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Medical device quality

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An essential capability and competitive edge for manufacturers

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Executive summary

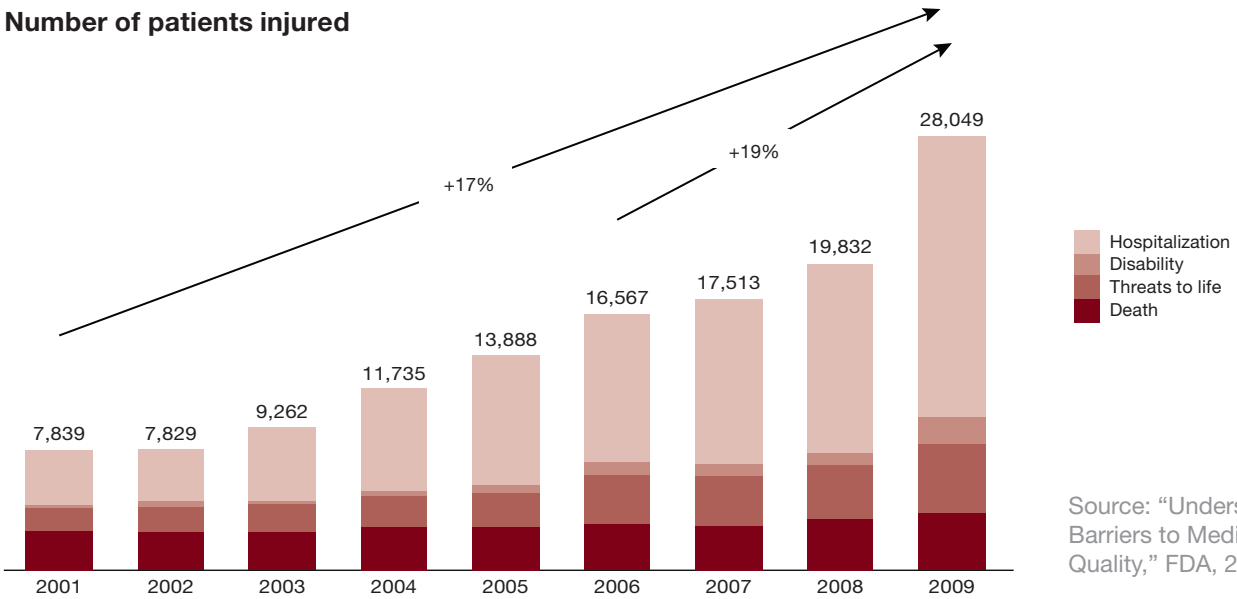
In our experience, there are three root causes for the rising incidence of product failures in the medical device industry: a siloed, reactive approach to quality; a lack of focus on continuous improvement; and the ever-increasing complexity of medical devices. To address them, manufacturers should consider developing quality management as an organizational capability. The principal components of such a capability are critical-to-quality (CTQ) management, systems engineering, and design for Six Sigma (DFSS). Companies that successfully weave these three elements into an integrated, preventive quality capability can achieve a competitive advantage and a leadership position in their industry.

The quality imperative

The incidence of product failures in the medical device industry is rising. According to the U.S. Food and Drug Administration (FDA), reports of serious adverse events — resulting in hospitalization, disability, threats to life, or death — caused by medical devices rose from 7,839 in 2001 to 28,049 in 2009, an average annual increase of 17 percent (*see Exhibit 1*). This rate of increase far outpaced annual industry growth of 9 percent over the same period, as well as the 11 percent annual increase in FDA premarket approvals for new Class III devices (which are essential in supporting human health and thus are the most stringently regulated).

Exhibit 1

Serious adverse event reports for medical devices in the United States are on the rise



Source: "Understanding Barriers to Medical Device Quality," FDA, 2011

Meanwhile, the FDA reports that nearly 70 percent of all device recalls were traced to failures in product design, supplied materials, or manufacturing processes. The financial costs associated with quality defects are on the rise too. The average decline in a device manufacturer's share price after a major quality event was 16.8 percent between 2006 and 2009, an increase from an average decline of 9.8 percent between 2000 and 2002.

The consequences of quality misses are not isolated in share price. They reverberate throughout a company, negatively affecting revenues, margins, and costs. In many industrial companies, the cost of non-quality, which is defined as the aggregate time, money, and opportunities lost by doing things incorrectly, is less than 4 percent of sales, and sometimes much less in best-in-class manufacturers. In contrast, many medical device companies incur non-quality costs exceeding 6 percent; in some cases, we've seen costs exceeding 10 percent.

A recent analysis conducted by Strategy& for a medical device manufacturer revealed a negative impact of non-quality amounting to 4 to 7 percent of revenues over a three-year period. The loss associated with non-quality derived from a variety of sources:

- Revenue declines due to delays in time-to-market, as well as lost sales and market share
- Margin declines due to losses in reputational capital and brand equity
- Increased costs due to the additional time that R&D, regulatory, operations, and marketing staffs must spend to address and resolve quality issues
- Increased costs due to products and materials that must be scrapped
- Increased costs due to labor and materials needed to rework and repair defective products
- Increased costs due to litigation, fines, and liability for restoring the health of patients

Quality misses give rise to serious consequences in both human and corporate terms, but as is often the case, this industry-wide problem harbors a valuable opportunity for those select companies that can capture it quickly and effectively. Medical device manufacturers that can raise the quality of their products will improve the human health benefits they offer, accelerate their speed-to-market, and enhance shareholder value. Quality — whether measured by a lack of defects, long-term reliability, and/or ease of use — is a powerful driver of market

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share and company performance, especially when it translates to a marked improvement in one company's products versus its competitors'.

Of course, pursuing quality is not a trivial task. To create a competitive advantage in the marketplace, quality management would need to be developed as an organizational capability — with all of the skills, knowledge, behaviors, processes, structures, and technology that implies. This capability for quality would have to be proactive, not reactive. Its aim would be to ensure that flawed devices never reach the market.

Such a capability aligns directly with the demand in today's medical device marketplaces: In this post-reform era, care providers, insurers, and patients are all seeking out high-quality devices in an effort to improve outcomes and better manage the total cost of care. Manufacturers that can fulfill this demand will gain a valuable edge, while the laggards will be forced to play catch-up or risk being locked out of their markets.

The causes of non-quality

To effectively address the quality conundrum in medical devices, it is necessary to understand its root causes. We have found three of them in our work with companies across the industry: a siloed, reactive approach to quality; a lack of focus on continuous improvement; and the ever-increasing complexity of medical devices.

Siloed, reactive approach to quality

Too often, medical device companies adopt an approach to quality that is overly narrow, functionally centered, and not properly integrated across the business. To some degree, this is a natural, but unintentional, by-product of the quality and reliability (Q&R) function's role as the company's regulatory interface. It is also a prescription for trouble.

Because the responsibility for quality is vested in Q&R, the quest for quality can become siloed within that function. Other functions and business units may begin to see quality as someone else's job, when it should be everyone's job.

Moreover, because medical devices are subject to a high degree of regulation, Q&R can come to see its principal role as one of auditing and policing. This is true to some extent: Q&R must monitor the activities and processes of R&D, the supply chain, and manufacturing to ensure compliance with FDA-mandated controls. But if device quality comes to be something that is managed through inspection rather than design, the impetus for quality becomes reactive, not proactive.

A siloed approach to quality raises the likelihood of flawed inspection criteria. When development teams do not include Q&R or do not receive robust quality feedback, it becomes more difficult to isolate the parameters of a product that are critical to quality. This may result in any number of criteria flaws that can create "quality escapes," such as incorrect tolerances in supplied materials and unclear or erroneous usage specifications for patients and clinicians.

If device quality is managed through inspection rather than design, the impetus for quality becomes reactive, not proactive.

Inspection has its own set of drawbacks. Inspection systems are easily taxed, increasing the risk that defects that can have a significant negative impact will slip by. High levels of inspection also entail significant costs in monitoring the quality of materials, components, and finished goods. Further, because inspection is usually the last step in a process, tracking the causes of non-quality can be an onerous and expensive task. Resolving quality problems after the fact is also difficult. To ensure designed-in quality, the Q&R function must be embedded in project teams and in systems engineering. These are where the early decisions regarding product design and characteristics that will determine quality and reliability outcomes are being made.

Lack of focus on continuous improvement

Many medical device manufacturers do not make full use of one of their most important quality enablers: past experience. Data such as customer and patient complaints, feedback on products from the field, corrective and preventive actions, testing outcomes, and inspection results is collected, but the use of it often falls short. In addition, too few companies employ a rigorous and repeatable framework to (1) collect and consolidate data, (2) analyze the data to capture the insights it harbors, and (3) apply those insights to the improvement of device quality. Unless these three tasks are developed and linked in a closed loop, continuous improvement is impossible.

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The regulatory environment can also serve as an inhibitor. Once material choices, system interactions, and manufacturing processes have been established and approved by regulators, changing them often requires a time-consuming and expensive new round of regulatory oversight, which companies may be loath to undertake.

In short, continuous improvement is not pursued in a systematic way, which contributes to a lack of understanding about what drives quality outcomes.

Ever-increasing complexity of medical devices

Advances in technology have led to a welcome explosion in the sophistication and application of medical devices. The industry can now help improve human health in ways that were unthinkable just a few years ago. But sophistication almost always means greater complexity, and greater complexity is almost always accompanied by the increased potential for unanticipated defects and adverse reactions — especially when dealing with an environment as unique and varied as the human body.

Defining a capability for quality management

In response to these serious — and rising — challenges, manufacturers should consider adopting quality management as an organizational capability. When a company organizes around the capability to deliver high-quality products, it transforms quality from an unconnected bundle of tools, process, and procedures into a performance ethic that informs how work is done throughout the value chain. Instead of the control and assurance focus of the conventional approach to quality, a quality capability is focused on prevention and integration.

Such a capability is preventive in the sense that it enables manufacturers to design quality into medical device products and processes. It requires rigorous system-level testing and analysis, the design of processes and products for manufacturing quality, and defining and meeting predetermined parameters that are critical to high-quality outcomes.

This capability seeks to embed quality at all stages of the product life cycle and track meaningful quality metrics at every step in that life cycle, from market research to concept to design to manufacturing to delivery. The objectives and scope of such a capability far exceed those typically used in the conventional stage-gate development process that is reconciled to FDA requirements for design control (*see Exhibit 2, next page*).

In this scenario, quality becomes a cultural value — part and parcel of "what we do around here." In other words, the pursuit of quality becomes a holistic endeavor. Like companies that deliver high quality in other complex products, such as those in the aerospace and automotive industries, medical device makers should ensure that quality bridges the functional and business boundaries within the company, as well as stretches across the value chain, via collaboration with supply chain partners and end-users, whether they are care providers or patients.

An integrated quality capability is explicitly tied to a business's strategy and its product and service portfolio in a manner that is clear to the entire organization and the marketplace. Leaders recognize and promote the capability and its requirements as critical enablers of commercial success, not barriers to performance.

Exhibit 2

Preventive quality's extra effort

	Design control requirements	Incremental efforts for preventive quality
Inputs	Design inputs documented before design phase, covering relevant aspects	Patient use cases and requirements fully understood in the planning phase Customer and physician feedback incorporated and understood as "lessons learned"
Design practice	Design outputs meet requirements and characterize the design to allow verification and validation Acceptance criteria established before verification and validation Design reviews conducted and change control maintained Design correctly transferred	Critical-to-quality parameters identified in planning and tracked through development Design for Six Sigma tools employed where needed Design for manufacturing and assembly analysis conducted in the planning phase
Testing	Verification and validation at the end of preclinical stage ensures design meets requirements Validation conducted on production devices, or equivalents shown	Testing for robustness completed in the planning phase, including a sequence for connecting functionality and component testing Systems integration testing completed during the design phase
Risk management	Risk analysis addressed in the design plan and risk considered throughout the design process Risk analysis completed in design validation Hazards analysis completed	Suppliers selected in the planning phase, informed by capability assessment Risk assessment completed in the planning phase and updated through design and beyond

Source: Strategy&

Three essential components

Our experience suggests that a quality capability in medical device companies is best developed using three interdependent components: critical-to-quality (CTQ) management, systems engineering, and design for Six Sigma (DFSS). Together, these three elements serve as the capability's core enablers.

Critical-to-quality management

The objective of CTQ management is to identify design features that are essential to product quality and ensure that they are delivered. CTQ helps manufacturers answer two questions: What are the key quality characteristics of a product? How will the key characteristics be quantified and/or translated into design and manufacturing specifications?

When properly executed, CTQ ensures that device performance requirements are articulated in system and component terms, and ultimately into supplier and process requirements. A CTQ cascade includes tools for identifying customer priorities, product features and characteristics, and specific dimensional and material properties as well as process outputs (*see Exhibit 3, page 15*).

The identification of CTQ parameters — that is, the specific characteristics of the device and its components that have the most influence on its quality — is an important quality enabler and can have a significant positive effect on supplier and manufacturing performance. To capture the full potential of CTQ management, medical device companies should embed CTQ activities across the development process, audit these activities, and formally communicate the process outcomes across functions. CTQ management must also be extended across the supply chain; when designs are transitioned to suppliers, development teams typically confirm product function, but they often do not monitor and control CTQ parameters.

Systems engineering

Systems engineering ensures that medical device components and the processes that produce them behave as anticipated when they are brought together. It answers essential quality questions, such as how key parts and components of a device will interact, and how the design of the device can mitigate quality risks that might arise from these interactions.

Many medical device companies do not place enough emphasis on systems engineering as a critical capacity that provides the means of making the decisions and trade-offs needed to deliver high quality and reliability outcomes. As aerospace and automobile manufacturers that deliver best-in-class quality levels have demonstrated, several factors contribute to such a capacity:

- First, a company must employ senior systems engineers who have the skills and experience needed to see the big picture and guide the development process toward its CTQ and reliability targets. Toyota, for instance, has created a career development path for its chief engineers that includes the acquisition of multidisciplinary experience and strong leadership skills.

- Second, systems engineering must begin early in the product development process. In this way, device requirements are effectively managed, the right design trade-offs are made, and the system performance tests needed to identify and mitigate quality and reliability risks can be validated.

- Third, systems engineering leaders must team up with project managers to ensure that project planning — as well as quality and reliability measures — addresses the greatest quality escape and premature product failure threats.

Design for Six Sigma

DFSS is a guided design philosophy backed by a set of tools that help isolate the most important clinician and patient needs and ensure that the device design and operability meet those needs with first-time quality and with desired reliability over the device's life cycle.

A robust DFSS capability is employed throughout the development and launch life cycle. It employs structured user research and quality function deployment (QFD) to establish design priorities and evaluate trade-offs. In the midst of the design process, design for manufacturing and assembly analysis (DFM/A) and design and process failure mode and effect analyses (dFMEA and pFMEA) are used to ensure robustness

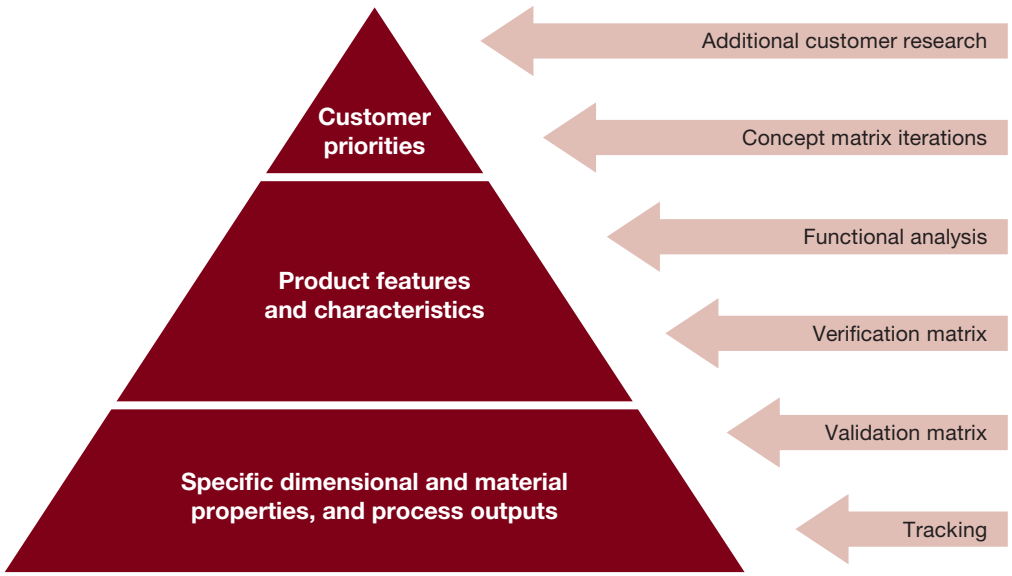
and consistently enable delivery of key priorities. Finally, root cause analysis can be used to find the origin of any performance problems revealed in testing.

Some tools, such as QFD, DFM/A, dFMEA, and pFMEA, are almost universally deployed in medical device development. However, they often are not used properly or at the right points in the development process to actually detect and eliminate quality problems. For instance, when we diagnose project failures, we commonly discover that quality tools have been applied after the design is frozen in response to regulatory requirements, rather than in a preventive way throughout the design phase. Other tools, such as root cause analytical methods, which are more applicable in some companies than others, are often missing altogether.

To take full advantage of DFSS, manufacturers should examine the full suite of tools available and identify which of them will be most useful in their particular environment. Then they should define when and how the selected tools should be deployed, develop the organizational skills they require, and build reinforcing mechanisms into the design process to monitor their use.

Exhibit 3

The CTQ cascade: Methods and tools



Source: Strategy&

Initial steps

Creating a capability for quality that is robust and rigorous enough to provide a competitive edge in the marketplace is an ambitious task. Medical device manufacturers can take several steps to start the journey on the right foot.

First, assess your company's existing capacity for quality. The development of an integrated, preventive quality capability requires you to thoroughly understand your company's existing quality practices and performance levels, and compare them with current quality standards and best practices — both within the medical device industry and in other industries. One way to complete such a benchmarking assessment is to focus on five quality categories — portfolio management, project delivery, design practice, sustaining practice, and capability development — and rank each specific performance area within them against industry performance on a relative scale (*see Exhibit 4, page 18*).

Second, identify the causes of performance gaps. These causes tend to fall into four principal categories:

- *Organization and decision rights,* including the structure of the quality organization and the composition of important decision groups. Does the current structure (formal or otherwise) enable the people with the right skill sets and knowledge to influence major decisions in a way that delivers product quality?

- *Incentive structure and culture*, including the compensation, career paths, and values needed to motivate behavior. Do existing incentives and culture promote an end-to-end quality mind-set that properly balances quality concerns against competing priorities?

- *Processes and performance management,* including the coordination of activity, the transfer of knowledge, and performance metrics. Are the right processes in place with the right quality metrics to quickly detect and respond to problems? Is the quality loop closed to enable continuous improvement?

- *People and resources*, including the systems, training, and talent needed to support superior performance in key areas of quality delivery. Does the quality staff have the proper tools in key areas — such as supplier management, project management, and systems engineering — and the skills to use them?

Third, identify and prioritize improvement actions. The gaps revealed in the preceding steps need to be translated into capability-building actions, and then those actions need to be prioritized according to their urgency and impact. Typical high-priority actions include the following:

- The creation of a strong, independent systems engineering function with the ability to influence development decisions

- The integration of quality practices into project plans to reduce the need for trade-offs between launch speed and rigorous quality processes

- The establishment of career ladders and paths for essential talent, such as systems engineers and DFSS practitioners

- The adoption of quality by senior leaders as a core mandate of the entire organization, and the creation of a culture that supports it

Exhibit 4

A framework for quality performance benchmarking

	Performance area	Definition
Portfolio management	Project and portfolio management	Identifying and prioritizing projects to enhance allocation of company resources
	Quality performance management KPIs	Using metrics to monitor performance and drive appropriate trade-offs to achieve quality goals
Project delivery	Design for quality system and culture	Establishing and reinforcing quality objectives and culture
	Design for quality ownership and influence	Establishing roles and responsibilities for managing and delivering against quality goals
	Cross-functional teaming	Collaborating across the product life cycle
	Project planning and management	Managing cost, schedule, and quality trade-offs through effective project management
	Gate effectiveness and design for quality	Establishing properly scheduled phase exit reviews by appropriate review groups
Design practice	Systems engineering approach	Designing and testing new products to ensure positive interaction with existing and new components
	Process effectiveness and design for quality	Using quality processes and procedures
	Integrated use of DFSS, DFM/A tools	Applying preventive quality and DFSS tools throughout the design process
	Requirements cascade to CTQs	Identifying and tracking critical-to-quality elements during the design process
	Supplier selection	Employing advanced skills and procedures to select and qualify suppliers
	Design transfer effectiveness	Transferring design intent from R&D to operations and communicating CTQ parameters
Sustaining practice	Supplier management (production)	Fostering strong, collaborative relationships with suppliers to improve quality outcomes
	Closed-loop feedback	Integrating lessons learned from complaint data, field reports, and launch reviews
Capability development	Recruiting	Finding and hiring new staff with required skills and experience
	Integration and training	Onboarding and training of staff
	Knowledge management	Capturing and archiving best practices for efficient retrieval and reuse

Source: Strategy&

A small price to pay

Developing an integrated, preventive quality capability requires investment, but it is far less costly in the long run than dealing with failure after the fact. A quality capability can also drive dramatic reductions in total cost: In our experience, companies typically earn payoffs of five-to-one in the first year of these initiatives.

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