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Establishment of criteria for the selection and adaptation of objectives and indicators in ISO9001:2008 quality system in a university pharmaceutical pilot plant

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RESUMEN

Objetivos: El objetivo de este trabajo es el correcto establecimiento y seguimiento de los objetivos de calidad y sus indicadores, como pilar fundamental de un sistema de garantía de calidad, en este caso centrado en ISO9001.

Material y métodos: En este trabajo, los autores presentan los criterios que, a su juicio, una organización debe seguir para una mejor selección y adaptación de objetivos e indicadores en el marco de la norma de calidad ISO9001:2008, aplicada a una planta piloto farmacéutica universitaria. Se realiza una evaluación de los errores en el establecimiento de objetivos e indicadores.

Resultados: En base a la experiencia de varios años en SDM (Servicio de Desarrollo del Medicamento) en la Facultad de Farmacia de la Universidad de Barcelona, los resultados muestran que el establecimiento de objetivos e indicadores apropiados no resulta una tarea sencilla. Una cuidadosa selección tanto de objetivos como de indicadores debe ser un paso obligado para el establecimiento de un sistema de aseguramiento de calidad robusto y fiable a lo largo del tiempo.

Conclusiones: El aprendizaje basado en la experiencia de años demuestra ser una herramienta poderosa para acabar seleccionando los objetivos e indicadores correctos que se adapten al sistema de calidad en cuestión. Dado que este hecho no siempre resulta fácil, es necesario establecer unos criterios con el objetivo de obtener información útil que contribuya a la mejora continua del sistema de calidad.

PALABRAS CLAVE: Indicadores, ISO9001:2008, Objetivos, Sistema de calidad.

ABSTRACT

Aims: The aim of this work is the correct establishment and follow-up of quality objectives and indicators as the cornerstones of a quality assurance system, in this case focused on ISO9001.

Materials and methods: In this work, the authors present the criteria that, in their view, an organization must follow for a better selection and adaptation of the ISO9001:2008 quality system objectives and indicators applied to a university pharmaceutical pilot plant. The evolution of errors in setting objectives and indicators is assessed.

Results: Based on the experience of several years at the SDM (Service of Development of Medicines) at the Faculty of Pharmacy of the University of Barcelona, the results show that the establishing of appropriate objectives and indicators is not an easy task. A careful selection of both objectives and indicators must be a compulsory step prior to the establishment of a robust, reliable quality assurance system through years.

Conclusions: Experience over time proves to be a powerful tool to end up selecting the right quality objectives and indicators for such quality system. Since this task is not always easy to carry out, is necessary to set a selection of criteria in order to obtain useful information that contributes to the continuous improvement of the quality system.

KEY WORDS: Indicators, ISO9001:2008, Objectives, Quality system.

INTRODUCTION

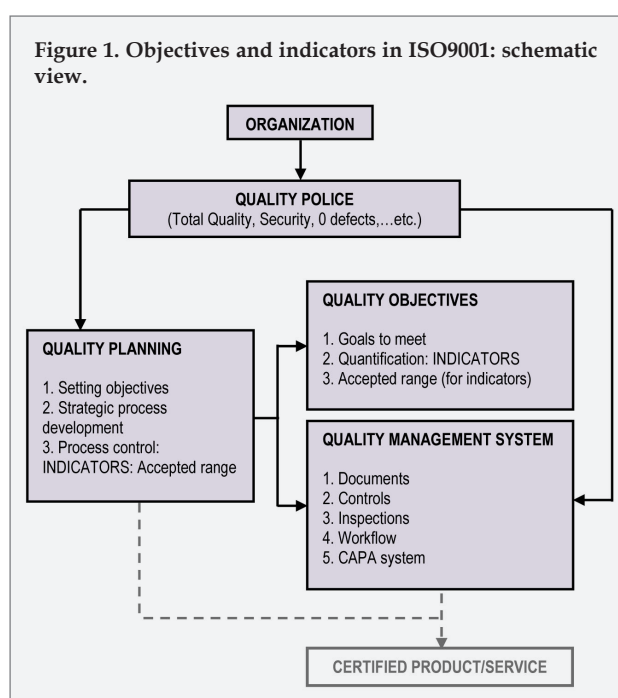
One of the pillars of any organization is the establishment of objectives, which must be consistent with the quality policy present at all levels of the organization. Organizations must define their quality objectives as the goals that the company wants to achieve in the future. Naturally, in order to ascertain the degree of achievement there is a need for indicators that easily show its evolution in time. In the area of pharmaceutical development and/or manufacturing organizations, this need (the establishment of a system of indicators to measure the performance of processes that affect the organization's quality system) can be found in several quality systems. ISO9001 standard¹ implies a highly generic system of quality assurance, applicable to any type of organization in all its fields, and in which the establishment of quality objectives and indicators is, of course, a fundamental pillar.

In the ISO9001 environment, when a company defines and sets an objective, this becomes a requirement of the quality assurance system, thus failure to comply constitutes non-conformity. Figure 1 shows the contextualization of the objectives and indicators in an ISO9001 quality system.

Any organization, as those certified by ISO9001 as is the case treated in this work, must measure its own performance. The organization must do so without distinguishing the type of activity it is engaged in, and regardless of compliance with regulations since if the activity carried out is monitored, the organization will be able to be prepared for changes and will be able to take measures for continuous improvement that such standards require (PDCA cycle: Plan-Do-Check-Act). In order to produce an easy-to-manage quality system, two basic points need to be established without errors: clear objectives and indicators with a good monitoring system.

But the wise selection of objectives is not always easy, especially for research centers and companies that are just beginning to establish ISO9001 standards. Most companies find it difficult to find quantifiable objectives during the initial implementation of the standard, until they learn the concept and start devising more practical indicators than those that arise during the initial rollout. Even the help of an external quality consultancy does not guarantee that the most appropriate objectives will be chosen, because the particularities and intricacies of each organization often represent a challenge for the consultants themselves.

This article aims to give a conceptual vision of objectives and indicators according to ISO9001 applicable in any type of organization that needs to continually improve and measure this improvement, as well as errors in the



application. This article, which is based on the real case of a university pharmaceutical pilot plant that complies certified for ISO9001, also aims to show the evolution in the implementation of quality objectives and indicators year after year and the overall improvement gained by the quality system, thanks to experience and system audits.

MATERIALS AND METHODS

Objectives and indicators. Basic Concepts and differentiation

As mentioned previously, sometimes these concepts can be confused, so it is necessary to give them the right approach². The methodology is clear, and follows three steps:

- *Identify* the goals that are pursued in the field of quality (*quality criteria*).
- *Establish* a methodology to ascertain whether these objectives are being reached over the set period of time (numerical index that informs about the exact situation, which is called an *indicator*).
- *Define* an *acceptable range* within which the indicator (acceptable quality standard) should move.

It is important to insist on the fact that objectives must be measured using associated indicators. Indicators respond to the critical variables of the objective, which will affect its scope. By means of a calculation formula, indicators allow monitoring the achievement of the planned results, and this in turn allows identifying trends that diverge from or approach the initially proposed objective. Thus, each quality

objective must be associated with at least one indicator. The organization can also measure other indicators that are not associated with targets but which additionally allow the measurement of key strategic processes and/or support the organization's quality assurance system³.

Definition of an objective. Critical elements of the objectives

An objective can be defined as a goal or a challenge, and this is something that the organization (lab, company) can and wants to achieve. The objectives should include those actions that will help to achieve the principles set out in the Quality Policy. Targets are defined at the end or beginning of year or season by the management team (or Quality Committee), and once approved, the stakeholders of the organization are informed. In this way, the personnel can get as involved as possible in their achievement. Before setting objectives it is necessary to ascertain the current situation. For example, to set an objective for the improvement of the delivery time of products, it is necessary to know the current delivery time. Targets cannot be assigned randomly, but in such a way that they represent achievable goals.

It is important to acknowledge that ISO has not invented the model for improvement based on objectives. This improved model is identical to the one used by the majority of multinational companies. The essence is the same, although the complexity of the system of objectives may differ. For this reason, the improvement system based on objectives can be and is used for other purposes besides quality⁴.

In any case, in order to properly implement or monitor the organization's quality system, the quality objectives must be *clearly defined and very well structured*.

All objectives must have three characteristics so that they can be considered appropriately set:

1. *Clear*: the objective must be clearly defined, so that what is being measured can be easily understood.
2. *Measurable*: the objective must contain information that can be represented *numerically and in terms of time* so that it can be measured, and so that it can be determined whether it has been reached at the end of the period.
3. *Reachable*: the goal must be attainable in that if the resources are provided and the work is focused it can be achieved.

It is common to not know where to start to define objectives, and so it is worth carefully studying the quality policy of the organization. From this study, several quality objectives

can emerge.

In summary, the critical elements of the objectives are the concrete results for achievement and the plan of actions (activities or resources) to be put into motion to ensure the objectives are achieved. Once the objectives for achievement are clear and the activities to do so have been arranged, the objectives must be quantified. This is when the indicators with their measurement systems come into play.

Definition of an indicator and indicator measurement system

Indicators are parameters that are used to measure the level of compliance of an activity, event or goal. It is a numerical expression that allows expressing objectives quantitatively, and also measuring trends over time, and therefore fulfillment of the target.

A quality system should initially consider a limited number of indicators, since once the system gets underway and departments begin to understand the meaning and use of indicators, they will start to consider which ones are more useful. For the selection of indicators, it is recommended to start with the map of processes of the organization. According to their weight in the organization, processes are normally divided into three types: key, support and strategic. Initially, it is useful to focus on the key processes and on processes that are potentially harmful to the image of the organization before the customer (delays, lack of quality, etc.). In the processes considered most relevant, the key requirements that would be interesting to monitor should be identified. A simple and easy way of establishing the relevant indicators is to ask the fundamental questions of the process. Subsequently, the ratio or the data on which the indicator will be controlled is decided.

Thus, to properly establish the indicators, the following points should be taken into account:

- The best way to measure compliance for each critical element of the objective (*outcome or goal*) should be determined.
- Each indicator must be assigned: a name, form of measurement (calculation formula and conditioning factors or delimitations) and unit of measurement.
- A goal or planned result to be achieved must be established for each indicator. The goal is the quantitative (numerical) specification of what you want to achieve by the intended deadline, i.e. the objective. The team must be informed as to the goals and appoint a person responsible for monitoring and measuring. The goals must be achievable and, of course, must be met.

Table 1. Common errors in setting quality objectives, with an error code assigned.

<i>Error</i>	<i>Description</i>	<i>Error code</i>
<i>Objectives not consistent with the quality policy of the organization</i>	It may happen that, by going for the easy choice, objectives become inconsistent with the quality policy of the organization	O1
<i>Objectives that lack associated indicators</i>	In this case, it will not be possible to objectively calculate the degree of achievement of such objective	O2
<i>Confusion between objectives and indicators</i>	Although at first it seems that there is no room for such a confusion because of the differences between both concepts, this confusion may sometimes occur; along with the initial lack of familiarity with the standard, the use of confusing record templates for objectives, despite being provided by consultancies, may hinder their proper understanding	O3
<i>Poor description of the objective</i>	An objective that is not likely to result in a measurable indicator is not suitable to establish goals for the organization	O4
<i>An achieved goal cannot be maintained as an objective for the following year</i>	Since ISO9001 continuous improvement, in case you want to keep an objective, it must be substantially improved. For previous objectives already achieved, their associated indicators can be kept as a way to continue trending	O5
<i>Objective not related to a quality process</i>	The objective must take into account the purpose of the quality process and try to ensure that the associated indicator can effectively demonstrate the ability of the process to fulfill such objective.	O6

Table 2. Common errors in setting indicators, with an error code assigned.

<i>Error</i>	<i>Description</i>	<i>Error code</i>
<i>Indicators that do not reflect any target variables</i>	In such a case, the indicator will not be useful to measure the achievement of the objective as it cannot reflect the variables that influence this achievement	I1
<i>Indicators only "measurable" at the end of period</i>	They do not indicate trend. The indicator becomes meaningless as the evolution of the reflected objective cannot be known	I2
<i>Extremely difficult indicators to measure and monitor</i>	They are not practical indicators since they can lead to errors in the design of the calculation formula	I3
<i>Calculation formula inconsistent with planned results</i>	It is usually due to indicators that are complicated to monitor, impractical and unintuitive	I4
<i>Indicators not associated to objectives, thus not providing information on quality</i>	From ISO9001 point of view, they provide no information on performance improvement. Still, the organization itself may use additional quality indicators not associated to objectives	I5

This is a systematic and permanent mechanism to control the progress, result and scope of the organization, used to evaluate the fulfillment of its objectives.

The presentation of the results in terms of tendency to fulfill the objectives will be managed through the Indicator Control Board. The advantages of this system are clear: it provides objective decision-making information, it allows ascertaining the level of effectiveness and efficiency of the organization without room for ambiguity, and it allows the dissemination of the achievement of objectives and timely decision-making before non-fulfillment of the planned result.

Finally, this system should include a process of continuous

validation, in which the definition and calculation of indicators are improved through experience.

In table 1 we present some of the errors that can occur while setting the quality objectives that often become evident in system audits, when it is already too late. For each objective, an error code has been assigned (with the letter O and a number), which served to identify the types of mistakes in the establishment of quality objectives over the years in the real case of the SDM.

Indicators are the key to finding out the trend of a process in ISO9001 and checking if the intended result is achieved. While the selection of an objective (consistent with the policy while measurable) is not easy, nor is the establishment of

associated indicators that allow for monitoring processes over time.

Table 2 shows the errors that can occur in the quality indicators, and just as for the objectives, each error is assigned an error code (letter I with a number indicator), which later served to identify the types of errors made in the organization in establishing quality indicators over the years in the real case of the SDM.

RESULTS

Evolution of the SDM

In 2006 the SDM began to implement ISO9001, with the help of a consultant. One of the first steps was to set quality objectives and indicators for the following year, 2007. Over time, the results from audits and experience as well as various training activities have meant that the initial system set for objectives and indicators has shown a gradual evolution.

To do so, we analyzed the objectives and indicators for several years, which were assigned the common error codes described in tables 1 and 2, at the discretion of the organization based on the knowledge gained and the ability to detect the mistakes made. Certain targets or indicators may be associated with even more errors than those described. Despite experience, is not easy to identify such errors. Results were obtained with regard to developments in the establishment of objectives and indicators in the SDM, the types of errors and progress towards an improved system, which allows the effective establishment of quality objectives and indicators to measure the trend in the accomplishment of the objectives.

Figures 3 and 4 show the data concerning types of errors over the years and their evolution according to tables 1 and 2.

DISCUSSION

The ISO9001 quality standard is useful to systematize routine activities, clarify responsibilities, achieve greater transparency in the transfer of technical knowledge, establish conditions for laboratory use, improve resource management, promote the development of the laboratory and at the same time, achieve external recognition of the work done.

However, there are always points for improvement, for example the system of quality objectives established in the organization. Specifically, organizations that embark on a quality system of this type can make mistakes in its establishment. Experience should manage to correct these

mistakes and adapt them to real objectives that can be measured using a suitable indicator.

Therefore, the indicator system is useful insofar as it is used properly. It must be clear that to measure quality, these steps must be followed: define the quality criteria, develop the quality indicator, and then set the measurement system consistently and simply. Experience in establishing them and their real use to measure trends will determine their review, to detect errors in their establishment and thus subsequently improve them.

In the specific case of the SDM, and according to the data analyzed for four years referring to quality objectives and indicators, it can be said that sometimes, wanting to set certain objectives by force means that, over time, it is found that their achievement may not depend so much on the resources and activities carried out to achieve them as on external factors or situations that can lead to non-achievement.

By analyzing the types of errors in objectives, the most common error proves to be O4, regarding the poor description of the objective, which may derive to a meaningless quantification. In any case, any allusion to quantify the achievement of the objective should be described in the indicator.

Although concrete targets are not specified here, it can be said in the case of the SDM that experience year after year is capable of reducing errors in setting goals.

Most common type of error in indicators is I2 regarding indicators showing no trend. If an indicator has a target of two actions a year, for instance, it does not and cannot show any tendency, as we are dealing with just two actions per year, measurable only at the end of the period.

For both objectives and indicators, a marked decrease in errors is detected just at the turn of 2008 - 2009. The SDM obtained ISO9001 certification in mid-2008. Internal system as well as pre-certification audits helped detect most errors.

CONCLUSIONS

If the results of objectives and indicators are analyzed together, it can be seen that globally there are more errors in the establishment of indicators than objectives. This shows that although the objective is well established, it can be difficult to find a suitable indicator for measuring trend and therefore whether or not the associated objective is achieved.

1- When you set new targets and indicators you must

Figure 2. Objectives and indicators: evolution. In the legend, "obj" and "ind" stand for Objectives and Indicators, respectively.

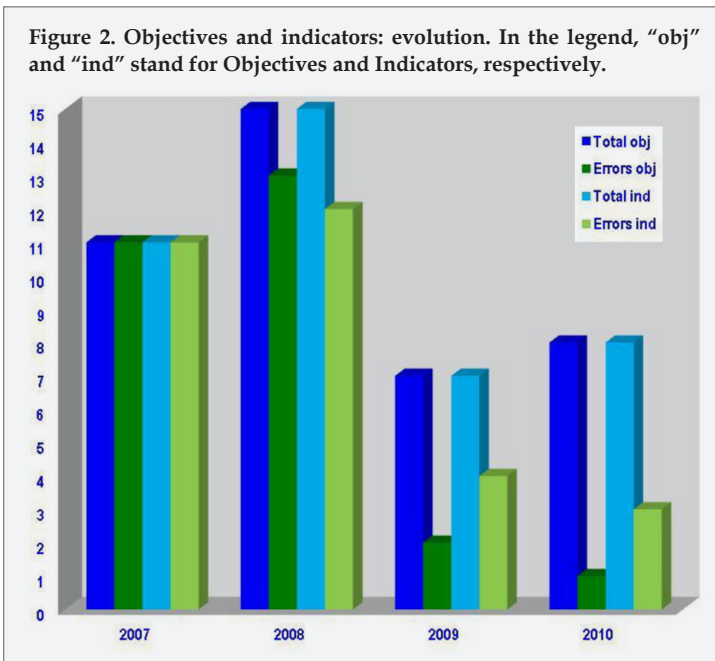


Figure 3. Evolution of different type of errors in objectives.

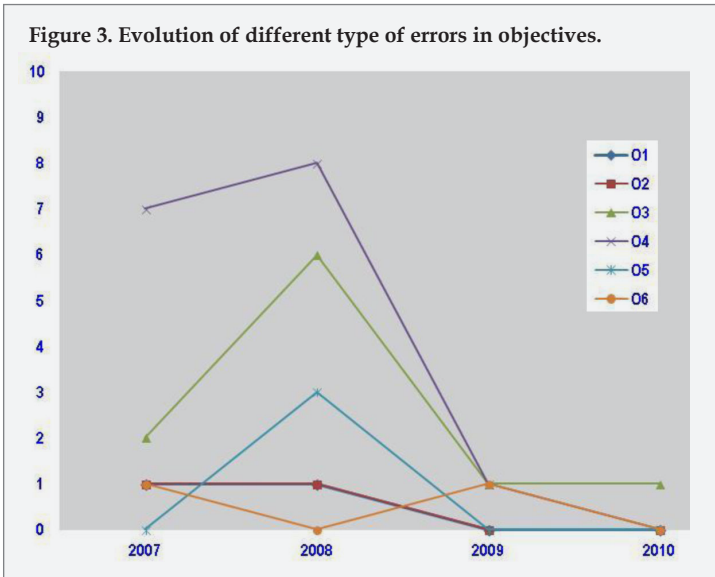
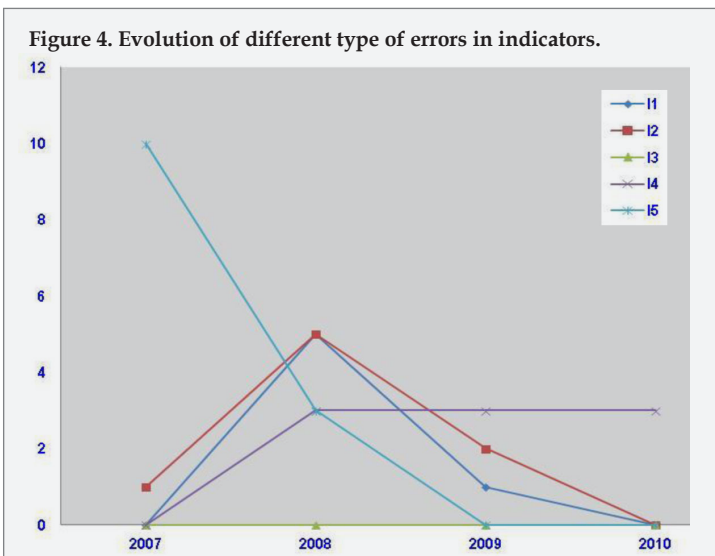


Figure 4. Evolution of different type of errors in indicators.



check in error type tables that they do not suffer from any of them.

- 2- You should try to perform an assessment of the trend during the first months of the period, and not wait until the end and find out too late that there are failures in the formula that could be insurmountable.
- 3- Avoid the use of indicators that show no trend during the year as there is no clear control period.
- 4- It is not necessary for indicators always to be related to objectives, but the opposite is true. That is, an objective must always have at least one associated indicator.
- 5- It is not necessary to establish numerous objectives, just the essential ones.
- 6- Continuous improvement in a Quality Management System through the ISO9001: 2008 can and should be managed through proper choice of quality objectives and indicators, which involves reviewing, planning, doing and measuring or checking and acting again.

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