

Indian Regulatory Requirements

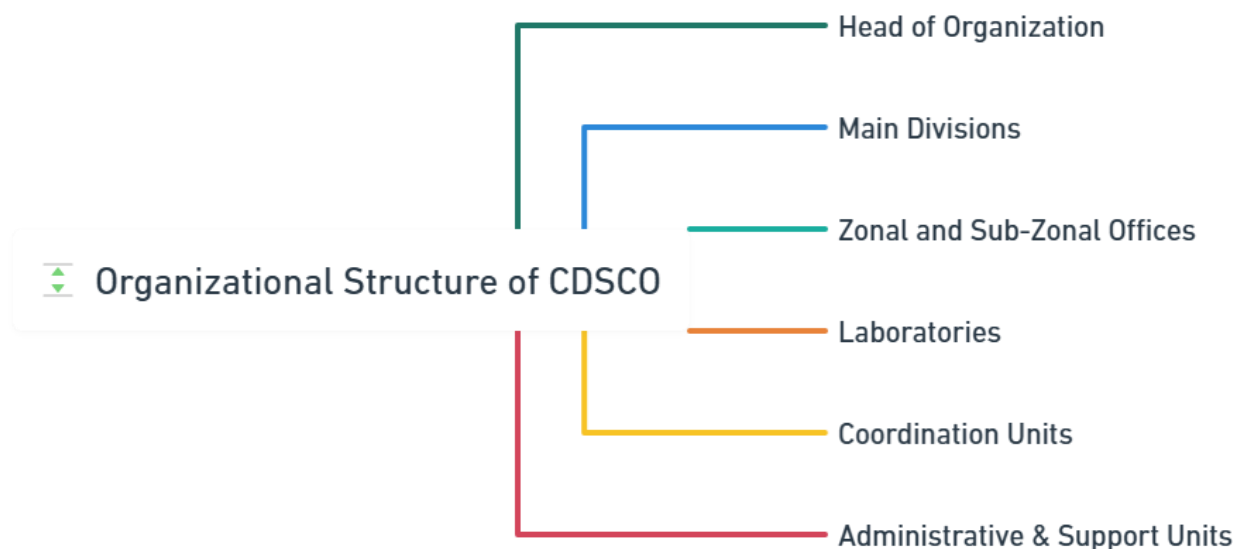
Central Drugs Standard Control Organization (CDSCO)

- The Central Drugs Standard Control Organization (CDSCO) is India's primary regulatory body for pharmaceuticals and medical devices.
- Operating under the Ministry of Health & Family Welfare, it ensures drug quality, safety, and efficacy in India and aligns with global standards to support India's international competitiveness in pharmaceuticals.

Key Functions

1. **New Drug Approval:** Approves new drugs, both domestically produced and imported, for sale in India.
2. **Clinical Trials:** Regulates clinical trial approvals and oversight for drug safety and efficacy.
3. **Standards & Quality:** Sets standards for drugs, cosmetics, and medical devices, ensuring all products meet established benchmarks.
4. **Import Control:** Oversees drug imports to ensure compliance with quality standards.
5. **Licensing:** Issues licenses, including import and clinical trial approvals.
6. **Pharmacovigilance:** Runs the Pharmacovigilance Programme of India (PvPI) to monitor adverse drug reactions.

Organizational Structure of CDSCO



1. Head of Organization:

- **Drug Controller General of India (DCGI)** oversees CDSCO operations, ensuring drug safety, efficacy, and alignment with public health goals.

2. Main Divisions:

- **New Drugs:** Approves new drugs, evaluating safety and quality.
- **Biological:** Regulates vaccines, biosimilars, and biotechnological products.

- **Medical Devices:** Manages medical device regulation, licensing, and quality assurance.
- **Import & Registration:** Handles registration of pharmaceuticals and medical devices for import, ensuring compliance.
- **Pharmacovigilance:** Monitors and addresses adverse drug reactions.
- **Standards:** Sets and enforces standards for drugs, cosmetics, and medical devices.

3. Zonal and Sub-Zonal Offices:

- **Zones:** North, South, East, West, and Northeast.
- **Sub-Zonal and Port Offices:** Manage region-specific regulatory compliance and oversee imports/exports.

4. Laboratories:

- **Central Drugs Laboratory, Kolkata:** Main lab for quality control.
- **Central Drugs Testing Laboratories:** Support regional testing and quality control functions.

5. Coordination Units:

- Enhance communication with government bodies, industry, and international partners to ensure cohesive regulatory functions.

6. Administrative & Support Units:

- Handle HR, IT, and other operational support functions, ensuring efficient organization.

Responsibilities

- **Regulation & Supervision:** Oversees drug manufacturing, sales, and quality.
- **Approval & Licensing:** Grants new drug and clinical trial approvals, issues licenses.
- **Standard Setting:** Sets and enforces pharmaceutical standards.
- **Safety Monitoring:** Evaluates drug safety through programs like PvPI.
- **Coordination:** Liaises with state drug control agencies and the central government.
- **Regulatory Oversight:** Ensures compliance for drug imports/exports.
- **Law Formulation & Amendment:** Advises the government on drug-related laws.

CDSCO plays a crucial role in ensuring public health by maintaining stringent regulatory standards for pharmaceuticals and medical devices in India.

State Licensing Authority (SLA)

- The State Licensing Authority (SLA) operates at the state level in India, overseeing drug manufacturing, sale, and distribution to ensure compliance with the Drugs & Cosmetics Act, 1940.



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