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PRACTITIONER'S REPORT

Quality assurance in research: incorporating ISO9001:2000 into a GMP quality management system in a pharmaceutical R+D+I center

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Abstract There is currently no universal or standardized quality system for the recognition of excellence of a research center. Knowledge and competence may not be enough in the current rapidly changing world in which high productivity and continuous improvement are essential. The purpose of this study was to assess the impacts of implementing the ISO9001:2000:2000 standard in an academic research center dedicated to R+D+I (research, development and innovation) in the pharmaceutical industry. The article describes the stages we followed to implement the ISO9001:2000 system, which was achieved by integrating it into the previous regulatory system of GMP (Good Manufacturing Practices). As a result of implementing ISO9001:2000, the center has seen distinct improvements, such as fewer errors in project documentation, improved assessment of customer satisfaction, and the effective implementation of periodic plans, e.g., in calibration, preventive maintenance, and investments. Overall, ISO9001:2000 implementation has been beneficial for the organization and could be applied to other research centers.

Keywords ISO9001:2000 · Quality · University · Research · GMP · Certification

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Introduction

The critical factors that determine economic growth, prestige, and competitiveness in a research center are technical-scientific competence, technological development, and innovation. These factors are essential for the survival of an academic pilot plant when faced with the challenges of an increasingly globalized marketplace. There have been many calls for the accreditation of research activities [1–3]. In academia, however, quality management is a neglected topic [4] that is sometimes considered an obstacle to progress [5, 6]. Nevertheless, quality systems are mandatory for the development and manufacture of pharmaceuticals and other related substances. As a result, specific quality management systems have been developed [7, 8].

The implementation of quality management standards in medical research laboratories [9] would ensure the quality and integrity of data and of products and devices, while establishing mutual confidence among all the parties concerned [8]. Nevertheless, an individual quality assurance program for each system would be difficult to manage [10–13] so most centers choose ISO9001:2000 [14–16] due to its universal application. Spain has developed a standard for the certification of R+D+I management systems (UNE 166.000). Its main goal is to develop European standards to facilitate quality certification that recognizes excellence in management within a research center. The implementation of effective problem-solving strategies during project development should result in various improvements. For example, it should reduce the risk of inconclusive results, improve the control of or reduce project timing, and simplify the internal and external auditing process. In doing so, this should benefit the center from both an economical and a managerial perspective [17]. From a practical point of view,

the main reason for the Service of Development of Medicines (SDM) taking the step towards ISO9001:2000:2000 certification was to give recognition to the quality of research and development activities being carried out. This was beneficial in that we were able to implement a quality management system into the existing quality management structure and various other projects in an useful and flexible way.

The novelty of this paper refers to the process of implementing a quality management system, based on the ISO9001:2000 standard, in an university pilot plant dedicated to the research, design, and development of drugs; 50% of resources go towards teaching activities and 50% to research and development.

After achieving ISO9001:2000 certification the center distinctly improved, particularly in the following areas: communication between staff members, the assessment of customer satisfaction, the management and organization of projects, and achieving targets. No similar studies have been published before on this issue concerning academic field.

Methods

Initial assessment and choice of solution: integrating ISO9001:2000 into GMP quality system

The ISO9001:2000 system was incorporated into a pre-existing quality system based on a GMP [18] compliance scheme [17]. Following a previous study into GMP compliance, in which several aspects were identified as requiring attention, it was necessary to establish the guidelines for applying the ISO9001:2000 (Table 1).

The next step consisted of studying and planning the stages (Table 2) that would lead to ISO9001:2000 certification. At this point, it was necessary to achieve a perfect fit between both standards to improve the system as a whole.

Table 2 Phases for the development of ISO 9001:2000 implementation

ISO 9001:2000 Implementation: phases
1 Analysis of ISO 9001:2000 requirements in front of GMP
2 Personnel awareness/training versus ISO 9001:2000 new elements
3 Writing/implementation of specific procedures of ISO 9001:2000 rule
-Quality manual
-Specific ISO procedures
4 Internal audit and strategic quality planning focused on continuous improvement
5 External audit previous to ISO 9001:2000 certification
6 ISO 9001:2000 certification

Implementation of ISO9001:2000

This section will discuss the main themes of each phase outlined in Table 2, emphasizing the areas that went undetected during the first steps of implementation and those which emerged during the pre-certification audit.

Review of ISO9001:2000 requirements and analysis of the different aspects with regard to GMP regulations

The main elements of ISO9001:2000 that complement GMP regulations implemented in the SDM are shown in Table 3. Table 3 also compares the main requirements of ISO9001:2000 with those of the GMP system. The last column shows the added value achieved after implementation.

Table 1 Analysis of starting point before ISO 9001 implementation

Analysis of starting point	
Aspects to be changed	Reasons for the change
Need for organizational changes such as:	Even in a research task, innovative and with intangible results at the beginning, many tasks and determinations are routine and must be done in a formal way
(1) Standardization of methods	
(2) Elimination of redundant tasks	Tasks that are traditionally justified although not essential, not adding quality to the project or to the center
Lack of communication between personnel about observed deviations and/or improvements	To seize opportunities to improve department functioning and offer staff training
Absence of a quality culture	Establishment of a quality culture, independent of quality assurance department: To teach the language of quality
	Improve information flow among the personnel of the center
	Insist on professional responsibility of each member of staff
Gradually introduce ISO procedures in work processes	They are indispensable to achieve certification. Their introduction must be carried out without implying a burden in daily work

Table 3 Comparison between GMP and ISO 9001 requirements

ISO 9001:2000 The main aim is to achieve the maximum customer satisfaction		GMP The main aim is the obtaining of specified quality in order to assure user's safety		Added value due to ISO 9001:2000
Requirement	Document	Requirement	Document	
Chapter 4		Chapter 4		
Identification of organization's processes	Map of processes	NA	NA	To work and think by processes eliminates barriers between departments
				Department flow improvement
Existence of a Quality Manual to describe the whole system	Quality manual	Existence of a site master file document	SITE MASTER FILE	The QM is public and available to anyone in the organization
Need for written procedures to fulfill main standard requirements	ISO 9001 procedures	All activities must be documented according to standard operating procedures (SOPs)	SOPs	NA
Other procedures necessary to plan, operate, and control processes	SOP's			
There must be documents to register all generated data	Templates for data registration	There must be documents to register all generated data	Templates for data registration	
Chapter 5		NA	NA	Implication of all collaborators/ working groups in the establishment and achievement of general and specific objectives
Establishment on behalf the directorship of a quality policy and objectives that must be periodically checked	Objective and quality policy			
Review by directorship	Directorship review report	NA	NA	Improving the knowledge and involvement on behalf directorship about how organization operates as a whole
Chapter 6		Chapter 2		Assesment of effectiveness of training activities helps to manage training resources and to adapt training activities to real needs
Evaluation of the effectiveness of training activities performed	Evaluation of training activities	Personnel must be adequately trained	Training records	
Chapter 7		Chapter 7		Effective communication with customers to inform about the state of contract projects and to assess their level of satisfaction at any level, even in absence of complaints
Effective communication with customers to inform about the state of contract projects and assess their level of satisfaction	Customer satisfaction survey	Communication with customers is regulated just in case of contract manufacture and analysis or complaints	Quality agreements and complaints	
Chapter 8		Chapter 9		NA
Self-inspections	Audit reports	Self-inspections	Audit reports	
Quality indicators to track continuous improvement	Quality indicators documents	NA	NA	A periodic and quantifiable revision procedure has been established to evaluate quality indicators
Well-established system for the management of non-conformities. Existence of preventive actions. Tracking and measuring actions focused on all organization areas	SOP for non-conformities management quality reports C.A.P.A. tracking	Non-conformities must be registered and solved. Tracking actions derived from self-inspections are focused on the product and its productive environment	NA	Establish preventive actions to avoid potential non-conformities and enhance continuous improvement

Awareness of staff and training

Training sessions focused on discussion and opinion sharing. At this point, the organizational structure of the center was redefined and job descriptions were revised, making them anonymous instead of nominative. Other changes planned were the promotion of two people to heads of department, and the new post of project supervisor was created.

Development of specific ISO9001:2000 documentation

The phases for establishing documentation are detailed in this section, as are the most important aspects and the lessons learned.

Process mapping: basic processes of the center It is important to consider the reason that a research centre exists: to facilitate research and development. Process mapping of a research center is difficult because the projects tend to be disjointed, making it difficult to formulate a generalized system. However, we managed to achieve this; in the same map the different types of process were categorized into strategic, key, or support processes. Furthermore, it was useful to complete Section 7 of ISO9001:2000 and adapt it to certain aspects of the SDM, as well as Vermaercke did in 2000 [5]. Table 4 was developed to illustrate this process; the right column shows the ISO9001:2000 standard specifications, while the left column shows the detailed processes of the SDM.

Quality policy If the quality policy is not a well-structured and transparent document, it will not be understood or followed by staff. Our quality policy was redesigned to include a clause referring to the customer. As a result of the new quality policy, quality goals were drafted. Broad goals were used because drafting specific goals for each department had proved inoperative in previous years. A table of quality indicators was designed to regularly monitor the quality policy. Some of the quality indicators included in this table were the following: obtaining a score higher than 8/10 in satisfaction questionnaires; number of actions implemented in order to improve electronic management of documents, and number of meetings carried out to treat quality issues and facilitate communication among personnel.

Quality manual According to ISO9001:2000, the quality manual is a basic document that refers to the overall quality management system of an organization. During the implementation period, several versions of the quality manual were written. The structure was based on the eight

Table 4 Breakdown of the activities developed in order to comply with several clauses of Section 7 of ISO 9001:2000 showing the SOP that describes the process

Activity in the SDM	SOP	Correspondence with ISO 9001:2000		
7.1 PLANNING OF PRODUCT REALIZATION				
7.2 CUSTOMER RELATED PROCESSES				
Customer: Product requirements Interview/Request to SDM Requirements: customer/legal/SDM/others project viability Budget (Technical Director)	ISO009	7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO PRODUCT		
Budget: Approval CONTRACT (Annex: project goals) Contract signing		7.2.2 REVISION OF REQUIREMENTS RELATED TO PRODUCT		
7.3 DESIGN AND DEVELOPMENT				7.2.3 CUSTOMER COMMUNICATION
Opening of project sheet: - Planning	GEN033	7.3.1 PLANNING OF DESIGN AND DEVELOPMENT		
Input data: - Project sheet - Protocol writing (by technician)		7.3.2 INPUT ELEMENTS OF DESING AND DEVELOPMENT		
- Output data: project goals (protocol)		7.3.3. RESULTS OF DESIGN AND DEVELOPMENT		
Revision of project protocol: Head of Department and/or Project Quality Management.		7.3.4 REVISION OG DESING AND DEVELOPMENT		
Verification of project protocol: Head of Project Quality Management		7.3.5 VERIFICATION OF DESIGN AND DEVELOPMENT		
Technical Direction: verifies again and VALIDATE the project's protocol		7.3.6 VALIDATION OF DESIGN AND DEVELOPMENT		
Meetings Partials reports: - Head of project: establish requirements - Head of Department and/or Project Quality Management - Technical Direction	GEN033	7.3.7 CHANGE CONTROL OF DESIGN AND/OR DEVELOPMENT		
7.4 PURCHASING	GEN 020			
7.5 PRODUCTION AND SERVICE PROVISION				
-PROJECT NOTEBOOK: Product development - SOPs (Standard Operating Procedure) - Verification/equipment maintenance - In-process controls - Meetings and/or protocol modifications: Revision-Verification-Validation - Final report: Revision-Verification-Validation	GEN006-GEN076	7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION	7.2.3 CUSTOMER COMMUNICATION	7.2.2 REVISION OF REQUIREMENTS RELATED TO PRODUCT
Whenever in-process controls are not available		7.5.2 VALIDATION OF PROCESSES		
- Project notebook - Samples - Etc.		7.5.3 IDENTIFICATION AND TRACEABILITY		
- Warehouse - Sample collection	GEN018	7.5.4 CUSTOMER PROPERTY		
		7.5.5 PRODUCT PRESERVATION		
7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT				

chapters of the standard. Each chapter explains the different aspects of the SDM and many of the activities required by ISO9001:2000 were specified with the aim of facilitating audits.

Specific ISO procedures: organization and control of documentation The ISO9001:2000 standard sets a minimum of six written procedures which should explain the general aspects of the quality assurance management system. A total of 12 procedures were drafted and added to the pre-existing procedures (see Table 5) not previously covered in GMP requirements. The nature of our center made it necessary to establish procedures related to departmental processes, marketing management, and teaching activities. The organization of the documentation system used paper copies and by December 2007 it accounted for more than 300 procedures. The control of such a large number of procedures was complicated and the management of the paper documentation had overloaded the quality assurance department. Therefore, an attempt was made to simplify and streamline their control. This simplification unified both the procedures drafted under GMP and the procedures established exclusively under ISO9001:2000. For instance, one measure was to fuse the procedures relating to the same type of equipment, e.g., balances of the same model and weight range. Calibration operations were also combined into a general procedure for each piece of equipment, instead of separate procedures.

With regard to the distribution of documentation, it was decided to keep only the paper documentation concerning equipment by placing a copy of the procedure near the equipment. The rest of the SOP remained on the intranet. Every printed copy is recorded in the original document with the number of the copy (1, 2,…) and its location.

Table 5 A total of 12 new procedures were created on aspects not previously covered by GMP regulations

ISO 9001 Procedures for the SDM	
ISO001	Control of documentation
ISO002	Control of records
ISO003	Approve suppliers
ISO004	Strategic quality planning
ISO005	Marketing management
ISO006	Teaching activities
ISO007	Non-compliant product management
ISO008	Customer management
ISO009	Galenic development processes
ISO010	Quality control processes
ISO011	Quality assurance processes
ISO012	Regulatory affairs

A system of password-protected PDF files was designed (the password was only known by two people in quality assurance department). Moreover, these files were customized so that no modifications, printing, etc. were allowed. In addition, personnel could only read PDF on the screen with no possibility of editing in any manner, so they were indeed like an image. So far, this system has proved its effectiveness.

The control of all types of documents is now carried out using an excel worksheet, customized to facilitate the detection of revocation, distributed and printed copies, annexes, etc. Annexes related to procedures are also now controlled with this excel sheet and are made available to personnel who may need them, through a common folder hosted on the SDM server. In this case, printing and consultation are allowed but changes to these documents cannot be made. Although this is time consuming in the beginning stages, it ultimately facilitates excellent control of documentation.

Development of strategic quality issues

Quality policy, goals and indicators, regular meetings, evaluation of customer satisfaction, and system revision were the tools developed to carry out quality planning focused on continuous improvement, which was not covered by the pre-existing GMP system.

Quality indicators Establishing appropriate quality indicators to monitor continuous improvement was a challenge. It was not easy to select indicators that could be monitored both quantitatively and objectively. In fact, some of the indicators initially established were almost impossible to quantify. Among the problems identified, some of the quality goals were not associated with indicators, making it impossible to track them. In addition, it was necessary to implement indicators that were directly related to the activities described in the process mapping. To monitor indicators, a special excel sheet was designed from which indicators were based on the type of process they measured according to process mapping. The excel sheet also indicated the time period by which the measurement had to be verified (minimum time frame in order to have enough time to correct non-compliance by the end of the year was twice a year).

Direction review and leadership The role of head management is an issue that cannot be ignored when establishing a truly effective quality assurance system, as described by ISO9001:2000. Therefore, it was important to assess the director's involvement and understanding of the development of the system. The review was extremely useful in providing an overview of the quality system as a

whole, as well as identifying potential areas for improvement. The involvement of the director in this review led to a better understanding and awareness on his part, and therefore allowed for informed decision making when it came to improvements. The resulting report of the director's review was made public at a quality meeting, so that all personnel could state their support and interest in achieving ISO9001:2000 certification.

Customer satisfaction In the context of the ISO9001:2000 standard, the ultimate purpose of the quality assurance system is customer satisfaction. It is therefore essential to implement procedures that objectively measure customer satisfaction with the product. To do, this required a questionnaire in which the answers were quantifiable, e.g., a numerical value. After customers had completed the contract of service, the questionnaire was forwarded to them by e-mail and in this way used as a tool to evaluate satisfaction. However, in this study it was not always easy to obtain this information, because questionnaires were not always completed and returned. To avoid this, the format was amended. The questionnaire was made available on line so that the completed file could be forwarded immediately. Additionally, the time between completion of the contract and forwarding the questionnaire by SDM was reduced in an attempt to avoid distortions of perception that the client could have about the service due to the passage of time.

Quality committee The quality committee held meetings on the revision of targets, indicator monitoring, and other themes aimed at addressing issues related to the ISO9001:2000 standard, which must be brought to the attention of all personnel in the organization. For each meeting, as a record of the topics addressed, a report is issued, which is validated by the director and quality assurance committee. In addition, to facilitate internal communication, a copy of each record is posted on the SDM intranet in electronic format. The members of the committee are the following: the technical director, deputy technical director, head of quality assurance, head of quality control, head of regulatory affairs, and the new head of quality assurance projects.

Audits for quality improvement To identify areas for improvement in the implementation of the organization's procedures, both internal and external audits are now planned annually and regularly carried out [15]. In terms of audits, the traceability of the developed projects deserves special attention, so the documentation related to projects was frequently targeted in internal audits. A risk analysis was also performed to prioritize specific traceability issues, which resulted in faster and more effective audits. As for the external audits, the consultancy hired by the organization carried out an audit prior to that carried out by the certifying entity.

Results

After action was taken to adapt the quality management system to the requirements of the ISO system, there were some improvements.

Customer service assessment

Thanks to the ISO9001:2000 standard, there has been a significant improvement in all areas of management, which is reflected both in the documents delivered to the customer and in feedback obtained from the questionnaire mentioned above. In response to the questionnaire, customer satisfaction—which was ranked based on a point system, with 10 being the highest—scored 8.46 in 2006 (3 months after the implementation of ISO9001:2000), increasing to 9.76 in 2007, and 8.64 in 2008.

Following an analysis, it was revealed that the value for 2007 was abnormally high since only four out of twenty 20 questionnaires were completed and returned. This system was improved in 2008 resulting in 80% of the questionnaires being recovered. We received a suggestion for improvement and a note of thanks. Currently, new methods to measure customer satisfaction are being implemented in addition to questionnaires. Documents such as gratitudes, e-mails, possible complaints and even congratulations are also taken into account.

Quality of documentation: archive, backups, etc

One of the best results of the ISO9001:2000 implementation was the improvements seen in the system documentation. We developed a quality manual and described the specific procedures of ISO9001:2000. This fact in itself illustrates an improvement in the documentation system. The center focused on improving the recording, control, and archiving of documentation because of shortcomings in the past, specifically with regard to the distribution of copies through the intranet system. In addition, all network documentation relating to projects were secured by a new backup system.

The initial 359 procedures (data from January 2007) were reduced to 226 in February 2009. Taking into account that the quality system is now larger, the reduction in the number of procedures [and copies distributed] shows a significant achievement in terms of the fusion of procedures, which has facilitated better documentation control.

Direction review

Based on the direction reviews, we decided to change some equipment and to distribute resources to deal with certain calibration requirements that previously could not be achieved by the organization due to lack of personnel or time. Resources were also assigned for the continual training of personnel, and new web page updates of the center were launched.

Quality committee

Between January 2007 and February 2009, the committee held a total of sixteen quality meetings (independent of project meetings), with a 90% attendance rate. Now, four meetings per year are planned.

Audits

In 2006, only two GMP audits were performed, while in 2007 they increased to five. These were completed with six ISO9001:2000 internal audits and one external audit; in the latter, six minor non-conformities were detected. In 2008, five GMP audits and eight ISO9001:2000 internal audits were carried out. The audit for certification detected four minor non-conformities.

Staff and training activities

Promotions helped to improve communication in the center. Prior to this, technicians reported directly to the technical director, which delayed decision making and disrupted the efficiency of the department. A new position was created making one person responsible for project quality assurance. This person also acts as director of technical staff and oversees the implementation of quality standards of technical data. General training (not just training that focused on meeting ISO9001:2000 criteria) was widely and effectively implemented in the SDM. An activity was implemented to assess the effectiveness of the general training activities. The interest in training activities shown by personnel also illustrates the effectiveness of the implementation of the quality system. In 2006 only one internal training activity was carried out, but this increased to ten in 2007, with an additional seven external training activities carried out. In 2008, the same number of internal training activities was carried out, and the external activities increased to eight.

Non-conformities (CAPA system)

The evolution of non-conformities as a quality indicator proved inoperative, but it was useful to assess the management of non-conformities and CAPA (Corrective Actions & Preventive Actions). In 2006, 32 non-conformities were detected, which increased to 50 in 2007 and 64 in 2008. These increases do not mean that the quality systems have worsened but rather give evidence that there is a major awareness of the need to improve quality issues so that non-conformities are better detected and can be corrected. As for preventive actions, there were none in 2006; in 2007 there were three and in 2008 the number of preventive actions increased to six. All actions were carried out and are now functional.

Calibration planning

Although a calibration planning was to be performed annually, the center rarely reached the end of the year with 100% compliance. In fact, in 2006 the calibration planning was temporarily discontinued due to a lack of resources, such as personnel. Thus, calibrations have been progressively outsourced and other equipments that produce significant results have been included in scheduled calibrations. Compliance for calibration planning was 83% in 2007 and 81% in 2008. The number of pieces of equipment included in calibration planning increased from 39 in 2007 to 52 in 2008, and 58 in 2009. The aim has been to extend calibration planning as well as to achieve 100% execution.

Timing compliance

It should be stressed that in 2009 compliance for project timing was established as being a new quality indicator. Now, compliance for project timings is consistent with that previously planned for all projects audited in 2009.

Discussion

Quality is an essential element in successful and productive companies and is therefore an essential component for research and development centers. However, the quality system must be flexible and simple, modular and non-redundant, self-sustained in daily work, and above all, it must add value to work, creating an innovative culture for the center.

From a practical point of view, the pre-existing SDM quality management system provided defined criteria for project development and its subsequent quality control. Furthermore, it provided a system for the easy monitoring of activities, prioritized goals of the organization, and permitted the transition of data.

Quality is a strategic resource, since the first stages of the ISO9001:2000 implementation, quality management in our organization has improved. Three quality indicators can be used to illustrate this:

- The results of customer satisfaction questionnaires have shown an improved ranking of customer satisfaction in the SDM.
- The director's involvement in the organization has increased the focus of staff and improved the accuracy of resource allocation.
- Personnel awareness and involvement in the system have resulted in the creation of eight new proposals since September 2007, which have brought about significant improvements to the system. This is significant as there were no proposals prior to ISO9001:2000 implementation.

Obviously, the whole implementation process had a cost. This is something that has to be appropriately foreseen and planned before the process so that the budget is not exceeded in any way.

In conclusion, we would say that ISO9001:2000 compliance in the GMP environment has allowed us to incorporate the SDM quality system into a virtuous cycle of continuous improvement that will lead to improved customer satisfaction, which is the main objective of the SDM. Nevertheless, economical benefits, which are less easily proved, have yet to be determined [15]. Fortunately, our results can now be backed up by the quality indicators established by the organization. The next step for the continuous improvement of the SDM will be the achievement of the UNE 166.000 standard.

From our experience, we would suggest that ISO9001:2000 implementation could be easily applied to other organizations such as hospital pharmacies, laboratories, and research centers. It would be interesting to discuss whether quality systems influence research activities in terms of reducing creativity. In our case, this theory has been proved wrong; quality assurance has given our staff and the results of our research more credibility.

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References

1. Greenfield D, Braithwaite J (2008) Health sector accreditation research: a systematic review. Int J Qual Health Care 20:172–183
2. Pomey MP, Francois P, Contandriopoulos AP et al (2005) Paradoxes of French accreditation. Qual Saf Health Care 14:51–55
3. Shaw C (2005) Evaluating accreditation. Int J Qual Health Care 15:455–456
4. Halbo L, Lund K, Froystein HA (2005) Quality management education over internet. Accred Qual Assur 10:116–120
5. Vermaercke P (2000) Sense and nonsense of quality assurance in an R+D environment. Accred Qual Assur 5:11–15
6. Mathur-De-Vré R (1997) Approach to quality system in research and development. Accred Qual Assur 2:63–68
7. Minkman M, Ahaus K, Fabbricotti I, Nabitz U, Huijsman R (2009) A quality management model for integrated care: results of a Delphi and Concept Mapping study. Int J Qual Health Care 21:66–75
8. Robins MM, Scarll SJ, Key PE (2006) Quality assurance in research laboratories. Accred Qual Assur 11:214–223
9. Camman K, Kleibohmer W (1997) The need for quality assurance in analytical research and development. Accred Qual Assur 2:262–263
10. Tzavaras T, Kelley ED, Legros S, Massoud R, Bouchet B (2008) The evaluation of quality assurance: developing methods and testing practical methods for managers. Int J Qual Health Care 14(Suppl 1):75–81
11. Jovanovic M (2005) Comparative analysis of laboratory accreditation in Bulgaria, Lithuania, Slovakia and Serbia and Montenegro. Accred Qual Assur 10:125–129
12. Sanchez E, Letona J, Gonzales R, García M, Darpon J, Garay JI (2006) A descriptive study of the implementation of the EFQM excellence model and underlying tools in the Basque Health Service. Int J Qual Health Care 18:58–65
13. Counte M, Meurer S (2001) Issues in the assessment of continuous quality improvement implementation in health care organizations. Int J Qual Health Care 13:197–207
14. Llorens-Montes FJ, Ruiz-Moreno A (2005) Self-implementation of ISO9001:2000 versus external support: an examination in laboratories involved in chemical measurement. Accred Qual Assur 10:304–309
15. Ehrmeyer SS, Laessig RH (2008) Can auditing save us from a quality disaster? Accred Qual Assur 13:139–144
16. Schilling J, Cranovsky R, Straub R (2001) Quality programmes, accreditation and certification in Switzerland. Int J Qual Health Care 13:157–161
17. García-Montoya, Ticó JR, López-Paz S, Aparici M, Miñarro M, Suñé-Negre JM (1997) Implementation of a quality assurance system in a university laboratory of pharmaceutical technology practice. Ind Farm Marzo-Abril 41–46
18. Good Manufacturing Practice (GMP) Guidelines. Eudralex, vol 4. http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/eudralex_en.htm. Accessed June 2009