ICS 11.120

CCS C 10

CNPPA

Social Organization Standard

T/CNPPA 3025-2023

药包材质量协议管理指南

Quality agreement management guidelines for pharmaceutical packaging materials

Issued on 2023-12-16 Effective on 2024-02-16

Issued by China National Pharmaceutical Packaging Association

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Foreword

This guideline is prepared in accordance with GB/T 1.1-2020 "Directives for standardization — Part 1: Rules for the structure and drafting of standardizing documents".

The attention is drawn to the possibilities that some of elements of this guideline may be the subject of patent rights, the issuing agency of this guideline shall not be held responsible for identifying any or all such patent right.

This guideline was prepared and interpreted by China National Pharmaceutical Packaging Association.

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Introduction

The abundant connotation of quality in the terminology nowadays has been enriching and extending along with socio-economic progress, scientific and technological advance. What is the true meaning of the quality of pharmaceutical packaging materials nowadays? In addition to the previous concepts of quality, which include the quality by design (QbD) and total quality management, in the present age the enriched connotation of quality concept is being gradually acceptable that the pharmaceutical packaging materials in align with the requirements of pharmaceutical products by means of the risk management in the pharmaceutical packaging materials life cycle, shall ensure the safety, efficacy and controllable quality of pharmaceutical products. The related elements of whole process from design to use for pharmaceutical packaging materials include process development, equipment configuration, in-process control, all of which is an indispensable components to ensure the Consistency quality of the product.

According to the provisions of Article 68 and Article 69 of the "Good Manufacturing Practice for Pharmaceutical Packaging Materials (Public Draft)"--- The pharmaceutical packaging manufacture hold the responsibility that " Quality department should sign Quality Agreement with Users, which is as an integral part to the commercial contract of Pharmaceutical Packaging Materials" , " Product name, product size, roles and responsibilities of both parties should be clearly stated in the Quality Agreement". Pharmaceutical Packaging Chapters in Chinese Pharmacopoeia (Ch.P) (public draft) furtherly indicated that some quality attributers "shall conform to Quality Agreement standard or Enterprise Standard".

For the same type of pharmaceutical packaging materials, there exist various types of production equipment, processes and various in-process control strategy (e.g. on-line visual inspection and measurement, continuous manufacturing process etc.). Whenever choosing and evaluating the pharmaceutical packaging products, the user and manufacturers shall establish scientific, reasonable and applicable evaluation methods and criteria for packaging products, on the ground of the actual facts of production and use of pharmaceutical packages, nature of the drugs, and characteristics of the dosage forms. which shall be stipulated in the Quality Agreement, to ensure the consistent quality of the pharmaceutical primary packaging in its life cycle in align with the quality needs of drug product.

The manufacturer and users shall benefit from practicing and application of the Quality Agreement to clarify quality expectations, identify the risk control area, reduce the possibility of un-homogeneous product quality caused by improper production control, lower the product risk due to insufficient management of changes for raw materials, technology, equipment and process. Quality Agreement is a critical tool for pharmaceutical packaging materials quality management in whole life cycle.

Quality agreement management guidelines for pharmaceutical packaging materials

1、Scope

This guideline specifies general descriptions, preparation and implementation of quality agreement for pharmaceutical packaging materials.

It is applicable to all pharmaceutical primary packaging manufacturers and users, which are involved in any aspect of preparing, approval and implementation of quality agreements.

2、Normative references

This guideline is not subjected to any normative references.

3、Terms and definitions

To the purposes of this document, the following terms and definitions is given and apply.

3.1 Quality agreement for pharmaceutical packaging materials

Quality agreement for pharmaceutical packaging materials will be the legal binding directives mutually agreed by the manufacturers and users to ensure effectively fulfillment of the relevant responsibilities and obligations stipulated and committed by of both parties in conformity with norms at acceptable risk when packaging materials are manufactured and used according to its intended use.

Note: The quality agreement of pharmaceutical package materials is referred to as Quality Agreement in this document.

3.2 Pharmaceutical packaging material standard

Technical requirements and specifications formally defined to secure the effectiveness of the packaged drugs, and ensure the consistency product quality.

Note: Pharmaceutical packaging material standards are commonly known as the registration standards, combined standards and agreement standards.

3.3 Registration standard

The standard submitted by Pharmaceutical Packaging Registration Document Holder, which is registered on the "excipient packaging registration filing platform" in the website of Center For Drug Evaluation.

3.4 Combined standard

The standard of packaging materials associated with drug is simultaneously approved with drug itself by National Medicinal Product Administration.

3.5 Agreement standard

Quality Agreement standard is the specifications and requirements which were defined in the Quality Agreement by the manufacturer and user in conformity with the registration standards and combined standards.

Note: The agreement standard may be a segment of the Quality Agreement, also an exclusive document linked to the Quality Agreement. It can be fully or partially used as the releasing standard by the manufacturer, and as the incoming inspection standard by the user.

4、General content of the quality agreement

The Quality Agreement shall include general information of both parties (the “manufacturer” and the“user”), responsibilities, other requirements mutually agreed by both parties.

4.1 General information

4.1.1 The information related to both parties (the “manufacturer” and the “user”), such as company name, legal address (single address or multiple address), postal code, etc. shall be scoped in.

4.1.2 Quality Agreement should specify the packaging material information, such as product name (single or multiple), product configuration (if any), product standards and its corresponding registration in the regulatory authorities (e.g. registration in Center For Drug Evaluation , and registration in regulation authorities outside China if any).

4.1.3 The quality agreement may include a description of relevant terms or definitions, if necessary.

4.2 Responsibility of both parties

The Quality Agreement should define the responsibilities of both parties, including but not limited to the followings:

a) The packaging products for drugs chosen by the user should meet the requirements for medicinal use, be conformity with safety standards and health directives, ultimately ensure the quality, safety and efficacy of medicinal products. The legal obligations and responsibilities of the User shall not be transferred to the Manufacturer via the Quality Agreement.

The user shall evaluate the manufacture’s production, technical and quality management system, verify the compliance of the manufacture’s quality management system in accordance with the "Good Manufacturing Practice for Pharmaceutical Packaging Materials (Public Draft)". Periodical audit and assessment of the quality management system of the manufacturer shall be conducted by User.

b) The manufacturer shall strictly comply national regulations and standards, fully establish quality management system. It shall hold responsible for the maintaining and updating of the information and documentation of packaging materials, which are submitted to the drug regulatory agencies or authorities, to ensure accuracy, authenticity and completeness of the registration document of packaging materials.

The manufacturer shall comply with Good Manufacturing Practice for Pharmaceutical Packaging Materials, and is responsible for the product quality, which is manufactured and released by the entity.

4.3 Content of the agreement

The general content in the Quality Agreement shall be included, but are not limited to followings.

4.3.1 Quality Assurance for manufacturer

In accordance with the "Good Manufacturing Practice for Pharmaceutical Packaging Materials (Public Draft)" and on the ground of the specific requirements of the user, the followings shall be defined (if any, but not limited to) by both parties (the “manufacturer” and the “user”)

a) Quality Management

The approach and frequency of quality audits by the user, as well as corrective and preventive actions of nonconformity identified by audit shall be defined by both parties. It is necessary for both parties to establish a reasonable audit frequency and duration based on experience and risk assessment.

b) Organization and personnel

The competence and qualification shall be specified mutually by both parties for person responsible for production and quality department respectively.

c) Plant and facilities

The parties may agree on specific requirements for the production premise and facilities.

d) Equipment

The specific requirement for production equipment shall be described clearly by both parties..

e) Materials and products

The handling procedures of nonconforming products (e.g. rework process and following acceptance criteria, etc.) shall be detailed in the Quality Agreement.

f) Verification and validation

Verification and validation requirement for facilities, utilities, equipment and testing method shall be defined by both parties.

g) Documentation and control of records

The parties may agree on specific document retention time.

h) Production management

The principle of batch numbering shall be addressed by both parties.

i) Quality control and quality assurance

The handling procedure of the deviations and non-conformity of products shall be specifically described in the Quality Agreement.

j) Contracted manufacturing and Contracted testing

In the condition of disagreement between the two parties on the product testing results, both parties can agree on the arbitration laboratory and sample handling details.

k) Distribution and Recall

Product label content such as product name, batch number, manufacturing address, etc. shall be specified by both parties. Product batch numbering principle and rules, delivery lead

time, acceptable batch size, delivery quantity shall be agreed by both parties. The two parties shall specify the content of Certificate of Analysis (CoA) issued by the manufacture, in which the testing items and its corresponding acceptance criteria etc. for delivered products may be included. The specific requirement of transportation and storage (e.g storage temperature and humidity, product loading and delivery requirements) shall be mutually specified by both parties.

l) User management

The communication and handling requirements for quality complaints shall be addressed by both parties, such as complaint response time management and complained product handling process.

4.3.2 Agreement Standard

comprehensive risk assessment should be conducted by both parties, on the ground of stability of production process, and process capacity, on-line measurement competency of products, product quality historical data review. Necessary testing items, applicable testing method, acceptable quality level shall be scientifically developed listed in the Agreement Standards. Agreement Standard should be developed jointly by both parties in accordance to the following principles;

a) The Agreement Standard shall comply with the corresponding requirements in the Chinese Pharmacopoeia, and the relevant mandatory requirements of national standards. Both parties shall actively implement the recommended standards issued by nation and association.

b) The Agreement Standards shall be enacted originating from the registration standards and/or combined standards.

c) Validation or verification of testing methods for product in the scope, which is not listed in the Chinese Pharmacopoeia, should be conducted by both parties.

4.3.3 Management changes of pharmaceutical package materials.

The manufacture shall take the initiative study on the changes of production sites, raw material, product formulations, production process, in-process control, product specification, product packaging, and or other changes that may affect the quality of the pharmaceutical primary package material and its intended use. The study on the change of package materials may refer to T/CNPPA 3009-2020 and T/CNPPA 3019-2022.

The user of the pharmaceutical package material shall conduct the corresponding study and assessment with combining the outcome of studies by manufacturer and the drug classification. The study and assessment shall follow the guidelines of "Technical Guidelines for Pharmaceutical Change Studies of Listed Chemical Drugs", "Technical Guidelines for Pharmaceutical Change Studies of Listed Biological Products", "Technical Guidelines for Pharmaceutical Change Studies of Listed Traditional Chinese Medicines" . The user shall submit the supplementary application or registration form, or annual report to national and provincial Drug Evaluation Organizations according to the "Administrative Measures for Drug Post-marketing Changes”

Quality Agreement should specify change management process of both parties, change notification time requirement, communication channel and contact person for changes etc. shall be included.

5 Approval and implementation of quality agreement

5.1 Approval

5.1.1 Quality Agreement of pharmaceutical package materials is an integral part of the business contract.

5.1.2 The terms and wording in the Quality Agreement should be clear, precise, to avoid ambiguous description, multiple interpretations and understandings.

5.1.3 The Quality Agreement shall be drafted and reviewed jointly by quality, technology and relevant departments. If need, legal advisor shall be involved in.

5.1.4 Quality Agreement should be signed at least by quality responsible personnel of two parties, or by authorized personnel, and stamped with the official seal of the parties.

5.1.5 Effective date of the quality agreement should be clearly stipulated.

5.2 Implementation

5.2.1 Communication of Quality Agreement

An effective communication mechanism should be established by both parties to facilitate solving the problems timely during implementation of the Quality Agreement. For example, if the disputes occur in the process of change management, implementation of Agreement Standards, deviation handing, non-conforming product handling, or other aspects, both parties shall timely exchange information, conduct effective communication and coordinate to mitigate risk, appropriately solve the problems, with proper solutions in accordance with regulatory requirement. The outcome of the communication should be recorded in written document, signed by both parties and archived properly.

5.2.2 Maintaining and Reviewing of Quality Agreement

The original copy or reliable electronic copy of the valid Quality Agreement shall be archived respectively by both parties.

The Quality Agreement shall be regularly reviewed to ensure constant compliance with current regulations and corresponding mandatory requirement. When there is change of the agreement content or when there is change of the products in the scope. the Quality Agreement or the list of products (including the corresponding annex) should be updated accordingly. Updates shall be documented in history of the Quality Agreement, general description of the changes may be noted in the agreement change history if necessary.

The validity period of the Quality Agreement, the conditions for its renewal and termination shall be

addressed by both parties.References

1. T/CNPPA 3005-2019 Guidance of Good Manufacturing Practice for Packaging Materials for Medicinal Products.
2. T/CNPPA 3009-2020 Technical Guidance for Research on Changes of Pharmaceutical Packaging.
3. T/CNPPA 3019-2022 Guidance of Equivalence/Replaceability Assessment and Compatibility Studies for Post-approval Changes to Pharmaceutical Packages.
4. Drug Administration Law of the People's Republic of China. National Medical Products Administration. August 2019.
5. Administrative Measures for Drug Post-marketing Changes. National Medical Products Administration. January 2021.
6. Good Manufacturing Practice for Pharmaceutical Packaging Materials (Draft).National Medical Products Administration. June 2022.
7. Technical Guideline for Making Post Approval Changes to Chemical Drug Products(Trial Implementation). CDE. February 2021.
8. Technical Guideline for Post Approval Pharmaceutical Changes of Biological Products(Trial). CDE. June 2021.
9. Technical Guideline for the Study of Pharmaceutical Changes in Traditional Chinese Medicines. CDE. April 2021.