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HOW TO CREATE A PRODUCT QUALITY ROADMAP

eBook

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EXCELLING AT PRODUCT QUALITY WINS MORE CUSTOMERS

Striking a balance between external, customer-driven quality metrics and internal, efficiency oriented ones is a challenge every manufacturer confronts as they grow. Excelling on both is a challenge and creates a strong foundation for growing a manufacturing business today. Making manufacturing quality what you're most known for is also the quickest way to increase sales.

B2B buyers rely more on independent articles, industry analyst and crowdsourced product reviews than ever before. According to Forrester, 74% of B2B buyers research half or more of their work purchases online before buying. The same study found that 30% make half or more of their work purchases online today, and 56% expect to make half or more of their work purchases online in 3 years. The ultimate goal of having your organization appear on the first page of Google search results by analysts, industry press and review sites - all because of your efforts in improving product quality - is certainly possible.

The following are the seven ways product quality is winning more customers today:

1. Build a reputation for excelling at the most challenging, stringent quality standards in your industry, especially if you produce medical devices.

Marketing, lead generation, and selling programs that show measurable results help prospects see themselves attaining their quality goals. In medical device manufacturing expertise in FDA, 21 CFR Part II, and ISO standards are invaluable in attracting new prospects who are willing to pay a premium for the highest quality products. Excelling at, meeting, and exceeding quality standards pays.

2. Look to find ways for your customers to validate your product quality by arranging calls with industry analysts, industry press and encourage them to leave reviews online.

A strong reputation for quality validated by customers is what industry analysts, the press, and the blogging community need to keep producing content. All three of these groups of influencers are looking for compelling stories of how B2B products and services are solving customer problems. Add to this the proliferation of review sites that bring Amazon and Yelp-like features to product reviews, and the implications are clear: excelling on this dimension of product quality generates new opportunities.

3. Use the strong product quality foundation to create new products for new markets, attracting entirely new prospects and customers.

Every manufacturer knows about the areas of opportunity in their markets and industries no one has the production capacity to focus on. The more customer-driven quality is, the more opportunities there are to invest the time savings into new product development, spin off product line extensions, and strive to create entirely new markets. Using product quality strengths as a foundation, manufacturers are successfully opening up new markets adjacent to those they are in today.

4. When product quality becomes a core strength of any manufacturing business, faster response times, greater accuracy, and the potential to improve every customer interaction is possible.

Getting in control of product quality and minimizing its potential to disrupt operations is the first step in accelerating any manufacturer's ability to compete. There are too many benefits to list how much product quality accelerates a production operation. The bottom line is that it leads to excelling on the dimensions that matter most, and those are the customer's expectations and needs for on-time delivery and perfect order performance.

5. Trust is the most powerful sales accelerator there is, and it's earned every time a product or service delivers more than is expected, earning praise from customers and new prospects via word of mouth.

Making a greater level of trust happen starts by revolutionizing quality and making it so strong it redefines daily customer experiences. Manufacturers often use Net Promoter Scores (NPS) to measure the relative level of customer satisfaction in their customer bases. Knowing how customers perceive quality and which areas are the most in need of improvement is essential. NPS also has a word of mouth index which is a great way to track how quality is impacting referrals and new prospects.

6. Improving product quality reduces Return Material Authorizations (RMA), warranty costs, service recovery and recall costs, all leading to less customer churn.

Customers leave when product quality drops below their minimum expectations. They also leave when a manufacturer's services department becomes too difficult to deal with due to outdated, bureaucratic procedures and when product recalls make items worthless. Manufacturing Intelligence software is capable of providing insights into which points of failure are driving the worst possible outcomes for customers.

7. Launching Configure-Price-Quote (CPQ) as a growth strategy requires product quality be the most scalable, high-speed process in manufacturing.

Pursuing a CPQ strategy that provides a range of products customizable by customers requires each phase of product quality management and compliance be fine-tuned and very efficient. It's possible to launch a CPQ strategy anytime.

Quality processes and systems must be scalable, quick, integrated and reliable to excel and realize the potential this product and selling strategy offers.

HOW EXCELLING AT COST OF QUALITY ACCELERATES COMPANY GROWTH

- 67% of executives believe Cost of Quality is essential to excel at if their companies are to stay competitive in an era of rapid globalization (Kaur, 2009).
- 89% of manufacturers rely on Cost of Quality to improve customer satisfaction, and 84.52%, for ISO 9000 compliance (Kaur, 2009).

Extending product quality far beyond the boundaries of compliance is the catalyst that drives increased sales and satisfied customers. Innovations are proliferating across all medical products manufacturing sectors, from 3D printing to WiFi-enabled products capable of realtime data integration. What's lacking is a corresponding intensity to innovate quality at the same pace and scale.

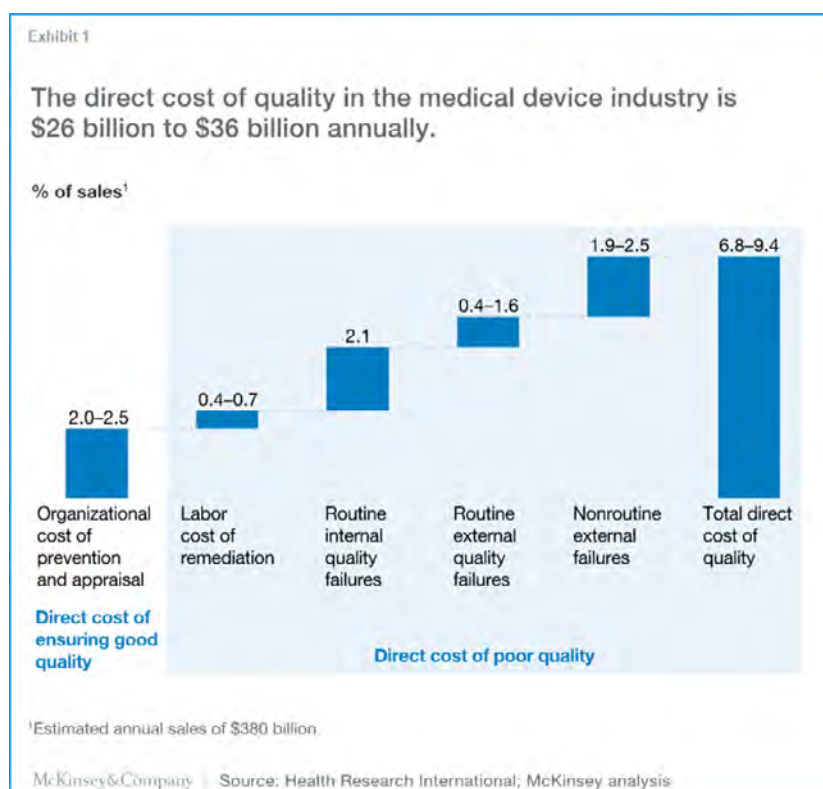
Accepting The Challenge Of Innovating Quality As Fast As New Products

Medical device manufacturers face the challenge of being as innovative at achieving excellent quality levels as they are at inventing new products. The cornerstone of any successful new product is how quickly customers trust, adopt and integrate it into their daily approaches to getting work done. For any new product to achieve its full revenue potential, the product and offering company have to earn a reputation for quality and trust quickly.

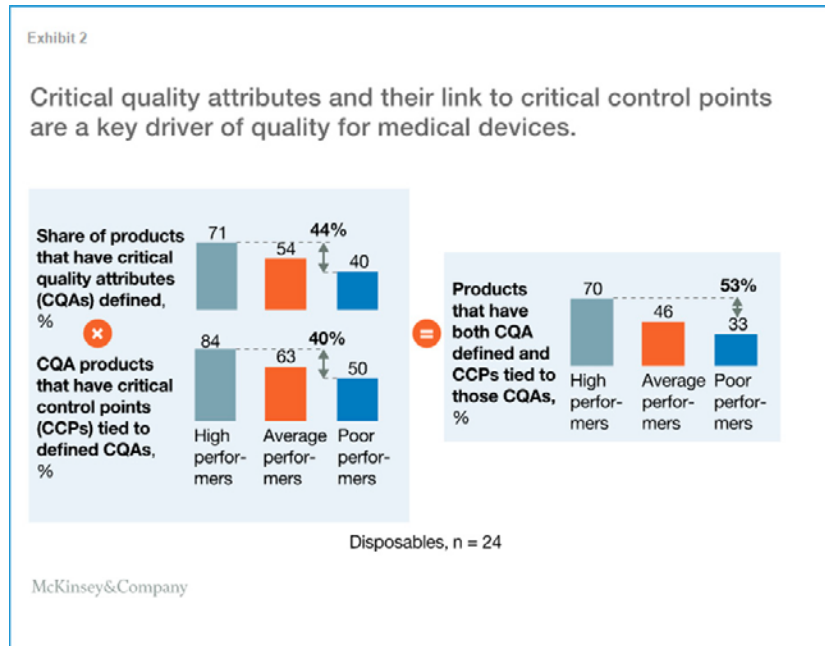
A recent McKinsey & Company article, *Capturing the Value of Good Quality in Medical Devices*, estimated the total direct cost of quality at 6.8% to 9.4% of industry sales. McKinsey's research team found that the pace of quality improvements in medical device manufacturing isn't keeping pace with patent creation and new product development. Getting beyond just tracking the costs to prevent or detect quality flaws and addressing the indirect and direct quality costs is needed. McKinsey's study focused on these cost components to gain greater insights into the true Cost of Quality for medical device manufacturers. The following are the key takeaways from the McKinsey study on how high product quality drives revenue for medical device manufacturers:

- **The medical device industry's direct Cost of Quality of approximately 6.8% to 9.4% of industry sales equals \$26 billion to \$36 billion annually.**

These estimates are based on the industry's current annual revenue run rate of approximately \$380B. McKinsey found that the direct cost of ensuring good quality is one-third of this total cost, with the remainder resulting from the direct cost of poor quality. The following graphic from the article (*Exhibit 1*), *Capturing The Value of Good Quality in Medical Devices*, provides an analysis of the direct cost of quality in the medical device industry.



- Medical device manufacturers who design for quality and manufacturability to the plant floor are more effective at defining and optimizing the core set of Critical Quality Attributes (CQA) that deliver lower Cost of Quality.** The quicker a medical device manufacturer can define and act on CQAs, the more effective they become at assigning Critical Control Points (CCP) before any products are produced. By concentrating on improving a core set of CQAs, medical device manufacturers improve revenue by reducing costs and increasing customer satisfaction. Excelling at CQAs over time earns customer loyalty and trust and further engrains quality into new products. McKinsey’s findings are illustrated in the graphic below (*Exhibit 2*).



- Four key medical device quality manufacturing factors are driving greater revenues with the product and process controls being most valuable.**

McKinsey found that the four factors of robust product and process controls, stronger operational maturity relating to people and assets, mature quality systems (especially supplier controls and non-conformance, corrective action/preventative action (CAPA) management), and an analytics-driven quality culture and processes across an organization are critically important.

- By bringing a greater level of intensity to improving product quality, medical device manufacturers can recover from \$6B to \$11B a year.**

There is ample room for medical device manufacturing improvements in quality, with recoverable costs industry-wide ranging from 1.5% to 3% of sales or \$6B to \$11B a year. The lower figure of 1.5% is based on lower-performing medical device manufacturers reaching an average level of quality, and the 3% reflects best-in-class medical device manufacturing quality.

HOW TO DEVELOP A QUALITY AUDIT PLAN THAT TRACKS IMPROVEMENTS

Your prospects, customers, channel, and service partners evaluate you more on product quality than anything else. Making that reputation a solid one your company can grow on for years to come, it starts by focusing on quality metrics and key performance indicators (KPIs) that are customer-driven.

- The majority of manufacturers have Statistical Process Control (SPC) processes in place to measure, monitor and improve manufacturing quality, yet could be achieving more by taking a systematic approach to internal quality audits.
- Manufacturing audits most often find Non-Compliance and Corrective Action Preventative Action (CAPA) areas for improvement that, once addressed, lead to higher production yields and faster time-to-market
- Bringing an energized intensity to each phase of the Deming Cycle is essential if any audit is going to deliver lasting change in product quality.
- Getting on a regular cadence of internal quality audits often uncovers areas for improvement across a diverse series of process and product-related areas including Supplier Quality Management (SQM), Document Control, Training, Production Scheduling, regulatory compliance and product returns.

The Best Internal Audits Always Keep Customers First

Nonconformance, Corrective Action/Preventative Action (CAPA), returns, reworked sales orders and rejected orders are early warning signs that customer relationships are at risk. When designing any audit it's important to take the quality metric or key performance indicator (KPI) that has a direct impact on customers. The following are the key factors why the best internal audits always keep customers first:

- **The greatest strength of Six Sigma is improving business processes so they exceed customer expectations.**
At the center of any excellent Six Sigma-based quality audit is a quantified definition of customers' expectations and requirements. Integral to Six Sigma is the DMAIC (Define, Measure, Analyze, Improve and Control) methodology that provides a flexible framework for troubleshooting where processes are falling below customers' expectations and which process improvements will make the greatest positive impact.
- **Committing to a strong and quickly deployed service recovery strategy based on internal audits creates credibility and customer goodwill.**
Immediately after an internal audit is complete it's time to launch a service recovery strategy to resolve the problems that initially led to the audit. An example of service recovery strategy is providing a free year of maintenance on a product that may have quit working. The goal of service recovery strategy is to compensate customers for the time they lost due to poor product quality.
- **The urgency to excel for customers' needs means to drive the Deming Cycle in each audit until it becomes a core part of the quality DNA of any manufacturing operation.**
Bringing an energized intensity to each phase of the Deming Cycle is essential if any audit is going to be a lasting change in product quality. Defining and executing the PDCA (Plan, Do Check Act) approach to audits and improvements increases their chances of success. Over time this approach ingrains quality into the DNA of any manufacturer.

How To Do A Quality Audit That Tracks Improvements

The scope and scale of quality audits vary by type of manufacturer yet all share a common set of characteristics. The following are the lessons learned on how to do a successful quality audit:

- 1. Capture data on process and product areas that will be the focus of the audit.**
The best data is from customers and the failures they are experiencing, coupled with internal data on specific products and workflows. Getting this data will help define the scope and scale of the audit company-wide.
- 2. Define the audit goals, timing and type based on the data obtained from customers and company-wide.**
Full-scale audits include interviews with members of manufacturing, operations, supplier quality and product quality assurance. Define customer-centric audit goals taking into account the PDCA approach to solving product and process quality problems. A critical success factor to any audit is setting accurate timeframes and schedules. Defining the best possible audit timeframes (matching the audit type) to get the most valuable data possible is key to troubleshooting problems quickly.

3. Select a cross-functionally-based trained audit team and appoint a senior executive as champion.

A member of the senior management team can quickly remove roadblocks to getting audits done on time and delivering customer-driven results. Having a cross-functional team brings the needed insights to quickly complete the audit and take action to alleviate the systematic and product-based challenges. If trained auditors are not available, create an Auditor Certification Program. This program needs to include courses on the essentials of Quality Management Systems as defined by ISO 9000, audit execution, the role of an ISO Lead assessor, training in TQM, Business Process Mapping and other techniques to analyze and take action on quality data. Auditor training also needs to cover embedded workflow functionality, workflow Gantt charts and document control.

4. Define audit modules and assign auditors to complete each according to the overall audit project plan.

Each audit module focuses on a specific product quality, workflow or business process area that contributes to the overall audit plan. It's important to define a standardized approach or protocol to completing each of the audit modules so the data and insights captured are scalable and useable across all manufacturing operations.

5. Perform the plant audit on a module-by-module basis, designing the cadence and timeframes to meet ISO requirements.

The best internal audits are designed to capture interactions of manufacturing systems and processes. As a result they are scheduled for a specific time frame or duration. It's important to have a schedule of module completion that guides internal audits to capture all available troubleshooting data.

6. Summarize the findings and propose a plan of action for solving the quality problems immediately.

The senior executive leading the audit team works with each author to summarize and provide a clear roadmap for improving product and process quality. The audit champion also needs to define and take action on strategies to turn around the supplier quality, sourcing, and work floor quality levels to the work instruction level to solve the quality problems.

7. Audits often surface new metrics and key performance indicators (KPIs) that provide insights into a new area of process improvement and manufacturing quality.

Having auditors provide the most useful metrics and KPIs they found during their individualized audits and adding them to the manufacturing quality dashboard helps drive improvement. Being able to use existing data to gain new insights is how manufacturers begin the journey of continually improving quality.

8. Using Six Sigma and DMAIC-based data to drive Manufacturing Intelligence and predictive analytics of where and how quality can be improved is an evolving best practice today.

The ability to quickly interpret and act on Manufacturing Intelligence is going to be the strongest competitive differentiator many companies will have in the coming decade. Manufacturers have the opportunity to take quality management to a predictive level of performance by using Manufacturing Intelligence-based solutions to gain insights into Six Sigma-based data.

ADOPT THE FIVE QUALITY METRICS PREDICTING THE FUTURE OF MANUFACTURING

- 46% of manufacturers agree that implementing and using data analytics is necessary to staying competitive and growing their businesses.
- 69% of decision-makers believe analytics will be crucial for business success in 2020, with 15% considering it crucial today.
- 32% see the potential for big data analytics and Industrial Internet of Things (IIoT) to improve supply chain performance and increase revenue. Manufacturers perceive data analytics as a key component of a successful Industrial Internet of Things (IIoT) strategy across their operations.

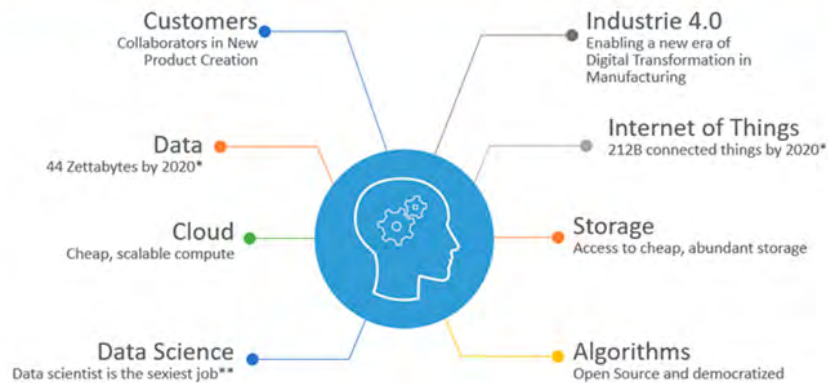
Manufacturing is at an inflection point today. Analytics applications and tools are making it possible to gain greater insights from the massive amount of data manufacturers generate daily. Manufacturing leads all industries on the planet when it comes to the amount of data generated from a typical day of operations. The challenge all manufacturers face is defining clear, precise goals that are measurable based on the massive amount of data they generate daily.

Manufacturing's Proliferation of Data Provides A Glimpse Into The Future

Every manufacturer has the potential to gain greater insights into their operations using prescriptive and predictive analytics. This can be done without massive amounts of investments in expensive new software technologies. The graphic below shows the data ecosystem many manufacturers either have today or are quickly becoming. Orchestrating each of these sources of data is critically important to creating a base of manufacturing intelligence that can flex, scale, serve customers and drive revenue.

With great volumes of data comes great responsibility. Strip away the hype surrounding machine learning, Artificial Intelligence (AI) and Big Data in manufacturing and what's left are the core metrics and Key Performance Indicators (KPIs) that define and predict customer satisfaction and quality.

Conditions Are Ideal For Quality Metrics To Scale In Manufacturing



*IDC Digital Universe report, 2014 <http://www.emc.com/information/digital-universe-2014.htm>

**Data Scientist: The Sexiest Job of the 21st Century, Oct 2011 <https://hbr.org/2012/10/data-scientist-the-sexiest-job-of-the-21st-century>

Source: *Using Big Data for Machine Learning Analytics in Manufacturing*

FIVE QUALITY METRICS AND KPIS THAT PREDICT THE FUTURE OF MANUFACTURING

Getting visibility from the shop floor to the top floor, increasing order accuracy, reducing order cycle times and improving Overall Equipment Effectiveness (OEE) are a few of the many goals manufacturers are looking to achieve with higher quality metrics. By enabling real-time integration between Enterprise Resource Planning (ERP), Customer Relationship Management (CRM) and Supply Chain Management (SCM) systems manufacturers can choose the metrics that matter the most.

The five quality metrics and KPIs that most predict the future of manufacturing include the following:

1. Manufacturing Cycle Time

Quantifies the amount of elapsed time from when an order is taken until the product is produced and entered into finished goods inventory. Cycle times vary by segment of the manufacturing industry, size of manufacturing operation, global location and relative stability for supply chains supporting operations. Real-time integration, applying Six Sigma to know process bottlenecks, and re-engineering systems to be more customer-focused improve this metrics' performance. Cycle Time is a predictor of the future of manufacturing as this metric captures improvement made across systems and processes immediately.

2. Overall Equipment Effectiveness (OEE)

Many manufacturers consider this the most important metric there is for making sure their daily production operations are stable and profitable. OEE measures the performance of a given machine, product line, work team or entire production center. These metrics are most often used at the machine level to track each production asset's utilization rate, performance levels, and quality. It's calculated using the formula of **Availability x Performance x Quality**. It's also pervasively used for predictive maintenance of machinery, which the following graphic is based on:



Figure 4: The Predictive Maintenance Solution for the OEM Plant

3. Production Yield Rates By Product, Process, and Plant Location

Yield rates reflect how efficient a machine or entire process is in transforming raw materials into finished products. Process-related manufacturers rely on this metric to manage every production run they do. Microprocessor, semiconductor, and chip manufacturers are continually monitoring yield rates to determine how they are progressing against plans and goals. Yield rates also reflect how stable OEE rates are and how the overall production workflows are operating. Greater real-time integration, improved quality management systems, and greater supply chain quality and compliance all have a positive impact on yield rates. It's one of the key measures of production yield as it reflects how well orchestrated entire production processes are performing.

4. Perfect Order Performance

Perfect order performance measures how effective a manufacturer is at delivering complete, accurate, damage-free orders to customers on time. The equation that defines the perfect order Index (POI) or perfect order performance is the following: **% orders delivered on time x % orders complete x % orders damage free x % orders with accurate documentation x 100.**

According to the The American Productivity and Quality Center (APQC), the majority of manufacturers are earning an order performance level of 90% or higher. The more complex the product lines and configuration options (including build-to-order, configure-to-order and engineer-to-order workflows), the more challenging it is to attain a high/perfect order level. Greater analytics and insights gained from real-time integration and monitoring help complex manufacturers earn higher perfect order levels over time.

5. Return Material Authorization (RMA) Rate and % Of Manufacturing

The percentage of products shipped to customers that are returned due to defective parts or not otherwise meeting their requirements is the Return Material Rate Authorization (RMA). RMAs are a good leading indicator of potential quality problems. This is a leading indicator of manufacturing's future as the more integrated RMAs are linked to Product Lifecycle Management (PLM) and Customer Relationship Management (CRM) systems. As this becomes more prevalent, the more valuable the data becomes, acting as a catalyst for improvement in the future.

For more information, please visit www.iqms.com or call 1.866.367.3772

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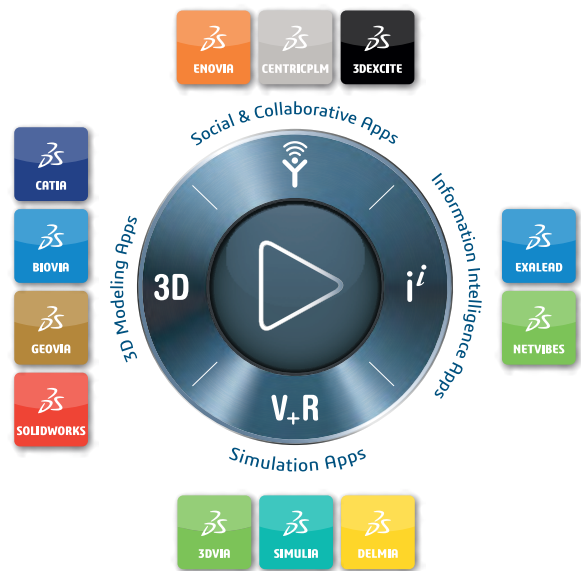
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