business needs

This panel discussion will focus on best practices, challenges and trends that medical device companies are facing within supplier quality as they try to adapt to this changing environment

Panel Discussion Questions

Topic Area 1: Increased Regulatory Scrutiny

How, if at all, has the *increasing level of regulatory oversight and scrutiny* affected the extent of engagement that you maintain on your supply base?

Examples

- Incoming inspection (or devolvement of II to suppliers)
- Quality audits (frequency, breadth and depth)

How (if at all) has the increased scrutiny changed the capabilities required within your Supplier Quality Organization?

- How have you reassessed internal organizational processes to ensure compliance needs are appropriately prioritized against broader business needs
  - Interface between Supply Chain, Procurement, Quality

Topic Area 2: Supply Chain Globalization

How has *globalization of the medical device supply base* affected the operating model of the Supplier Quality organization at your firms/firms you have worked with?

- Risk management/risk assessment of suppliers (real vs. perceived risk of off-shore / LCC suppliers)
- In-sourcing/outsourcing supplier quality capabilities (audit etc)
- Effectiveness of internal versus external assessments of potential suppliers
- Integration of supplier operations – e.g. JIT delivery

Have you *changed how you interact* with suppliers in high risk areas (e.g. China)?

- Do you distinguish between geographies in terms of supplier quality?

Topic Area 3: Evolving Supplier Capabilities

As suppliers increasingly begin to own design, development, manufacturing and distribution – and potentially other elements subject to regulatory or government oversight – *what capabilities or transitions are needed* in the Supplier Quality organization?

- Third party design and development
- Third party manufacturing and distribution
- How does this change the focus of how you interact with these third party organizations?

Has the growing breadth of supplier capabilities changed the way Supplier Quality *interfaces with other functions*?

- Manufacturing
- R&D
- Business Development / Marketing

Topic Area #4: Price / Margin Demands

How have balanced the previously discussed themes (Increased Regulatory Scrutiny, Supply Chain Globalization, Evolving Supplier Capabilities) with *continued price / margin demands*?

- How are companies looking to parnter with their suppliers?
- Is there a new model?
- What expectations do manufacturers have of suppliers and vice versa?
- Are companies looking to partner with other companies (their peers) in supplier management?