INTERNATIONAL STANDARD

ISO 15378

Fourth edition
2017-09

Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)

Articles d'emballage primaire pour médicaments — Exigences particulières pour l'application de l'ISO 9001:2015 prenant en considération les bonnes pratiques de fabrication (BPF)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This fourth edition cancels and replaces the third edition (ISO 15378:2015), which has been technically revised. The main technical and editorial changes comprise:

— the integration of the sector-specific requirements on quality management systems for medicinal products into ISO 9001:2015;

— the deletion of the requirements on quality manual;

— the inclusion of all annexes of ISO 9001:2015 into this document;

— adjustments to the terminology of ISO 9000:2015, where relevant;

— the inclusion of an alphabetical index of defined terms used in this document.

Introduction

0.1 General

This document 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 document is an application standard for primary packaging materials, which contains the text of ISO 9001:2015.

The conventions for the layout of this document are the following.

— Those clauses, subclauses or annexes that are quoted directly and unchanged from ISO 9001:2015 and ISO 9000:2015 (under Clause 3) are in boxes.

— Additional GMP related requirements and recommendations as well as terms and definitions relevant to the manufacture of primary packaging materials are outside boxes.

ISO 9001:2015, Quality management systems — Requirements

0.1 General

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

This International Standard can be used by internal and external parties.

It is not the intent of this International Standard to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this International Standard;

— the use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

A key objective of this document is to specify GMP for primary packaging materials.

0.2 Quality management principles

ISO 9001:2015, Quality management systems — Requirements

0.2 Quality management principles

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

ISO 9001:2015, Quality management systems — Requirements

0.3 Process approach

0.3.1 General

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. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the related risks.

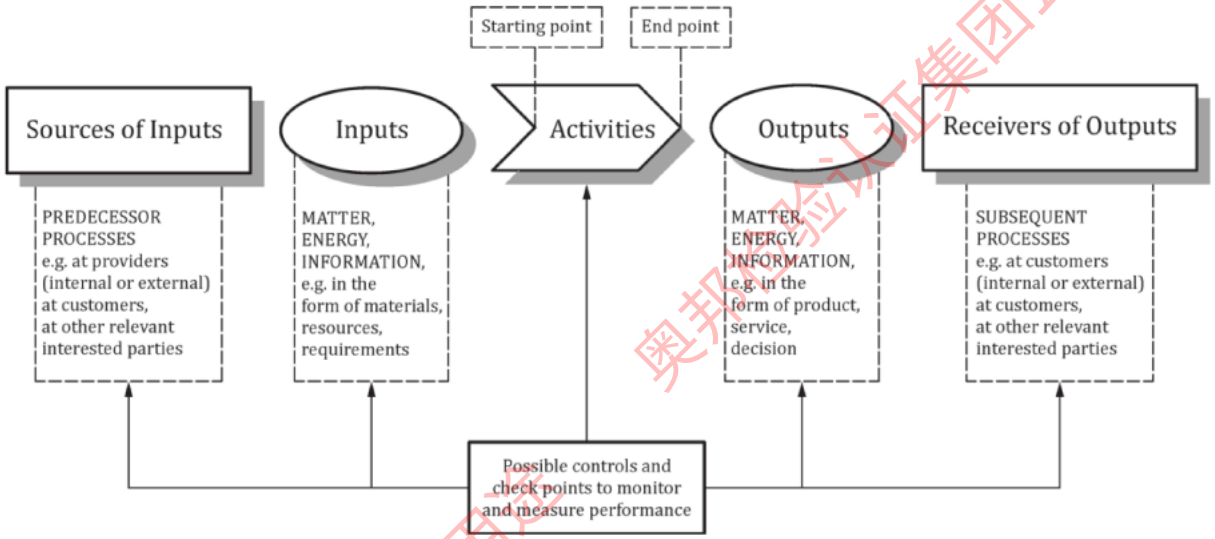


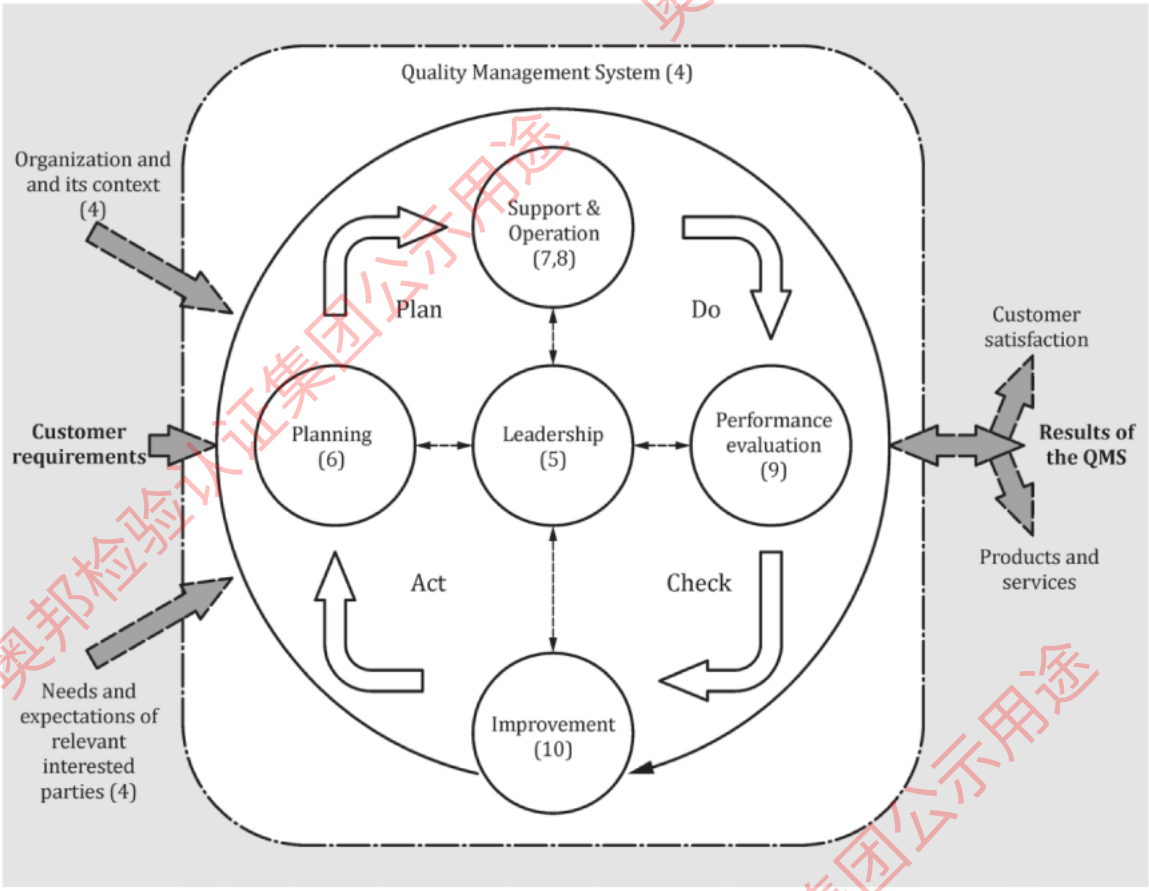
Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

ISO 9001:2015, Quality management systems — Requirements

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.



NOTE Numbers in brackets refer to the clauses in this International Standard.

Figure 2 — Representation of the structure of this International Standard in the PDCA cycle

The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

— **Act**: take actions to improve performance, as necessary.

INTERNATIONAL STANDARD

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前言

ISO（国际标准化组织）是一个由国家标准机构（ISO 成员机构）组成的世界性联合会。编制国际标准的工作通常是通过 ISO 技术委员会进行的。对已设立技术委员会的主题感兴趣的每个成员机构都有权派代表参加该委员会。国际组织，政府和非政府组织，与国际标准化组织联络，也参与这项工作。ISO 与国际电工委员会（IEC）在电工技术标准化的所有问题上密切合作。

ISO/IEC 指令第 1 部分描述了用于编制本国际标准和进一步维护本国际标准的程序。尤其应注意不同类型的 ISO 文件所需的不同批准标准。本国际标准根据 ISO/IEC 指令第 2 部分（见 www.ISO.org/Directives）的编辑规则起草。

请注意，本国际标准的某些要素可能是专利权的主体。ISO 不负责识别任何或所有此类专利权。在编写本国际标准过程中确定的任何专利权的详细情况将在介绍和/或收到的专利声明的 ISO 清单中列出（见 www.ISO.org/patents）。

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关于标准的自愿性、与合格评定有关的 ISO 特定术语和表达的含义，以及关于 ISO 在技术性贸易壁垒（TBT）中遵守世界贸易组织（WTO）原则的信息，见以下网址：www.ISO.org/ISO/forward.html。

本国际标准由 ISO/TC 76 “医用和药用输血、输液和注射及血液处理器具” 专业技术委员会编制。

第四版取消并替换第三版（ISO 15378:2015），该版本已进行了技术修订。主要技术和编辑上的变化包括：

— 将医药产品质量管理体系的行业特定要求纳入 ISO 9001:2015；
— 删除质量手册的要求；
— 将 ISO 9001:2015 的所有附件纳入本文件；
— 对 ISO 9000:2015 术语的相关调整；
— 包含本国际标准中使用的已定义术语的字母索引。

引言

0.1 总则

本国际标准把生产质量管理规范（GMP）原理和质量管理体系规定的要求应用于药品的初包装材料。由于初包装材料与药品直接接触，组织对初包装材料的生产和质量控制中的领会 GMP 原理对于患者使用药品时的安全性具有重要意义。药用包装材料应用 GMP 应能确保这些材料满足制药工业的需求。

本国际标准是一份包含了 ISO 9001:2015 标准内容的初包装材料的应用标准。

本国际标准布局惯例如下：

— 方框内的文字表示直接引用且未经修改的 ISO 9001:2015 和 ISO 9000:2015（根据第 3 条）条款、子条款或附件。

— 方框外的文字表示其他与GMP相关的要求和建议以及与初包装材料制造相关的术语和定义。

ISO 9001:2015,质量管理体系 — 要求

0.1 总则

采用质量管理体系是组织的一项战略决策，能够帮助其提高整体绩效，为推动可持续发展奠定良好基础。

组织根据本国际标准实施质量管理体系的潜在益处：

a) 稳定提供满足顾客要求以及适用的法律法规要求的产品和服务的能力；

b) 促成增强顾客满意的机会；

c) 应对与组织环境和目标相关的风险和机遇；

d) 证实符合规定的质量管理体系要求的能力。

本国际标准可用于内部和外部各方。

实施本国际标准并非需要：

— 统一不同质量管理体系的架构；

— 形成与本国际标准条款结构相一致的文件；

— 在组织内使用本国际标准的特定术语。

本国际标准规定的质量管理体系要求是对产品和服务要求的补充。

本国际标准采用过程方法，该方法结合了“策划-实施-检查-处置”（PDCA）循环和基于风险的思维。

过程方法使组织能够策划其过程及其相互作用。

PDCA 循环使组织能够确保其过程得到充分的资源和管理，确定改进机会并采取行动。

基于风险的思维使得组织能够确定可能导致其过程和质量管理体系偏离策划结果的各种因素，采取预防控制，最大限度地降低不利影响，并最大限度地利用出现的机遇（见附录 A.4）。

在日益复杂的动态环境中持续满足要求，并针对未来需求和期望采取适当行动，这无疑是组织面临的一项挑战。为了实现这一目标，组织可能会发现，除了纠正和持续改进，还有必要采取各种形式的改进，比如突破性变革、创新和重组。

在本国际标准中使用如下助动词：

— “应”表示要求；

— “宜”表示建议；

— “可以”表示允许

— “能”表示可能或能够

“注”是理解和说明有关要求的指南。

本国际标准的主要目的是对初包装材料的 GMP 进行具体说明。

0.2 质量管理原则

ISO 9001:2015,质量管理体系 — 要求

0.2 质量管理原则

本国际标准是在 ISO 9000 所阐述的质量管理原则基础上制定的。每项原则的介绍均包含概述、该原则对组织的重要性的依据，应用该原则的主要益处示例以及应用该原则提高组织绩效的典型措施示例。

质量管理原则：

— 以顾客为关注焦点；
— 领导作用；
— 全员积极参与；
— 过程方法；
— 改进；
— 循证决策；
— 关系管理。

0.3 过程方法

0.3.1 总则

ISO 9001:2015,质量管理体系 — 要求

0.3 过程方法

0.3.1 总则

本国际标准倡导在建立、实施质量管理体系以及提高其有效性时采用过程方法，通过满足顾客要求增强顾客满意。采用过程方法所需考虑的具体要求见 4.4。

将相互关联的过程作为一个体系加以理解和管理，有助于组织有效和高效地实现其预期结果。这方法使组织能够对其体系的过程之间的相互关联和相互依赖的关系进行有效控制，以提高组织整体绩效。

过程方法包括按照组织的质量方针和战略方向，对各过程及其相互作用进行系统的规定和管理，从而实现预期结果。可通过采用 PDCA 循环（见 0.3.2）以及始终基于风险的思维（见 0.3.3）对过程和整个体系进行整体管理，旨在有效利用机遇并防止发生不良结果。

在质量管理体系中应用过程方法能够：

a) 理解并持续满足要求；
b) 从增值的角度考虑过程；
c) 获得有效的过程绩效；
d) 在评价数据和信息的基础上改进过程。

单一过程的各要素及其相互作用如图 1 所示。每一过程均有特定的监视和测量检查点以用于控制，这些检查点根据相关的风险有所不同。

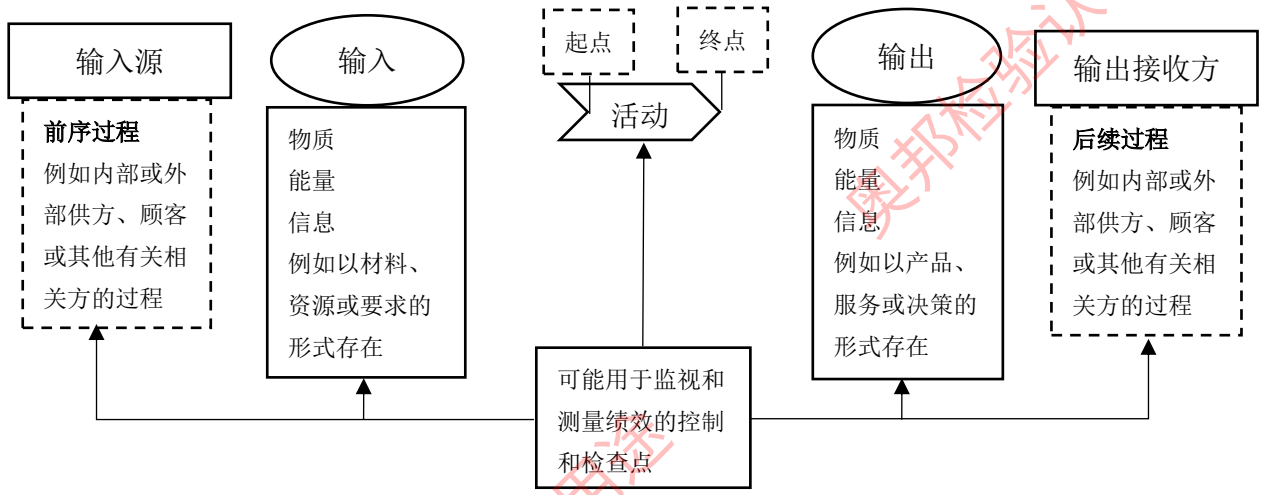


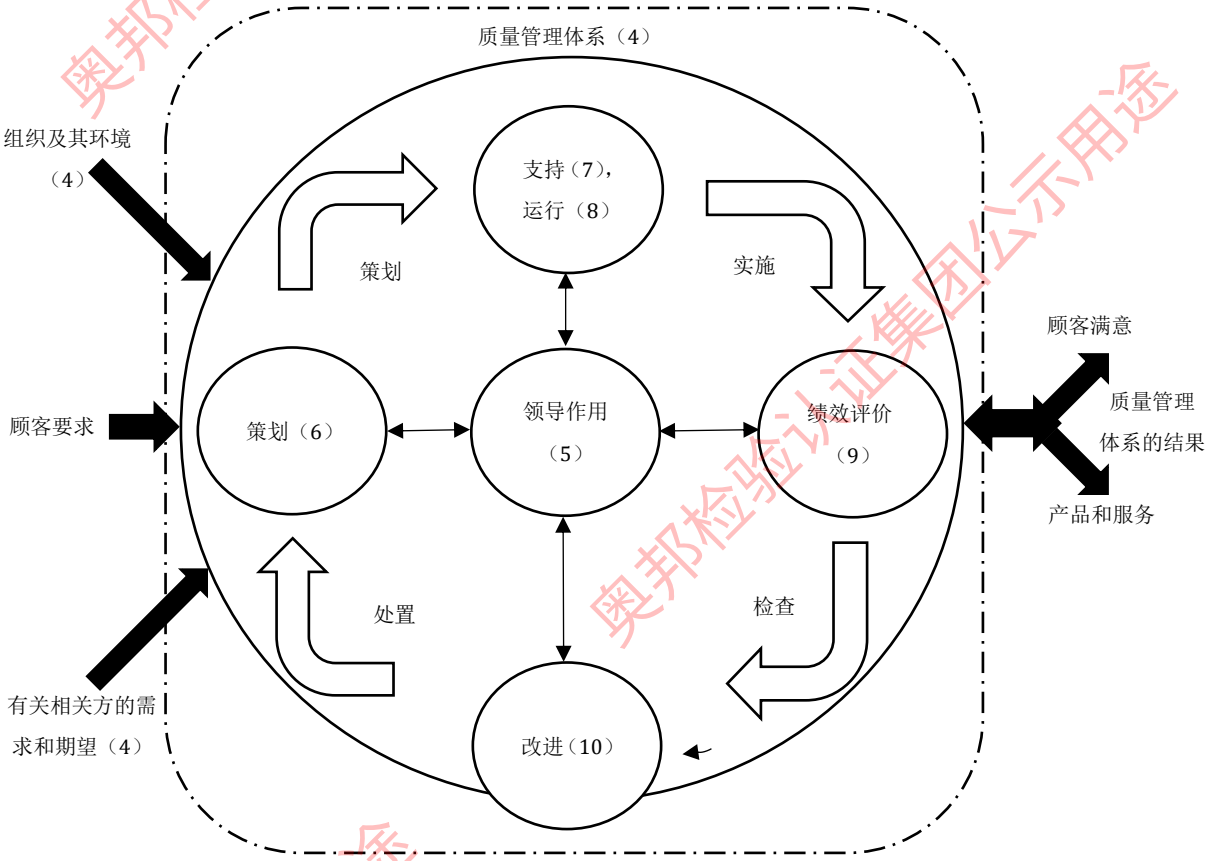
图 1：单一过程要素示意图

0.3.2 “策划-实施-检查-处置”循环

ISO 9001:2015,质量管理体系 — 要求

0.3.2 “策划-实施-检查-处置”循环

PDCA 循环能够应用于所有过程以及整个质量管理体系。图 2 表明了本国际标准第 4 章至第 10 章是如何构成 PDCA 循环的。



注：括号中的数字表示本国际标准的相应章节。

图 2：本国际标准的结构在 PDCA 循环中的展示

PDCA 循环可以简要描述如下：

— **策划**（Plan）：根据顾客的要求和组织的方针，建立体系的目标及其过程、确定实现结果所需的资源，并识别和应对风险和机遇；

— **实施**（Do）：实施所做的策划；

— **检查**（Check）：根据方针、目标、要求和所策划的活动，对过程以及形成的产品和服务进行监视和测量（适用时），并报告结果；

— **处置**（Act）：必要时，采取措施提高绩效。

0.3.3 基于风险的思维

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0.3.3 基于风险的思维

基于风险的思维（见附录 A.4）是实现质量管理体系有效性的基础。本国际标准以前的版本已经隐含基于风险思维的概念，例如：采取预防措施消除潜在的不合格，对发生的不合格进行分析，并采取与不合格的影响相适应的措施，防止其再次发生。

为了满足本国际标准的要求，组织需策划和实施应对风险和机遇的措施。应对风险和机遇，为提高质量管理体系有效性、获得改进结果以及防止不利影响奠定基础。

某些有利于实现预期结果的情况可能导致机遇的出现，例如：有利于组织吸引顾客、开发新产品和服务、减少浪费或提高生产率的一系列情形。利用机遇所采取的措施也可能包括考虑相关风险。风险是不确定性的影响，不确定性可能有正面或负面的影响。风险的正面影响可能提供改进机遇，但并非所有的正面影响均可提供机遇。

由于初包装材料的性质，基于风险的方法应用于组织的所有过程。

0.4 与其他管理体系标准的关系

本国际标准包含了 ISO 9001:2015 的全部要求。此外，还包含了初包装材料的特殊要求，这些要求是从药品生产和控制的 GMP 中衍生出来的，并根据需要进行了调整。

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0.4 与其他管理体系标准的关系

本国际标准采用 ISO 制定的管理体系标准框架，以提高与其他管理体系标准的兼容性（见附录 A.1）。

本国际标准使组织能够使用过程方法，并结合 PDCA 循环和基于风险的思维，将其质量管理体系要求与其他管理体系标准要求进行协调或整合。

本国际标准与 ISO 9000 和 ISO 9004 存在如下关系：

— ISO 9000，*质量管理体系—基础和术语*，为正确理解和实施本国际标准提供必要基础；

— ISO 9004，*追求组织的持续成功—质量管理方法*，为组织选择超出本国际标准要求的质量管理方法提供指南。

附录 B 给出了质量管理和质量保证技术委员会（ISO TC/176）制定的其他质量管理和质量管理体系国际标准的详细信息。

本国际标准不包括针对环境管理、职业健康和安全管理或财务管理等其他管理体系的特定要求。

在本国际标准的基础上，已经制定了若干行业特定要求的质量管理体系标准。其中的某些标准规定了质量管理体系的附加要求，而另一些标准则仅限于提供在特定行业应用本国际标准的指南。

本国际标准的章节内容与之前版本（ISO 9001:2008）章节内容之间的对应关系见 ISO/TC176/SC 2 的公开网站：www.iso.org/tc176/sc02/public。

医药产品用初包装材料——应用ISO 9001:2015的特殊要求及参照生产质量管理规范（GMP）

1 范围

ISO 9001:2015,质量管理体系 — 要求

1 范围

本国际标准为下列组织规定了质量管理体系要求：

a) 需要证实其具有稳定地提供满足顾客要求和适用法律法规要求的产品和服务的能力；

b) 通过体系的有效应用，包括体系改进的过程，以及保证符合顾客和适用的法律法规要求，旨在增强顾客满意。

本国际标准规定的所有要求是通用的，旨在适用于各种类型、不同规模和提供不同产品和服务的组织。

注 1：在本国际标准中，仅适用于预期提供给顾客或顾客所要求的产品和服务；

注 2：法律法规要求可称作为法定要求。

除 ISO 9001 外，本国际标准还规定了适用于初包装材料质量管理体系的生产质量管理规范（GMP）的要求，其中组织需要证明其有能力持续提供满足顾客要求的用于医药产品的初包装材料，包括法规要求和国际标准。

在本国际标准中，“如适用”一词被多次使用。当一项要求被这一短语限定时，除非该组织能够以文件证明正当理由，否则该要求被视为“适用”。

本国际标准是药品初包装材料设计、制造和供应的应用标准。

2 规范性引用文件

ISO 9001:2015,质量管理体系 — 要求

2 规范性引用文件

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件，仅注日期的版本适用于本文件。凡是不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

ISO 9000:2015，*质量管理体系—基础和术语*

以下文件在正文中的部分或全部内容引用构成本文件的要求。凡是注日期的引用文件，仅引用版本适用。凡是不注日期的引用文件。其最新版本（包括任何修订内容）适用于本部分。

ISO 14698-1,*洁净室及相关相关控制环境—生物污染控制—第 1 部分：总则和方法*

ISO 14698-2,*洁净室及相关相关控制环境—生物污染控制—第 2 部分：生物污染数据的评价与解释*

如需获取全文，请联系奥邦检验认证集团客户服务部门：

1）通过邮件提出申请。请发送到邮箱：**17312273399@163.com**

2）也可通过客服电话咨询 **025-85307007**。