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Best practices to improve quality in medical devices

Presentation to MDIC
October 26, 2016

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Context and approach

Focus of today's presentation

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


Overview and impact
Quality improvement practices
Case examples

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

SOURCE: POBOS Quality – 2016 update


Overview and impact
Quality improvement practices
Case examples

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

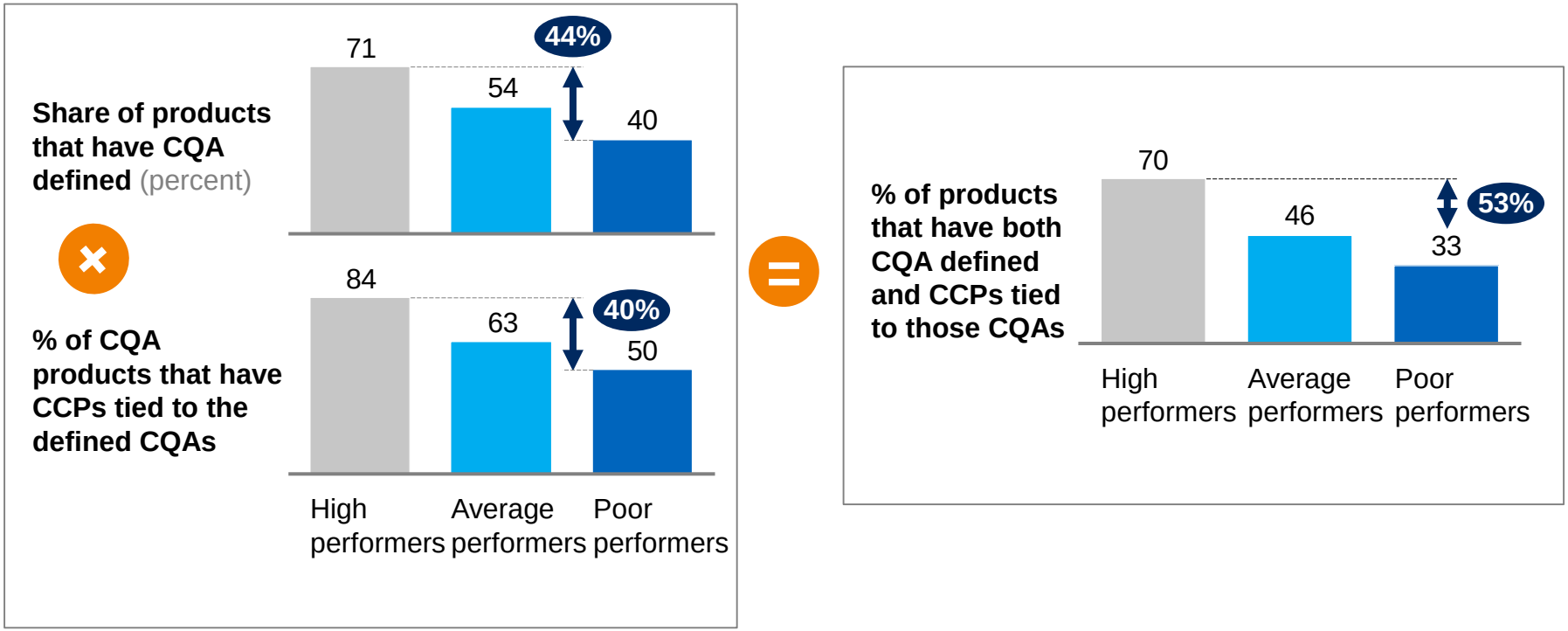
NOT EXHAUSTIVE

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

SOURCE: POBOS Quality – 2016 update

1 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

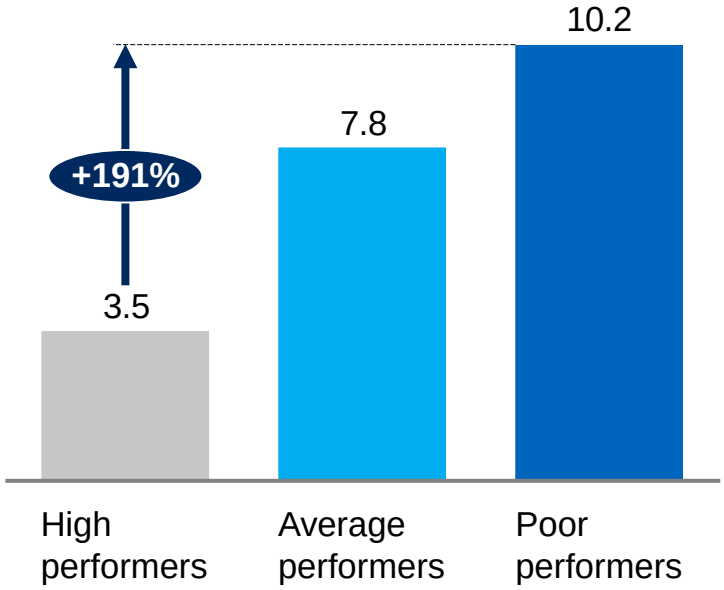


Companies that have a high share of products with defined CQAs – and CCPs tied to those CQAs – have a significantly lower share of low quality product in the market

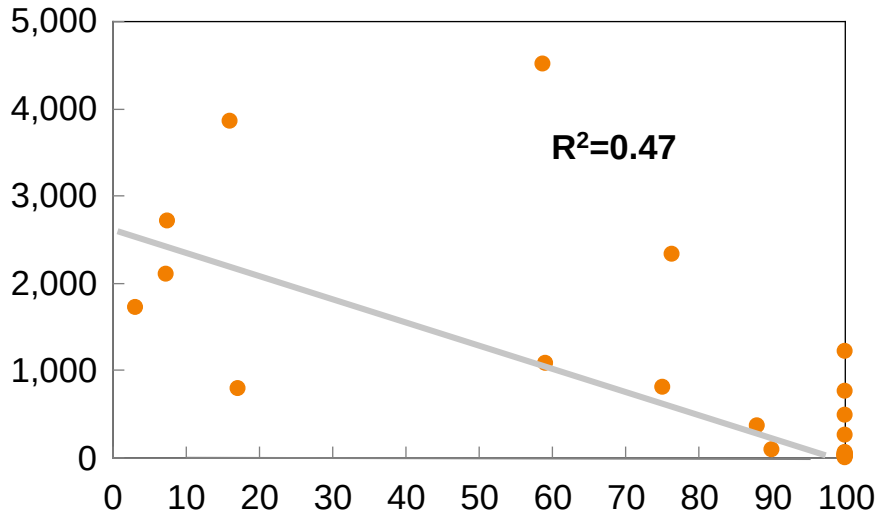
SOURCE: POBOS Quality - 2016 update

2 Operational maturity - people: Improving employee retention and adding quality targets to incentives structure leads to better quality

Average employee turnover, %
Disposables and implants, N = 38



Share of low-quality products, per 1 mm units
Disposables, N= 24



Employees with quality targets
% of total FTEs

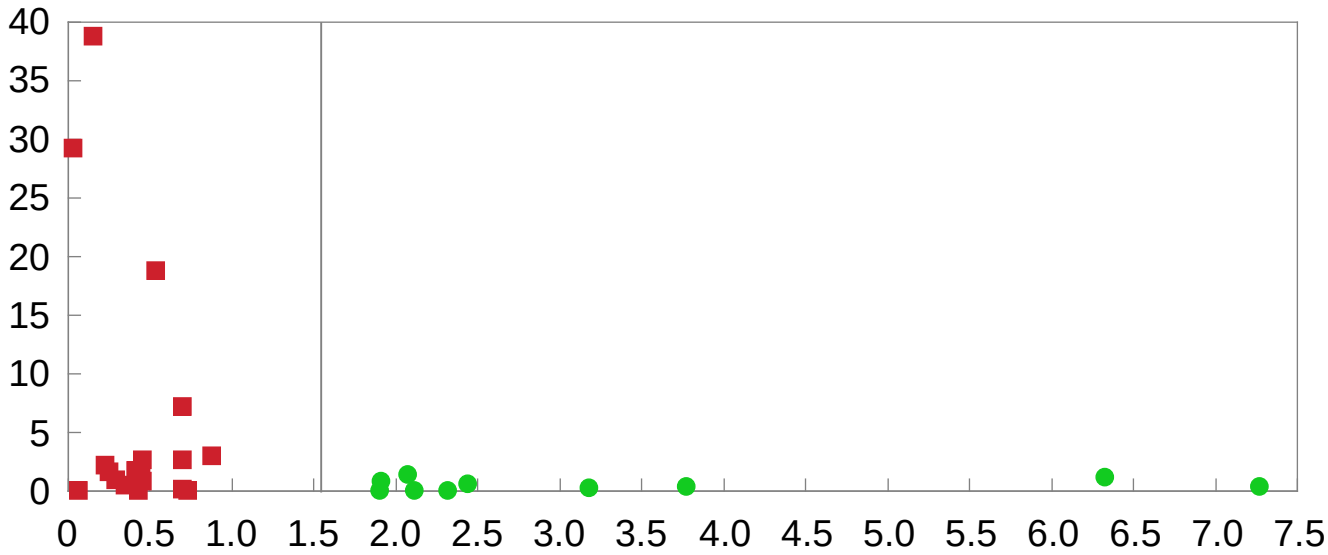
Sites with higher product quality have lower employee turnover

High share of employees with quality targets correlates with better quality outcomes

SOURCE: POBOS Quality – 2016 update

3 Operational maturity – assets: Healthy level of preventative maintenance results in fewer deviations

Number of deviations related to equipment, per 1 MM units
Disposables, N=24



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

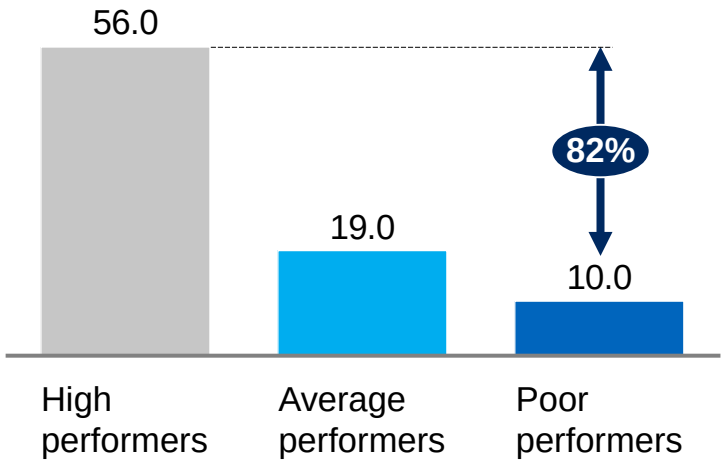
The preventative maintenance spend must be balanced with appropriate levels of asset renewal (capital investment should be at 1.3-1.4x of annual depreciation)

SOURCE: POBOS Quality – 2016 update

4 Quality systems: Supplier quality as well as investigations speed and robustness are drivers of good quality

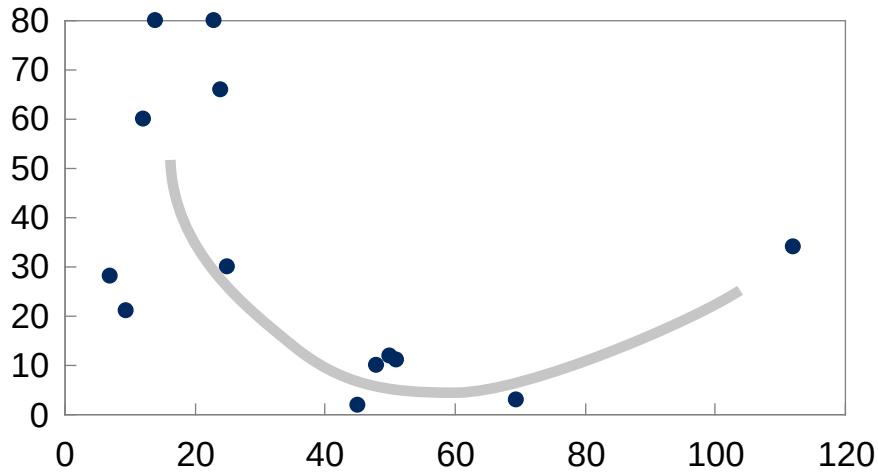
% of suppliers that have translated product CQAs into their processes and linked them to critical control points

Disposables, N=24



% recurring non-conformances

Implants, N=14



Average time to close a deviation investigation

Days

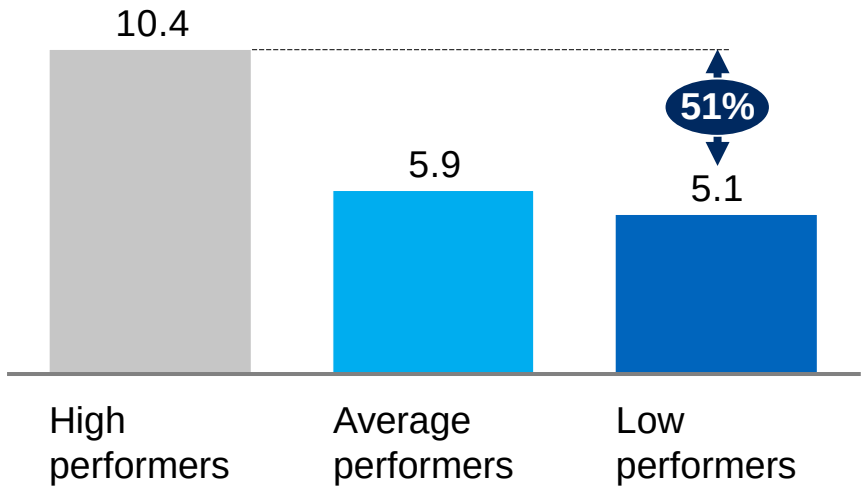
Assessing suppliers based on their capabilities in relation to product CQAs, sharing CQAs with suppliers, and translating CQAs into supplier CCPs helps improve product quality

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

SOURCE: POBOS Quality – 2016 update

5 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



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

SOURCE: POBOS Quality – 2016 update


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

	Device manufacturer automating data collection to drive quality improvements	Device manufacturer launching a holistic quality improvement initiative after a corporate WL
Best practices applied	Improving investigations and CAPA effectiveness [4] product and process design [1] ▪ Implement a closed loop manufacturing execution system (MES) – Early issue detection / prevention – Speed and visibility in finding / correcting root causes – Continuous improvement current dashboards for key metrics – Consistent data across plants and supply chain	Product and process design [1] ▪ Replace manual systems with an automated MES ▪ Remove human intervention and control over labelling (key issue for field actions) through automation featuring MES and SAP Global standardization of QMS, complying with global regulations and standards [4]
Impact	41% Production NCRs 58% Overall complaints 65% Workmanship complaints 100% Document errors 6-10% Operation impact – productivity	70% Field actions reduction from baseline 10% CAPA cycle time improving annually >8.5% Cost improvement across the quality system annually

SOURCE: McKinsey

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

	Device manufacturer facing shortages due to insufficient product yield	Device manufacturer using quality initiatives to drive manufacturing line improvements	Device manufacturer leveraging a predictive model for parts failure
Best practices applied	Product and process design 1 ▪ Increase production through lean manufacturing ▪ 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	Improving investigations and CAPA effectiveness, 4 product and process design 1 ▪ Thorough complaint investigation and identification of critical quality attributes ▪ Appropriate design of process controls ▪ Improve the product by design and process changes ▪ Process automation to improve quality & repeatability	▪ Enhance product and process design through predictive model for parts failure 1 3 – Predict probable part failures and replacement needs ahead of planned maintenance and permit preventive maintenance – Proactive replacement and maintenance, minimizing warranty costs in long run – Focus on customer feedback by eliminating key dissatisfactions
Impact	50% Throughput increase in less than one month 100% Yield increase	Reduced ppm complaint rate 12x Product 1 18x Product 2 Capacity and footprint improvements 210% Incr. in capacity 50% Red. In footprint Headcount reduction 38% Product 1 75% Product 2	Field service calls rate 20% Financial returns of initiatives (% of sales) 3%+ Field failure (breakage) and negative customer feedback rates fell significantly

SOURCE: POBOS Quality – 2016 update

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