

Quality certification in research laboratories

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Abstract

In the health care centers, also in Italy, a new mentality based on Quality Certification is developing. This is, today, the hallmark between a business that wants to grow up, evolve and give warranties to its own customers, and another one that doesn't deem it necessary to modernize and modify its strategic standard for health caring. The trial of the Quality Certification, at present applied in many diagnostic laboratories, can be and must be introduced also in the research laboratories: it would be desirable that, nowadays, their credibility should not be based exclusively on the researchers' fame, the originality of the results and the echo of their names in the scientific literature. A certificate service has a tangible value based on the efficiency, the reliability and the safety; this value makes the service adequate to the European market, that is now more and more exacting in asking for warranties of quality. The use of newly conceived, yet certified devices collide, in many laboratories, with the pre-existing structures. On this subject, the Quality Certification is realized by using the UNI EN ISO 9001:2000 Norm, which of many has the worth of being suitable for the single service, directed to the exploitation of what is going, and able to answer to the politics of the continuous improvement. Therefore in a research laboratory, the Quality Certification results a valid instrument to make evident and controlled all the procedures, the basic activity, the guidelines, to validate the final results through a continuous monitoring of

the apparatuses and of the materials and to guarantee the workers' security.

A new approach based on Quality Certification is, even in Italy, acquiring ever more importance in healthcare facilities: it is the so called "Excellence Accreditation" system, which is recently setting apart those healthcare providers that intend to grow, develop, and, above all, offer quality services to their customers, and those that do not believe in the need for changing and updating their strategic criteria in healthcare provision. Quality Certification, already applied in several diagnostic labs, can and must be introduced also in research laboratories. It would indeed be desirable for their credibility not to be based only on the fame of researchers who work there, on the original nature of the results attained, and on the renown enjoyed by their names in the scientific literature.

A certified facility provides a tangible added value, granted by its efficiency, reliability, and safety, making it competitive on the international market, by which we mean cooperation relations in research projects, for which ever more demanding quality assurance standards are required. When talking about Quality and a Quality Management System, the right definitions are important: Quality means "the degree by which a whole set of intrinsic features meets the requirements", whereas Quality Management System means "the whole set of correlated and interacting elements (processes and resources) implemented to plan and carry out quality policies and achieve correlated goals"¹. In the international scenario, of all the available routes to excellence accreditation, we will consider the ISO system, which is by now quite common also in Italian healthcare facilities.

Why was the ISO model chosen? It is an internationally recognized model applicable to all organizations, irrespective of their size and the nature of their finished product (which, for a research laboratory means investigation results).

It focuses on a policy of continuing improvement and on "Quality Management" to get customer satisfaction (customer, which, in our case is the client of the research or the journal that is going to publish the work). Last but not least, it is a model designed to leverage all the organization's practices and assets.

The ISO model consists of two consistent standards (ISO 9001 setting out the requirements and ISO 9004, which is a guideline for performance improvement), both focused on customer satisfaction, on the process, and on improvement. They are both based on the following 8 principles:

- Customer-focused organization
- Key role of the Management
- People involvement
- Process-based approach
- Systemic management view
- Continuing improvement
- Fact-based decisions

Mutual advantage in supplier relations

Since the study of processes lies at the core of Quality Management Systems, we would like to remind you here that process means "The whole set of correlated and interacting activities that turn input into output"¹.

However, if we analyze in practice the actual procedure required to be granted an ISO Quality Certification, we can say that an organization must be able to identify both primary and support processes, which make up its operations, define work sequences and interactions between these processes, and identify the necessary criteria and methods for effective process operation and control. Further, the organization must identify the professionals concerned (who are the process players), define their responsibilities, verify conformity of equipment resources, and manage available resources.

In a Quality Management System, the production of documents is fundamental, which depends on the size of the organization, type of activity, process complexity and interactions, level of personnel training, and the risks caused by the lack of documented procedures.

The purpose of document production is to ensure a homogeneous behaviour across the organization, raise personnel awareness of quality issues, and obtain more reliable results. As a matter of fact, there are no certain results, when there is no certainty as to how an activity will be carried out.

Hence, prescriptive documents must be produced, namely documents setting out, at different levels of detail, how an activity must be carried out, as well as other evidence documents proving that a specific activity was completed as per the required standards.

Through accurate documents, we will gain information, for example, about the preservation method of a specific reagent, or get the instructions for instrumentation checks, as well as the evidence of when and by whom these activities were carried out.

Also, we should not forget, that documenting means to transfer the experience from the individual to the organization, thus turning it into a corporate asset.

If we take some of the items referred to in the Standards, we can make some practical examples which highlight the critical points in the work of a research lab.

Section 6.2 concerning Human Resources, states that all personnel must be instructed, trained, and must be adequately skilled to carry out the job assigned to them. Therefore, the organization must be able to determine the right personnel skills, provide the necessary training, and ensure that all personnel are aware of the value and importance of their individual contribution to achieving quality goals, maintaining records on personnel education and training levels, skills and expertise, and assessing the efficacy of undertaken measures.

Section 6 also refers to infrastructures that must be defined, set up, and maintained (indeed, the use of newly acquired equipment that meets the standards in many labs clearly clashes against existing facilities).

Work environment is another very important issue.

Work conditions inside the lab premises must be defined and controlled, in order to ensure service conformity and operator safety.

With regard to design and development, section 7.3 states that planning, review, assessment and validation must be carried out, and any change must be duly controlled, with proper records maintained of all these activities.

Further, the procurement process is fundamental: ways must be defined to ensure that all product and service providers are able to supply products and services that meet the organization's requirements.

Finally, Section 7.6 refers to the management of monitoring and measuring equipment.

In order to ensure valuable results, all measuring units must be calibrated and adjusted either periodically or before their use, and must be identified in order to assess their calibration conditions, must be protected against damage or adjustments that could invalidate the results.

It would appear that the criteria to be applied in order to attain a Quality Certification clash against creativity and originality, which are necessary to researchers to carry out the tests on which a research work is developed. Actually, getting certified means to be able to leverage and formalize what is already there, by conducting continuing process checks, ensuring the application of specific methods, and providing evidence of all this through adequate documentation. A certified lab will thus be able to guarantee reproducible results with an added value, whose benefits will be felt on the international market.

Further, it should not be neglected that the organization's commitment to pursuing full conformity with the standards, in addition to promoting customer satisfaction, will also benefit all those who are concerned with the Organization's performance.

References

¹ Italian UNI EN ISO 9001: 2000 Standards.