

Quality Beyond Six Sigma

Contributors: Abdurrahman Coskun, Ibrahim Unsal, et al.



About the Book

Six Sigma is a disciplined, data-driven approach to improving product and process quality. Six Sigma as one of the most strategic initiatives undertaken has seen its adoption increase dramatically across the world. Enterprise quality management systems play a key role in the Six Sigma deployments. The basics of Six Sigma are actually designed to improve the performance of manufacturing industry. It was originally developed as a kind of quality control especially for large scale manufacturing companies. The main purpose of this quality control system was to improve the manufacturing processes along with eliminating the number of defects found in them. Later on the methodology of Six Sigma was extended to various other types of industries irrespective of their size all over the world.

This book, *Quality Beyond Six Sigma*, provides a practical approach of Fit Sigma. Supported by research studies and phased action plans, it focuses on all functions, manufacturing or service, for any size of business.

Six Sigma identifies and removes the defect causing elements along with reducing the changeability of the business and manufacturing processes to improve the quality of outputs of a manufacturing process. In this methodology, a set of quality management methods is used to create within the organization for a special infrastructure of the people who can use these methods like experts. An organization follows a defined set of steps to quantify the targeted value of the project while using each project of Six Sigma. For instance the organization can reduce pollution, reduce time cycle of a process and reduce cost of production for increasing profits and satisfaction level of its customers.

While the essence of Six Sigma quality is the reduction of variability, management must get involved in the inevitability of variability in all kinds of business processes, set achievable measures on a good target to track a long-term commitment to attain the Six Sigma quality. Quality progress on a breakthrough project is in cost reductions, reduced scrap, increased production capacity, faster turnaround, quicker time to market, more profitable sales, faster delivery, and increased customer loyalty. As these accomplishments realized, the company grows closer to its customers and shift customer needs to develop the marketing mechanisms. Six Sigma quality system positions the company for greater customer satisfaction, profitability, and competitiveness. In large organizations where clear communication channels and extensive management infrastructure is available most effective results are shown by this type of programs. Most of the companies which have adopted this quality control system for improving their products and services are among the most successful ventures of the world. The comments of these companies reveal the fact that by embracing Six Sigma they have saved lots of money than earlier. But before adopting this system for you manufacturing company it is recommended that you should spend some time for researching about Six Sigma as the success of this process is questioned by some of the experts of manufacturing industry.



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Preface

Six Sigma is a disciplined, data-driven approach to improving product and process quality. Six Sigma as one of the most strategic initiatives undertaken has seen its adoption increase dramatically across the world. Enterprise quality management systems play a key role in the Six Sigma deployments. The basics of Six Sigma are actually designed to improve the performance of manufacturing industry. It was originally developed as a kind of quality control especially for large scale manufacturing companies. The main purpose of this quality control system was to improve the manufacturing processes along with eliminating the number of defects found in them. Later on the methodology of Six Sigma was extended to various other types of industries irrespective of their size all over the world.

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Six Sigma identifies and removes the defect causing elements along with reducing the changeability of the business and manufacturing processes to improve the quality of outputs of a manufacturing process. In this methodology, a set of quality management methods is used to create within the organization for a special infrastructure of the people who can use these methods like experts. An organization follows a defined set of steps to quantify the targeted value of the project while using each project of Six Sigma. For instance the organization can reduce pollution, reduce time cycle of a process and reduce cost of production for increasing profits and satisfaction level of its customers.

While the essence of Six Sigma quality is the reduction of variability, management must get involved in the inevitability of variability in all kinds of business processes, set achievable measures on a good target to track a long-term commitment to attain the Six Sigma quality. Quality progress on a breakthrough project is in cost reductions, reduced scrap, increased production capacity, faster turnaround, quicker time to market, more profitable sales, faster delivery, and increased customer loyalty. As these accomplishments realized, the company grows closer to its customers and shift customer needs to develop the marketing mechanisms. Six Sigma quality system positions the company for greater customer satisfaction, profitability, and competitiveness. In large organizations where clear communication channels and extensive management infrastructure is available most effective results are shown by this type of programs. Most of the companies which have adopted this quality control system for improving their products and services are among the most successful ventures of the world. The comments of these companies reveal the fact that by embracing Six Sigma they have saved lots of money than earlier. But before adopting this system for your manufacturing company it is recommended that you should spend some time for researching about Six Sigma as the success of this process is questioned by some of the experts of manufacturing industry.

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SIX SIGMA AS A QUALITY MANAGEMENT TOOL: EVALUATION OF PERFORMANCE IN LABORATORY MEDICINE

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INTRODUCTION

In medical school, the first concept expressed to students is a Latin phrase, *primum non nocere*, meaning “first, do no harm.” This phrase is well known among health workers and dates back to Hipocrates. However, in reality, the situation is slightly different. According to the report of the Institute of Medicine, each year in the USA, approximately 98,000 people die from medical errors (Kohn et al., 2000). Unfortunately, more people have died each year during mid-1990s from medical errors than from AIDS or breast cancer (Kohn et al., 2000). Despite this situation, we cannot say that adequate attention has been paid to the application of high standards in the healthcare sector to effectively prevent medical errors. Yet in industry, for more than a century, modern quality control has been applied to prevent errors and produce high quality goods. The result of these long-term efforts is that in many companies, the rate of errors approaches a negligible level. Regrettably, we cannot say the same thing for medical services, because the components that produce errors or defects in medical services are many more than those involved in any industrial or business sector. Despite these facts, it is clear that the quality of medical services is more important than the quality of most other goods. Consequently, healthcare professionals must pay more attention to quality than any industrial professionals do.

Among healthcare services, clinical laboratories are particularly important because physicians make their decisions mostly in accordance with laboratory results (Forsman, 1996). In this context, accurate test results are crucial for physicians and their patients. First, the laboratory must be able to produce an accurate test result before any other dimension of quality becomes important. From this point of view, the evaluation of laboratory performance is critical to maintaining accurate laboratory results (Coskun, 2007).

In clinical laboratories, we traditionally divide the total testing processes into three phases: pre-analytical, analytical, and post-analytical phases. However, the selection and interpretation of tests are also prone to errors and

must be considered in the total testing process. For this reason, in laboratory medicine, we analyze the total testing process in five phases: pre-preanalytical, pre-analytical, analytical, post-analytical, and post-post-analytical phases (Goldschmidt, 2002). Errors that occur in each phase may affect patients negatively, and for a realistic approach, the total frequency of errors in all five phases must be calculated (Coskun, 2007). Except for the analytical phase, the quality of work in the other phases is not presently satisfactory (Coskun, 2007). In the past decade we have found that in clinical laboratories, the analytical errors made by instruments have been reduced to acceptable levels. The high quality of the analytical phase is a result of continuous efforts made by manufacturers because they must produce high-quality instruments to be competitive in the marketplace. As laboratory workers, we have to improve the quality of the other phases, especially the pre-analytical phase, to produce accurate test results for patients.

Mistakes are unfortunately a part of human nature; but fortunately, the ability to create solutions and find better alternatives is also a part of human nature. We can shift the balance toward solutions and better alternatives using modern quality-management tools such as Six Sigma.

Six Sigma methodology represents an evolution in quality assessment and management that has been implemented widely in business and industry since the mid-1980s (Westgard, 2006). Six Sigma methodology was developed by Motorola, Inc. to reduce the cost of products, eliminate defects, and decrease variability in processing. It consists of five steps: define, measure, analyze, improve, and control (DMAIC) (Westgard, 2006a; Westgard, 2006b; Brussee, 2004). These steps are universal and could be applied to all sectors of industry, business, and healthcare. The sigma value indicates how often errors are likely to occur; the higher the sigma value, the less likely it is that the laboratory reports defects or false test results. The best or “world class” processes for industry or business have a sixsigma level, which means that in such a process, fewer than 3.4 defects (or errors) occur per million products (Westgard, 2006a; Westgard, 2006b; Brussee, 2004). However, in the healthcare sector, the six-sigma level may not be adequate for many situations. For example, in blood banking or other critical medical services, an error may cause fatal or irreversible results. Thus, in medical services, the six-sigma level should not be accepted as the ultimate goal. We have to decrease the number of defects by as much as possible, and indeed, the sigma level should be higher than six. Our slogan should be ‘zero defects.’



Figure 1: Six Sigma may not be adequate for quality in healthcare sector.

To calculate the sigma level of a laboratory, we have to determine the errors or defects and measure the performance of the unit or process in which we are interested. If you do not measure, you do not know, and if you do not know, you cannot manage. So Six Sigma shows us how to measure and, consequently, how to manage the laboratory.

In this chapter we will examine the Six Sigma methodology and its application to healthcare services, particularly laboratory medicine. We will also evaluate laboratory performance using sigma metrics.

CLINICAL LABORATORIES IN THE HEALTHCARE SECTOR

One of the most important units of the healthcare sector, particularly in hospitals, is undoubtedly clinical laboratories. Obviously, without accurate test results, physicians cannot make diagnoses or provide effective treatment. This is true even for experienced physicians. Currently, clinical laboratories affect 60~70% of all critical decisions, such as the admission, discharge, and drug therapy of patients (Forsman, 1996). Based on our experience, we believe that this rate is even higher. Despite these vital functions, in the healthcare sector, laboratory costs are a very low proportion (5~10%) of the total cost of patient care (Forsman, 1996).

To be effective, clinical laboratories must be organized and accredited. Accreditation by independent non-profit organizations is indispensable for modern clinical laboratories. Accredited laboratories usually perform more than

500 different tests, and as many as 1500 tests may be performed in well-organized central laboratories. This means that the laboratory produces 1500 different products. This is very high in comparison with any industrial sector. Furthermore, the accuracy of each test (product) is vital because it is directly related to patient health. To obtain accurate test results, clinical laboratories are organized according to sub-disciplines such as clinical biochemistry, clinical microbiology, hematology, anatomical pathology, and genetics. Each sub-discipline may be organized further into sub-sub-disciplines. For example, clinical microbiology is further divided into immunology, virology, bacteriology, parasitology, and mycology. The organization scheme may differ from country to country and even from laboratory to laboratory. All these subdisciplines increase the diagnostic power of laboratories, which are crucial for hospitals.

Despite the vital functions of clinical laboratories, healthcare managers have not paid adequate attention to them. In addition, healthcare administrators frequently manipulate laboratories. These interventions decrease the diagnostic and competitive power of laboratories relative to other medical services.

TOTAL TESTING PROCESS

Total testing process is a multistep process that begins and ends with the needs of the patient (Barr, 1994). The number of steps may vary according to test types and laboratory organisation. We can describe nine activity steps in laboratory medicine:

- 1. Test selection and ordering a laboratory test request
- 2. Collecting the sample (seum, plasma, urine and so on)
- 3. Identification
- 4. Transport the sample to laboratory
- 5. Preparation of the sample
- 6. Analysis
- 7. Reporting test results
- 8. Interpretation of test results
- 9. Action

Historically in clinical laboratories, the total testing process was assumed to consist of only three phases:

- Pre-analytical phase (step 2-5),
- Analytical phase (step 6), and
- Post-analytical phase (step 7).

Further, the pre-analytical phase contain two sub-phases:

- Outside the laboratory (step 2-4) and
- Within the laboratory (step 5).

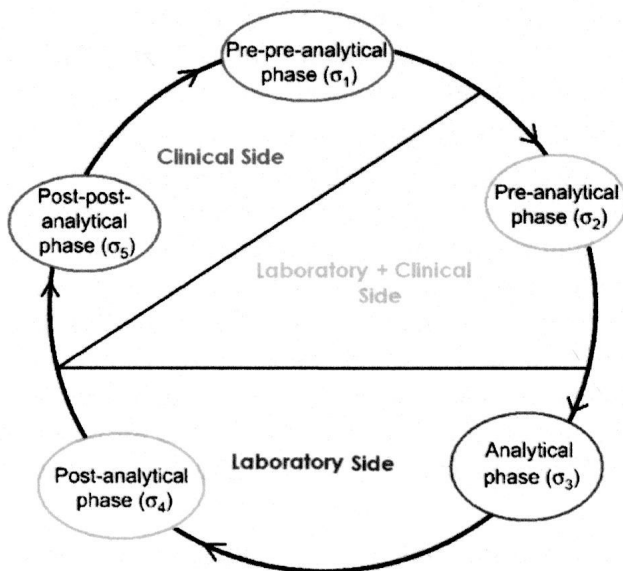


Figure 2: Total testing process in modern clinical laboratories.

Currently this classical approach is not adequate for clinical laboratories. The total testing process begins when the patient is examined by a physician, and it ends when the patient leaves the hospital (Goldschmidt, 2002). To cover all steps in this cycle, currently we examined the total testing process in five phases. In addition to classical pre-analytical, analytical and post-analytical phases, pre-pre-analytical (step 1) and post-post-analytical phases (step 8 and 9) are also indispensable part of the total testing process. In the pre-pre-analytical phase, the physician decides which test(s) should be requested for the patient, and in the post-post-analytical phase, the physician interprets the test results. In daily practice items such as ‘Pre-pre-’ and ‘post-post-’ seem to be more abstract for many laboratory workers. Instead of these items we thought that the re-named of phases of total testing process which is listed below (Table 1) will be more useful. To evaluate laboratory performance, we must add the errors made in all phases of the total testing process.

Table 1: Phases of total testin process. The names that we recommend is more meaningful and is not abstract

Current names	Recommended names
Pre-pre-analytical phase	Clinical pre-analytical phase
Pre-analytical phase	Laboratory pre-analytical phase
Analytical hase	Analytical phase
Post-analytical phase	Laboratory post-analytical phase
Post-post-analytical phase	Clinical post-analytical phase

ERRORS IN LABORATORY MEDICINE

The report To Err is Human: Building a Safer Health System by Kohn et al. was a milestone in the history of quality and safety in the healthcare sector. The report stated, “Each year, more than 1 million preventable injuries and 44,000–98,000 preventable deaths occur in the United States alone” (Kohn, 2000). This report shocked many healthcare managers and officials, as they had not considered this reality. Furthermore, this report has broken the silence that has surrounded and masked medical errors. Since 1999, reducing medical errors and improving patient safety have become an international concern. The World Health Organization (WHO) has launched the World Alliance for Patient Safety (www.who.int/patientsafety) in response to increasing public and officials’ awareness of this issue worldwide. In the United States, approximately 2 trillion dollars are spent on medical care each year, and the health standards are higher than in many other countries. Therefore, we postulate that preventable injury and death rates due to medical errors in many countries are higher than those in the United States.

To make a comparison, in 1999 (the year when the report was published), nobody died due to errors in the aviation sector in the United States. For healthcare managers, 1999 was a time when they had to accept reality. One of the main differences between the healthcare and aviation sectors is the application of quality assessment. Unfortunately, healthcare managers do not pay as much attention to quality assessment as do aviation managers. In the aviation sector, an error that has accident potential may mean the end of a company. The same is not true for a hospital. In addition, if a pilot makes a mistake that causes the plane to crash, he or she dies along with the passengers, but a doctor does not die when he or she kills a patient because of a mistake. To decrease medical errors to acceptable levels, physicians and other healthcare staff must periodically be strictly audited, both professionally and legally.

The reactions and approach of people to hospitals and aviation companies are quite different. The approach of people to hospitals is more psychological than logical. Community reactions to deaths in hospital and to deaths in accidents are not the same. The first may be accepted as an ordinary event, whereas this is not the case for an accident. Despite these realities, we cannot claim that adequate attention has been paid to quality in the healthcare sector. For example, Six Sigma quality management has been applied to almost all major industrial organizations since the mid-1980s. Unfortunately, as far as we know, no international hospital has applied Six Sigma quality management. This is partly due to the different types of work, services, and products produced in hospitals versus companies. However, despite all these differences, Six Sigma quality management can be easily applied to any hospital because Six Sigma quality management has no restrictions or limits that are not suitable for hospitals or any healthcare organization (Westgard, 2006a; Nevalainen, 2000). Six Sigma quality management is universal and can be applied to all sectors easily.

How much are clinical laboratories responsible for medical errors? Unfortunately we have limited data about medical errors originating from clinical laboratories (Bonini, 2002; Plebani, 1997). General practitioners from Canada, Australia, England, The Netherlands, New Zealand, and the United States reported medical errors in primary