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**Course development guide for education about standardization
- Pharmacy standardization**

标准化教育课程建设指南 药学标准化

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Table of Contents

- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 General Principles of Course Design
 - 4.1 Overall Process of Course Development
 - 4.2 Course Needs Survey
- 5 Course Content
- 6 Course Implementation
- 7 Course Effectiveness Evaluation

Foreword

This document is a standard or guiding technical document. This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed and is under the jurisdiction of the National Standardization Education Standardization Working Group (SAC/SWG27). This document was drafted by: Shenzhen Institute for Drug Control, Shenzhen Polytechnic, Shenzhen Technology University, and Shenzhen Institute of Standards and Technology. Institute, Shenyang Pharmaceutical University, Shenzhen Life Science Industry-University-Research-Funding Alliance, Nantong University of Science and Technology, Qiqihar University, Liaoning He's Medical College, Hebei Universities, Zhongke Health Industry Group Co., Ltd., Fuwai Hospital of Chinese Academy of Medical Sciences, Lanzhou University, South-Central University for Nationalities, Shenzhen Landmark Standardization Association. The main drafters of this document are. Wang Bing, Liu Ran, Du Jiating, Li Qing, Wang Xiaowei, Wang Ke, Wang Tiejie, Xu Huarong, Yin Guo, Li Wenli, and Yan Yan. Xu Ziqu, Guo Yaping, Li Taosha, Zhang Cailing, Li Ming, Yu Tianfei, Guo Yan, Jiang Shan, Liu Zhenghao, Zhou Yajie, Yan Xinxin, Yang Lijuan, Li Xiaojun Dan Dan, Wei Mei, and Lin Suling.

The biopharmaceutical industry has always been a vital sector related to national welfare and people's livelihoods. my country will continue to solidify its people-centered Healthy China goal. The goal is to leverage the domestic and international dual circulation development pattern to promote the transformation of industries from large-scale to

high-quality development. With the accelerated construction of a "quality-strong nation," this is particularly important in the industrial sector. During the upgrading and transformation process, the demand for pharmaceutical industry professionals with both quality-oriented thinking and standardization awareness has surged. In light of this, the development of standardized pharmaceutical courses is crucial. Establishing, popularizing, and promoting standardized practices can significantly shorten the training cycle for employees in enterprises; while the training of standardized pharmaceutical professionals can greatly enhance enterprises' alignment with international standards. ability. This document aims to implement the requirements of the "National Standardization Development Outline," standardize the content and methods of standardized pharmaceutical courses, and improve pharmaceutical education. The quality and efficiency of standardized talent training provide a continuous source of power for the sustainable development of the national biopharmaceutical industry. This document aims to provide specific guidance for the development of standardized pharmacy courses in general higher education, clarifying the course's positioning and teaching... Learning Objectives. Implementing this document will help popularize standardization knowledge and enhance learners' standardization awareness and practical skills. At the same time, this document also... This can provide a reference for the development of standardized general education courses in vocational education and continuing education, thereby expanding the scale of the standardized talent pool in pharmacy. Coverage. This initiative will help cultivate professionals with an international perspective who can work in the fields of drug research and development, production, quality inspection, regulation, and distribution. Talented individuals with a strong sense of professionalism and standardization will provide powerful support for my country's implementation of its standardization strategy and the promotion of high-quality economic development, as well as for the development of my country's biopharmaceutical industry. Contribute to the high-quality development of the industry. Guidelines for the Development of Standardized Educational Curriculum in Pharmacy

1 Scope

This document gives guidance on building a course on pharmacy standardization: the pharmacopoeia, the quality standards that govern a medicinal product and its excipients, and the way analytical methods are validated and monographs are written. Pharmacy is the field where standardization has the shortest distance to a patient. A monograph is not a recommendation - it is the definition of what the substance in the bottle has to be, and the analytical method beside it is the only thing that makes the definition checkable. At 23 000 words this is one of the most substantial of the education guides, because that ground cannot be covered briefly. Issued on 3 December 2025 by SAMR and SAC as a guiding technical document, in force from the same day, under the technical jurisdiction of the Standardization Administration of China.

This document provides information on curriculum design, content, implementation,

effectiveness evaluation, and quality assurance systems for the development of standardized pharmacy courses. The document provides guidance on aspects such as teaching methods and offers examples of teaching plans. This document applies to the design of standardized pharmaceutical courses and the assessment of course effectiveness.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 20000.1 Guidelines for Standardization Work - Part

3 Terms and Definitions

The terms and definitions defined in GB/T 20000.1 and GB/T 43294, as well as the following terms and definitions, apply to this document.

3.1 In order to achieve optimal order in pharmaceutical-related fields, provisions for common and repeated use should be established to address existing or potential problems. Activity.

Note. The above activities mainly include the process of developing, publishing and implementing standards applied to pharmaceutical practice and other aspects.

4.1 Overall Process of Course Development

4.1.1 Establish a standardized knowledge course development team.

4.1.2 Based on the teaching objectives, determine the standardized knowledge points and skill requirements, and determine the teaching content and teaching methods.

4.1.3 Determine teaching resources. faculty, textbooks/reference books/lecture notes/courseware, case studies, teaching aids, infrastructure, corporate resources, and standard data. Source, software.

4.1.4 Determine the teaching syllabus.

4.2 Course Needs Survey

4.2.1 It is advisable to conduct thorough research, forecasting, and feasibility studies on industry talent needs.

4.2.2 It is advisable to update the standards in a timely manner based on scientific

evaluation, taking into account the needs of national and regional economic and social development, especially the needs of industry development. For new and effective implementation, it is necessary to focus on industry needs and develop reasonable course content based on survey results and the actual career development issues of graduates.

4.3 Course Objectives The elements that should be considered in course objectives include, but are not limited to, the following.

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