

# ISO 9001:2008 – A review of the latest edition of the Quality Management System Standard

by John Deavin

## Introduction

**I**SO 9001:2008, a new edition of ISO 9001 quality management system standard, was published on the 14th November 2008. This is the fourth edition of a standard first published in 1987, which has acquired the status of a global benchmark for quality requirements and customer satisfaction in supplier-customer relationships. ISO 9001 is intended for organisations involved in products that result from a process such as hardware, software, services and processed materials. Such organisations are potential suppliers to the pharmaceutical industry.

It is stated in the introduction to ISO 9001:2008 that the quality management system requirements specified in the standard are complementary to requirements for products. Thus for pharmaceutical product manufacture, the requirements of the EU Good Manufacturing Practice Guidelines Chapter 7 on contract manufacture and analysis should be adhered to. Likewise for medical device manufacture, the appropriate standards relevant to medical devices should be observed.

ISO 9001: 2008 contains no new requirements compared to the 2000 edition, which it replaces. However, it does provide clarifications based on experience acquired since 2000 in implementing the standard worldwide. It also introduces changes intended to improve consistency with ISO 14001: 2004, the environmental management system standard.

The ISO committee responsible for the ISO 9000 family of standards is ISO/TC 176 (quality management and quality assurance), which involves expertise from 18 participating countries and 19 international organisations plus other technical committees. The review of ISO 9001 resulting in the 2008 edition was carried out by subcommittee SC 2. The inputs to the review carried out by ISO/TC 176 included a justification study against the criteria of ISO Guide 72:2001, a two-year systematic review of ISO 9001:2000, a worldwide user survey and further data from national surveys and other feedback.

The purpose of this article is to highlight the changes introduced into ISO 9001:2008.

- ★ The new quality management system standard, ISO 9001:2008 clarifies and replaces the 2000 edition
- ★ This review compares the old and new editions

## Implementation Plan and Guidance

ISO and the International Accreditation Forum (IAF) have agreed an implementation plan to ensure a smooth transition of accredited certification to ISO 9001:2008. (Details are available on the ISO web site<sup>1</sup>.)

ISO/TC 176 advises that users will obtain the greatest value by adopting the entire family of standards in an integrated manner.

It is further recommended by ISO/PC 176 that organisations first use ISO 9000 to become familiar with basic concepts before adopting ISO 9001 to achieve a first level of performance. ISO 9004 (Guidelines for performance improvements) practices may then be implemented to make the quality management system more effective and efficient.

ISO 9001:2008 does not introduce additional requirements nor does it change the intent of the ISO 9001:2000 standard.

In order to benefit from the clarifications of ISO 9001:2008, users of the former version will need to consider whether these clarifications have an impact on their current interpretation of ISO 9001:2000, as changes to their Quality Management System(QMS) may be necessary.

Section 1.3 of ICH 10 makes it clear that for pharmaceutical manufacture, regional requirements, the ICH Q7 guidelines, and ISO QMS guidelines (as expressed by ISO 9001:2008) form the foundation for ICH Q10.

To meet the objectives inherent in ICH Q10, ICH Q10 augments GMPs by describing specific quality system elements and management responsibilities.

All user groups are strongly advised to note the joint IAF-ISO communique for implementation of accredited certification to ISO 9001: 2008:

- ★ Accredited certification to ISO 9001: 2008 should only be granted after a routine surveillance or re-certification audit against ISO 9001:2008.
- ★ Validity of certification to ISO 9001:2000. One year after the publication of ISO 9001:2008, all accredited certifications issued (new certifications or re-certifications) shall be to ISO 9001:2008. Two years after publication of ISO 9001:2008, any existing certification issued to ISO 9001:2000 shall not be valid.

★ Other documents based on ISO 9001:2000 are expected to be amended to incorporate the requirements of the revised version. It is likely that the changes to documents, which will include ISO 14001 and ISO/TS16949 (automotive products), will be limited to the changes to ISO 9001. Although there is a no exact alignment between ISO 9001:2008 and ISO 14001, the plan is to achieve as close alignment as possible.

ISO 13485:2003, the standard specific to medical device manufacture, will not be amended to be in line with the new version of ISO 9001:2008, so organisations will have to demonstrate how they conform to the requirements of ISO 9001. It seems that several of the changes in ISO 9001:2008 reflect wording that is present in ISO 13485:2003.

The changes between the versions of the ISO 9001 standard will not affect conformity with the requirements of ISO 13485:2003. (see *Deavin J*<sup>2,3</sup>).

## Key points on the content of the Standard

Comparison between ISO 9001:2000 and ISO 9001:2008

- 0 **Introduction**
- 0.1 **General**  
Statutory requirements are given the same emphasis as customer and regulatory requirements applicable to the product
- 0.4 **Compatibility with other management systems**  
Due consideration is given to the provisions of ISO 14001: 2004
- 1.0 **Scope**  
Statutory requirements are referred to in connection with purchase of product and product realisation
- 2. **Normative references**  
ISO 9000 is now referred to as ISO 9000: 2005
- 3 **Terms and definitions**  
Explanations of customer organisation and supplier are omitted
- 4 **Quality management System**
- 4.1 **General requirements:** In clause (a) 'determine' replaces 'identify' A note of clarification states that processes needed for the QMS include purchase processes as well as product realisation
- 4.2 **Documentation requirements** specify a documented statement of a quality policy and objectives, a quality manual and documented procedures. ISO 9001:2008

specifically requires an organisation to have documented procedures for the following six activities: Control of documents, Control of records, Internal audit, Control of nonconforming product, Corrective action, Preventive action

It would seem that one of the main objectives of ISO 9001:2008 is to allow an organisation some flexibility in the way it chooses to document its quality management system (QMS). It is intended that each individual organisation should be enabled to develop the minimum amount of documentation needed in order to demonstrate effective planning, operation and control of its processes and the implementation of continuing improvement of the effectiveness of its QMS. Documents may be in any form or type of media; the definition of document in ISO 9000:2005 clause 3.7 gives certain examples such as paper, magnetic, electronic or optical computer disc, photograph or master sample

- 4.2.1. A single document may include requirements for more than one procedure and the requirements of one procedure may appear in more than one document
- 4.2.3 Clarification that external documents are identified for the quality management system
- 5.1 Clause (a) the word 'statutory' is added
- 5.5.2 The Management representative, who, irrespective of other responsibilities, shall have responsibility and authority on the performance of the QMS, should be a member of the organisation's management but does not necessarily have to be a full-time employee. A consultant, who is not a member of the organisation's management, cannot be the Management representative
- 6.2 A change in words from 'affecting product quality' to 'affecting conformity to product requirements'
- 6.2.2 Clause (b) the words 'provide training or take other actions to satisfy these needs' is changed to 'where applicable provide training or take other actions to achieve the necessary competence'.  
Clause (c) The emphasis is to ensure competence rather than effectiveness  
Clause (e) The organisation shall maintain appropriate records of education and training skills  
It is up to the organisation to determine how competence is going to be verified. A job description may not be sufficient to

demonstrate competency, as in many instances job descriptions relate to qualification requirements rather than competence. Records for education and skills and experience, in addition to training are needed and should be added to the training record

- 6.3 Clause (c) Information Systems are included
  - 6.4 A new note: noise, temperature, humidity lighting or weather are part of the working environment
  - 7.1 Clause (c) 'Measurement' has been added to the activities
  - 7.2.1 Clause (a) a slight change of words. Clause (c) the word 'applicable' replaces 'related'. Clause (d) has a slight change of words and a note added to explain what is meant by 'post delivery activities'
  - 7.3.1 Note of clarification added stating that design review, verification and validation are separate processes but that they may be conducted together
  - 7.3.3 Note of clarification to indicate production and service can include 'preservation of product'
  - 7.5.3 A requirement is added specifying that product traceability is required throughout product realisation
  - 7.5.4 There is a requirement to inform the customer of any problem regarding his property and a note has been amended to the effect that personal data is also included as customer's property
  - 7.5.5 Change in words from 'conformity of' to 'in order to maintain conformity to requirements'
  - 7.6 A change of words here from 'devices' to 'equipment'. The reference to paragraph 7.2.1 is removed. Clause (c) is changed from 'be identified to enable the' to 'have identification in order to'
- The reference to ISO 10012 is removed (presumably as it is not intended to be used as a prerequisite for demonstrating conformance with ISO 9001). There is an additional note of explanation about when configurations of a computer must be applied when a computer is used for monitoring and measurement processes. This means that a computer that provides any kind of measurement service is considered a monitoring and measuring device
- 8.2.1 A note is added to suggest some means of conducting customer satisfaction evaluation
  - 8.2.2 Requirement for audit evidence and results has been added and management is responsible for ensuring preventive and corrective actions to be taken. The reference to ISO 10011 is changed to ISO 19011 which replaces ISO 10011

- 8.2.3 Change of words. 'To ensure conformity of the product' has been removed and a note of clarification added to the effect that the organisation should determine the type of the monitoring and measuring according to the processes and how this will affect the quality management system
- 8.2.4 Change in wording 'Maintain evidence of conformity with acceptance criteria' has been removed but it is still a requirement
- 8.3 An additional clause (d) specifies how to deal with non-conforming product discovered after delivery

So, in summary, what are the principal new requirements of the ISO 9001:2008?

Statutory requirements are given prominence alongside other regulatory or customer requirements and observance of statutory requirements is required of the suppliers. A purchasing process is just like any other product that the organisation has purchased and must be under the quality management system. It is possible to include two quality processes in one document and to split one process into two documents. The Management representative must be a member of the management team. Training should be suitable for product realisation. Information Systems are now officially considered as a substructure of supporting services within the infrastructure. Parameters such as humidity noise and temperature relating to employee health are considered as working environment. Measurement is considered as one of the activities of product realisation. The product must be identified not only on the shelves but also throughout the product realisation process.

Thus the principal benefits identified for ISO 9001:2008 can be considered as providing clarity, increased compatibility with ISO 14001, maintaining consistency with the ISO 9000 family of standards and improvement in translatability and implementation.

## References

1. www.iso.org ISO Press release 2008-11-14.
2. Deavin J. The quality systems approach to good manufacturing practice in the medical device industry-comparison of ISO 9001:2000 and ISO 13485:2003. *Regulatory Rapporteur* December 2006; 3(12).
3. Deavin J. The quality systems approach to GMP in the medical device industry-comparison of ISO 9001:2000 and ISO 13485:2003. *JD.18.03.09. GMP Review* July 2007; 6(2).

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