

Integrating Six Sigma into Quality Management Systems in the Medical Device Industry

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Abstract. *Six Sigma is a valuable management strategy to improve business processes, reduce development and production costs, increase profit margin and improve customer satisfaction. The purpose of this paper is to describe how applicable Six Sigma concepts may complement and support formal quality management systems (QMS) in the medical device industry.*

A significant number of issues, which increase the development costs and times, is often found during different phases of a medical device life cycle. Some defects with high patient safety risk may result in dangerous and very costly product recalls.

The basic idea of this paper is to explore the possibilities of integrating Six Sigma techniques with an existing QMS throughout the entire life cycle of a medical device. This paper addresses how Six Sigma techniques, when appropriately integrated into the QMS at medical device companies, can eliminate defects earlier in the medical device life cycle, identify major opportunities for cost savings, focus on customer needs and expectations, and improve the overall business processes.

Keywords. medical device, QMS, quality improvement, quality management system, Six Sigma

1 Introduction

The medical device industry faces a number of challenges and opportunities [6] in the global medical technology market. Growing competition, pricing pressures, fast-moving competitive markets which require frequent design changes, more sophisticated customers, shorter delivery time, assembly of small parts with complex geometry and tight tolerances, and difficult to work with materials such as titanium and

silicon are just a few of many challenges for manufacturers of medical devices.

Recent trends in medical device innovation include increased system miniaturization, new biocompatible materials, low power sources, tissue engineering for replacement organs, monitoring of device data via wireless connections to ensure earlier use of more accurate diagnostics (i.e. telemedicine), etc.

Quality issues can have significant financial implications for a company, particularly for medical device companies for which quality is so closely related to safety. Such implications include liability costs and market capitalization loss due to brand damage. For example, the Food and Drug Administration's (FDA) analysis [10] reveals that, of the 5338 product recalls conducted in 2005, 1598 of them (29.94%) were medical devices. However, this may be a conservative estimate as a number of product recalls may be issued voluntarily by device manufacturers under the strategic guise of "market withdrawal" and are hence not reported to the FDA.

Of all the recalls conducted for medical devices in 2005, 77 were Class I, 1351 were Class II and 170 were Class III recalls. Class I recalls are the most serious and continue to increase (Figure 1) [9].

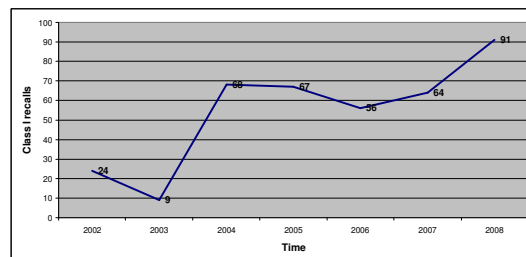


Figure 1. Medical device Class I recalls by FDA [9] (November 1, 2002 – June 13, 2008)

Medical device companies need to be flexible and open to new approaches to win the competitive game on the market, increase customer satisfaction and meet compliance requirements in a highly regulated industry. Current quality management practices (e.g. investigation, root cause analysis, risk management, internal audits, corrective and preventive actions, supplier evaluation, customer focus, etc.) can be improved by applying lean concepts and Six Sigma tools. This paper describes an integrated approach on quality management with Six Sigma in the medical device industry.

2 The costs of poor quality

A significant number of issues, which increase development costs and time, is often found during different stages of a medical device life cycle. Ongoing business demands a need for cost reduction, compliance to tough regulatory requirements, faster time to market, improved features and reliable high quality and safe products to achieve higher customer satisfaction.

Many experts on the costs of poor quality (COPQ) estimate losses in the range of 20 to 30 percent of gross sales for defective or unsatisfactory products [25]. According Ritzman and Krajewski [25] as well as Rusell and Taylor [26] four major categories of costs are associated with quality management:

- *prevention costs*: costs associated with preventing defects before they happen (e.g. quality planning, product design, training, information and process costs, etc.),
- *appraisal costs*: costs incurred in assessing the level of quality attained by the operating system (e.g. inspection and testing, test equipment, supplier evaluation, quality audits costs, etc.),
- *internal failure costs*: costs resulting from defects that are discovered during the production of a product or service before the customer receives the product or service (e.g. scrap, rework, process failure, process downtime and price-downgrading costs, etc.)and
- *external failure costs*: costs associated with defects that are discovered after the customer has received the product or service (e.g. customer complaint, product return, warranty claims, product liability and lost sales costs, etc.).

To demonstrate this point, we can use the example of a malfunction found in a Ricoh copier model, which was reported by Mr Hiroshi Hamada, president of Ricoh [29]. He claimed the cost of fixing a single defect was: \$35 during the design phase (i.e. prevention costs), \$177 before procuring parts (i.e. appraisal costs), \$368 before beginning production and \$17,000 before shipping the product (i.e. internal failure costs) and \$590,000 on customer site (i.e. external failure costs). Based on this example, if we consider design problems of medical device systems, the potential cost savings are very high.

Figure 2, based on Hiroshi Hamada's data, graphically illustrates that the cost of fixing a single error increases exponentially with the discovery time. Thus, the earlier a problem can be identified the more money a company will save.

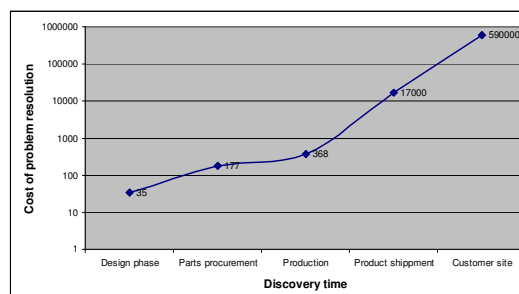


Figure 2. Costs of problem resolution increase with discovery time

The most expensive failures in the medical device industry are issues detected by customers or any issues which lead to product recall. Detection of defects and prevention measures as early in the product life cycle as possible may significantly reduce costs of failure resolution.

Figure 3 [27] exhibits the costs of quality from two different views. The classical view on the left considers failure costs as a cost of doing business. With the classical approach to quality, each level of product innovation increases the level of risk which is driving costs up. In contrast to the classical view, the modern view on the right shifts the failure prevention and quality control costs downward. The business is moving toward zero defects, and therefore is cost-effective. When quality is designed into the process and throughout the whole product life cycle (i.e. from idea creation until disposal), risk is reduced at every stage of development. Initial costs are lower and decrease throughout the product life cycle. Therefore profit can be maximized in the early growth stage.

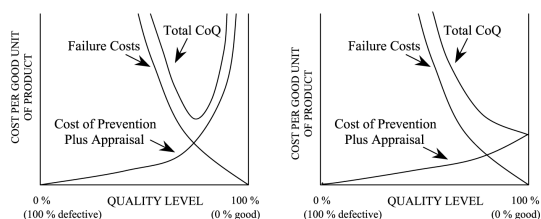


Figure 3. Comparison of costs of quality – classical view on the left vs. modern view on the right [27]

3 Quality improvement practices as part of the QMS

Medical device companies need to ensure that their products are safe, reliable and suitable for the intended purpose, and that their quality management systems meet regulatory requirements.

Both 21 CFR Part 820 Quality System Regulation (QSR) [8] by FDA and ISO 13485:2003 international standard [13] define basic requirements for the quality management systems in the medical device industry. In addition, medical device manufacturers who want to compete globally must comply with quality system requirements in the countries in which their products are sold. Though most countries recognize ISO 13485:2003, many governments such as those in Canada, Argentina and Japan interpret the requirements slightly differently.

Similar to the ISO 9001:2000 standard [16], ISO 13485:2003 standard for medical device manufacturers has a strong focus on customer satisfaction and improvement, but with an added focus on safety. This explains why ISO 13485:2003, unlike ISO 9001:2000 requires medical device companies to maintain a risk management system.

Key practices for improving quality in a traditional quality management systems used at medical device companies are described below.

3.1 Designing quality

Quality of design involves designing quality characteristics into a product or service to meet the different wants and needs of individual consumers [26]. Though customer requirements are not emphasized in FDA's QSR as they are in ISO 13485:2003, both QSR and ISO 13485:2003 state clear requirements for design control, which are intended to ensure quality is designed into medical devices. These requirements include design planning, determining design inputs that include functional, performance and interface (e.g. user and system related) requirements, developing design outputs, conducting verification and validation tests to ensure design outputs meet specified inputs, and conducting design reviews at appropriate stages of development [8].

3.2 Statistical techniques

21 CFR Part 820 (paragraph §820.250) as well as ISO 13485:2003 (clause 8.1) require the use of appropriate statistical techniques for establishing, controlling and verifying the acceptability of processes and products. Sampling plans, when used, shall be based on valid statistical rationale [8] [13].

The use of valid statistical tools appropriate to the stages of a product life cycle can make a significant contribution to the improvement of quality and productivity in medical device manufacturing [18]. Some examples of common used statistical tools and are: statistical process control (SPC), design of experiments (DOE), sampling plans, trend analysis, simulation, process capability, hypothesis testing, regression, analysis of variance (ANOVA), acceptance sampling, forecasting, cumulative survival rate analysis, quality function deployment (QFD), etc.

3.3 Risk management

Risk management requirements need to be utilized throughout all stages of the medical device life cycle. It is very important and most effective to start early with risk management activities in medical device design. Using risk management tools helps to make better decisions and ensures better use of resources.

ISO 14971:2007 is the international standard for risk management most often used to demonstrate compliance with the risk management requirements within the medical device industry. In addition the standard is quoted within the quality management system standard ISO 13485:2003 (i.e. clauses 7.1 and 7.3.2). Thus, risk management is a regulatory requirement for medical devices and their accessories.

The key elements of risk management according to ISO 14971:2007 include: risk management planning, developing a cross-functional risk management team, risk analysis that includes evaluation and reduction methods and a risk management report that describes any and all residual risks. Residual risks need to be analyzed to determine if expected benefits outweigh the risks [14].

Also, medical device companies need to be aware of the new IEC 60601-1-6:2006 collateral usability standard. This standard specifies general requirements for medical electrical equipment to provide adequate usability and the risks resulting from normal use and use errors are acceptable [12].

3.4 Internal audits

Conducting internal audits is not only a good business practice, but also a regulatory requirement. 21 CFR Part 820.22 as well as ISO 13485:2003 (clause 8.2.2) require conducting quality audits. Audits can be costly and therefore management needs to understand how audits improve quality and ultimately reduce costs.

Internal audits should be conducted at least once a year by independent and qualified internal auditors for management review and internal purposes. All elements of quality management system should be audited. The outputs of internal audit activity should lead to continuous improvements, process innovations, corrective actions, preventive actions, corrective action closures, lessons learned, positive/negative observations, etc.

3.5 Supplier quality evaluation

Medical device manufacturers depend on outside suppliers for some of the materials and equipment used in producing their products. Large companies may have hundreds of suppliers. Purchased parts that do not conform to specifications can impact every aspect of the company's business. Both the buyer's approach and specification management are keys to

controlling supplier quality. Competitive cost, service, delivery time and product quality are fundamental criteria of the supplier evaluation [25].

Both ISO 13485:2003 and FDA's QSR requires supplier evaluation and control and control of outsourced processes that may affect the conformity of the product [8] [13]. These requirements extend to include provisions for re-evaluating suppliers on an ongoing basis. Medical device companies that outsource the entire manufacturing process – from procurement of raw materials to final packaging – must also be aware of more stringent requirements for supplier control, particularly in the European Union. Any company whose name a medical device is marketed under is considered the legal manufacturer (i.e. private label manufacturer) and is therefore ultimately responsible for manufacturing controls regardless of where manufacturing operations occur [31].

Typical evaluation methods used to initially assess suppliers are contract reviews, supplier surveys or questionnaires and supplier audits. Re-evaluation of suppliers may be based on statistical trending of quality of incoming product and/or delivery time, re-evaluation surveys, follow up audits, etc.

3.6 Corrective and preventive actions

One of the most critical components of a QMS for medical device companies is the corrective and preventive action (CAPA) process. This is often the first process that FDA inspectors and ISO certifying notified body auditors look at. For medical device manufacturers, corrective and preventive action (CAPA) requirements defined by the FDA are stated in 21 CFR 820.100. The CAPA related requirements are stated in clauses 8.5.2 and 8.5.3 of ISO 13485:2003 standard as part of the quality improvement.

Corrective action is taken to prevent recurrence of a problem and is defined as *action to eliminate the cause of a detected nonconformity or other undesirable potential situation* [15]. Preventive action is defined as *action to eliminate the cause of a potential nonconformity or other undesirable potential situation* [15]. Preventive action is taken to prevent occurrence (i.e. before the event actually happens). It is important to distinguish between these terms as both FDA and notified bodies expect companies to focus on both and prefer to see a stronger focus on preventive action. Common examples of activities that may lead to preventive action are: training, risk assessments, trend analysis, design reviews, preventive maintenance and calibration of equipment, etc.

The purpose of the CAPA system is to collect and analyze information to identify existing and potential product and quality problems. The next step is to investigate the problem, determine the root cause and take appropriate and effective corrective and/or

preventive action. The effectiveness of corrective and preventive actions needs to be verified or validated to ensure occurrence or re-occurrence of the problem is avoided. Adequately implemented and effective CAPA system is a powerful tool for quality improvement and cost savings.

3.8 Training

Training requirements for medical device companies are stated in 21 CFR 820.25 and clause 6.2 of ISO 13485:2003.

Appropriate and effective staff training helps maintain and improve product quality and productivity. Training is relevant not only to increase productivity but also to motivate employees by letting them know how important their jobs are. Employees need to be trained on how their work affects product quality and ultimately customer satisfaction.

Poor training or lack thereof may cost the manufacturer a lot of money due to inadequate skills which can increase errors, employee turnover, work injury, recruitment costs, waste of materials and time, and waste of customers who will not return.

3.7 Management review

The full commitment to quality needs to be driven from the top. The requirements for management review are defined in clause 5.6 of ISO 13485:2003 and in 21 CFR 820.20 (b) of the QSR. The purpose of the management review is to assess opportunities for improvement and the need for changes to the quality management system in order to meet quality objectives and customer requirements. Management review should be conducted by top management at planned intervals, but no less than once per year [13]. The inputs to management review shall cover all areas of the QMS. Outputs include decisions and resource allocations from upper management based on management review inputs.

4 Applicable Six Sigma and lean concepts

The Six Sigma concept was introduced in 1986 by Bill Smith, a senior engineer and scientist at Motorola. Six Sigma is a methodology, customer-driven and strategic approach for reducing variation and eliminating defects in any process. A defect is considered anything that results in customer dissatisfaction.

From a statistical point of view, Six Sigma means a failure rate of 3.4 parts per million or 99.99966%. Most companies operate between three and four sigma levels. Even at four sigma, the number of defects is 6,210 per million [5]. The term Six Sigma in practice is used to emphasise more than simply

counting defects. Six Sigma also includes a set of tools and techniques used to drive process improvement.

Six Sigma is guided by the following key principles: customer satisfaction, data and fact driven management, reach-out goals, team based problem solving, total employee involvement, clear definition and understanding of roles and personnel growth [19].

Six Sigma focuses on process quality, which ultimately affects product quality. The Six Sigma concepts can apply to a wide variety of processes. Six Sigma can be applied in small-, medium sized [2] and large enterprises like General Electric [23].

Pfeifer et al. [22] presented that Six Sigma concept can be integrated with quality management systems. For an effective integration of the Six Sigma and quality management system approaches it has to be determined which benefits QMS can provide as information source and which benefits can be realised through the documentation of Six Sigma approaches and results [22].

4.1 Design for Six Sigma

El-Haik and Mekki [7] discovered that some companies in the medical industry that have mature Six Sigma deployment programs see the application of design for Six Sigma (DFSS) to product and internal processes as an investment rather than a needless expense. DFSS generates financial value by providing new products without defects and thereby generates new revenue.

DFSS is a disciplined methodology that embeds customer expectations into the design, applies the transfer function approach to ensure that customer expectations are met, predicts design performance prior to the pilot phase, builds into the design performance measurement systems with scorecards to ensure effective ongoing process management, leverages a common language for design, and uses tollgate reviews to ensure accountability [7].

4.2 Problem solving quality tools and techniques

Hagemeyer and her colleagues [11] proposed a classification scheme for problem solving tools which allows the user to identify the correct tool at the proper time in the problem solving process. Similarly, Bamford and Greatbanks [3] described the use and application of quality management tools and techniques in everyday situations. Their structured approach to the application of the basic quality management tools can be used for root cause analysis and problem solving.

Some of the Six Sigma tools used with problem solving processes are: box plot, capability analysis, cause and effect diagram, check sheet, control plan, cost benefit analysis, DOE, FMEA, Pareto diagram,

histogram, hypothesis testing, multivariate chart, process flow diagram, scatter diagram, SPC control charts, thought process map, trend/run chart, etc.

4.3 Quality circles

A quality circle is a small group of employees, often 5 to 12 volunteers who meet to identify, analyze and solve production and quality problems relating to their job scope, and ultimately make suggestions to management [25]. Meeting frequency will depend on the scope of job. Members of the quality circle come from the same work area whereas non-members are those who are not members of the quality circle but may be involved in the circle recommendation [28].

4.4 Voice of the customer

Voice of the customer (VOC) is the process for capturing customer needs, requirements and desires. Understanding customer needs and expectations is a key first step in developing a successful product to achieve customer loyalty and to build customer relationships. The most common VOC techniques are customer surveys and focus groups. However, the problem with these methods is that, unless well thought out, they tend to be biased.

Another challenge with VOC is that customers do not always know what they want until presented with the product. The use of simulated or actual environments for observation purposes (i.e. empathic design) can provide valuable insight into the latent needs of customers [20]. In the medical device industry, it is often not possible to observe the use of a product in an actual clinical environment until most of the design and testing has been conducted. However, early observational market research can still be conducted by using simulated environments. For example, cadaver studies can be used with prototypical surgical tools to see how surgeons handle the device.

4.5 Kano model

The Kano model of customer satisfaction was developed by Dr Noriaki Kano and his colleagues [17] and published in 1984.

According to Kano's model, there are three types of product requirements which fulfil customer satisfaction to a different degree: (1) must-be or basic requirements (i.e. expected), (2) performance or spoken requirements and (3) attractive or delight requirements (i.e. unspoken). To achieve a high degree of customer satisfaction, a competitive product must meet basic requirements, maximize performance requirements and include as many delight features as financially feasible in the design.

4.6 Quality function deployment

Quality function deployment (QFD) is a means of translating customer requirements into the appropriate technical requirements for each stage of product or service development and production [24]. QFD is useful for developing design specifications when customer requirements are vaguely and ambiguously stated. Through a series of interdependent matrices, QFD allocates and maps requirements into specific design strategies, development processes, product characteristics and program operations controls. For each intended result of the process, engineers develop technical performance measures and specify corresponding threshold values to be met in order to achieve the required features of the overall system [30].

4.7 Key performance indicators

Key performance indicators (KPIs) are statistical measures used to monitor the effectiveness of key processes within a QMS. They are an important management tool for tracking progress against quality goals. Some examples of KPIs in a medical device company are: number of in process and finished product defects, complaint processing time, number of open CAPAs, etc.

By focusing on variation reduction, Six Sigma projects have the potential of simultaneously reducing cost and increasing customer satisfaction [4]. However, Raisinghani et al. [24] point out that Six Sigma implementation can have negative consequences if applied in the wrong project. Six Sigma quality projects can be chosen based on customer feedback and analysis of the key performance indicators. Projects that have major impact on customers and promise a high financial success are given top priority.

4.8 Design of experiments

Design of experiments (DOE) is a systematic and statistically driven approach for validating designs and processes and/or solving problems. In the preproduction phase, design of experiments can be used to refine processing specifications, thus speeding the transition to full-scale production [18].

Anderson and Kraber [1] identify eight keys for successful DOEs: 1) set good objectives, 2) measure responses quantitatively, 3) replicate to dampen uncontrollable variation, 4) Randomize the run order, 5) block out known sources of variation, 6) know which effects (if any) will be aliased, 7) do a sequential series of experiments, and 8) always confirm critical findings.

As we can see, of all the tools available, DOE is most in line with the classical definition of Six Sigma.

4.9 Failure modes and effects analysis

Failure mode and effects analysis (FMEA) is a tool sometimes used by medical device manufacturers for risk analysis. FMEA identifies all possible failures in a design or manufacturing process. Each component of the design or step in manufacturing is analyzed to determine what might happen (i.e. effect) should there be a failure in the particular component or step. The effect is then analyzed to determine the severity of the effect, possible causes, and the detectability of finding the cause before use.

While FMEA is an excellent tool for reliability purposes, it does not account for other possible risks associated with a device. Therefore, FMEA should be used in combination with other types of risk analysis.

5 Conclusion

Medical device manufacturers do not always recognise that the process of identifying and applying appropriate Six Sigma concepts/techniques is most effective if these concepts/techniques are integrated into their quality management systems.

The practice of designing quality into a product is often misunderstood. Too often, medical device companies who plan for designing quality into a product are focusing on safety and reliability. While these qualities are obviously important, it is more important for employees to understand that quality does not simply mean defect-free product, but includes meeting customers' needs [6]. It is not uncommon to hear development engineers and marketing professionals in a company complain that quality efforts restrict creativity and can delay market launch dates. Therefore, it is important for companies to identify their target market or intended user as early as possible. In the medical device field this can be a difficult task, particularly because often the customer is not the same as the user.

Typically the hospital or clinic will purchase devices from a medical device company, but ultimately the patient (i.e. user) needs to be satisfied with the device. Marketing must therefore conduct research to find out what features and characteristics intended users (i.e. patients) and clinics desire in a medical device. Engineers must listen to these customer requirements and put aside their own biases. Engineers are a unique breed as they are innovators. As such, their thoughts on what a customer would like often do not accurately match those of the target market (unless of course the target market is engineers). As Geoffrey Moore points out in his best-selling book, *Crossing the Chasm*, there is a large gap in the acceptance of innovative products between early adopters (similar to innovators) and early majority [21]. Unlike innovators and early adopters, the early majority value reliable products, and this certainly cannot be denied in the medical device industry. Hence employees across all functions must

work together to ensure the products delivered are safe, reliable and incorporate key features that customers desire. By incorporating concepts such as Design for Six Sigma, voice of the customer (VOC), quality functional deployment (QFD) and/or Kano models into an existing quality management system medical device companies can build quality into the design by better identifying and defining customer requirements.

Risk management activities should begin soon after defining customer requirements. Medical device companies can use multiple tools to perform risk analysis. Although FMEA does not account for business risks associated with customer requirements, it is an excellent tool for reliability purposes and preventive measures. Therefore, FMEA should be used in combination with other types of risk analysis.

Likewise, statistical methods can be useful in the design and problem solving process. For example, design of experiments (DOE) is particularly useful in validating product designs and manufacturing processes. However, it is important to point out that the field of statistics, as with other professions, has a number of specialties (e.g. economic statistics, biostatistics, process statistics). Therefore, it is important that key personnel are well versed in operational process statistics to they can identify the appropriate statistical methods to be utilised throughout the product development lifecycle. Rusell and Taylor [26] point out that training in quality tools and statistical skills enable employees to diagnose and correct day-to-day problems related to their job.

The use of key performance indicators (KPIs) is effective in measuring key processes within a quality management system. Though, it is important that appropriate KPIs are developed in line with company quality goals and objectives. Otherwise the process becomes a futile attempt and waste of time. Likewise, data sources for capturing KPIs should be integrated to avoid unnecessary burdens. Data scattered throughout the company and using different or incompatible databases will result in metrics not being captured within appropriate timeframes. Employees will be spending more time organizing and analyzing data rather than problem solving

While quality is the responsibility of all employees, an example needs to be led from the top. Integrating Six Sigma concepts into quality management systems requires an executive support. The use of quality circles can provide valuable input into the management review process. However, the success of the quality circles depends solely on the attitude of the top management and plays an important role to ensure the success of implementation of quality in the organization [28].

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