

Brief Introduction to CDSCO (Central Drugs Standard Control Organization)

Basic Idea

- **CDSCO** is the main regulatory authority for drugs in India.



- It works under the Ministry of Health and Family Welfare and is responsible for ensuring that drugs and medical products in India are safe, effective, and of good quality.

Head of CDSCO

- The organization is headed by the **Drugs Controller General of India (DCGI)**.

Main Objectives of CDSCO

- To ensure safety, efficacy, and quality of drugs
- To regulate clinical trials
- To approve new drugs and vaccines
- To control standards for imported drugs

Main Functions of CDSCO

CDSCO Functions



1. Approval of New Drugs

- CDSCO approves **new medicines** before they are sold in the market.
- **It checks:**
 - Safety
 - Effectiveness
 - Quality

2. Regulation of Clinical Trials

- Grants permission to conduct **clinical trials** in India.
- **Ensures:**
 - Ethical standards are followed
 - Safety of participants

3. Control of Drug Imports

- Regulates import of drugs into India.
- Ensures imported drugs meet Indian standards.

4. Standard Setting

- **Sets standards for:**
 - Drugs
 - Cosmetics
 - Medical devices

5. Coordination with State Authorities

- Works with **State Drug Control Departments** for enforcement.

Legal Basis

- **Operates under:**
 - Drugs and Cosmetics Act, 1940
 - Drugs and Cosmetics Rules, 1945

Structure of CDSCO

- Headquarters: New Delhi
- Zonal, sub-zonal, and port offices across India

Importance

- Acts as the **central authority** for drug regulation
- Ensures public health safety

- Maintains uniform standards across the country

WHO (World Health Organization)

Basic Idea

- WHO is a **specialized agency of the United Nations (UN)** responsible for **international public health**.



- Established in **1948**, it works globally to improve health standards.

Main Objectives

- Promote global health
- Control diseases
- Improve healthcare systems

Key Roles in Pharmaceuticals

1. Setting International Standards

- **Provides guidelines for:**
 - Drug safety
 - Quality control
 - Manufacturing practices (GMP)

2. Essential Medicines List (EML)

- Publishes a list of **essential drugs** needed for basic healthcare.
- Helps countries prioritize important medicines.

3. Prequalification Programme

- Evaluates quality of medicines and vaccines.
- Helps countries purchase **safe and effective drugs**.

4. Disease Control Programs

- **Works on:**
 - Vaccination
 - Epidemic control
 - Public health emergencies

5. Policy Guidance

- **Advises countries on:**
 - Drug regulation
 - Pricing
 - Access to medicines

Role in Pharmaceuticals

- Does not approve drugs for sale
- Provides guidelines and recommendations
- Influences national regulatory systems

USFDA (United States Food and Drug Administration)

Basic Idea



- The **USFDA** is the regulatory authority of the United States responsible for protecting public health by ensuring the **safety, efficacy, and security** of drugs, biologics, and medical devices.

Main Objectives

- To ensure drugs are **safe and effective**
- To regulate food, drugs, cosmetics, and medical devices

Key Functions

1. Drug Approval

- Approves new drugs before marketing.
- **Requires:**
 - Preclinical studies
 - Clinical trials

2. Regulation of Clinical Trials

- Monitors clinical trials conducted in the USA.
- Ensures safety of participants.

3. Inspection and Compliance

- Inspects manufacturing facilities worldwide.

- Ensures companies follow:
 - Good Manufacturing Practices (GMP)

4. Post-Marketing Surveillance

- Monitors drugs after approval.
- Detects side effects and risks.

5. Control of Imports

- Ensures imported drugs meet US standards.

Types of Applications

1. IND (Investigational New Drug)
2. NDA (New Drug Application)
3. ANDA (Abbreviated New Drug Application for generics)

Importance

- Considered one of the **strictest regulatory authorities**
- Approval from USFDA is globally respected

EMA / EMA (European Medicines Agency)

Basic Idea

- **EMA** (earlier called EMEA) is the **regulatory agency of the European Union (EU)** responsible for evaluating and supervising medicines.



Main Objective

- To ensure medicines in Europe are:
 - Safe
 - Effective
 - High quality

Key Functions

1. Centralized Drug Approval

- A single approval allows a drug to be sold in **all EU countries**.

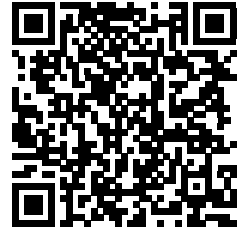


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