

UNIT – 5

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority

Central Drug Standard Control Organization (CDSCO):

Organization:

- **CDSCO:** Central Drug Standard Control Organization is the national regulatory authority in India.
- **HQ:** Located in New Delhi, with regional offices across India.

Responsibilities:

1. **Drug Approval:** Evaluates and approves new drugs, clinical trials, and fixed-dose combinations.
2. **Regulatory Oversight:** Ensures compliance with drug standards, licensing, and good manufacturing practices.
3. **Post-Market Surveillance:** Monitors safety and quality of marketed drugs.
4. **Quality Control:** Conducts quality control checks on drugs.
5. **International Collaboration:** Collaborates with international regulatory agencies.

Certificate of Pharmaceutical Product (COPP):

- **Definition:** A document issued by the regulatory authority, certifying that the product is authorized for sale in the country of origin.
- **Purpose:** Required for export of pharmaceutical products.

Regulatory Requirements and Approval Procedures for New Drugs:

1. Investigational New Drug (IND) Application:

- Submission to CDSCO for permission to conduct clinical trials.
- Includes data on preclinical studies, chemistry, manufacturing, and clinical trial protocols.

2. Clinical Trials:

- Phases I to IV, with increasing scale and complexity.
- Approval granted after evaluation of safety and efficacy data.

3. New Drug Application (NDA):

- Submission to CDSCO for marketing approval.
- Includes comprehensive data on preclinical and clinical studies, manufacturing, and safety profiles.
- CDSCO reviews the data and grants marketing approval if satisfied.

4. **Review Process:**

- CDSCO appoints a Subject Expert Committee (SEC) to review the application.
- The Drug Controller General of India (DCGI) takes the final decision.

5. **Post-Approval Monitoring:**

- Continuous monitoring of the drug's safety and efficacy after marketing approval.
- Manufacturers are required to submit periodic safety updates.

6. **Good Manufacturing Practices (GMP):**

- Stringent adherence to GMP is crucial for manufacturing authorization.
- CDSCO conducts inspections to ensure compliance.

7. **Pharmacovigilance:**

- Manufacturers must establish a pharmacovigilance system to report and monitor adverse drug reactions.
- CDSCO plays a role in overseeing pharmacovigilance activities.

8. **Post-Market Surveillance:**

- Ongoing monitoring of the safety, efficacy, and quality of marketed drugs.
- Regulatory action taken in case of non-compliance.

State Licensing Authority:

- **Responsibility:** Each Indian state has its own State Licensing Authority responsible for implementing drug regulations within its jurisdiction.

Key Functions:

1. **Licensing:** Issues licenses to pharmaceutical manufacturers, distributors, and retailers.
2. **Inspections:** Conducts inspections to ensure compliance with licensing conditions and GMP.
3. **Regulatory Oversight:** Monitors and enforces drug regulations within the state.
4. **Adverse Event Reporting:** Receives and acts upon reports of adverse drug reactions.

Challenges in the Indian Regulatory Landscape:

1. **Workload:** High workload for regulatory authorities due to the large number of applications.
2. **Resource Constraints:** Limited resources and manpower.
3. **Harmonization:** Challenges in harmonizing regulations across states for consistency.

The Indian regulatory environment, led by CDSCO and State Licensing Authorities, plays a crucial role in ensuring the safety, efficacy, and quality of pharmaceutical products. Regulatory processes are evolving to meet the challenges posed by the dynamic pharmaceutical landscape in India.

PHARMACY PEERS