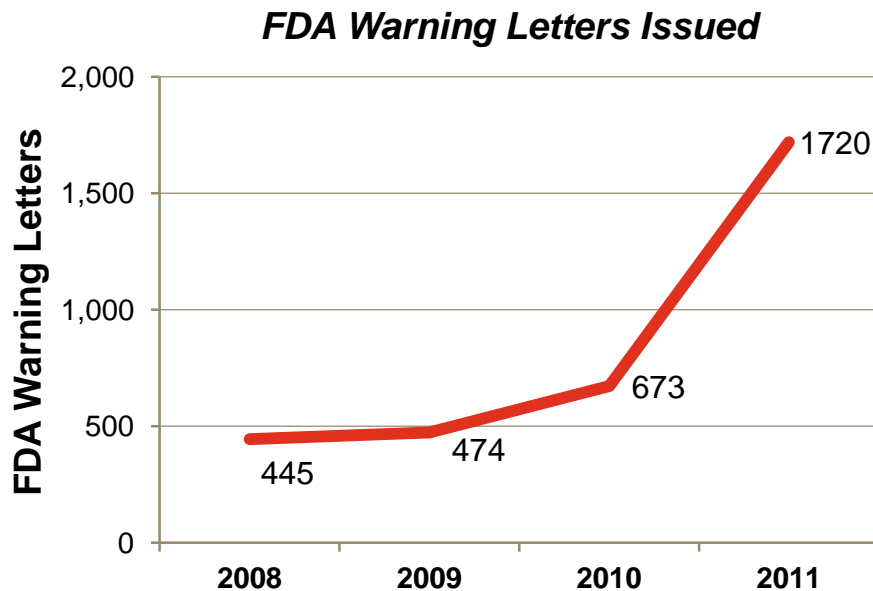


Increasing Regulatory Scrutiny in the Medical Device Supply Chain

May 2013

FDA & local health authorities are significantly stepping up regulatory efforts



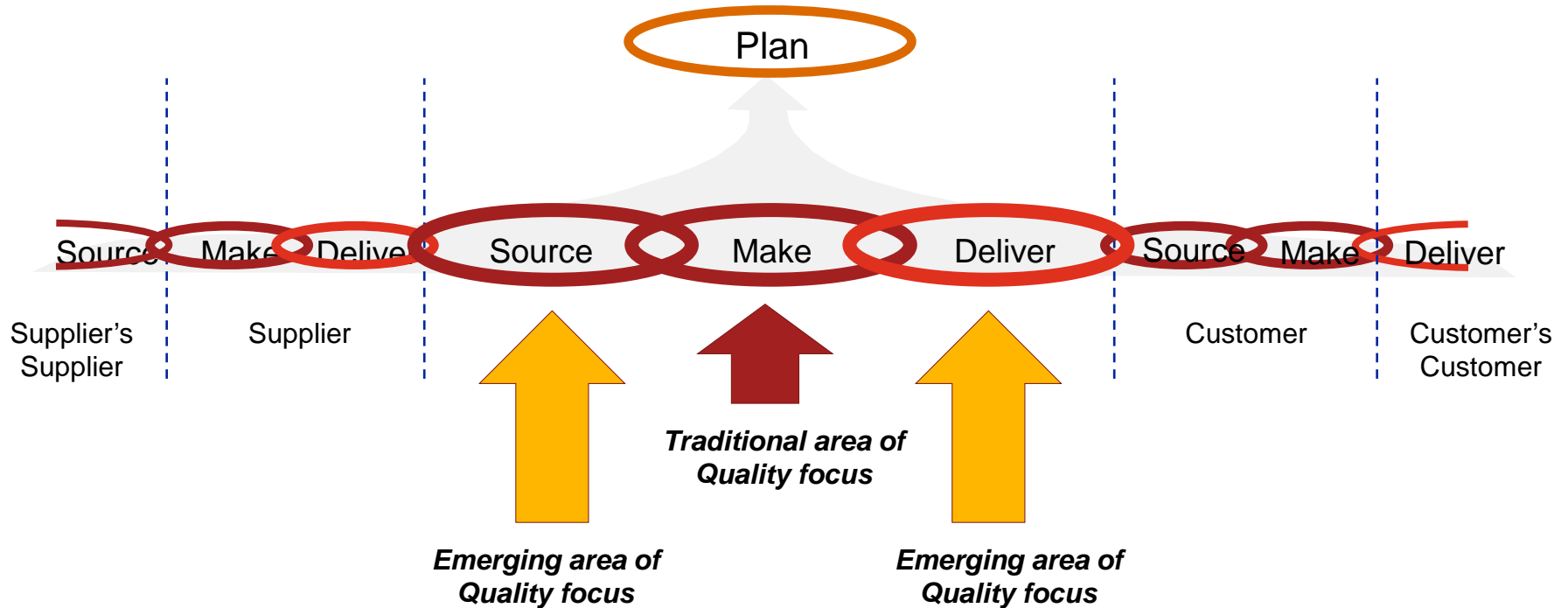
Sources: www.FDA.gov

- Device related FDA inspections increased 18% between 2009 and 2011
- Device related Warning Letters increased 86% between 2009 and 2011
- Regulatory scrutiny is expanding throughout the value chain – FDA is pursuing more robust inspection program on globalized supply chains
- Other countries and regional regulatory bodies are also stepping up requirements and oversight of global supply chains

Most member companies interviewed perceive heightened regulatory scrutiny in the last 2-3 years

As supply chains become more complex, regulatory scrutiny has expanded beyond the four walls of manufacturing

Supply Chain Operations Reference Model (SCOR)



Are companies investing enough in their Quality organizations and systems to address this changing landscape?

Supplier Quality

Supplier Quality Has Become an Increasing Focal Point of FDA Scrutiny

Comments from the FDA Commissioner reflect the strengthening stance on supplier quality:

- “A second key element of our strategy is to hold companies responsible for their supply chain... companies must be able to effectively demonstrate that safety, quality and compliance with international and U.S. standards are built into every component of every product and every step of the production process...”

Margaret Hamburg

And, the intent is borne out by our recent industry experience:

- Device companies are reporting increased inspections and audits of purchasing controls and supplier process. Most have observations related to purchasing controls and supplier quality.

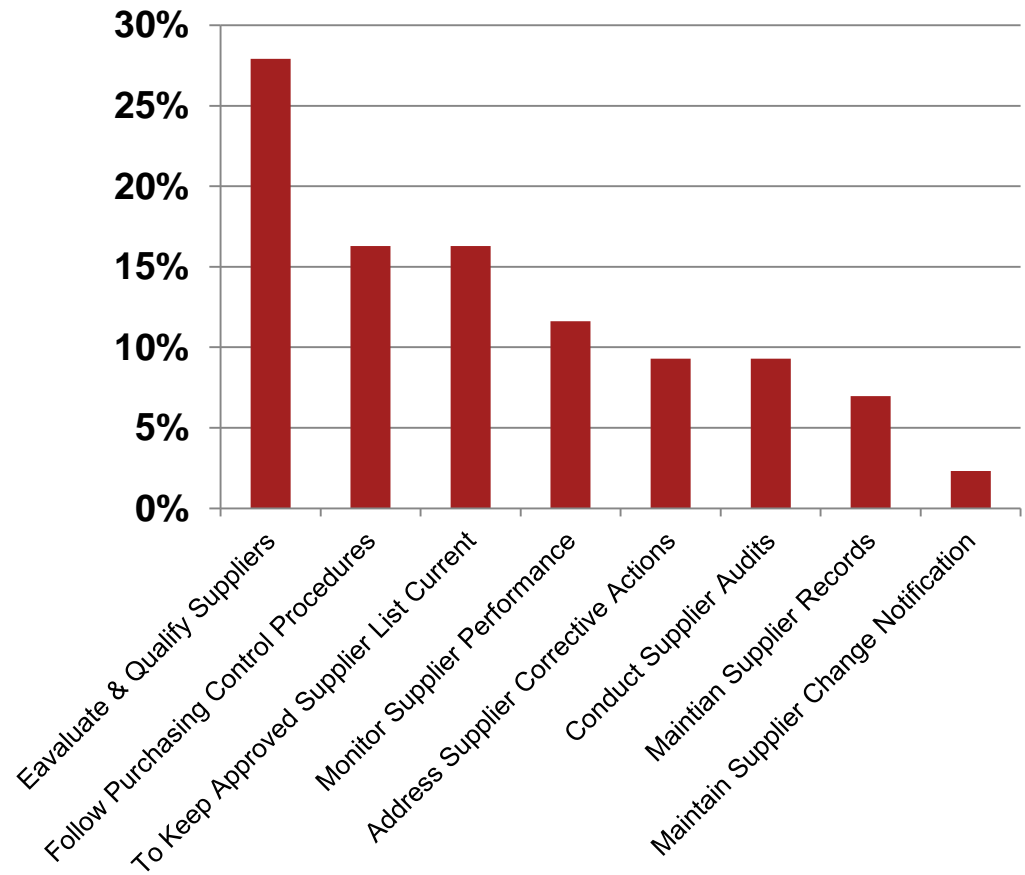
PwC clients and MedSC member interviews

Recent data bare out the increasing emphasis on supplier quality

Since 2012, percent of CDRH warning letters issued to Medical Device companies citing purchasing control issues

12%

2012 – 2013 (YTD) Purchasing Control Issues Failure to...



Sources: www.FDA.gov

What trends are we seeing regarding supplier Quality within Medical Device companies?

Supply chains are becoming more complex with more globalization of the supply base and a greater willingness to outsource to contract manufacturers

- This complexity increase often outpaces existing supplier management and Quality oversight

Companies are investing in supplier management and supplier Quality programs

- But action is sometimes taken only after negative findings by regulatory bodies

Suppliers often lack the capabilities and systems required to meet the Quality and Regulatory requirements of the device industry

- Quality systems should be a major consideration when evaluating and selecting suppliers
- Existing suppliers can require significant effort to ensure compliance with Quality standards

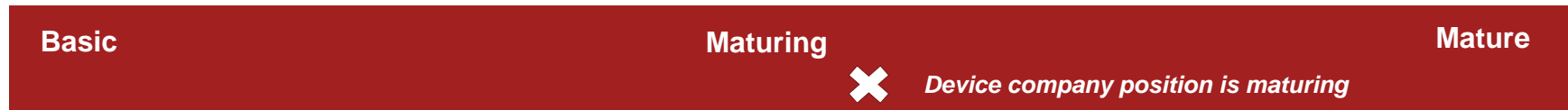
Prior to regulatory actions, supplier Quality activities are often understaffed and lack clear reporting lines to Quality

- Formal Supplier Quality function and procedures needed to oversee supplier Quality
- Program can yield significant payback through reduced risk of recalls and avoidance of remediation activities

While Quality and Compliance metrics are generally included in supplier scorecards, they often take a back seat to delivery performance and cost metrics

Supplier quality maturity has increased significantly but additional development is still required

Supplier Quality Characteristics		
Organization	<ul style="list-style-type: none"> Limited and understaffed Reporting to supply chain, procurement or engineering Reactive 	<ul style="list-style-type: none"> Dedicated Supplier Quality function, adequately staffed Standalone function, reporting to SVP/VP of Quality Proactive
Processes	<ul style="list-style-type: none"> Peripheral involvement of Quality in supplier evaluation and selection Irregular or haphazard supplier audit program Limited collaboration with suppliers to ensure/improve quality 	<ul style="list-style-type: none"> Quality embedded in supplier evaluation and selection processes Consistent, global supplier audit program, calendar and process Active involvement in supplier improvement and quality programs
Metrics & Tools	<ul style="list-style-type: none"> Quality metrics missing or low priority in supplier scorecards No senior level visibility of supplier quality metrics 	<ul style="list-style-type: none"> Quality metrics are a prominent component of supplier scorecards Reported at SVP/VP of Quality level



Case Example: Purchasing Controls Remediation

Situation: A global medical device manufacturer under Consent Decree with the FDA/DoJ due to systemic deficiencies in quality systems. Client working to remediate gaps in purchasing control procedures, processes and documentation.

- Process and procedures did not exist to cover regulatory requirements as per 21 CFR 820.50
- **Limited focus on** supplier performance trending and development activities, **no standard metrics were established**
- **Organizational resources dedicated to purchasing controls were inadequate to ensure procedural requirements were met**

Actions: Redesign / remediation of purchasing controls at six sites across US, Mexico and China

1 **“Retrospective”:** Review adequacy of procedural and executable purchasing control gaps

- Assess regulatory gaps against compliance requirements set out in the FDA compliance requirements
- Identify gaps, by reviewing procedures for efficient operation against industry practices, clarity in roles & responsibility definition, and quality of documentation

2 **“Preventive”:** Design and implement a compliant purchasing controls system

- Design a comprehensive purchasing control system to capture all process elements including supplier: evaluation & qualification, part approval process, audits, performance monitoring, non-conformance communication & tracking, change notifications
- Revise/create SOPs that clearly define the process requirements, roles and responsibilities
- Develop and execute remediation plan to ensure compliance to new /revised SOP's

3 **“Sustainable”:** Establish governance mechanisms to ensure sustained compliance

- Establish & maintain a controlled and centralized approved supplier list that provides products, parts or services
- Establish supplier performance metrics and dashboards to review and monitor supplier performance
- Establish supplier audit calendar and process for conducting audits and documenting results and follow up actions
- Maintain updated supplier files in a central location including supplier quality agreements and other documentation required as per supplier category defined in the procedure

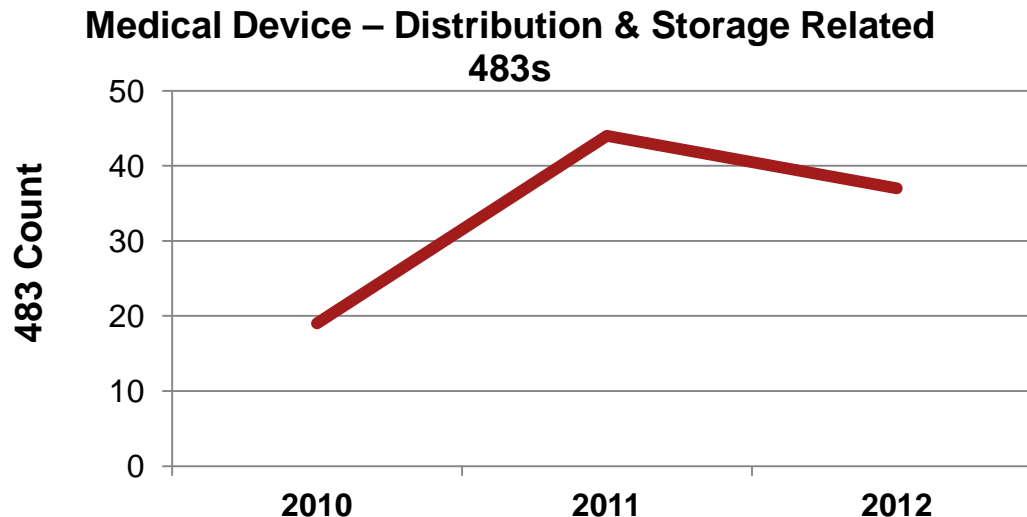
Distribution Quality

Distribution is also a growing area of concern as requirements increase

Regulatory requirements in distribution are increasing

- Anti-counterfeit, serialization and temperature control & monitoring are common areas of focus
- Updated standards and regulatory requirements are focusing specifically on product distribution
- Expansion into emerging markets is increasing proliferation of distribution requirements due to diverging rules for product labeling, traceability, expiry management and temperature control

While FDA findings remain relatively low in this area, we anticipate an uptick over the next 2-3 years



What trends are we seeing regarding distribution Quality within Medical Device companies?

Level of outsourcing of distribution & logistics services increasing significantly

- Quality capabilities of 3PL and transportation providers improving though still immature

Leading companies investing in dedicated Distribution Quality resources and capabilities

- Others will need a catastrophic regulatory event to drive change

Currently, Distribution Quality organizations' primary function are to develop standards and oversight

- Differing models exist with regards to execution of Quality activities at distribution centers (DC's)

Companies facing challenges in developing Distribution Quality organizations

- Cultural resistance to invest in this space given lack of regulatory scrutiny in the past
- Instilling Quality mindset in distribution space ("it's not a package, it's a patient")
- Limited resources with experience/education in Distribution and Quality

Monitoring during transportation, quality at 3PL distribution centers and managing temperature control among top Quality concerns

- Inconsistency in deployment of QMS and Standards globally also a common concern

Supplier quality maturity has increased significantly but additional development is still required

Distribution Quality Characteristics		
Organization	<ul style="list-style-type: none"> • Ad hoc, event based distribution Quality oversight • No clear organizational ownership • Reactive 	<ul style="list-style-type: none"> • Dedicated resources overseeing distribution Quality and Compliance • Reports to head of Quality • Proactive
Processes	<ul style="list-style-type: none"> • QMS and distribution standards vary by country or region • 3PLs not subjected to the standard Quality evaluation / oversight programs • Irregular or haphazard use of Quality Agreements with distribution providers 	<ul style="list-style-type: none"> • Consistent deployment of QMS and distribution standards globally • 3PLs included in supplier evaluation and Quality programs • Quality Agreements established with all third party providers
Metrics & Tools	<ul style="list-style-type: none"> • Incident driven response • No senior level visibility of Distribution Quality metrics 	<ul style="list-style-type: none"> • Metrics and trends driven activities • Distribution Quality metrics reported at SVP/VP of Quality level



Case Example: Building a Distribution & Market Quality Strategy

Situation: A global medical device manufacturer with increasingly globalized supply chain structure proactively looking to build Distribution Quality capabilities

- Heightened regulatory scrutiny had increased the need for effective management of Quality & Compliance in distribution, transportation, and market Quality space
- Company operated under a highly decentralized structure with varying levels of Quality system maturity between its sectors and regions

Actions: Defined strategy for managing Quality & Compliance in the Distribution & Market Quality space globally including the creation of five new Distribution Quality Director positions

Projected Benefits: Significant improvement in costs associated with distribution remediation activities

1 Reduction in cost of Field Actions (FA)

- 15 FA's in 2010 associated with DC's
- Field Action costs ranging from \$300 to \$530K

2 Reduction in cost of remediating Internal Audit Observations

- 4 Audits conducted of key DC's in 2011; 26 critical observations and many majors and minors
- \$1.1M approximate cost of remediating observations

3 Reduction in cost of remediating External Audit Observations

- 8 External Audits conducted of DC's in 2010 : 2 major and 18 minor observations
- \$25K approximate cost of remediating observations

4 Reduction in risk of catastrophic Quality event

Final thoughts...

- There are multiple organizational models that can work to address Quality in each of the areas, e.g. single Quality organization to cover Supplier, Manufacturing and Distribution or specialized organizations for each. The key is that roles, responsibilities and accountabilities are clear with no gaps.
- Quality approach may need to be difference between mature versus emerging markets. Both mature and emerging markets may be underserved from a Quality standpoint but it may be unrealistic to apply mature market "oversight" on emerging markets from a cost perspective.
- Establishing robust Supplier and Distribution Quality capabilities is a 3-5 year journey:
 - Start with understanding where you will be in 5 years from a supply base, commercial and distribution landscape
 - Develop a Quality strategy accordingly that addresses Organization, Standards, and Systems
 - Put in place metrics to monitor performance
 - Begin the implementation journey

Thank you

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