# SLOVENSKI STANDARD
# oSIST prEN ISO 15378:2014

**01-maj-2014**

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**Primarni embalažni materiali za zdravila - Posebne zahteve za uporabo ISO 9001:2008 v povezavi z dobro proizvodno prakso (DPP) (ISO/DIS 15378:2014)**

Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2008, with reference to Good Manufacturing Practice (GMP) (ISO/DIS 15378:2014)



Primärpackmittel für Arzneimittel - Besondere Anforderungen für die Anwendung von ISO 9001:2008 entsprechend der Guten Herstellungspraxis (GMP) (ISO/DIS 15378:2014)



Articles de conditionnement primaire pour médicaments - Exigences particulières pour l'application de l'ISO 9001:2008 prenant en considération les Bonnes Pratiques de Fabrication (BPF) (ISO/DIS 15378:2014)

**Ta slovenski standard je istoveten z:** **prEN ISO 15378**

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**ICS:**

| | | |
|---|---|---|
| 03.120.10 | Vodenje in zagotavljanje kakovosti | Quality management and quality assurance |
| 11.040.01 | Medicinska oprema na splošno | Medical equipment in general |
| 55.040 | Materiali in pripomočki za pakiranje | Packaging materials and accessories |

**oSIST prEN ISO 15378:2014** **en,de**

DRAFT INTERNATIONAL STANDARD

# ISO/DIS 15378

ISO/TC **76**

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# Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2008, with reference to Good Manufacturing Practice (GMP)

*Articles de conditionnement primaire pour médicaments — Exigences particulières pour l'application de l'ISO 9001:2008 prenant en considération les Bonnes Pratiques de Fabrication (BPF)*

[Revision of second edition (ISO 15378:2011)]

ICS: 11.040.01;03.120.10



## ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.



Reference number
ISO/DIS 15378:2014(E)

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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15378 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use.*



This third edition cancels and replaces the second edition (ISO 15378:2011) which has been technically revised.

— by including requirements on risk management and by replacing the former guidance on risk management by references to relevant standards and guidelines;



— by extensively revising the guidance on verification, qualification and validation requirements for primary packaging materials;

— by amending the requirements on infrastructure, work environment, maintenance and cleaning activities, customer communication, control of production and service provision and batch release.

# Introduction

## General

*This International Standard identifies Good Manufacturing Practice (GMP) principles and specifies requirements for a quality management system applicable to primary packaging materials for medicinal products. The realization of GMP principles in production and control of primary packaging materials within organizations is of great importance for the safety of a patient using the medicinal product, because of their direct product contact. The application of GMP for pharmaceutical packaging materials helps ensure that these materials meet the needs and requirements of the pharmaceutical industry.*

*This International Standard is an application standard for primary packaging materials, which contains the normative text of ISO 9001:2008.*

*The conventions for the layout of this International Standard are the following.*

— *Those clauses or subclauses that are quoted directly and unchanged from ISO 9001:2008 are in boxed text.*

— *Texts in italics contain additional relevant GMP information regarding primary packaging materials.*

*GMP terms and definitions are included in Clause 3. If listed, the source is referred to in brackets.*

.**ISO 9001:2008, Quality management systems — Requirements**

## 0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by

a) its organizational environment, changes in that environment, and the risks associated with that environment,

b) its varying needs,

c) its particular objectives,

d) the products it provides,

e) the processes it employs,

f) its size and organizational structure.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.



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212 *A key objective of this International Standard is to define harmonized primary packaging material*
213 *requirements. It includes some particular requirements for primary packaging materials, which are derived*
214 *from Good Manufacturing Practices for the production, control, etc. of medicinal products.*

## 0.2 Process approach

**ISO 9001:2008, Quality management systems — Requirements**

### 0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.



The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

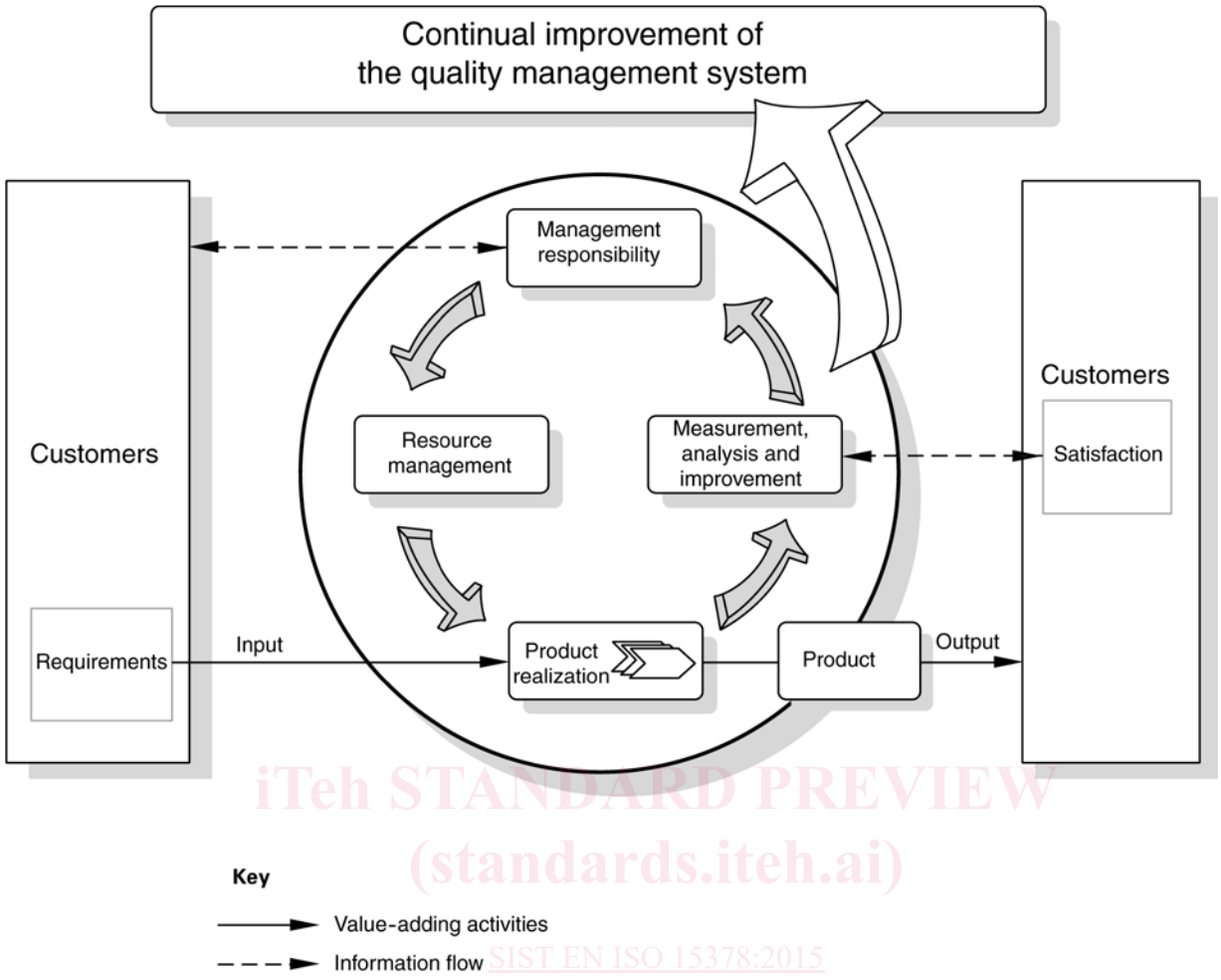




**Figure 1 — Model of a process-based quality management system**

## 0.3 Relationship with ISO 9004

**ISO 9001:2008, Quality management systems — Requirements**

### 0.3 Relationship with ISO 9004

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

## 0.4 Compatibility with other management systems

*This International Standard incorporates the requirements of ISO 9001:2008 and, additionally, particular requirements for primary packaging materials, which are derived and adapted, as appropriate, from Good Manufacturing Practices for the production and control of medicinal products.*

**ISO 9001:2008, Quality management systems — Requirements**

### 0.4 Compatibility with other management systems

During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

NOTE ISO 9001:2008, Annex A is not included in this standard

# Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2008, with reference to Good Manufacturing Practice (GMP)

## 1 Scope

### 1.1 General

*This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide primary packaging materials for medicinal products, which consistently meet customer requirements, including regulatory requirements and International Standards applicable to primary packaging materials.*

*In this International Standard the term "if appropriate" is used several times. When a requirement is qualified by this phrase, it is deemed to be "appropriate" unless the organization can document a justification otherwise.*

**ISO 9001:2008, Quality management systems — Requirements**



**1.1 General**

This International Standard specifies requirements for a quality management system where an organization



a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" only applies to

a) product intended for, or required by, a customer,

b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

### 1.2 *Application*

*This International Standard is an application standard for the design, manufacture and supply of primary packaging materials for medicinal products. It is also applicable for certification purposes.*