

## Chapter 2

# Quality Management Systems

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### What Is Management?

Management can be defined as “administration” and can be summarized as the group of people that interact in a physical or virtual environment and have the same goal: the success of the “company’s business.” Companies perform sets of activities in order to produce and offer goods and/or services, with the objective of meeting some human needs. They can be public or private, with or without profits.

All consumers are interested in fulfilling their needs; however, there is something in common that pervades this entire universe of desire, which is the feeling of satisfaction and pleasure. Once decided to spend on a product or service, consumers want to obtain a certain feeling of accomplishment or, in other words, be able to say that what they have spent was worth it.

In case the consumer is fully satisfied, he will be able to say that it was really worth it. Therefore, we can say that the service provider, company, self-employed professional, or other organizations are on the right way to achieve customer fidelization, but before proceeding in this universe of emotions, let’s reflect about it. This feeling is wonderful but how can consumers be able to feel it? Obviously, nobody has the exact answer to this question; otherwise, he would be selling it by a great amount of money! But there is one aspect that everybody must pay attention to, regardless of tips and magic formulas, called “quality.”

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## What Is Quality?

Quality is a subjective concept that is directly related to the perceptions of each individual. Several factors such as culture, mental models, type of product or service, needs, and expectations directly influence this definition. Many people evaluate the quality of a product by its appearance; others by its price or perhaps by the material it is made of. But the only objective and measurable aspect of quality is the “process.” Based on the process, we can employ international methodologies and requirements, some of them disseminated by means of certifiable standards, such as the ISO 9001, ISO 14001, ISO 26000, and OHSAS 18001, respectively, directed to quality management, environmental management, social responsibility, and occupational health and safety. But before talking about standards, requirements, and certifications, it is important to understand what is a process and why it is so important in quality.

## What Is Process?

Any activity or set of activities that uses resources to transform raw materials, supplies, or simply labor (inputs) into products or services (outputs) can be considered a process. For an organization to function effectively, it must determine and manage various interconnected activities and processes. Often, the output of one process is the input of another one. A process can also be a set of interrelated subprocesses. This concept can be applied to all segments, such as administrative, medical, and manufacturing.

See below for an example of the organizational structure for a process:

My wife and I moved to a new town, and after consulting various schools to enroll our children, we received information about an institution that valued quality in all aspects. The concern was the quality of teachers, curriculum, evaluation of students' performance, meals, security, etc., besides the logistics at the entrance and exit of students and parents.

We noticed some differences right from the beginning, when scheduling the interview with the director. Accessing the website, we were able to set the date, time, and even place, because if we wanted, we could receive a school representative at our own house. Another fact that caught our attention was a video presentation of the facilities and staff.

We chose to personally go to the school to meet the director. When we arrived, the receptionist drew our profile and informed us of personalized services, such as extracurricular activities, access to library, cafeteria menu, meeting with parents, parties, socialization, transportation, uniforms, laundry,

sports, school's supplies, individual lockers for students, intranet, and even a "manager" for our children's account. After that, the receptionist took us to a comfortable room, with music and amenities, and we started our conversation with a representative of the direction. We could then visit the facilities and also receive information about tuition and payment plans.

After enrolling our children in the school, we were given access cards to all facilities and a login and password that allowed us to monitor the services offered by the school's intranet. Our children received a welcome kit, which included from the uniform to the school's supplies, besides a small tablet with GPS system to facilitate mobility in the school's buildings. It also included details about the infrastructure, schedules, and activities.

Accessing the Internet, we could get every detail of our children's "account" and also detailed information about their academic development through a quarterly assessment that was compared to a pool of national and international institutions. This allowed us to evaluate whether the school was aligned with the educational standards and also evaluate if the tuition paid was worth the services received.

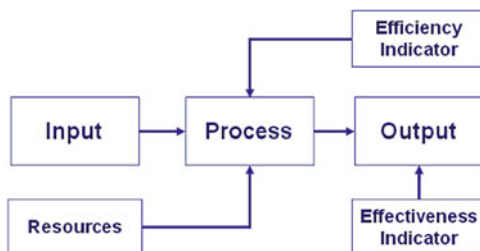
On the first day of class, the manager of our children's "account" was at the school gate waiting for our children in order to facilitate integration with the other students and teachers. Through a microchip installed in their uniform, they could be located inside the school, and one could know exactly when they arrived and left the facilities. When our children opened their lockers, all the school supplies were there, and classes started promptly at 07:30AM, with a snack break at 10:00AM and lunch at 12:30PM. Students were encouraged to practice sports at free choice, but always with experts' monitoring.

Due to the tracking system installed, the account manager and teachers were able to follow the footsteps of our children. When entering the classroom or other facility, students already received instructions on how to proceed.

There is a team that regularly gets in touch with parents to assess whether all is well and present a brief report about their children's development, both academic and about their behavior.

This is a fabricated story, or else a desire of a father. This institution does not exist; however, for this to happen, the institution would have to be organized by process. Parents would have to be assisted by a team and this would make all the difference. The operational process begins before parents and students go to the school and never end.

This view of a process goes back to medieval times, when an artisan, in order to produce a masterpiece, worked from purchasing the raw materials to delivering the finished work. When we have mapped and identified each of the subprocesses and interactions (inputs and outputs) of a process, we can fully understand and control it as a whole.

**Fig. 2.1** Process mapping

## Why Is a Process So Important in Quality?

Once we define what quality means to our business, we are able to assess whether the set of processes and subprocesses are structured and aimed to achieving this concept of quality. It is important to remember that quality is a subjective concept, as discussed earlier. That's why there is such concern with about its continuous improvement.

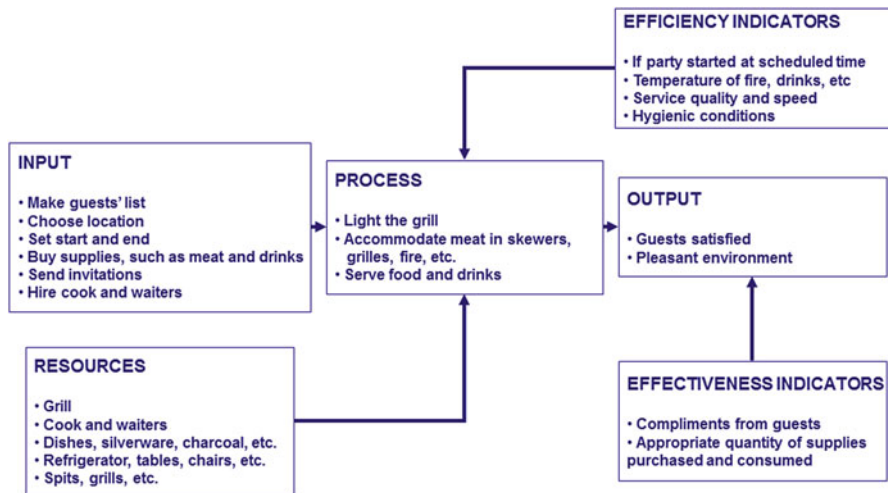
As quality improvement should be continuous, it must not be stagnated; therefore, nothing is better than knowing the various steps (processes and subprocesses) that shape our business, making it possible to implement necessary changes and updates quickly and safely. But how to know if the changes made are correct? There are performance indicators that classify processes into efficient and effective, for example. They help us monitor quality and also give measurable data to help in decision making and corrections, besides helping in the identification of the resources needed for this task. Figure 2.1 shows a process mapping model.

The conceptual difference between the indicators of efficiency and effectiveness is well explained through an example: “Mark is the production manager of company ALFA that produces its share of products. John is the production manager of company BETA that also produces its share of products, consuming 10% less energy. In this case, if the goal was simply the production, both were effective, but John was more efficient.” The indicators will enable us to refine and improve our process continuously, reinforcing the concept of “process management.”

Once the concepts of management, quality, and process are understood, there is a solid structure to advance and learn about some requirements, methodologies, and tools to help a business be successful. The word “some” was used because continuous improvement is endless and quality is subjective. Common sense and intuition are still the essence of a management with excellence. To better understand, see the example below, which shows the general resources and indicators to “prepare a barbecue party” (Fig. 2.2).

## Requirements, Methods, and Tools

The most popular and widespread international requirements for quality management are described in the ISO 9001, which is generic and applicable to all organizations in any economic sector, regardless of the type of product or service



**Fig. 2.2** Practical example of process mapping

offered. Some steps should be followed to develop and implement a quality management system:

1. Determine needs and expectations of customers and others (e.g., legislation, industry regulation).
2. Establish a quality policy and quality objectives for the organization.
3. Determine processes and responsibilities to achieve the quality objectives.
4. Identify and provide necessary resources to achieve the quality objectives.
5. Establish methods to measure the effectiveness and efficiency of each process.
6. Apply these measurements to determine the effectiveness and efficiency of each process.
7. Determine means to prevent nonconformities and eliminate their causes.
8. Establish and implement a process for continuous improvement of the quality management system.

An organization that adopts the previous approaches creates confidence in its processes and quality of its products and provides the basis for continuous improvement and consequent increase in customer satisfaction.

The current version of the ISO 9001 approved in the end of 2008 improved its compatibility with the ISO 14001 (environmental management). However, an important change in this version was the concept of exclusion. It allows standard requirements that are not applicable due to characteristics of the organization or its products to be excluded, since properly justified, ensuring its multi-sector or generic use.

A copy of the ISO 9001 is not allowed and is only available with the representative bodies of each country. It is described in items as below:

- Pages 1–2: Preface/Introduction
- Page 3: Purpose/Scope/Normative Reference/Terms and Definitions
- Pages 4–12: Requirements

- Section 4: Quality Management System
- Section 5: Management Responsibility
- Section 6: Resource Management
- Section 7: Product Realization
- Section 8: Measurement, Analysis, and Improvement
- Pages 13–20: Tables of Correspondence Between ISO 9001 and Other Standards
- Page 21: Bibliography

The six documents required of the standard are:

- Document Control (4.2.3)
- Control of Records (4.2.4)
- Internal Audits (8.2.2)
- Control of Product/Service does not conform (8.3)
- Corrective Action (8.5.2)
- Preventive Action (8.5.3)

In addition to the requirements of the ISO 9001, it is necessary to define and implement a “quality policy” and a “quality manual.” However, that does not mean they are the only documents needed. Once all procedures and operational routines are properly described, each organization must evaluate its entire process, enabling the retention of all information and intellectual capital, one of the “main assets” of any organization.

To implement the ISO 9001, the organization must first say what it does and then do what it says it does. One should write the way activities are performed and then verify if they are all being done as described, to validate what was written. This way, a pattern to control and operate all processes is intrinsically consolidated, establishing the habit of registering the activities as they are performed. These records provide important data for traceability and decision making. A well-implemented system can result in cost reduction since it helps reduce errors and waste.

The standards, by means of their respective requirements, contribute to sustainability, a current topic of great importance, since they support actions that are economically viable and environmentally correct.

There are consulting companies that assist in the implementation of the ISO 9001, sharing best practices for writing documents and manage information. However, having an internal group of employees study and help implement the standard is highly recommended to facilitate the dissemination of the internal culture. Managers should assess their needs and adopt the best practice for their company using external or internal resources.

Regardless of the strategy adopted, when the organization has properly implemented and disseminated the relevant ISO 9001 requirements, it should select an accredited agency to audit and certify the quality management system implemented. A certification is generally valid for 3 years with periodic audits to maintain certification. The objective of these audits is to verify if the system is active and updated.

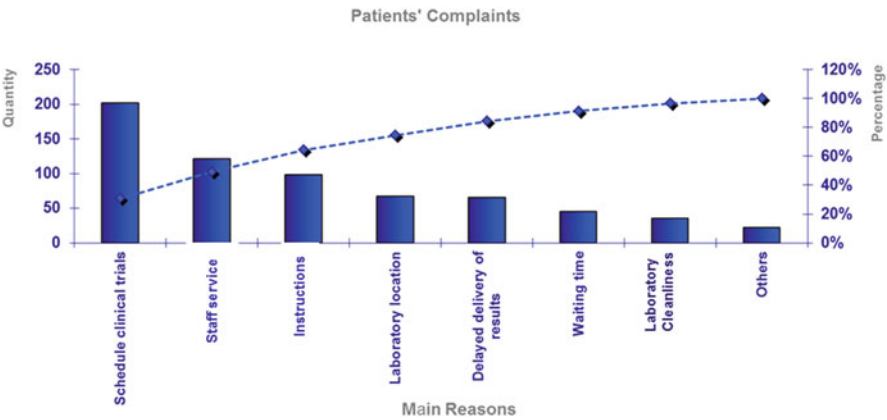


Fig. 2.3 Pareto diagram: main reasons for patients' complaints about clinical tests

### Quality Tools and Methods

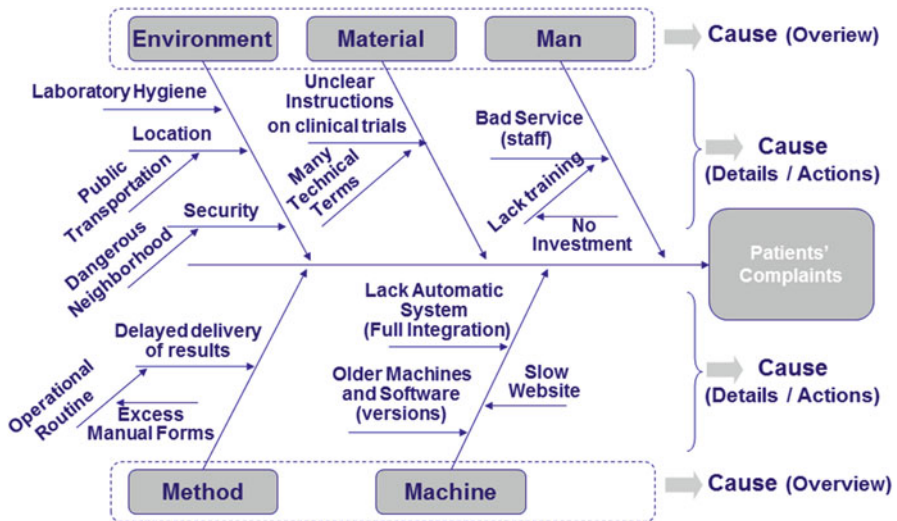
Quality management is more easily understood and implemented when we resort to some methods and tools, great allies of managers, as information, knowledge, and intuition are the main pillars for success. In an orchestra, for example, each instrument has its particular sound; when played harmonically by skilled musicians and under the command of the conductor, they produce a wonderful music. Making an analogy, the musical instruments are the methods and tools, the musicians are the employees, and the conductor is the manager. The musical instruments are used according to the melody chosen, as the methods and quality tools are chosen by the manager to achieve a predetermined goal. The combination of instruments (methods and tools) must be harmonious in order to extract as much knowledge of the processes as possible. Some quality methods and tools are presented below, without details, with the only objective of showing readers what is available. For more specific information about them, refer to the references at the end of this chapter [1–7].

### Quality Tools

#### Pareto Diagram

Objective: to prioritize problems to be solved (Fig. 2.3):

- Select the problems to be compared
- Set the standard for comparing data
- Select the time period for analysis



**Fig. 2.4** Diagram of cause and effect: analysis of possible causes of patients' complaints

- Collect data from each category
- Compare the frequency of each category
- Record the totals in descending order
- Calculate percentages to the various selected categories

### Diagram of Cause and Effect

Objective: to prioritize the factors that may cause an undesired effect (Fig. 2.4):

- Describe the problem clearly
- Brainstorm and record data on those involved
- Draw the diagram with the given problem on the right side
- Indicate the categories of causes
- Group the brainstorm results by category
- Elect the most important causes with the group

*Remember:* always ask “why it happens” to obtain the causes in the contributors’ answers.

### Control Chart

Objective: to monitor the stability or instability of a process (Fig. 2.5):

- Define mean values produced by the process
- Define the maximum variation the process reaches
- Obtain the maximum values allowed by the specification
- Prepare the chart and record the values obtained in uniform periods of time



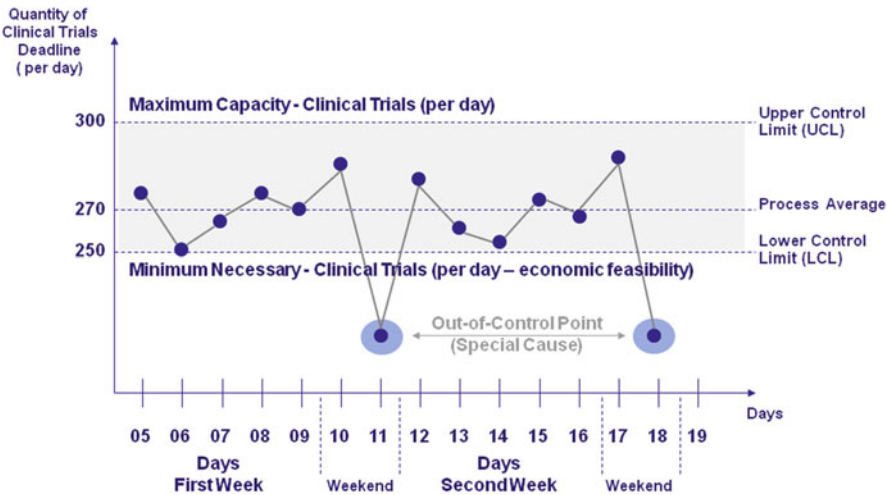


Fig. 2.5 Control chart: number of clinical trials per day and economic feasibility

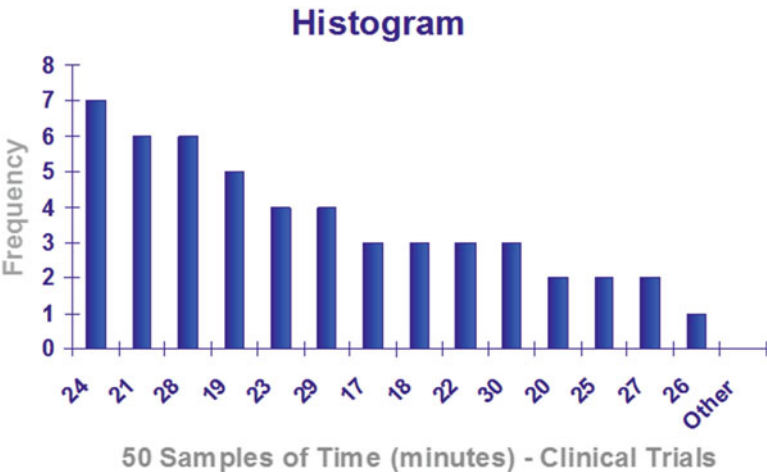
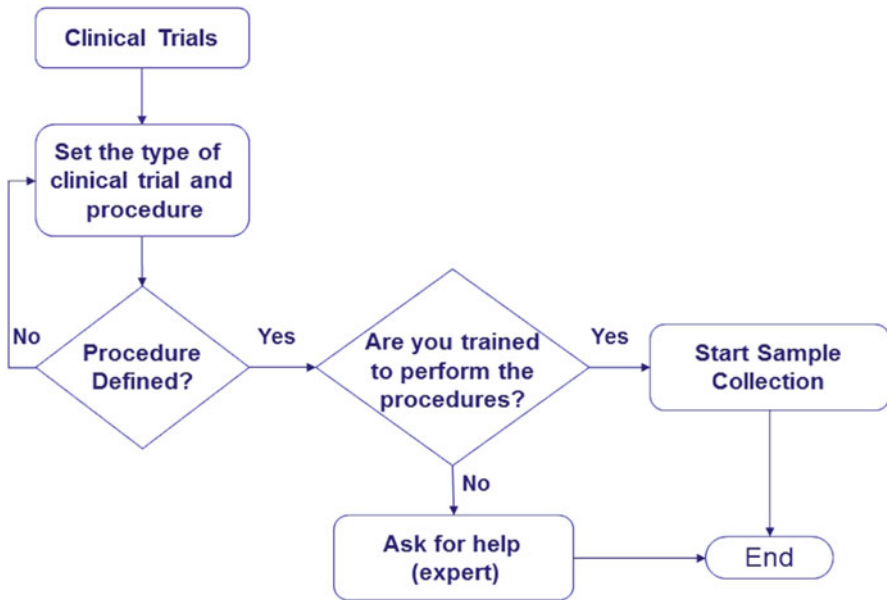


Fig. 2.6 Histogram: time spent on clinical trials during a period of time

### Histogram

Objective: to show how to distribute a set of data indicating how a given process varies (Fig. 2.6):

- Register the values found in the process
- Accumulate the data on steps near the specified central value
- Register how often the data repeats itself



**Fig. 2.7** Flowchart example

## Flowchart

Objective: to visualize a process and identify improvement opportunities (Fig. 2.7):

- Assemble all information about the process to be studied
- Draw the current flowchart
- Study the critical points and draw the flowchart with the steps that the process must follow if all goes well
- Compare and analyze the differences between flowcharts

## Quality Methods

### PDCA

Objective: to monitor, correct, and improve a process through a consistent and effective method (Fig. 2.8):

- Set the goals to be achieved and actions to achieve them
- Train all those involved in the outlined guidelines planned and implement the process
- After implementation, collect data to compare with what was planned
- After achieving the goals, formalize the process, making it a standard



**Fig. 2.8** PDCA methodology

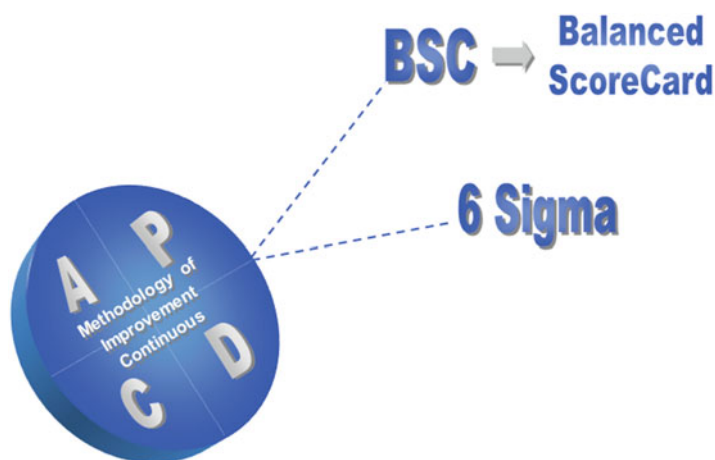
To better understand the PDCA method, let's go back to the practical example about the barbecue party:

- *Plan*=make the guests' list, set the location, define what will be served, buy food and drinks, etc.
- *Do*=have the party, following all the items previously planned, receiving guests, and serving food.
- *Check*=check if the food and drinks are being served appropriately, if the quantity of items purchased is meeting the demand of guests, etc.
- *Act*=if waiters are slow, request a faster service; if drinks are not at the proper temperature, provide more or less ice, etc.

You can integrate the PDCA methodology, with two others called 6 Sigma and BSC (Balanced Score Card), providing a breakthrough in organizational management model (Fig. 2.9):

*BSC*=supports the prioritization and management of institutional indicators (Fig. 2.10).

For better understanding, since it is a method to identify and monitor processes and organizational strategies, read the following example, where the color green means that the outcome indicators or groups of indicators are perfect, yellow corresponds to a state of alert because the indicators are within a tolerance but require further monitoring, and red means that the indicators are totally outside the expected or desired goals and need to be investigated, working on the cause and correcting



**Fig. 2.9** BSC—Balanced Score Card and 6 Sigma



**Fig. 2.10** BSC—Balanced Score Card

problems. It is a panel board in which the colors contribute in making decisions and monitoring results of previous plans (Fig. 2.11):

*6 Sigma* = it is a general map that helps integrate the tools to improve quality and reduce process variability (Fig. 2.12). Table 2.1 shows an example of process more stable and less likely to fail.

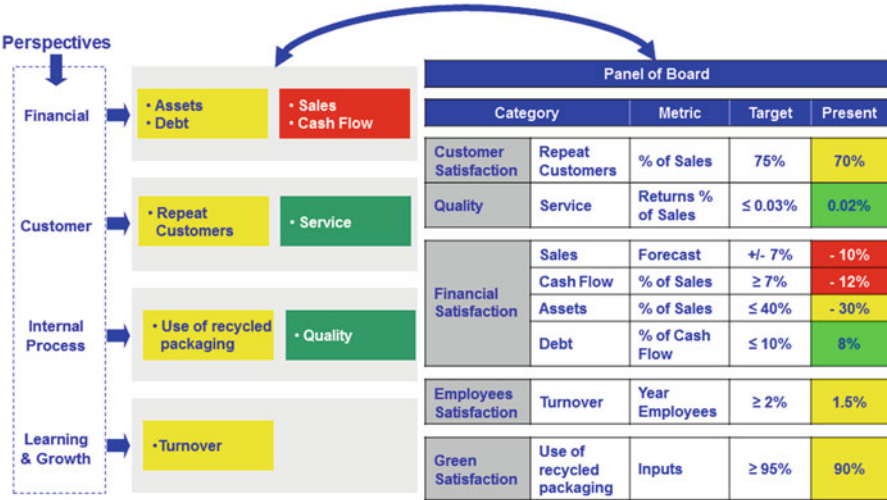


Fig. 2.11 BSC—Goals and targets

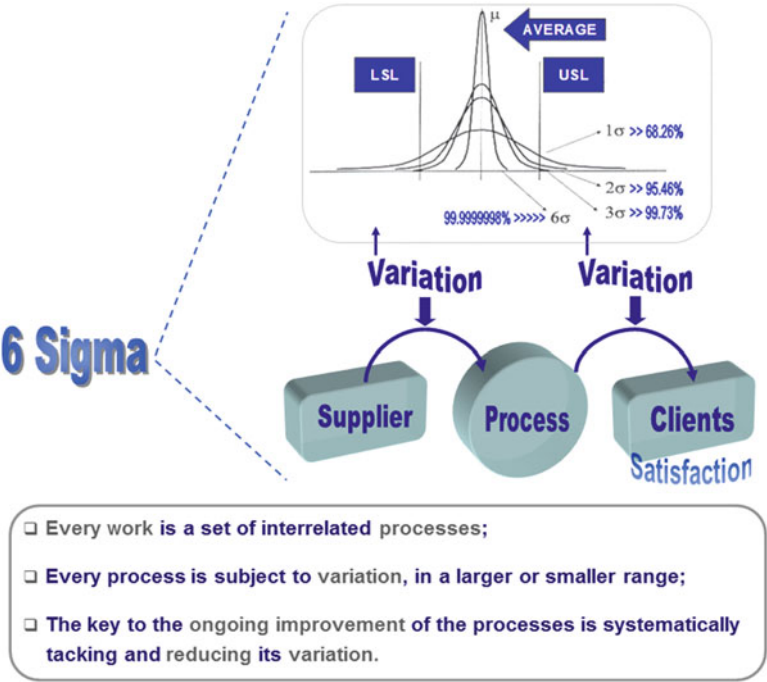


Fig. 2.12 6 Sigma

**Table 2.1** An example of a more stable process

One organization has 254,000 contacts per year with clients (through: call center and events)	
99% — variation (success)	6 Sigma—99.9999998% (variation/success)
2,250 unsatisfied contacts per year	1 unsatisfied every 19 years

The 6 Sigma and the BSC methods are used in the PDCA during the following stages:

- *6 Sigma*=during action (act), because the results obtained start a new cycle, improvements are made and expectations are reestablished.
- *BSC*=during control (check), since it is a panel of indicators which provide data for decision making and consequently direct improvement actions.

**Conclusion**

The company’s first step toward quality is to identify its critical processes, focusing on its strategy and vision. After this first stage, the process management starts using tools and methods to ensure quality, as discussed in this chapter, and thus implementing the concept of continuous improvement. Improvement opportunities will be viable only if the process mapping includes the subprocesses.

Another relevant aspect is to define indicators and goals for the processes and subprocesses, which must be periodically monitored. We cannot improve anything if we do not know the results achieved and if we do not compare them to previously defined goals.

The ISO 9001 certification (quality management), through its requirements, is an excellent resource because it defines a clear systematic management for continuous improvement. The written procedures and routines provide updated details about the organization operational system and also provide total traceability while maintaining the intellectual capital.

Learning the concepts of quality management, processes, standards, tools, and methods for quality may seem overwhelming at first, but it is great to see how much is gained and how a company can improve when all is put into practice. Establishing a quality management system may demand hours of work, especially in companies less structured, but it will certainly offer rewarding results.

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