

Exploration and Practice of Teaching Reform in Pharmaceutical Regulation Courses Based on OBE-CDIO Background

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Abstract: In response to the problems in practical teaching of pharmaceutical regulation courses, with the goal of cultivating students' abilities and comprehensive qualities at different levels, this paper explores the construction of a practical teaching system for pharmaceutical regulation courses under the OBE-CDIO concept. This paper conducts comprehensive curriculum reform research from three aspects: course content, teaching mode, and evaluation method, in order to cultivate professional and composite regulatory talents with a solid foundation in pharmaceutical law, familiarity with domestic and foreign medical and health policies and laws, and proficiency in the full life cycle regulatory operation of drugs.

Keywords: OBE; CDIO; Pharmaceutical regulations; Teaching reform

1. Introduction

Pharmaceutical regulation courses are compulsory for students majoring in pharmacy, which intersects and permeates with disciplines such as pharmacy, sociology, law, economics, management, and behavioral science. It covers the entire life cycle of pharmaceuticals, including drug development, production, distribution, use, pricing, advertising, information, and intellectual property management. The objective of the pharmaceutical regulation courses is to cultivate innovative professionals who are familiar with the current status of the biomedical industry, possess an international perspective, and can comprehensively apply interdisciplinary theories and methods to analyze social issues related to medicine. With the comprehensive advancement of the Healthy China strategy, both the industry and society have continuously raised the requirements for students' comprehensive abilities in applying pharmaceutical regulations theory to analyze and solve practical problems, posing new challenges to the teaching of pharmaceutical regulations courses.

In recent years, the internationalization of higher education has shown a comprehensive, multi-level, and wide-ranging development trend. China's higher education reform not only needs to absorb advanced educational and academic experience from foreign countries but also needs to benchmark China's national strategic needs and demonstrate its own characteristics. In 1981, American scholar Spady proposed the concept of Outcomes-Based Education (OBE), which is considered the correct direction for pursuing excellence in education and teaching. This concept is a goal-oriented approach that places students at the center and adopts a reverse thinking method for curriculum system construction. Compared with traditional higher education concepts, the OBE concept emphasizes value orientation based on outcomes/achievements, student-centered educational philosophy, and a culture of continuous improvement, aiming to shift from a teacher-centered approach to a student-centered approach and from a knowledge-based focus to the goal of achieving competencies^[1]. Currently, the OBE concept has been widely applied in curriculum design and assessment in China's education curriculum reform.

The CDIO (Conceive-Design-Implement-Operate) concept is an educational model jointly proposed by the Massachusetts Institute of Technology (MIT) in the United States and several universities in Sweden. Its core is an educational philosophy that manages the conception, design, implementation, and

operation of processes and systems throughout their life cycle. Based on the CDIO syllabus and standards, it guides students to learn actively and practically, applying theoretical knowledge to practice, thereby cultivating their practical abilities, innovation capabilities, and teamwork skills^[2].

In order to comply with the strategic thinking of putting people's health at the center and implementing the Healthy China strategy, the reform of pharmaceutical regulation courses needs to shift from a focus on knowledge to integrating theory and practice, comprehensively using modern information technology, and emphasizing student-centered education to cultivate students' comprehensive abilities in "learning through doing, doing while learning, and reflecting during doing." In order to further reform the teaching system of pharmaceutical regulation courses, improve the quality of teaching, and cultivate comprehensive and innovative talents, this paper will integrate the OBE and CDIO concepts to further study and construct a pharmaceutical regulation curriculum system that conforms to educational laws, reflects the characteristics of the times, and has Chinese characteristics.

2. Current situation and problems of teaching pharmacy regulations course

2.1 Complex content of regulatory provisions

The pharmaceutical regulation course is an emerging interdisciplinary subject between pharmacy and law, which primarily applies principles and methods from social sciences to study the basic rules of various activities in modern pharmaceutical industry. The course covers a large number of legal documents and provisions, which are diverse and complex. Legal knowledge can be obscure and difficult to understand, posing significant challenges for students^[3].

2.2 Weak understanding of pharmaceutical regulations among students

The pharmaceutical regulation course is a core course offered in pharmacy programs at various medical and pharmaceutical institutions, whose target students may be less familiar with learning methods used in humanities and social sciences. Consequently, studying this course, which leans towards literature and management, can be challenging. Additionally, complex and dry regulatory provisions often results in students' low motivation for active learning and poor classroom teaching effectiveness^[4].

2.3 Outdated teaching methods and singular approach

Currently, pharmaceutical regulation course teaching primarily relies on a confirmatory teaching approach. Teachers deliver lectures based on the syllabus and textbook content, with some course materials limited to the textbook itself. With numerous and scattered knowledge points, the lack of effective interaction during the teaching and learning process fails to stimulate students' interest in professional practice, enthusiasm for learning, and creativity.

3. The construction content of pharmaceutical regulation courses based on OBE-CDIO concept

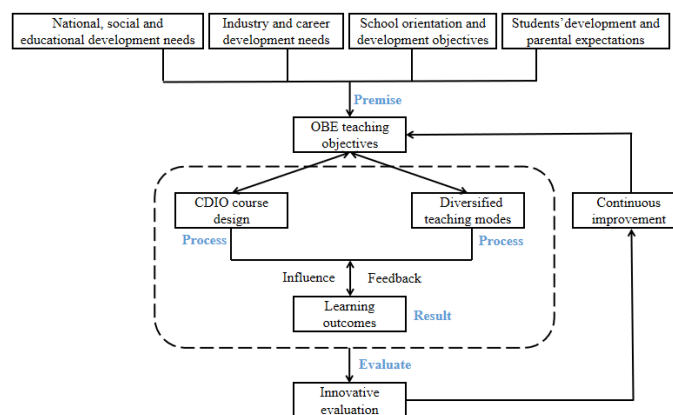


Figure 1: Construction of pharmaceutical regulation courses based on OBE-CDIO concept

This article proposes applying the outcome-based education (OBE) concept, and the CDIO concept, which uses projects as a means of education, to the teaching system of pharmaceutical regulations courses. The overall approach focuses on student-centered learning, with the goal of achieving future career development competencies. It introduces diversified teaching modes and establishes an innovative assessment and evaluation system. Based on competency objectives, the teaching practice process and learning outcomes are evaluated and continuously improved, thus constructing a curriculum and teaching system based on the OBE-CDIO concept (see Figure 1).

3.1 Positioning the teaching objectives of pharmacy regulation course based on OBE-CDIO concept

To construct the teaching system of the pharmaceutical regulation course based on the OBE-CDIO philosophy, it is necessary to shift from discipline-based education to goal-based education, Emphasizing the systematic cultivation of knowledge, capability, and quality (see Table 1). The objective is to enable students to not only master the fundamental theories of pharmaceutical regulations but also possess the ability to solve legal and policy issues in pharmaceutical activities. Additionally, they should develop a sense of rule of law, responsibility for people's health, and a service-oriented mindset in pharmacy.

Table 1: Teaching objectives of pharmaceutical regulation courses

Training Objectives	Specific description
Knowledge	<ul style="list-style-type: none"> ✓ Understand the basic laws of pharmacy activities, drug regulatory system and organizational structure ✓ Master the basic knowledge and skills of pharmacy management ✓ Familiarity with the regulatory legal system, regulations and their development in all aspects of pharmacy practice
Capabilities	<ul style="list-style-type: none"> ✓ Establish a legal foundation and mindset around Chinese pharmaceutical regulations with the framework of the Civil Code, Criminal Law and Administrative Law ✓ Obtain timely information on the dynamics of related regulations, and independently study, reflect and apply relevant regulations and policies ✓ Analyze laws and policies related to drug registration, manufacturing and distribution to solve practical problems ✓ Improve and innovate medical management policies and regulations
Quality	<ul style="list-style-type: none"> ✓ Establish the awareness of the rule of law, the awareness of responsibility and service for the people's health, and cultivate the pharmacy literacy of respecting life and being benevolent ✓ Cultivate high pharmacy professional ethics, protect the legal rights of drug users, and respect patient privacy ✓ Cultivate students' sense of social responsibility and scientific spirit to ensure the safety of people's medication

3.2 Constructing the content of pharmaceutical regulations course under the OBE-CDIO philosophy

The CDIO teaching model is characterized by a practice-oriented approach, emphasizing the cultivation of students' practical and innovative abilities. Based on the integration of CDIO educational model theory (syllabus and standards) with the pharmaceutical regulation courses, the teaching content standards are set as higher-order, innovation, and challenge. These standards are achieved through three aspects: ideological and political education, project practice, and course difficulty, making the teaching of pharmaceutical regulations course systematic, scientific, advanced, and effective.

3.2.1 Integrating ideological and political elements into the course syllabus—higher order

In the pharmaceutical regulation courses, ideological and political education should be integrated from a macro perspective to micro implementation. From a macro perspective, it is important to focus on the overall development goals of building a healthy China. From a micro perspective, efforts should be made to identify 1-2 ideological and political points in each chapter of the course (see Table 2). Using the knowledge points as carriers, teachers could adopt methods such as case-based teaching, thematic embedding, and implicit penetration. These approaches allow the infusion of patriotic sentiments, social responsibility, socialist core values, scientific spirit, and ways of thinking into the classroom, thereby achieving the goal of combining moral education and talent cultivation in curriculum-based ideological and political education^[5].

Table 2: Teaching examples of pharmaceutical regulations and thinking

Ideological and political education in courses	Typical examples	Corresponding knowledge and training points
Not forgetting the original intention Remembering the mission	The originality, mission and responsibility of pharmacists --Make valuable medicines for the people	Definition of drugs, the Definition of quality
	Grasp the times of drug regulation --Keeping the bottom line, chasing the high line	The process of change of drug regulatory system
	Revitalization of Chinese industry, clear responsibility and commitment --Zebutinib: Behind the birth of a new Chinese anti-cancer drug	Registration process for new drugs
Establishing moral values and educating people Enhancing legal awareness	Do what I write, write what I do, and know what I do --Clinical trial self-checking verification	Clinical study requirements, data management requirements
	Laws to follow, law enforcement must be strict, illegal will be punished --Changchun Changsheng Vaccine Incident	The meaning of legal responsibility in pharmacy
Building a Community of Human Destiny	China's speed in the development and launch of new Chinese crown drugs --From a pill to "Made in China"	Expedited marketing procedures for new drugs, the International drug registration knowledge
	Explore the connotation of innovation, coordination, openness and sharing --Chinese pharmacovigilance joins ICH	Introduction and role of ICH

3.2.2 Reflecting cutting-edge and contemporary aspects - innovation

The course content should reflect cutting-edge and contemporary aspects by incorporating the latest academic research findings in a timely manner, aligned with the development of the pharmaceutical industry. For instance, topics of general concern such as online drug sales and segmented drug production can be selected (see Table 3). Teachers could organize students to engage in inquiry-based learning, encompassing activities such as data collection, literature review, expert interviews, and project completion. Through the application of existing knowledge, students keep abreast of the academic frontier, tackle real-time problems and challenges in the pharmaceutical industry's development, and progressively develop practical skills and the ability to explore the cutting-edge of pharmaceutical advancements (see Figure 2).

Table 3: Frontier projects related to pharmaceutical regulations

Projects	Proposed Research Questions
Analysis of the difficulties and countermeasures of the new mode of drug network sales supervision	<ul style="list-style-type: none"> ✓ What is drug network sales ✓ What is the difference between the management of drug network sales and traditional drug sales ✓ What are the risk points of drug network sales ✓ How to apply the risks of drug network sales
Research on drug segment production supervision policy under the drug marketing license holder system	<ul style="list-style-type: none"> ✓ Management requirements for drug production ✓ The management requirements of the entrusted production of drugs ✓ The management requirements for the entrusted segmented production of drugs ✓ How to control the technical risks and management risks of segmented production

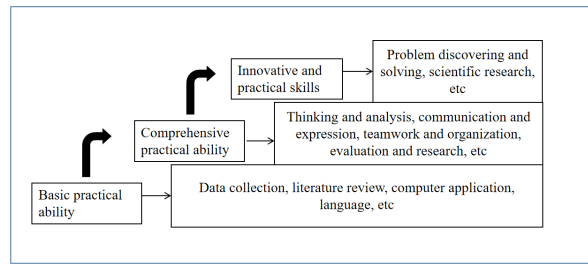


Figure 2: Practical competencies achieved by project-led courses

3.2.3 Increasing the difficulty of course content - challenge

In recent years, China has witnessed frequent adjustments in pharmaceutical-related policies and regulations. These reforms, including the encouragement of innovation and increased regulation at all stages, have had a significant impact on the industry's development. To meet the demands of industry and professional development, it is essential to ensure that the teaching content of pharmaceutical regulations courses remains synchronized with the practical activities in China. Teachers should adequately prepare the course content and regularly update it by incorporating the latest laws, regulations, policies, and relevant cases (such as the movie "Dying to Survive"). Additionally, the course design should incorporate research-oriented, innovative, and comprehensive elements. The learning outcomes of the course content should be demonstrated through activities such as seminars, research papers, and presentations, encouraging greater student engagement and involvement. By scientifically increasing the workload, students can experience learning challenges that require effort and perseverance.

3.3 Introducing diversified teaching models with OBE-CDIO

3.3.1 Blended online and offline teaching model

The "online + offline" blended teaching model combines the advantages of online and traditional teaching methods, which is conducive to implementing the OBE educational concept. It enhances student engagement, improves their interest and motivation to learn, and guides their learning towards greater depth. It also expands students' ability to integrate knowledge and think critically^[6]. In this teaching model, students are always the main participants and teachers formulate the teaching objectives and contents of each class according to students' learning needs.

Utilizing the advantages of the Internet, teachers and students can jointly create high-quality online courses on pharmaceutical regulations. Leveraging the excellent open educational resources related to pharmaceutical regulations provided by China Pharmaceutical University, such as ECLASS for pharmaceutical regulations and MOOC resources, teachers can publish the weekly learning content on the online platform. Prior to the class, students can preview and study the fundamental teaching knowledge through online instructional videos, complete online assignments, and participate in discussions assigned by the teacher. By analyzing the data from the online platform, teachers can assess students' learning outcomes and adjust the content and pace of teaching accordingly. Teachers can also strengthen online interaction and communication with students through the online course platform, addressing any questions or clarifications regarding students' learning process^[7].

During offline classes, based on students' online learning progress, teachers can design complementary knowledge points and content to be covered in class. Additionally, through various teaching methods such as problem-driven approaches, group discussions, and case analyses, teachers should emphasize the connection between theory and practice. This approach could enhance students' ability to analyze and solve problems, stimulates their learning interest, and strengthens their comprehensive application skills.

3.3.2 Integration ideological and political education with case studies

In May 2020, China's Ministry of Education issued the Guidance Outline for the Ideological and Political Construction of Curriculum in Higher Education Institutions (hereinafter referred to as "the Outline"), which emphasizes the integration of ideological and political education throughout the entire process of classroom teaching. It should be implemented in various aspects such as curriculum objective design, syllabus revision, textbook selection, and teaching plan, permeating through classroom teaching, teaching discussions, laboratory training, and assignments and papers^[8].

The case study method can change the traditional teaching approach, stimulate students' interest in

learning and promote active learning. It is important not only to impart knowledge to students but also to stimulate their initiative in learning, enabling them to not only acquire knowledge but also learn how to acquire knowledge, fully engaging their thinking and learning interests^[9]. Through the discussion of current hot topics and cases, students could gain a comprehensive understanding of the basic content, principles, and methods of management activities in pharmaceutical practices.

3.3.3 Developing a “Second Classroom” dual-innovation education model

In recent years, innovative entrepreneurship education has been implemented in universities across the country as a new talent development model. The goal of dual-innovation education is no longer limited to cultivating innovative talents but also focuses on the long-term effects of talent development.

The “second classroom” is an important platform for universities to cultivate students’ comprehensive qualities. It guides students in targeted practical activities based on real-world experience, complementing the primary classroom. Through the “second classroom”, students are encouraged to actively participate in extracurricular practical activities. It provides a stage for students’ personalized development and enhances their practical abilities, expanding the time and space dimensions of dual-innovation education. Furthermore, the “second classroom” is characterized by its diversity, flexibility, autonomy, and interactivity, catering to the psychological needs of college students. It greatly stimulates students’ enthusiasm for innovation and entrepreneurship, transforming them from passive participants to active contributors^[10].

3.4 Innovative evaluation and assessment methods guided by the OBE-CDIO concept

Traditional teaching evaluation methods often focus on the final exam scores, neglecting students’ progress, motivation, and learning values. Based on the OBE-CDIO, teachers should adopt a diversified assessment approach that evaluates students’ learning outcomes from various aspects, including knowledge level, skill level, and comprehensive qualities. Moreover, reasonable assessments should be conducted to evaluate students’ basic design abilities, comprehensive design abilities, and innovative design abilities. The discrepancies between students’ expected learning goals and actual learning results should be analyzed, thus guiding students to develop a more autonomous and proactive learning attitude.

The final evaluation results can be divided into comprehensive process assessment and end-of-term assessment (see Table 4). The process assessment includes learning attitudes, task quality, and incentive assessment. Learning attitudes include each member’s role in the group, task participation, and assessment of teamwork. Task quality is evaluated through a combination of teacher evaluation, peer assessment within the learning group, and student self-assessment. Additionally, to differentiate students’ learning levels, extracurricular extension tasks of different difficulty levels can be designed for students to choose autonomously. Upon completion, corresponding motivation assessment scores can be obtained, encouraging students with different ability levels to achieve the final learning results through different pathways and methods^[11].

Table 4: Course evaluation assessment methods and content

Evaluation results	Classification	Assessment content	Percentage of Achievement (%)
Process assessment	Learning Attitude	Attendance, class performance, pre-reading, completion of pre-class discussion questions, group division and completion	10%
	Task Quality	Students’ performance in conducting task-based reports, and their ability to access information and express themselves.	20%
	Incentive assessment	Extracurricular tasks with different levels of difficulty	10%
End-of-term evaluation	Final Exam Results	Students’ mastery of the basic knowledge	60%

4. Suggestions for the continuous reform of pharmaceutical regulations course teaching

4.1 Enhance communication and adjust teaching methods in a timely manner during the teaching process

During the teaching process, teachers should persist in continuous improvement, adopt suggestions

from identified issues and students' recommendations to ensure the continuous optimization and improvement of the entire process of academic evaluation, as well as the accuracy and fairness of the evaluation results. When problems are identified, timely assistance and guidance should be provided, and teaching methods can be adjusted based on students' learning situations.

4.2 Establish a continuous improvement QC group to summarize reform results in time

As the main responsible party for the quality of course teaching, teachers should combine the improvement of students and continuously improve the teaching objectives. A Quality Control (QC) team for continuous course improvement can be established, with specific arrangements made by the curriculum group or teaching and research office, including team leader and members. After achieving results in the pharmaceutical regulation courses, timely summaries should be made, and relevant materials should be properly organized and reported. Through a team format, the "normal teaching and research" of the pharmaceutical regulation courses teaching quality construction can be achieved.

5. Conclusion

With technological progress, the pharmaceutical industry has gradually raised the requirements for talent competence. Cultivating pharmaceutical professionals with innovative design abilities and comprehensive qualities has become the focus of talent development in pharmaceutical colleges. To address the issues in traditional teaching of pharmaceutical regulations courses, a practical teaching system for the pharmaceutical regulations course is constructed based on the OBE-CDIO concept. Reasonable recommendations and solutions are proposed to improve teaching quality, strengthen students' practical abilities, innovative capabilities, and comprehensive qualities. After long-term exploration, research, and practice, the course reform has achieved significant results, greatly stimulating students' learning abilities, innovative capabilities, practical abilities, and social adaptability, cultivating excellent pharmaceutical management talents for national development and social needs.

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