
by John Deavin

Introduction

ISO 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.

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 site1.)

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.


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 Q 10 augments GMPs by describing specific quality system elements and management responsibilities. All user groups are strongly advised to note the joint IAF-ISO communiqué 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.
ISO 9001:2008

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 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 2).

Key points on the content of the Standard


- **Introduction**
  - General: Statutory requirements are given the same emphasis as customer and regulatory requirements applicable to the product
  - Compatibility with other management systems: Due consideration is given to the provisions of ISO 14001:2004

- **Scope**
  - Statutory requirements are referred to in connection with purchase of product and product realisation

- **Normative references**
  - ISO 9000 is now referred to as ISO 9000:2005

- **Terms and definitions**
  - Explanations of customer organisation and supplier are omitted

- **Quality management System**
  - 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
  - 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

- **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’

8.2.1 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

8.2.3 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


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