Regulatory Requirements & Approval Procedures

Regulatory Requirements for Drugs

Basic Idea

- Drugs are regulated to ensure that they are safe, effective, and of good quality before they are made available to the public.
- In India, drugs are mainly regulated under the **Drugs and Cosmetics Act, 1940**, the **Drugs and Cosmetics Rules, 1945**, and the **New Drugs and Clinical Trials Rules, 2019**.
- The **Central Drugs Standard Control Organization (CDSCO)** is the national regulatory authority responsible for approving new drugs.

Regulatory Requirements

1. **Manufacturing License**
   - Every manufacturer must obtain a valid manufacturing license before producing drugs.
2. **Good Manufacturing Practices (GMP)**
   - Manufacturers must follow Good Manufacturing Practices to ensure consistent product quality.
3. **Quality Control**
   - Drugs must pass quality tests for identity, purity, strength, and stability.
4. **Clinical Trial Approval**
   - New drugs must undergo approved clinical trials before marketing.
5. **Proper Labeling**
   - Drug labels must contain complete and accurate information required by law.

Approval Procedure

A. **Submission of Application**
   - The manufacturer submits an application along with scientific and technical documents.

B. **Preclinical Studies**
   - Laboratory and animal studies are performed to evaluate safety.

C. **Clinical Trials**
   - Human studies are conducted to evaluate safety and effectiveness.

D. **Regulatory Review**
   - CDSCO reviews all submitted data carefully.

First Hope

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

E. Marketing Approval

- Approval is granted if the drug satisfies all regulatory requirements.

F. Post-Marketing Surveillance

- The safety of the drug continues to be monitored after marketing.

Regulatory Requirements for Cosmetics

- Cosmetics are regulated to ensure that they are safe for human use and do not contain harmful substances.
- Cosmetics are regulated under the **Drugs and Cosmetics Act, 1940** and the **Cosmetics Rules, 2020**.

Regulatory Requirements

1. Manufacturing License

- Cosmetic manufacturers must obtain the required license.

2. Quality Standards

- Cosmetics should comply with prescribed quality standards.

3. Safe Ingredients

- Only approved ingredients should be used in cosmetic products.

4. Proper Labeling

- Labels should provide complete product information.

5. Product Testing

- Cosmetics should be tested for safety and quality before marketing.

Approval Procedure

A. Application Submission

- The manufacturer or importer submits the required application.

B. Document Verification

- Regulatory authorities verify manufacturing and quality documents.

C. Inspection

- Manufacturing facilities may be inspected to verify compliance.

D. License Approval

- Approval is granted if all legal requirements are fulfilled.

First Hope

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

E. Market Monitoring

- Cosmetics continue to be monitored after entering the market.

Regulatory Requirements for Medical Devices

Basic Idea

- Medical devices are regulated to ensure that they are safe, effective, and perform as intended.
- Medical devices are regulated under the **Medical Devices Rules, 2017**.
- CDSCO is responsible for regulating medical devices in India.

Regulatory Requirements

1. Device Classification

- Medical devices are classified into Class A, B, C, and D based on risk.

2. Manufacturing License

- Manufacturers must obtain the required license before production.

3. Quality Management System

- Manufacturers should maintain an approved quality management system.

4. Safety and Performance Evaluation

- Medical devices must be tested for safety and intended performance.

5. Proper Labeling

- Labels should include all required information for safe use.

Approval Procedure

A. Application Submission

- The manufacturer submits an application with technical documents.

B. Technical Evaluation

- The device is evaluated for safety, quality, and performance.

C. Inspection

- Manufacturing facilities may be inspected.

D. License Grant

- Approval is issued after successful evaluation.

E. Post-Market Surveillance

- Device safety is continuously monitored after approval.

First Hope

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

Regulatory Requirements for Biologicals

- Biological products are medicines prepared from living organisms or their biological components.
- Biological products require strict regulatory control because they are complex in nature and sensitive to changes during manufacturing.
- In India, biologicals are regulated under the **Drugs and Cosmetics Act, 1940**, the **Drugs and Cosmetics Rules, 1945**, the New Drugs and Clinical Trials Rules, 2019, and applicable CDSCO guidelines.

Regulatory Requirements

1. Manufacturing License

- Manufacturers must obtain the required license before producing biological products.

2. Good Manufacturing Practices (GMP)

- Manufacturing facilities must follow Good Manufacturing Practices to maintain product quality.

3. Quality Testing

- Products must be tested for purity, potency, identity, sterility, and stability.

4. Clinical Trial Approval

- Biological products must undergo approved clinical trials before marketing.

5. Cold Chain Maintenance

- Proper storage and transportation conditions must be maintained to preserve product quality.

Approval Procedure

A. Application Submission

- The manufacturer submits all required scientific and technical documents.

B. Preclinical Studies

- Laboratory and animal studies are conducted to evaluate safety.

C. Clinical Trials

- Human studies are performed to evaluate safety and effectiveness.

D. Regulatory Review

- CDSCO reviews manufacturing, quality, safety, and clinical data.

E. Marketing Approval

- Approval is granted only after all regulatory requirements are satisfied.

First Hope

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

F. Post-Marketing Surveillance

- Safety monitoring continues after the product enters the market.

Regulatory Requirements for Herbals

- Herbal medicines are products prepared from plants or plant materials and are regulated to ensure their quality, safety, and proper manufacturing.
- Herbal products in India are mainly regulated by the **Ministry of AYUSH** and relevant provisions of the **Drugs and Cosmetics Act, 1940**.

Regulatory Requirements

1. Quality of Raw Materials

- Herbal ingredients should be correctly identified and free from contamination.

2. Good Manufacturing Practices

- Manufacturers must follow approved manufacturing standards.

3. Quality Control Testing

- Products should be tested for identity, purity, strength, and contamination.

4. Proper Labeling

- Labels should contain complete information about ingredients, dosage, manufacturer, batch number, and expiry date.

5. License Requirement

- Manufacturers must obtain the required license before producing herbal medicines.

Approval Procedure

A. Application Submission

- The manufacturer submits the required application and supporting documents.

B. Document Evaluation

- Regulatory authorities verify manufacturing and quality information.

C. Inspection

- Manufacturing facilities may be inspected to ensure compliance.

D. Quality Assessment

- Product quality is evaluated according to prescribed standards.

E. License Approval

- Approval is granted after all requirements are fulfilled.

First Hope

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

First Hope

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

firsthope.co.in

Click here to visit >

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

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