Best practices to improve quality in medical devices

Presentation to MDIC
October 26, 2016

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Context and approach

We initiated a study to **refresh McKinsey’s 2011/2 analysis of the cost of quality** and **research on practices that lead to improvement of quality and reduction of quality cost**.

The study uses 3 lenses to characterize cost of quality:

- **Direct cost of ensuring good quality** – the organizational costs involved in preventing or detecting quality issues, including quality personnel and operations staff involved in quality work
- **Direct cost of poor quality** – including labor costs to remediate failures and material and financial costs of internal and external quality failures
- **Indirect quality costs** – including revenue loss and risk exposure from non-routine compliance issues, as well as market cap losses

The study estimates capturable quality savings opportunities through **applying a set of best practices to bring industry to median or top quartile performance levels**.

We relied on a broad array of data sources in calculating quality costs and savings, including McKinsey’s POBOS quality benchmarking tool for devices, MDIC industry survey responses, annual financial reports and other publically-available data, and interviews with McKinsey and industry experts.
We identified 5 broad sources of maturity that correlate with good quality

1. Product and process design
2. Operational maturity - people
3. Operational maturity - assets
4. Quality system maturity
5. Quality culture maturity
Overview and impact

Quality improvement practices

Case examples
Device manufacturers can leverage different practices across these sources of maturity to improve

1. **Product and process design practices:**
   - Quality controls (CQAs defined and tied to CCPs)
   - Product simplicity (number of different materials in the BoM)

2. **Operational structural factors related to people,** e.g.,
   - Sufficient production support staff
   - Better retention activities
   - Shared quality targets

3. **Operational structural factors related to assets,** e.g.
   - Spend on preventive maintenance and calibration
   - Investments in assets renewal

4. **Quality system maturity aspects:**
   - Supplier usage of CQA and CCP
   - Fast but thorough investigations

5. **Culture maturity aspects:**
   - Involving operations personnel in quality activities
   - Management presence and daily quality dialogue on shop floor
Product and process design: Critical to Quality Attributes and their link to Critical Control Points is a key driver of quality for medical devices

Disposables, N=24

Companies that have a high share of products with defined CQAs – and CCPs tied to those CQAs – have a significantly lower share of low quality product in the market

SOURCE: POBOS Quality - 2016 update
2 Operational maturity - people: Improving employee retention and adding quality targets to incentives structure leads to better quality

**Average employee turnover, %**

- High performers: 3.5%
- Average performers: 7.8%
- Poor performers: 10.2%

+191% increase

**Share of low-quality products, per 1 mm units**

- Disposables and implants, N = 38
- Disposables, N = 24

- R² = 0.47

**Sites with higher product quality have lower employee turnover**

**High share of employees with quality targets correlates with better quality outcomes**
Operational maturity – assets: Healthy level of preventative maintenance results in fewer deviations

Well performing sites spend over 1.9% of their COGS on preventative measures related to equipment.

The preventative maintenance spend must be balanced with appropriate levels of asset renewal (capital investment should be at 1.3-1.4x of annual depreciation).
Quality systems: Supplier quality as well as investigations speed and robustness are drivers of good quality

% of suppliers that have translated product CQAs into their processes and linked them to critical control points
Disposables, N=24

Assessing suppliers based on their capabilities in relation to product CQAs, sharing CQAs with suppliers, and translating CQAs into supplier CCPs helps improve product quality

Too fast and too long investigations both drive high recurrence of non-conformances

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SOURCE: POBOS Quality – 2016 update
Culture maturity: Higher involvement of non-quality employees in quality work helps improve quality outcomes

Non-quality FTE involved in quality, % of total headcount
Disposables, N = 24

- High performers: 10.4%
- Average performers: 5.9%
- Low performers: 5.1%

Quality work should be shared across multiple functions to deliver good quality outcomes

SOURCE: POBOS Quality – 2016 update
Overview and impact

Quality improvement practices

Case examples
Examples of how companies have applied some of these best practices to reduce the cost of quality (1/2)

<table>
<thead>
<tr>
<th>Best practices applied</th>
<th>Device manufacturer automating data collection to drive quality improvements</th>
<th>Device manufacturer launching a holistic quality improvement initiative after a corporate WL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Improving investigations and CAPA effectiveness</td>
<td>Product and process design</td>
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<tr>
<td></td>
<td>- Implement a closed loop manufacturing execution system (MES)</td>
<td></td>
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<td></td>
<td>- Early issue detection / prevention</td>
<td>- Replace manual systems with an automated MES</td>
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<td>- Speed and visibility in finding / correcting root causes</td>
<td>- Remove human intervention and control over labelling (key issue for field actions) through automation featuring MES and SAP</td>
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<td>- Continuous improvement current dashboards for key metrics</td>
<td>- Global standardization of QMS, complying with global regulations and standards</td>
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<td></td>
<td>- Consistent data across plants and supply chain</td>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Impact</th>
<th>Production NCRs</th>
<th>41%</th>
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<tbody>
<tr>
<td></td>
<td>Overall complaints</td>
<td>58%</td>
</tr>
<tr>
<td></td>
<td>Workmanship complaints</td>
<td>65%</td>
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<tr>
<td></td>
<td>Document errors</td>
<td>100%</td>
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<tr>
<th>Operation impact – productivity</th>
<th>6-10%</th>
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<th>Field actions reduction from baseline</th>
<th>70%</th>
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<th>CAPA cycle time improving annually</th>
<th>10%</th>
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| Cost improvement across the quality system annually | >8.5% |

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SOURCE: McKinsey
Examples of how companies have applied some of these best practices to reduce the cost of quality (2/2)

<table>
<thead>
<tr>
<th>Best practices applied</th>
<th>Device manufacturer facing shortages due to insufficient product yield</th>
<th>Device manufacturer using quality initiatives to drive manufacturing line improvements</th>
<th>Device manufacturer leveraging a predictive model for parts failure</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>▪ Increase production through lean manufacturing</td>
<td>▪ Thorough complaint investigation and identification of critical quality attributes</td>
<td>• Enhance product and process design through predictive model for parts failure</td>
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<td>▪ Increase quality yield through analytics to understand yield loss, issue trees to prioritize resources, experiments to prove/disprove root causes, and acceleration of yield drivers</td>
<td>▪ Appropriate design of process controls</td>
<td>▪ Predict probable part failures and replacement needs ahead of planned maintenance and permit preventive maintenance</td>
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<td>▪ Improve the product by design and process changes</td>
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<td>▪ Proactive replacement and maintenance, minimizing warranty costs in long run</td>
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<td></td>
<td>▪ Process automation to improve quality &amp; repeatability</td>
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<td>▪ Focus on customer feedback by eliminating key dissatisfactions</td>
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**Impact**

<table>
<thead>
<tr>
<th>Impact</th>
<th>Product 1</th>
<th>Product 2</th>
<th>Product 1</th>
<th>Product 2</th>
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<tbody>
<tr>
<td>Throughput increase in less than one month</td>
<td>12x</td>
<td>18x</td>
<td>20%</td>
<td></td>
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<tr>
<td>Yield increase</td>
<td>100%</td>
<td>50%</td>
<td>3%+</td>
<td></td>
</tr>
<tr>
<td>Reduced ppm complaint rate</td>
<td>4</td>
<td>50%</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>Capacity and footprint improvements</td>
<td>210%</td>
<td>50%</td>
<td></td>
<td></td>
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<tr>
<td>Headcount reduction</td>
<td>38%</td>
<td>75%</td>
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Field service calls rate

**SOURCE:** POBOS Quality – 2016 update

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