
**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)*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2011

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
0.1 General	vi
0.2 Process approach	viii
0.3 Relationship with ISO 9004	x
0.4 Compatibility with other management systems	x
1 Scope	1
1.1 General	1
1.2 Application	1
2 Normative references	2
3 Terms and definitions	2
4 Quality management system	12
4.1 General requirements	12
4.2 Documentation requirements	13
5 Management responsibility	16
5.1 Management commitment	16
5.2 Customer focus	16
5.3 Quality policy	17
5.4 Planning	17
5.5 Responsibility, authority and communication	18
5.6 Management review	19
6 Resource management	20
6.1 Provision of resources	20
6.2 Human resources	20
6.3 Infrastructure	22
6.4 Work environment	22
6.5 Maintenance activities	23
7 Product realization	24
7.1 Planning of product realization	24
7.2 Customer-related processes	25
7.3 Design and development	26
7.4 Purchasing	29
7.5 Production and service provision	31
7.6 Control of monitoring and measuring equipment	36
8 Measurement, analysis and improvement	37
8.1 General	37
8.2 Monitoring and measurement	37
8.3 Control of nonconforming product	40
8.4 Analysis of data	41
8.5 Improvement	41
Annex A (normative) GMP requirements for printed primary packaging materials	43
Annex B (informative) Guidance on verification and validation requirements for primary packaging materials	47
Annex C (informative) Guidance on risk management for primary packaging materials	56

Bibliography63

Index.....65

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 second edition cancels and replaces the first edition (ISO 15378:2006), which has undergone a minor revision to adapt this International Standard to ISO 9001:2008 and update references.

Introduction

0.1 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.

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