CHINESE PHARMACOPOEIA AND PROGRESS IN THE COMPILATION OF CHINESE PHARMACOPOEIA 2020

Chinese Pharmacopoeia Commission

Zhang Wei, Secretary General

ChP-EDQM Workshop on Pharmaceutical Excipients

18 September, 2018, Strasbourg, France

国家药典委员会 CHINA PHARMACOPOEIA COMMISSION http://www.chp.org.cn

Main contents

- Overview of Chinese Pharmacopoeia
  - Overview of the Pharmacopoeia Commission
  - Overview of the Chinese Pharmacopoeia Commission
- ChP developing plan
- Progress in the new edition of ChP
- ChP-EDQM Cooperation

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The Status and Role of the Chinese Pharmacopoeia

The national drug standard is the technical regulation made by the state to ensure the quality of drugs, the quality specifications, testing methods and manufacturing processes of drugs. It must be abided by in all aspects of drug research, production, operation, use and supervision and management. It is a set of compulsory technical guidelines and statutory basis.

The Drug Administration Law of the People's Republic of China explicitly stipulates that "drug production must comply with national drug standards. The Pharmacopoeia of the People's Republic of China and the drug standards promulgated by the drug regulatory authority under the State Council are national drug standards".

- The "Chinese Pharmacopoeia" is promulgated by the State Drug Administration and is a drug code established by the state to ensure the quality of drugs, to ensure access to safe, effective and quality controllable drugs for the people. The Chinese Pharmacopoeia plays an important role in ensuring the quality of medicines, safeguarding and protecting the public health and legitimate rights of the people to use medicines. It also plays an important role in promoting the healthy development of China's pharmaceutical industry.

Overview of ChP Committees

- In 1950, the Ministry of Health established the Pharmacopoeia Committee, including a Secretariat (standing organization) and a team of experts, and began to organize the preparation of pharmacopoeia. It was the earliest established standardization body.
- So far, the 11th Pharmacopoeia Committee has been established and the preparation of the 10th edition of the Chinese Pharmacopoeia has been completed.
- It is jointly established by the Ministry of Health, the State (Food and Drug Administration), the State TCM Administration, and the Ministry of Health.
- A well-known Chinese and Western medicine experts are recruited as members of the committee, with each term lasting for five years
- One director member and several deputy director members.

Director members of previous terms

Director members are usually Minister of Health or Head of the Drug Authority at the time

Li Dequan
First, second

Tang Tenghan
Third

Qian Xinzhong
Fourth

Cui Yueli
Fifth

Chen Minzhang
Sixth, seventh

Shao Mingli
ninth

Chen Zhu
tenth

Bi Jingquan
eleventh

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Group photo of all members in the course of history

The first commission, 44 people, 1950

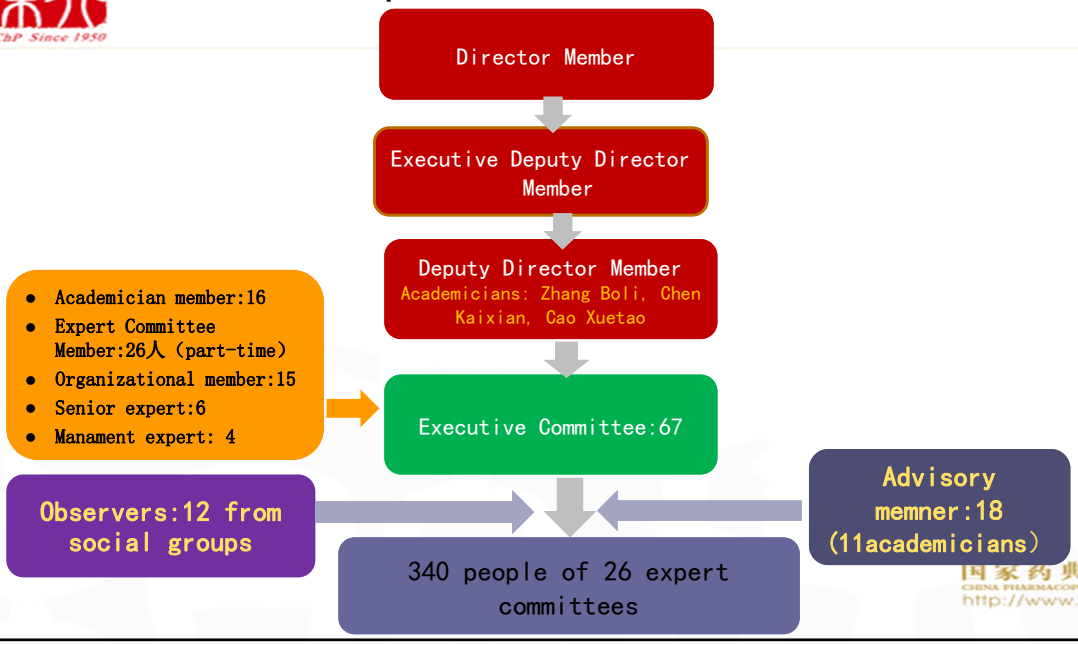
The sixth commission, 168 people, 1991

The tenth commission, 350people, 2010

The eleventh commission, 405 people, 2017

Number of committee members over the years

Composition of the 11th ChP Commission



Organizational Structure of 11th Pharmacopoeia Commission

- 26 Expert Committees, 340 members

Traditional Chinese Medicine(97 members)

- Expert Committee of Ethno- Medicine (16)
- Expert Committee of Chinese Materia medica and prepared slices of Chinese crude drugs I(16)
- Expert Committee of Chinese Materia medica and prepared slices of Chinese crude drugs II(16)
- Expert Committee of Traditional Chinese Patent Medicines I(15)
- Expert Committee of Traditional Chinese Patent Medicines II(15)
- Expert Committee of Natural Medicine(8)

Chemical Product (65 members)

- Expert Committee of Chemical Products I (13)
- Expert Committee of Chemical Products II (13)
- Expert Committee of Chemical Products III (13)
- Expert Committee of Chemical Products IV (11)
- Expert Committee of Biochemical Products (11)
- Expert Committee of Radiopharmaceutical (4)

Biological Product (42 members)

- Expert Committee of Biotechnology (13)
- Expert Committee of Vaccine Product (17)
- Expert Committee of Blood Products (7)

Medical Science(54)

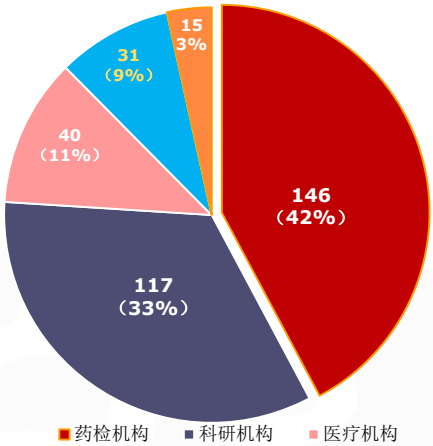
- Expert Committee of Traditional Chinese Medicine Science (31)
- Expert Committee of Medical Specialties (23)

preparation, Pharmaceutical Excipient, packaging Material

Expert Committee of Physical & Chemical Analysis (18), Expert Committee of Preparations (17), Expert Committee of Name and Terminology (9), Expert Committee of Bioassay (8),Expert Committee of Microbiology (9), Expert Committee of Pharmaceutical Excipient and Containers(13), Expert Committee of Reference Material (8)

Member composition for the 11th ChP Commission

Member breakdown



Facts and figures

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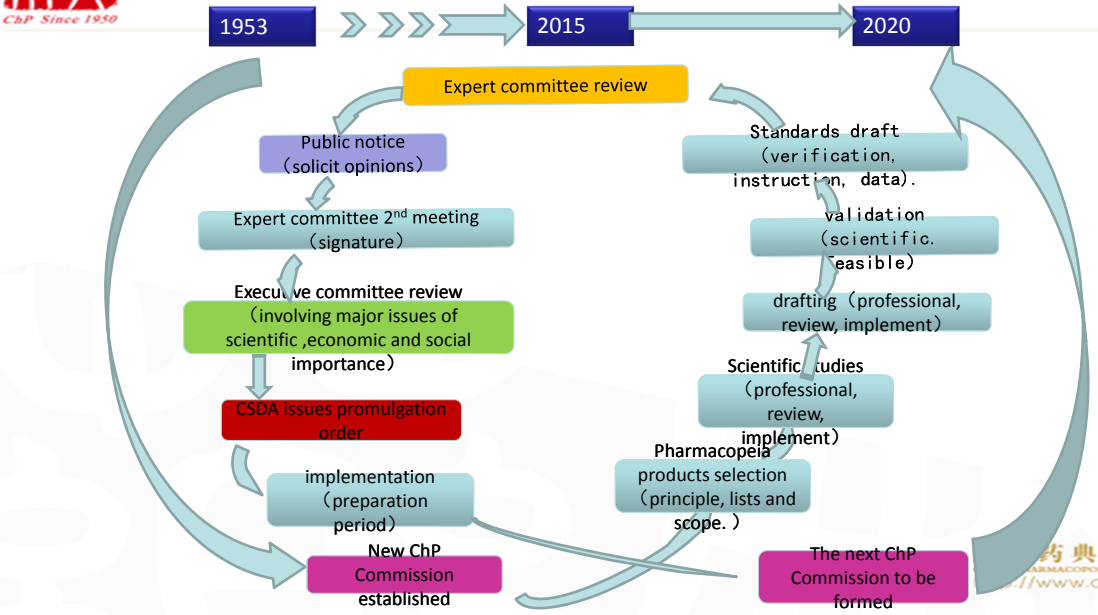
Work procedure of ChP Compilation



Standing Institution of ChP Commission

- A unit directly affiliated to the former CFDA
- Practice the Secretary General responsibility system
- Responsible for the formulation and revision of national drug standards in accordance with the provisions of the Drug Administration Law

ChP Commission

- Comprehensive Division
- TCM Standards Division
- Chemicals Standards Division
- Biologics Standards Division
- Medical Information Division
- General Office
- Personnel Affairs Division
- Publicity and Cooperation Division
- Quality Management Division

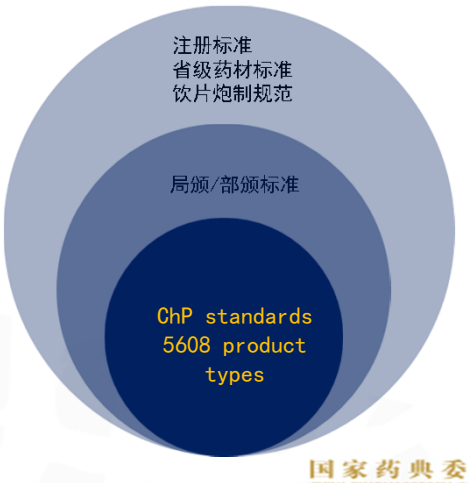
Zhang Wei, Secretary General

Responsibilities of Standing Institution of ChP Commission

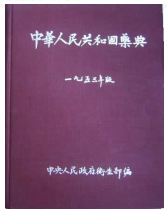
- Compiles and amends the Pharmacopoeia of the People's Republic of China (hereinafter referred to as the ChP) and its supplements;
- Sets the technical requirements and quality standards for pharmaceutical excipients and pharmaceutical packaging materials in direct contact with drugs;
- Participates in the evaluation of the implementation of ChP standards.
- Responsible for the promotion and technical consultation of the ChP and national drug standards.
- Participates in the formulation of management systems for pharmaceuticals, pharmaceutical excipients, pharmaceutical packaging materials in direct contact with drugs, and establish and improve drug standard management systems and related systems.
- Organizes studies on drug standardization strategy, standard management policy and technical regulations, and undertake analysis and evaluation of drug clinical information
- Conducts international exchanges and cooperation on drug standards, participates in international drug standards suitability cooperation and international drug standard development.
- Responsible for the construction of drug standard IT system
- Responsible for the compilation, publication and release of the *Chinese Pharmacopoeia series* and *China Drug Standards.*
- Under the Charter of the Pharmacopoeia Committee, responsible for the organization, coordination and service guarantee of the relevant work meetings of the Pharmacopoeia Committee.
- Other matters entrusted by CFDA(NMPA)

General introduction of national drug standards

- The national drug standards system is basically formed with ChP as the core, CFDA and drug registration standards as the basis, and local medicinal materials standards as the supplements
- Around 18,000 national drug standards
- As the core of China's drug standard system, the revision of the Pharmacopoeia exerts important and positive impact on the level of drug quality control and testing in China.



A total of ten editions of pharmacopoeias have been issued since 1953



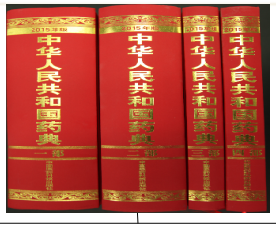


1953 1963 | 1977 1985 | 1990 1995 | 2000 2005 | 2010 2015





General information of ChP 2015



- TCM materials and herbal slices included
- Vegetable oils and extracts
- Formulations and single-flavor preparations, etc.

- Chemical drugs, antibiotics
- Biochemical drugs
- Radioactive drugs, etc.

- Biological products included
- Mainly vaccines, serum, biotechnology products, blood products, diagnostic reagents, etc.

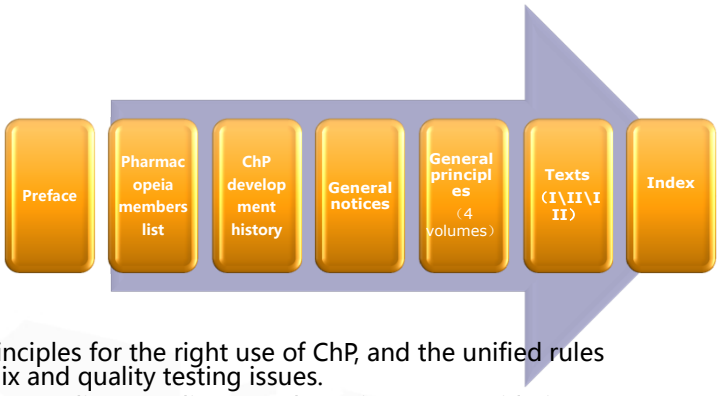
- General rules for pharmaceutical formulations
- General rules for general testing methods
- Guiding Principles
- Pharmaceutical excipients, etc.

General information of ChP 2015

Category		Types of products in ChP 2010	ChP 2015			
			Number of products planned to be included	Additional products	Revised products	Products excluded
TCM		2165	2598	440	517	7
Chemical drugs		2139	2603	492	415	28
Pharmaceutical excipients		132	270	137	97	2
Biological products	types	131	137	13	105	6
	General principles and chapters	10	108	10	21	/
total		4567	5608	1082	1134	43
General principles (appendix)		/	317	43	67	/

General information of the National Drug Standards

ChP 2015

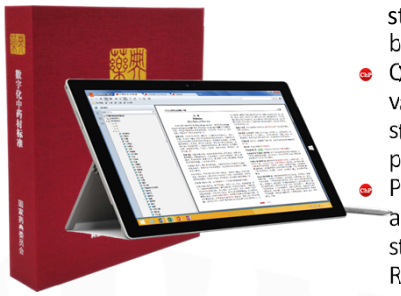


- **General Notices**: the basic principles for the right use of ChP, and the unified rules governing main texts, appendix and quality testing issues.
- Texts: specifications to test drug quality compliance and consistency considering physical and chemical properties of drugs and by following the approved prescription source, production process, storage and transportation conditions, etc.
- **General Principles**: The four parts of the Chinese Pharmacopoeia mainly contain the general principles of formulations, general testing methods and guiding principles.

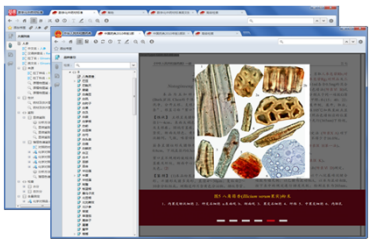
ChP Series Publications

- National Drug Standards Work Guidelines
- Infrared Spectrum of Drugs
- Chinese Generic Names
- Chinese Pharmacopoeia 2015 Edition (English version)
- Chinese Pharmacopoeia Notes
- Drug Clinical Use instructions
- TCM Powder Microscopic Identification Map
- TCM Thin Layer Chromatography Atlas
- China Drug Standards Magazine
- National Drug Standards Collection
- Standards Comparison of Pharmaceutical Excipients at Home and Abroad
- Digital TCM Standard
- Chinese Pharmacopoeia Analysis and Testing Technology Guide

Digital pharmacopoeia standards platform



- Explore for establishing a national drug standard digital information platform based on ChP
- One-stop solutions and information value-added service of national drug standard with "big data" and "Internet plus" concept
- Provide targeted information value-added service of characteristic drug standard for professionals from drug R&D, manufacturing, inspection, regulation, authentication, research and education



1、Provide complete and timely pharmaceutical excipients standards around the world.

2、provide big data for comparisons of each ChP edition

3、Serve as reference for setting excipients standards in the and supplements in the future

4、provide technical support to the associated review of APIs, excipients and packaging materials.

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Set up of the 11th ChP Commission

Founding Conference of the 11th ChP Commission
（August 29th, Beijing）

- Minister Bi Jingquan made an important speech at the conference to:
  - Highlight the great significance of drug standards
  - Raise five major issues needing earnest study
  - Raise requirements on work and discipline of all members
  - Reiterate the people-oriented development principle of drug standards, that should serve the need of drug regulation, reform and innovation, and industry. Encourage good drugs, and force inferior and counterfeit drugs out of market

Outline for ChP 2020——overarching target

- Improve the standard system of ChP and raise the overall standard and level
- Make ChP standards more rigorous, product selection more reasonable, standard system in line with internationally-recognized practice, and the standard forming system more scientific
- Make sure that the TCM standards continue to lead the formation of international standard, chemical drug and pharmaceutical excipient standards basically reach or get close to international level, and that biological product standards keep up with scientific and technological frontier level and basically on par with the world advanced level.

Outline for ChP 2020——overarching target

- **Moderately increase the number of products included to further meet clinical needs**
  - ✓ Adhere to the selection principles of "common use clinically, proven therapeutic effects, safety use, mature process and controllable quality"
  - ✓ Comprehensively cover the Essential Drug Catalogue and national basic medical insurance drug catalogue, to keep up with changing instructions on drugs for clinical treatment.
  - ✓ Focus on the inclusion of APIs, TCM raw materials, and pharmaceutical excipient; The inclusion of new preparations should fully reflect China's medical innovation achievements.
  - ✓ ChP 2020 plans to include a total of around 6500 monographs, among which, around 220 are added traditional Chinese medicines, around 420 are added chemical products, 30 are added biologics products, 100 added pharmaceutical excipients and 30 added packaging materials, totaling 800. It will have 1300 revisions for products, including 500 for TCM, 600 for chemical products, 150 for biological products and 150 for pharmaceutical excipients.

Outline for ChP 2020——overarching target

- **Gradually improves the mechanism for elimination of outdated drug standards**

Eliminate standards for drugs with approval number canceled, without production over a long time, without controlled quality, reasonable dosage and lasting stability.

- **Raise the common technical requirement of drugs to fully reflect drug QC level**

✓ follow the development trend of internationally advanced pharmacopoeia standards, and further expand application of advanced testing technologies based on China's pharmaceutical production practices

✓ Focus on studies and establishment of control methods of drug safety and effectiveness

✓ Add another 30 relevant testing methods, 20 new general chapters and general notices, 15 guiding principles; revise 60 testing methods, 12 general chapters and general notices as well as 10 guidelines

- **Promote harmonization between ChP and international standards**

Expand the international influence of ChP and quality of China made drugs, and promote import and export of pharmaceuticals

Outline for ChP 2020——goals and objectives

- Improved structure of ChP standards

✓ Further harmonize standards and format among different volumes of the Pharmacopeia

✓ Establish standardized nomenclature rules for general names (including chemical drugs, TCM, biological products, pharmaceutical excipient and packing materials)

✓ Formulate coding system of drug standards and glossary of terminology, and standardize use of terms in the Pharmacopoeia

- Improve standards system of ChP

✓ Develop a drug standard system horizontally covering TCM, chemical drugs, biological products, APIs, pharmaceutical excipient, packaging materials and reference products.

✓ Develop a technical requirement framework vertically covering monographs, general chapters (for testing method and preparation), general notics and guidelines relating to drug R&D, manufacturing, storage, transportation,etc.

Outline for ChP 2020—TCM（ volume I）

- Establish the TCM QC system and TCM standard
- Safety：
  - ✓ Effectively control impact of exogenous pollution on TCM safety, and develop limits on heavy metals, hazardous elements and pesticides in TCM materials and prepared slices.,
  - ✓ Set limits on TCM mildew, mycotoxin in TCM materials and prepared slices
  - ✓ Effectively control impact of endogenous toxic elements on TCM safety, with a particular focus on developing methods for prediction and assessment of hepatotoxicity and nephrotoxicity
  - ✓ Develop standards and guidelines for TCM safety testing
- Efficacy
  - ✓ Strengthen specificity and holistic feature of TCM standards, and innovate and improve TCM analytical and testing methods.
  - ✓ Conduct TCM clinical effects-based bio-evaluation and bioassay
  - ✓ Explore a system to reflect TCM efficacy based on combined morphology, microscopic, chemical composition and biological effects

Outline for ChP 2020——Chemicals （ volume II）

- Further develop analytical methods for impurities and relevant substances
- Improve controls on toxic and hazardous impurities
- Enhance studies relating to drug safety control and limits
- Highlight consistency evaluation outcomes in quality control
- Improve Dissolution and release test methods for solid preparations
- Set up effective quality control methods and control indicators for new drug formulations, such as sustained (controlled) release preparation

Outline for ChP 2020—Biologicals （volume III）

- Further standardize style and general names in monographs to achieve integration between the three volumes
- Improve whole process QC requirement on biological products, improve common technical requirements, and ensure systematic and standardized features of such requirements and their relevance with monographs；
- Further improve bioassay technique, methods and technical guidelines, and give priority to testing methods and technologies, to ensure the advanced nature of national biological drug standards, and serious, scientific and suitability nature of standards at the source level; develop standard testing methods, and further improve reference materials; conduct studies on the substitution of animal tests, and application of physiochemical analytical methods on QC performance of biologicals.
- Improve criteria for pharmacopeia inclusion, set up related common technical requirement for therapeutic biologics, and speed up inclusion of marketed, mature vaccines and therapeutic biologics into ChP

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Outline for ChP 2020—General Charpters（volume IV）

- Testing method

  Adhere to the scientific, standardized, practical and operable principles
  - Improve the universality, applicability and stability of common testing methods
  - Keep up with the trend of international pharmacopoeias and expand the use of advanced and mature testing techniques in drug analysis
- General chapters of preparations
  - Increase inclusion of mature new dosage forms
  - whole process control of preparations
  - Integrate excipients functions with the technical requirement in the general chapters of preparations, to guarantee stability and batch-to-batch consistency
- Guidelines
  - Keep up with development of relevant technical guidelines in international pharmacopoeias, and through drawing on strengths of others, improve China's drug R&D, Production and process control, analytical method validation, data testing and analysis, and packaging, transportation and storage of drugs.

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Outline for ChP 2020—General Chapters（volume IV）

- Pharmaceutical excipient and packing materials
  - Develop standard system on pharmaceutical excipient and packing materials
  - Reinforce the formulation of common requirement and guidelines, which would provide strong technical support to bonded reviews of APIs, pharmaceutical excipient and packing materials
  - Include standards for common excipients and key packing materials, and promote the upgrading of excipient and packing materials
  - Further strengthen safety control on excipient and packing materials, and live up to international level

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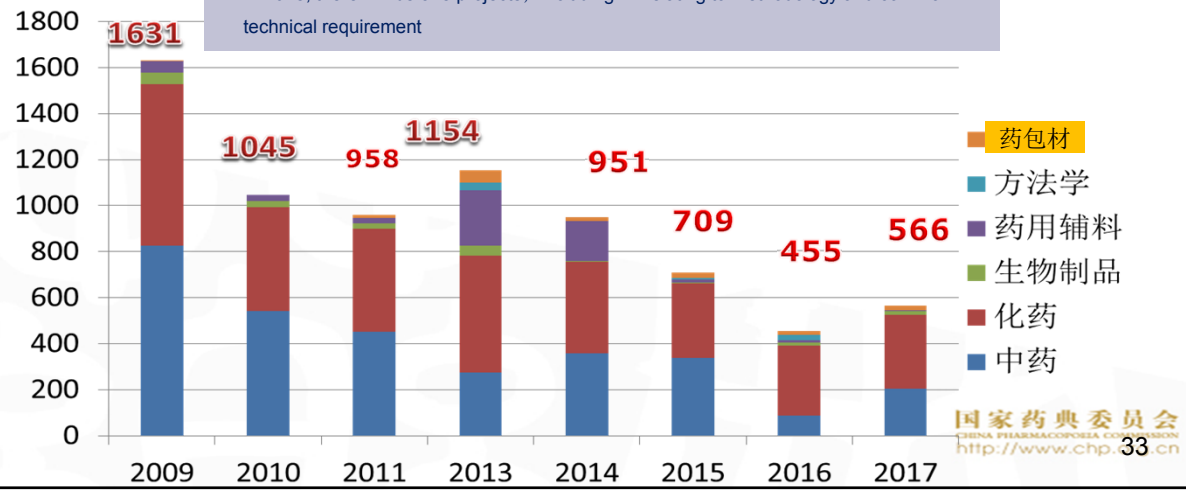
Drug standards assignments from 2009 to 2017

- 7756 drug standards assignments，5400+ already completed
- Improve 3050 drugs standards according to the 13th five year plan
- Set up over 1100 projects，and over 800 were completed as of the end of 2017
- In 2018, there will be 318 projects，including 24 relating to methodology and common technical requirement



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Improve the system building for drug standards

Build up a complete and sound pharmacopeia standards system

Improve standards system

Improve drug standards level

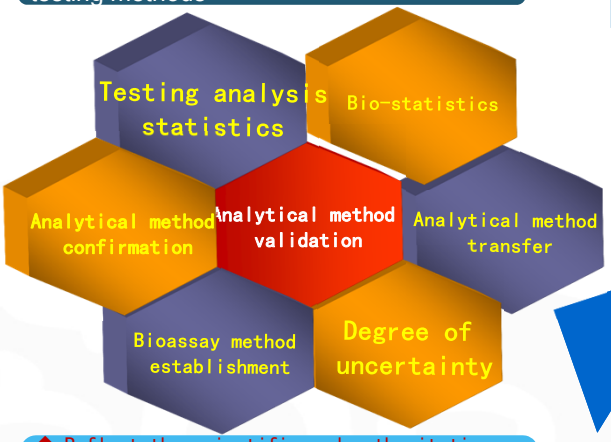
Reinforce ChP's central role in drug standards system

- General principles of formulations Standards system
- Pharmaceutical excipients standards system
- Packaging materials Standards system
- Biomolecular testing technique system
- Analytical testing technology system

Systematic, gap-closing, international coordination, and prominent in features

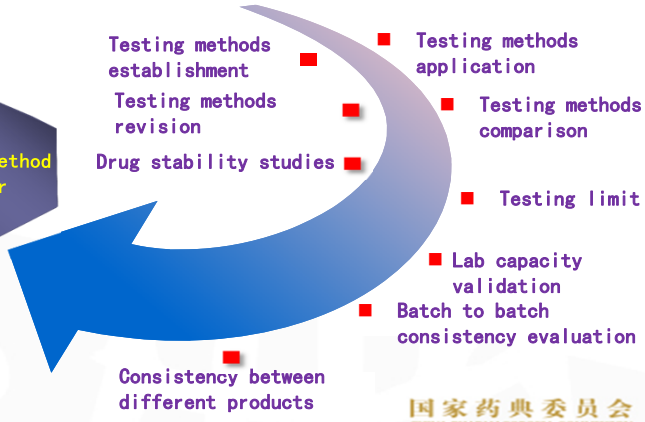
Analytical testing technology system

Analytical methods are the basis for drug testing methods



- Reflect the scientific and authoritative nature of ChP
- Set up the strictest standard baseline

IT platform to process testing and analytical data



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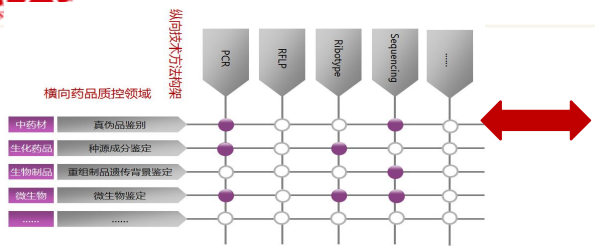
Application Platform for Molecular Biology Detection Technology



General chapters of technical requirements and identification methods for various drugs in QC

Application information platform

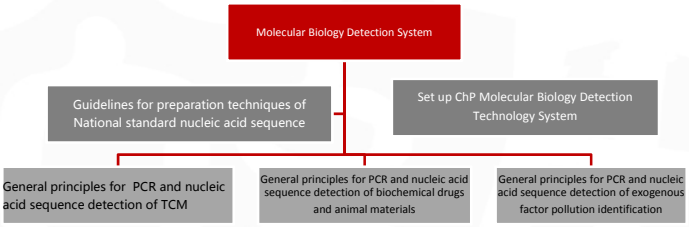
National standard nucleic acid sequence database

Database

provide authoritative and reliable basis for the national legal drug inspection results

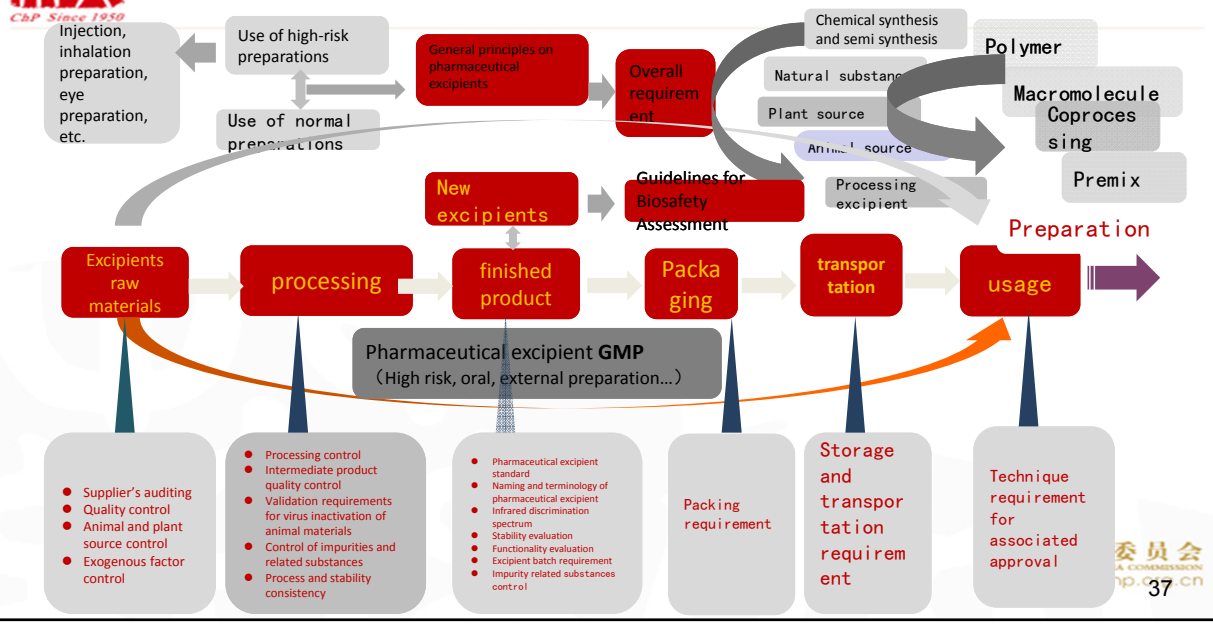
Set up ChP Molecular Biology Detection Technology System

A feature of ChP standard



Biological product

Establishment of Standard System of Pharmaceutical Excipient



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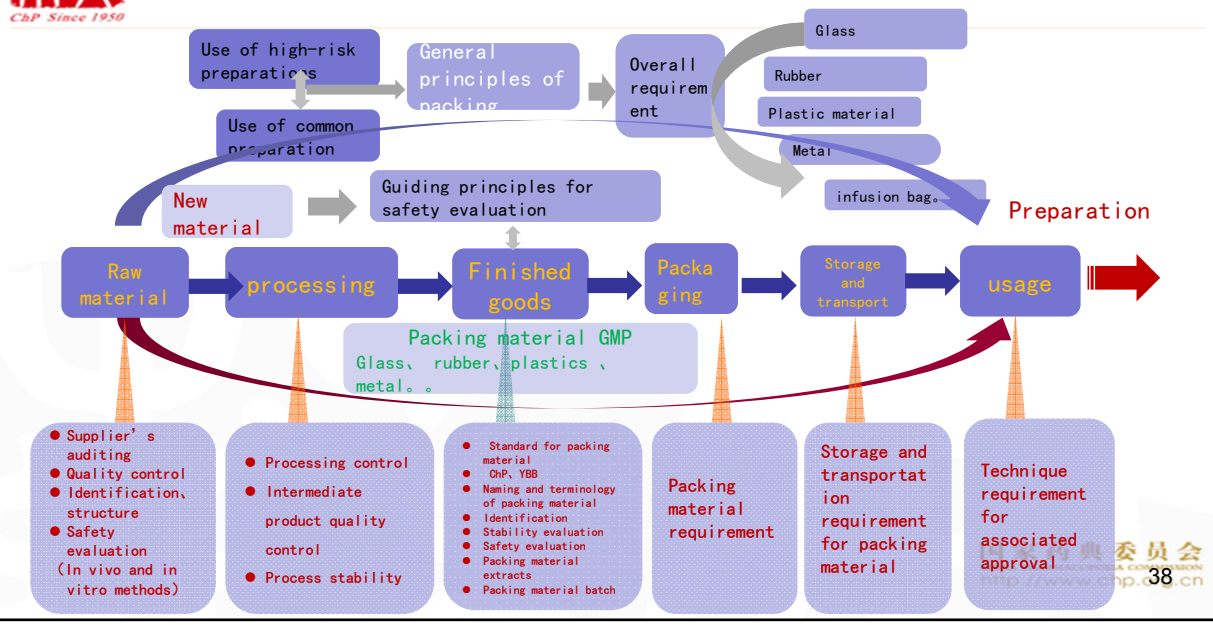
Establishment of Standard System on Packing Material



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Study on TCM safety

- TCM Safety Evaluation Studies
- Studies on safety evaluation of TCM exogenous pollutants
- Studies on limit standards of pesticide residue in 16 TCM crude drugs and prepared slices

  - 10 common herbs which can be either used as food or medicine

  - dangshen, angelica, orange peel, Chinese date, Radix Ophiopogonis, chrysanthemum, honeysuckle, lycium chinensis, pseudo-ginseng, ginseng
- Studies on limit standards of heavy metal and hazardous elements

  (Test for 50 pesticide residues in 160 TCM (prepared slices of Chinese crude drugs)

Enhance QC technology research of chemicals

- Drug formulation stability evaluation
- Sustained-controlled release drug quality evaluation and related guidelines
- Drug Crystal Form Study and Evaluation
- Liposome, microparticle guidelines
- Dissolution test Guidelines
- Dissolution test method improvement(flow pool method, reciprocating cylinder method)
- Residual solvent testing
- Drafting of Notes for the Second Edition of the 2015 Chinese Pharmacopoeia

Enhance study on QC technologies of biologics

- ➢ Relevant general chapters
- Nomenclature principles of biological products
- Establish common technical requirement (general notice) for quality control of PEG recombinant protein products
- Establish common technical requirement (general notice) for quality control of allergen products
- Establish specifications for common vaccine aluminium adjuvants
- Common technical requirement (general notice) for gene therapy products
- ➢ Testing methods
- Study on the determination of recombinant cytokines, impurities and related substances
- Establishment of methods for the analysis of recombinant monoclonal antibodies
- Human pegylated polypeptide

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Conduct project studies on common principles

General Chapter of testing methods

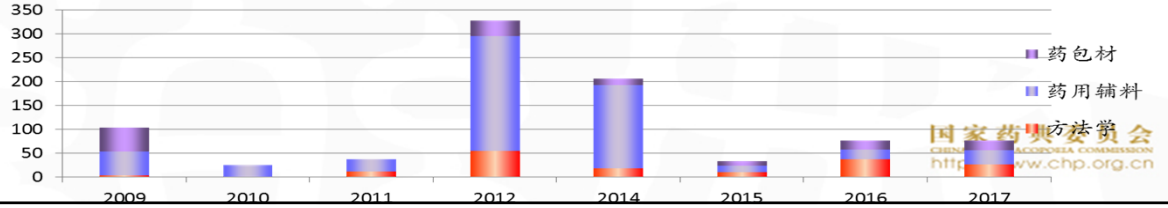
- Determination of bacteriostatic agent content in eye drops
- Establishment of a method for detecting mycotoxin in Chinese medicine (ELISA)
- Establishment of functional evaluation methods for pharmaceutical excipients
- Establishment of cytotoxicity and evaluation method for drug packaging materials
- Determination of molecular weight and molecular weight distribution of macromolecular pharmaceutical excipients
- Revision of the General Principles of Pharmaceutical Excipients
- Microbiological examination of drug packaging materials
- Drug packaging material sterility test

General Chapters of technologies

- Capsule (hollow capsule) general principle
- General principles for medicinal glass materials and containers
- Pharmaceutical packages
- Pharmaceutical water use (revised)
- Revision of the General Principles of Pharmaceutical Packaging Materials
- Drug packaging material naming principle
- Principles of naming of pharmaceutical excipients
- Revision of the General Principles of Pharmaceutical Excipients
- Prefilled syringe general principle
- General principle for the preparation of TCM formulations
- General principles for the preparation of injections
- Sterilization

Guiding principles

- Validation of analytical methods for drug quality standards
- Statistical Analysis
- Slow release, controlled release and delayed release preparations
- Study on Compatibility of Pharmaceutical Excipients and Drugs
- Biosafety evaluation of pharmaceutical excipients
- Applicability of pharmaceutical excipients
- Applicability study of drug packaging materials
- Evaluation of stability of drug packaging materials



Completed the first supplement of ChP 2015

The first supplement of ChP 2015 was approved by CFDA for release and implementation.

Item	supplements	amendments	total	sum
TCM	33	112	145	426
Chemical drugs	60	135	195	
Biological products	1	43	44	
Pharmaceutical excipients		42	42	
General principles	4	5	9	9

Translation and Implementation of ICH Q4 in China

- In June 2017, ICH formally accepted CFDA as its 8th regulatory authority member
- On June 7, CFDA was elected a member of the ICH management committee.

国家食品药品监督管理总局 CFDA
China Food and Drug Administration

国家食品药品监督管理总局成为国际人用药品注册技术协调会成员

2017年06月19日 发布

2017年5月31日至6月1日，国际人用药品注册技术协调会（ICH）2017年第一次会议在加拿大蒙特利尔召开。会议通过了中国国家食品药品监督管理总局的申请，总局成为国际人用药品注册技术协调会正式成员。

The International Council for Harmonization (ICH) met in Montreal, Canada from May 31 to June 1, 2017. The ICH Assembly approved the China Food and Drug Administration as a new Regulatory Member.

国家药品监督管理局 国家市场监督管理总局

中国国家药品监督管理局当选为国际人用药品注册技术协调会管理委员会成员

2018年06月07日 发布

当地时间6月7日下午1点30分，在日本神户举行的国际人用药品注册技术协调会（ICH）2018年第一次大会上，中国国家药品监督管理局当选为ICH管理委员会成员。

Translation and Implementation of ICH Q4 in China

➢ **Milestones and timelines of Q4 guidelines implementation in China**

2018
Texts translation and comparisons between ChP 2015 and ICH Q4B appendix

2019
Conduct studies, validation and field visits

2020
Assess need for harmonization as reviewed by ChP expert committees, in order to develop a draft

2021
The standard draft will be open to public suggestions before finalizing

2022
Release and put into effect together ChP

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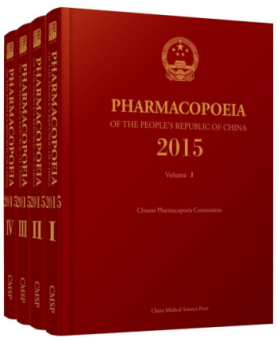
ChP related publications

- ChP 2015 English version (hard copy) and electronic copies of Chinese and English version
- The first analytical testing technology guidelines of ChP
- Notice of clinal drugs 2015 edition



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Main contents

- Overview of Chinese Pharmacopoeia
  - –Overview of the Chinese Pharmacopoeia Commission
  - –Overview of Standing Institution
- ChP compilation plan
- Progress in the compilation of the new edition of ChP
- ChP-EDQM Cooperation

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6th International Meeting of World Pharmacopoeia & Chinese Pharmacopoeia Annual Scientific Symposium

6th International Meeting of World Pharmacopoeia & ChP Annual Scientific Symposium (2015, Suzhou, Jiangsu Province, China)

ChP-EU Pharmacopoeia Cooperation

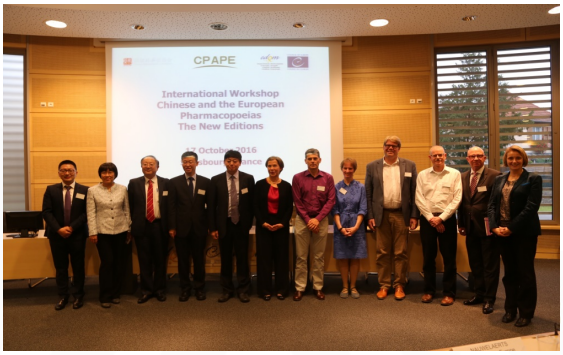
- On August 21st, 2014, the European Directorate for the Quality of Medicines (EDQM) Director, Doctor Susanne Keitel, and the European Pharmacopoeia Commission（EPC）Secretary General, Madam Cathie Vielle came to visit the Chinese Pharmacopoeia Commission.

9th WHO International Pharmacopeia meeting in Brazil

ChP and EP signed a MoU

ChP-PhEur Pharmacopoeia workshop

- 1th ChP-PhEur pharmacopoeia workshop held in the headquarter of EDQM , 13 October, 2016.
- Introduction the new edition of ChP and PhEur



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Thank you for your attention!

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