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Implementation guidances for knowledge management - Part 2: Pharmaceutical industry

知识管理实施指南 第2部分：制药

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Table of Contents

Preface III
Introduction IV
1 Scope 1
2 Normative references 1
3 Terms and Definitions 1
4 Organizational Environment 2
4.1 Understanding the organization and its internal and external environment 2
4.2 Understanding the needs and expectations of stakeholders 3
4.3 Determine the scope of the knowledge management system 3
4.4 Knowledge Management System 3
5 Leadership 3
5.1 Management Commitment 3
5.2 Developing a knowledge policy 4
5.3 Roles, responsibilities and authorities 4
6 Planning 4
6.1 Measures to address risks and opportunities 4
6.2 Knowledge Objectives and Plans 5
7 Support 5
7.1 Resources 5
7.2 Capabilities 7
7.3 Consciousness 7
7.4 Communication 8
7.5 Documented information 8
7.6 Document Information Management and Control 8
8 Run 8
8.1 Operational Planning and Control 8
8.2 Product R&D 8
8.3 Commercial production 9
8.4 Marketing 9
8.5 Operational Guarantee 9
9 Performance Evaluation 10
9.1 Monitoring and Evaluation 10

9.2 Internal Audit 10
9.3 Management Review 10
10 Improvement 11
10.1 Non-conformity control and corrective actions 11
10.2 Continuous Improvement11 12
Appendix A (Informative) Knowledge Maintenance and Knowledge Base Classification .. 12
Reference 13

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is Part 2 of GB/T 44651 "Guidelines for the Implementation of Knowledge Management". GB/T 44651 has been published in the following parts.

- Part 1: Equipment manufacturing industry;

- Part 2: Pharmaceuticals;

- Part 3: Electricity.

Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents.

This document is submitted by the State Intellectual Property Office.

This document is under the jurisdiction of the National Technical Committee for Standardization of Knowledge Management (SAC/TC554).

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0.1 Overview

The pharmaceutical industry is a strategic industry that is related to the national economy

and people's livelihood, economic development and national security, and is an important foundation for the construction of a healthy China.

R&D innovation is difficult, has a long cycle, high investment, and is knowledge-intensive. It is a typical high-tech industry. Knowledge management in the pharmaceutical industry runs through the pharmaceutical industry.

The pharmaceutical industry directly affects the development of life and health.

In order to promote the high-quality development of the pharmaceutical industry based on innovation, pharmaceutical companies It is necessary to implement knowledge management and plan and manage relevant knowledge resources and knowledge activities. ICHQ10 clearly states that pharmaceutical companies' knowledge Knowledge management is one of the driving forces behind the development of an enterprise's quality system. As a special commodity, medicines are closely related to people's life and health.

The life cycle is long, including the process of drug research and development, registration evaluation, marketing, re-evaluation, and delisting.

The knowledge management level of production, operation, circulation and other links is closely related to the quality of drugs.

Develop and utilize the data and experience in the process, fully explore and discover knowledge, guide production and operation, assist decision-making, and promote organizational structure and business Optimize processes, improve management systems, and promote enterprise transformation, transformation and upgrading.

0.2 Process Approach

This document aims to promote technological innovation and value creation in the pharmaceutical industry.

Part 1: Under the guidance of the Guidelines, the ideas and methods for pharmaceutical companies to carry out knowledge management work are proposed, in product research and development, commercial production, market In each link of marketing, operation guarantee, etc., we plan and manage the activities of knowledge identification, creation, acquisition, storage, sharing, and application, and comprehensively Use emerging knowledge management technologies to spread the pursuit of continuous improvement and innovation awareness within the organization, and promote the organization's innovation capabilities and Improved competitiveness.

GB/T 44651 "Guidelines for the Implementation of Knowledge Management" aims to provide guidance for the implementation of knowledge management systems in different industries.

It consists of the following parts.

- Part 1: Equipment manufacturing industry. The purpose is to provide a general framework, methods and construction guidelines for knowledge management in the manufacturing industry.

- Part 2: Pharmaceuticals. Aims to provide a general framework, methods and construction guidelines for knowledge management in the pharmaceutical industry.

- Part 3: Electricity. The purpose is to provide a general framework, methods and construction guidelines for knowledge management in the power industry.

Knowledge Management Implementation Guide Part 2: Pharmaceuticals

1 Scope

This document provides information on leadership, planning, support, operation, performance evaluation and improvement in the process of knowledge management in pharmaceutical companies. implementation guide.

This document is applicable to the planning, establishment and evaluation of knowledge management systems in pharmaceutical companies, and can be used as a reference for other types of organizations.

2 Normative references

GB/T 19000-2016

GB/T 23703.2-2010

GB/T 34061.1-2017

3 Terms and Definitions

The terms and definitions defined in GB/T 19000-2016, GB/T 23703.2-2010 and GB/T 34061.1-2017 and the following terms and definitions apply For use in this document.

3.1 knowledge

Knowledge, judgment or skills acquired through learning, practice or exploration.

[Source. GB/T 23703.2-2010, 2.1]

3.2 knowledge management

Activities for planning and managing knowledge, the knowledge creation process and the application of knowledge.

[Source. GB/T 23703.2-2010, 2.9]