ROI of Good Quality & Compliance

5th October 2016

American Medical Device Summit Chicago, IL
# Presentation Topics

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Introduction

Presentation Objectives

➢ The main objectives of this presentation are to discuss Investing in the Quality and Compliance Program within your organization and how to justify investments.

   Topics include:

   ❑ Ideas on how to quantify the costs of quality for investment justification

   ❑ Understanding indirect or potential costs of quality and compliance including:
     • Examining FDA’s recent and future approach to Medical Devices
     • The Potential Impacts of FDA’s approach to Medical Devices

   ❑ Understanding the Benefits of a Proactive Quality System

   ❑ Benchmarking - Good Investments in Quality and Compliance
Cost Of Quality – Where to start...

Breakdown of the Cost of Quality – How to Quantify for Justification?

Cost Of Good Quality
- Appraisal Costs
  - Inspections
  - Testing
  - Audit/Review
- Prevention Costs
  - Quality Planning
  - Process Planning
  - Process Control
  - Training

Cost Of Poor Quality
- External Failure Costs
  - Complaints
  - Corrections and Removals
  - Reputation
  - Loss of Market Share
- Internal Failure Costs
  - Scrap
  - Re-work
  - Supplier Scrap and Rework

- COGQ – fairly easy to calculate and monitor
- COPQ - Internal Failure Costs can also be calculated and monitored
- Using this data to justify business cases for Quality Expenditures
- Some External Failure Costs are typically more variable and could be extremely costly, especially if remediation is required.
- How can you Benchmark External Failure Costs? – Start with FDA Trends

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# FDA’s Focus on Medical Device

## Today’s FDA Inspections

### FY2015 FDA 483s Issued

<table>
<thead>
<tr>
<th>Category</th>
<th>#483s</th>
<th>Pct. of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foods</td>
<td>2,300</td>
<td>47%</td>
</tr>
<tr>
<td>Devices</td>
<td>1,008</td>
<td>21%</td>
</tr>
<tr>
<td>Drugs</td>
<td>678</td>
<td>14%</td>
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<tr>
<td>Veterinary medicine</td>
<td>294</td>
<td>6%</td>
</tr>
<tr>
<td>Bioresearch monitoring</td>
<td>283</td>
<td>6%</td>
</tr>
<tr>
<td>Biologics</td>
<td>123</td>
<td>3%</td>
</tr>
<tr>
<td>Human tissue for transplantation</td>
<td>81</td>
<td>2%</td>
</tr>
<tr>
<td>Parts 1240 and 1250</td>
<td>66</td>
<td>1%</td>
</tr>
<tr>
<td>Radiological health</td>
<td>17</td>
<td>0%</td>
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<tr>
<td><strong>2015 Total</strong></td>
<td><strong>4,850</strong></td>
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Source: Maetrics Analysis, FDA Website; Inspections between 10/1/2014 and 9/30/2015

### FY2015 Top 5 FDA 483s Issued (Excluding Foods)

- **Medical Devices**: 1,008 (42%)
- **Veterinary Medicine**: 283 (12%)
- **Biologics**: 294 (12%)
- **Pharmaceuticals**: 678 (29%)
- **Bioresearch Monitoring**: 123 (5%)

Nearly 3% increase in 483s issued in FY2015 over FY2014
FDA’s Focus on Medical Devices

Compliance Trends – FDA Medical Device Inspection Statistics

- **2015 Data**
  - 2082 company inspections
  - 797 companies received one or more 483s (38%)
  - Leading to 95 Warning Letters (4.5%)
  - This is NOT probability it depends on your state of compliance

- **Top 483 citations (Med Device)**

<table>
<thead>
<tr>
<th>Year</th>
<th>#1</th>
<th>#2</th>
<th>#3</th>
<th>#4</th>
<th>#5</th>
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<td>2015</td>
<td>CAPA</td>
<td>Complaint Files</td>
<td>Purchasing Controls</td>
<td>Process Validation</td>
<td>MDR</td>
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<tr>
<td>2014</td>
<td>CAPA</td>
<td>Complaint Files</td>
<td>Design Controls</td>
<td>Purchasing Controls</td>
<td>Receiving, In-Process, Finished Device Acceptance</td>
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<tr>
<td>2013</td>
<td>CAPA</td>
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<td>Receiving, In-Process, Finished Device Acceptance</td>
<td>Purchasing Controls</td>
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FDA's Focus on Medical Devices

FDA Future Initiatives

- FDA have plans to change from the current 25 district and regional offices managing inspections to 3 offices for worldwide coverage.

- ‘Program Alignment Medical Devices and Radiological Health FY2016 Action Plan’ – see also http://www.fda.gov/AboutFDA/CentersOffices/ucm477082.htm
  - More focused approach to Medical Devices- Manufacturers are no longer at an advantage during occasions where inspectors lack knowledge.
  - Highly trained resources and specialized inspectors.
  - Training from industry - Inspectors will keep up with new manufacturing methods and technologies (electronics, software, 3-D printing).
  - More enforcement action on imports and an increase in foreign inspections.
  - Data Integrity – systems validation, 21 CFR part 11, preventing the altering of electronic data.
  - Efficiencies in filing times due to better skill sets within FDA for review.
  - Conversely, will also be quicker action on compliance side, e.g. warning letters currently take months, anticipated to be much quicker.
Quality & Compliance Cost Impact

The Regulatory Cost of Doing Business is Rising

- Medical Device Manufacturers will need to continue to invest and evolve to keep up with Regulators and changing regulations

- Consequences of Non-Compliance
  - Corrections & Removals – Cost is variable but could be upwards of $2 Million or more in direct costs for a large scale recall
  - Litigation Costs – variable based on the situation, but are generally significant
  - QS Remediation Costs
    - Warning Letter Remediation can be upwards of $250 Million for a Large Company. Typically lasts 2-4 years in duration.
    - Consent Decree, Remediation cost up to $400 Million plus loss of market share during production stoppage.
    - Indirect costs – halts innovation and new product development
  - Reputation and Brand Damage - Immeasurable, several instances of recalls and brand issues causing > 10% drop in stock price in a single day (BSc, Valeant)

- Non-Compliance data (MDR and Recall Data) is becoming searchable by product type and readily available to the public – FDA’s UDI Initiative
Quality & Compliance Cost Impact

Tangible Costs of Non-Compliance (External Failures) - Selected Examples

**Invacare**
- 2012 Consent Decree
- Profitable in years leading up to WL and CD
- Revenue, operating profits/loss, and earnings per share all dropped after CD
- Earnings per share dropped to $-1.75/share in 2014

**Olympus Corporation of America**
- 3 separate regulatory citations (FDA, Anti-Kickback and false claims act, FCPA)
- Warning Letters and Recalls, Corporate Integrity Agreement, Deferred Prosecution Agreement
- Total Settlement $646 Million (2016)

**Boston Scientific**
- Well Publicized warning letter in 2006, lead to 5 year journey to improve quality system (remediation project). Earnings per share were negative for all 5 years
- Blocked approval of new products including a medicated heart stent that took 2 years longer than anticipated because of the QS system Issues (lost market share)
- March 2010, Recalled all implantable defibrillators, Shares fell 13% overnight

**Valeant**
- Virazole Microbial Contamination recall
- Accusations around improper relationships with Pharmacy Benefit Manager to recommend Valeant Drugs
- Hedge loss of over 1 billion in a single day (3/15/16)
- Former CEO subpoenaed to testify in front of the senate on drug prices
Proactive Quality Systems

Quality Systems can actually save money...

- Hallmarks of a Proactive Quality System:
  - Predictive Analytics
  - Reduced Complexity
  - Integration with Business Systems
  - Higher Investment in Prevention
  - Reinvestment in Innovation
  - Anticipate the External Regulatory Environment
  - Sustainable Culture of Quality

- Reduced spending on Cost of Poor Quality... less failures (internal and external)
- Increase spending on R&D to gain a competitive advantage in the Market
Proactive Quality Systems

Cost profiles of Reactive vs. Proactive

- Reactive QS typically cost more over the long run because of external failure costs and remediation projects followed by QS streamlining
- Proactive QS maintains a steady state of compliance at or above the minimum requirements
- Minimum Quality/Compliance Spend for an organization is typically 10-15% of operational costs (e.g. 10-15% of FTEs in Quality and Compliance)
Good Investments in Quality & Compliance

Dedicated/Independent Investigation & CAPA Resources

- CAPA = #1 FDA Audit finding year after year
- CAPA – Does have four letters…. but is not a bad thing…
  - Improvement program for the Quality System – Should lead to a Better QS and a reduction of failure costs
- Include the process owners but don’t make them own the entire CAPA
  - CAPAs = Work for process owners
- Make sure the process has a “coach” or “shepherd” as well as a coordinator
  - Independent Root Cause Analysis, the ability and motivation to continue to Ask Why? Isolated or Systemic?
  - Ensure the proposed actions match the root cause
  - Ensure VOE matches the Root Cause and Actions
  - Ensure the entire process is properly documented – Tell the whole story!
Good Investments in Quality & Compliance

A “Living” Risk Management Program

- Risk Management documents should not be historical documents that are put on a shelf, they should be living documents
- Risks are Quantified with RPNs (Risk Priority Numbers) that account for Occurrence, Severity, and Detection for a given risk
  - FMEAs are initially established using Historical or Theoretical Occurrences
- Design FMEAs and Process FMEAs should be re-evaluated at least periodically for real-world occurrence rates
  - Increase or decrease in field failures
  - Manufacturing failure rates
  - New failure modes
- Improve your products and processes
  - Adjust controls (up or down)
  - Process and Design Changes
Good Investments in Quality & Compliance

Quality KPIs and Metrics

- Goal = Predictive Analysis
- Quality KPIs & Metrics are required by QMR (21 CFR 820.20), not just busy work... Use the data to drive proactive decisions and culture
- Understand the KPIs that drive Quality & Compliance
  - Complaints, CAPAs, NCRs, Training, Audit Results
  - Numbers of events, timing to close, late filings, product trends
- Technology Investment – Real Time Trending and Corrections, PLM, Integrated eQMS
- Annual Goals, Objectives, and Incentives for individuals in the Quality Organization should be largely based on key quality KPIs and not largely based on bottom line P&L or financial goals of the firm...
Good Investments in Quality and Compliance

Harmonization/Integration of Quality Systems

- Growing number of acquisitions in Medical Device Industry
- De-centralized QS lends itself to potential systemic QS problems
- Integration and Harmonization is becoming more important
- Typical actions to take:
  - Corporate Level QS Policies provide governance at all locations
  - Local implementation of procedures and work Instructions to comply with corporate QS
  - Corporate Audit Function
  - Global eQMS implementation can serve many purposes:
    - Harmonize core QS processes
    - Process improvement opportunity to implement “Best of the Best”
    - Centralize data for trending and reporting
Good Investments in Quality & Compliance

Quality Culture

- “an environment in which employees not only follow quality guidelines but also consistently see others taking quality-focused actions, hear others talking about quality, and feel quality all around them.”

*Harvard Business Review* article “Creating a Culture of Quality” April 2014

- It assumes that people have effective quality guidelines to follow, and that there are effective incentives driving the activities

Specifications, Regulations & Standards  

Quality System Processes  

Process Measurement & Continuous Improvement
## Good Investments in Quality & Compliance

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<th>Quality Culture Element</th>
<th>Examples</th>
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| Defined **processes** with a high degree of excellence as it pertains to applicable specifications, regulations or standards | • Completely documented Quality Management System  
• Internal Audit Program  
• CAPAs with high percent of successful Verification of Effectiveness (VOE)  
• Continuous improvement program, with metrics |
| Defined **outcomes** with a high degree of excellence applicable specifications, regulations or standards | • Procedures that clearly list the required elements of documents and Quality Records  
• Clear product inspection processes, with evidence that the inspection techniques are utilized and are effective (validated inspection test methods)  
• Well defined acceptance criteria for validation activities that are linked to product requirements |
| Multiple **factors** that drive positive behaviors of individuals | • Peer award and recognition program  
• Regular meetings with management where results are presented and immediate consequences and actions needed identified  
• Regular discussion and follow up actions by leadership on issues regarding processes or behaviors |
Summary

ROI of a Good Quality System

- Direct Quality Costs can be determined and Indirect Costs can be estimated or benchmarked to justify spending in your quality organization.
- FDA’s Compliance and Quality Bar is continually being raised by new initiatives.
- Proactive Quality Systems are the ultimate goal for an organization.
- Good Areas for Investments to achieve a Proactive Quality Program include:
  - CAPA
  - Living Risk Management
  - Quality KPIs and Metrics
  - QS Harmonization/Integration
  - Culture
Q&A
Ed Roach brings nearly 20 years in the life sciences industry delivering compliance and quality consulting engagements to medical device, pharmaceutical and biologic clients. Mr. Roach has in-depth technical knowledge of Quality Systems and Quality Assurance, Validation, Corrective and Preventive Actions (CAPA), Root Cause Investigation, Change Management and 483/Warning Letter Remediation. Ed is also experienced in Validation Master Planning and Validation Program Development with a specialization in risk based approaches to validation projects.

Mr. Roach earned a Bachelor of Science degree from Miami University in Biological Sciences and has been actively involved with the American Society for Quality (ASQ) and the Indiana Medical Device Manufacturers Council (IMDMC).
Thank You!

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