

CMC (Chemistry, Manufacturing and Controls)

Definition

- **CMC (Chemistry, Manufacturing, and Controls)** refers to the section of regulatory submissions that provides detailed information about the composition, manufacturing process, quality control, and stability of a pharmaceutical product.

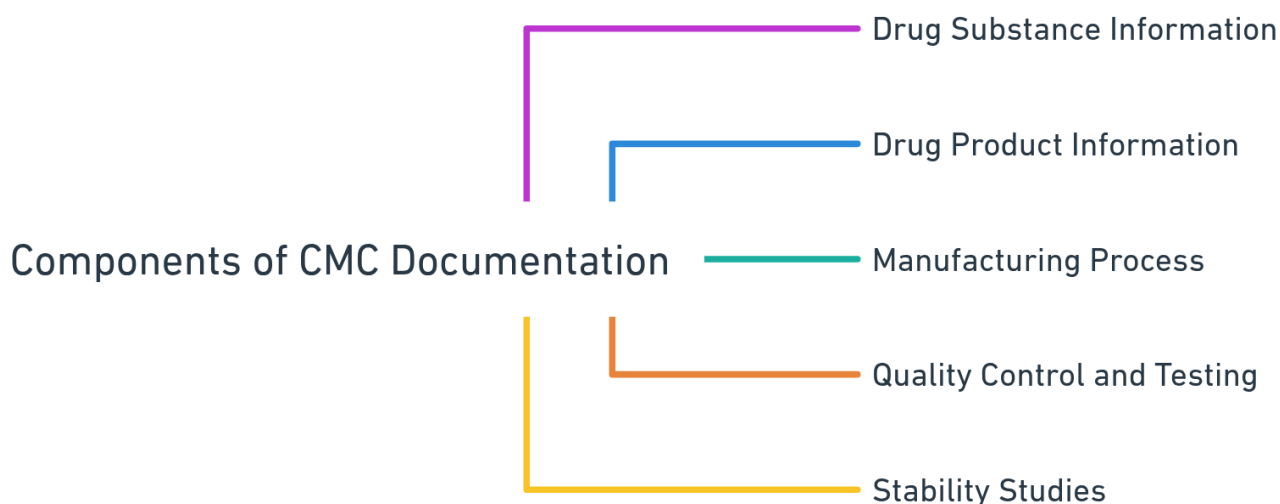


- It is an important part of regulatory applications such as:
 - NDA (New Drug Application)
 - ANDA (Abbreviated New Drug Application)
 - BLA (Biologics License Application)

Purpose of CMC

- Ensure that the drug product is consistently manufactured with required quality standards.
- Demonstrate that the manufacturing process is controlled and reproducible.
- Confirm that the product remains safe, effective, and stable throughout its shelf life.

Components of CMC Documentation



1. Drug Substance Information

- Information about the Active Pharmaceutical Ingredient (API).

- **Includes:**
 - Chemical name and structure
 - Molecular formula
 - Physical and chemical properties
 - API manufacturing process
 - Impurity profile
 - Specifications and analytical methods

2. Drug Product Information

- Information related to the final dosage form.
- **Includes:**
 - Formulation composition
 - Excipients used
 - Manufacturing process
 - In-process controls

3. Manufacturing Process

- Describes the step-by-step process for manufacturing the drug product.
- **Includes:**
 - Equipment used
 - Processing parameters
 - Batch size
 - Process controls

4. Quality Control and Testing

- Tests performed to ensure product quality.
- **Examples:**
 - Assay
 - Dissolution test
 - Uniformity of dosage units
 - Impurity testing
 - Microbial limit tests

5. Stability Studies

- Stability studies evaluate how the drug maintains quality under different conditions such as:

- Temperature
- Humidity
- Light exposure

➤ These studies help determine the shelf life and storage conditions.

Importance of CMC

- Ensures consistent drug quality and safety
- Supports regulatory approval
- Demonstrates reliability of manufacturing processes

Post-Approval Regulatory Affairs

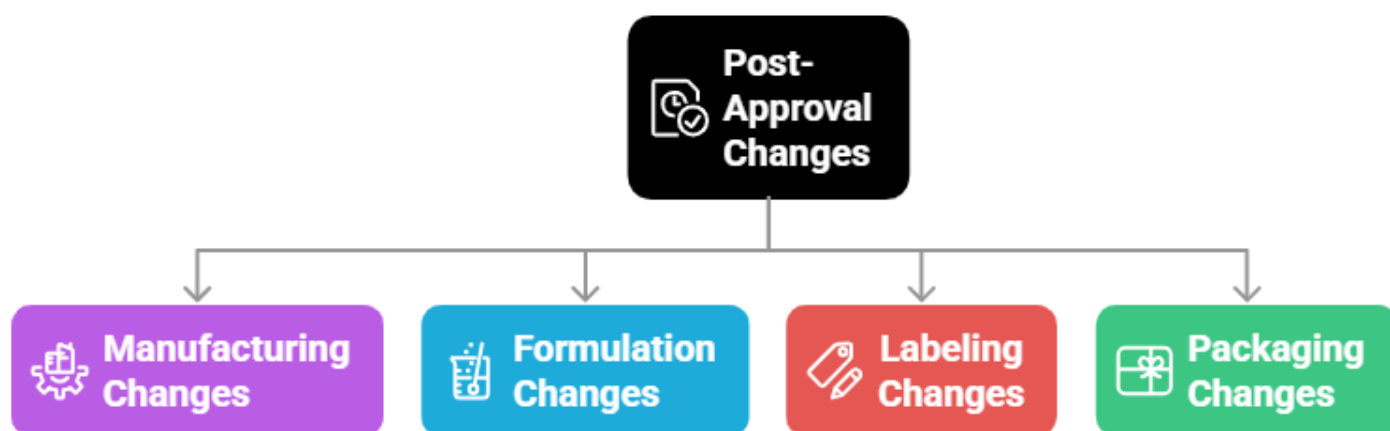
Definition

- **Post-approval regulatory affairs** refer to the regulatory activities carried out after a drug product has been approved by regulatory authorities.
- These activities ensure that any changes in the drug product, manufacturing process, labeling, or packaging remain compliant with regulatory requirements.

Objectives of Post-Approval Regulatory Affairs

- Maintain product quality and safety after approval
- Ensure continued regulatory compliance
- Manage changes in manufacturing, formulation, labeling, or packaging
- Supporting lifecycle management of pharmaceutical products

Types of Post-Approval Changes



1. Manufacturing Changes

- Changes related to the production process or manufacturing facilities.
- **Examples:**

- Change in manufacturing site
- Change in equipment
- Change in batch size
- Modification of manufacturing process

2. Formulation Changes

- Changes related to the composition of the drug product.
- **Examples:**
 - Modification of excipient composition
 - Change in formulation process

3. Labeling Changes

- Changes made to the product labeling or prescribing information.
- **Examples:**
 - Updated safety warnings
 - Revised dosage instructions
 - Addition of new indications

4. Packaging Changes

- Changes related to container or packaging materials.
- **Examples:**
 - Change in container-closure system
 - Modification of packaging materials

Regulatory Reporting Categories

1. Major Changes

- Changes that may significantly affect product quality, safety, or performance.
- **Examples:**
 - Change in manufacturing site
 - Major formulation changes
 - Significant manufacturing process modifications
- **Requirements:**
 - Prior approval from regulatory authorities

2. Moderate Changes

- Changes with moderate impact on product quality.

➤ **Examples:**

- Minor equipment modifications
- Process optimization

➤ **Requirements:**

- Supplemental regulatory submission or notification

3. Minor Changes

➤ Changes with minimal impact on product quality.

➤ **Examples:**

- Minor packaging changes
- Administrative updates

➤ **Requirements:**

- Usually reported in annual reports or simple notification

Post-Approval Responsibilities

• **After approval, pharmaceutical companies must:**

- Monitor drug safety
- Report adverse drug reactions
- Submit periodic safety reports
- Maintain consistent product quality and regulatory compliance

Importance of Post-Approval Regulatory Affairs

- Ensures continuous regulatory compliance
- Maintains product quality and patient safety
- Supports lifecycle management of pharmaceutical products
- Helps manage changes without affecting drug safety or efficacy

Regulation for Combination Products

Definition

- Combination products are medical products that combine two or more regulated components, such as:
 - Drug
 - Medical device
 - Biologic
- These components work together to achieve the desired therapeutic effect.



FREE PREVIEW

[Click here to visit our website](#)

PHARMACY PREMIUM NOTES

Complete subject
and semesters are
available on
FirstHope app only.



[Scan or click here](#)

Click here to get the app



Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram



[Scan or click here](#)

@FirstHopeNotes

Instagram

@firsthope.official

[Click here to follow >](#)

YouTube channel

FirstHope-Pharmacy / Live streams

[Click here to watch >](#)

WhatsApp channel

Follow FirstHope on WhatsApp

[Click here to join >](#)

FirstHope website

firsthopenotes.com

[Click here to visit >](#)

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Preview notes. Complete subjects and semesters in the FirstHope app.