

Clinical Trial Regulations in India

DCG(I) Structure & Function



Module 5 Topic 3_1

Clinical Trial Regulations in India

- India being one of the most populated countries with 1.3 billion people and a premier emerging economy is a key market for multinational pharmaceutical and biotech companies to launch their drug products
- As a growing market, innovator drug and biotech companies are required by the drug regulatory authority of India to conduct clinical studies involving the local population to prove safety and efficacy of the drug product



Regulatory Authorities in India: DCG(I)

- The Central Drug Standard Control Organization (CDSCO) is the key authority for new drug approvals in India which is headed by the Drug Controller General of India (DCGI)



Regulatory Authorities in India: DCG(I)

Key Regulatory Authorities and Their Responsibilities

Authority	Main Function	Description/Responsibility
Ministry of Health & Family Welfare	Policy making body	Overall Policy and Planning authority
Director General of Health Services	Advisory & oversight	Technical advisor on all medical & public health matters. Oversight of CDSCO
Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General of India (DCGI)	Regulatory Body	Market authorization of new drugs, clinical trials approvals, approval & monitoring of drugs manufacturing



CDSCO: Mission

- Vision
 - To Protect and Promote public health in India
- Values
 - To achieve the mission and mandate of the CDSCO, strive to act with transparency, accountability, punctuality, courtesy, openness, responsiveness, professionalism, impartiality, consistency, integrity and truthfulness.
- Mission
 - To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices



CDSCO: Introduction

- CDSCO is controlled and governed by **Directorate General of Health Services** which comes under ministry of health and family welfare, Government of India
- The headquarter of the Central Drugs Standard Control Organization is located at New Delhi, while it has **multiple zonal offices** throughout India
- CDSCO also works in close context with **Central Drug Laboratories** to perform quality control tests.



CDSCO: Introduction (contd)

- **CDSCO is headed by Drugs Controller General of India (DCGI)**
- To regulate imported drugs as authority, the CDSCO works with the **Drugs Technical Advisory Board** and the **Drugs Consultative Committee**, while the Central Drugs Laboratory undertakes testing of such drugs.



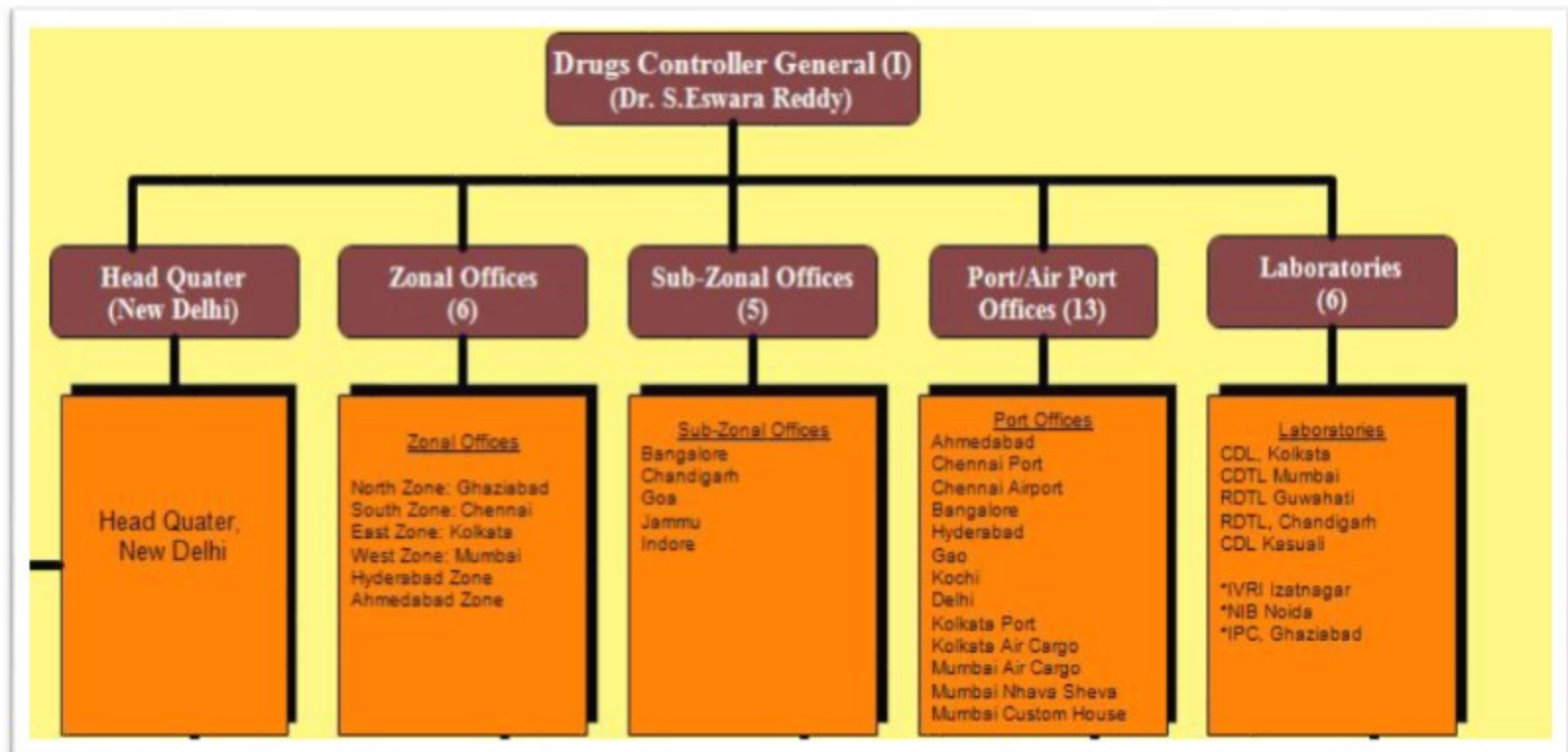
CDSCO: Introduction (contd)

CDSCO operates all over India by controlling

- **6** Zonal offices
- **5** Sub-zonal offices
- **13** Port offices and
- **6** Laboratories



Organisation Chart Central Drugs Standard Control Organisation



CDSCO: Functions undertaken by the central authority

- Laying down standards of drugs, cosmetics, diagnostics and devices
- Laying down regulatory measures, amendments to Acts and Rules
- To regulate market authorization of new drugs
- To regulate clinical research in India
- To approve licenses to manufacture certain categories of drugs as Central License approving Authority i.e. for Blood Banks, Large Volume Parenteral and Vaccines & Sera



CDSCO: Functions undertaken by the central authority (contd)

- To regulate the standards of imported drugs
- Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC)
- Testing of drugs by Central Drugs Lab
- Publication of Indian Pharmacopoeia



CDSCO: Functions undertaken by the state authority

- Licensing of drug manufacturing and sales establishments
- Licensing of drug testing laboratories
- Approval of drug formulations for manufacture
- Monitoring of quality of Drugs & Cosmetics, manufactured by respective state units and those marketed in the state
- Investigation and prosecution in respect of contravention of legal provisions.
- Administrative actions
- Pre- and post- licensing inspection
- Recall of sub-standard drugs



Zonal Offices Of CDSCO

- The Central Government have established four zonal offices of the CDSCO
 - Central Drugs Laboratory (CDL), Kolkata, West Bengal
 - Central Drugs Testing Laboratory (CDTL) Chennai, Tamil Nadu
 - Central Drugs Testing Laboratory (CDTL) Hyderabad, AP
 - Central Drugs Testing Laboratory (CDTL) Mumbai, Maharashtra
- The Zonal Offices work in close collaboration with the State Drug Control Administration and assist them in securing uniform enforcement of the Drug Act and other connected legislations, on all India basis



CDSCO: Supporting foundations

- Regional Drugs Testing Laboratory (RDTL) Guwahati
 - Established in 2002
- Regional Drugs Testing Laboratory (RDTL) Chandigarh
 - Established in 2007
- **Central Drugs Laboratory, CRI Kasauli**
 - Central Drugs Laboratory at Central Research Institute (CRI) Kasauli is a Central laboratory engaged in the testing of vaccines. It is a notified laboratory under the Drugs and Cosmetics Act, 1940 to function as Central Drugs Laboratory for testing of the biological origin products including sera, protein, vaccines, toxins, antigen, Sutures, bacteriophages etc



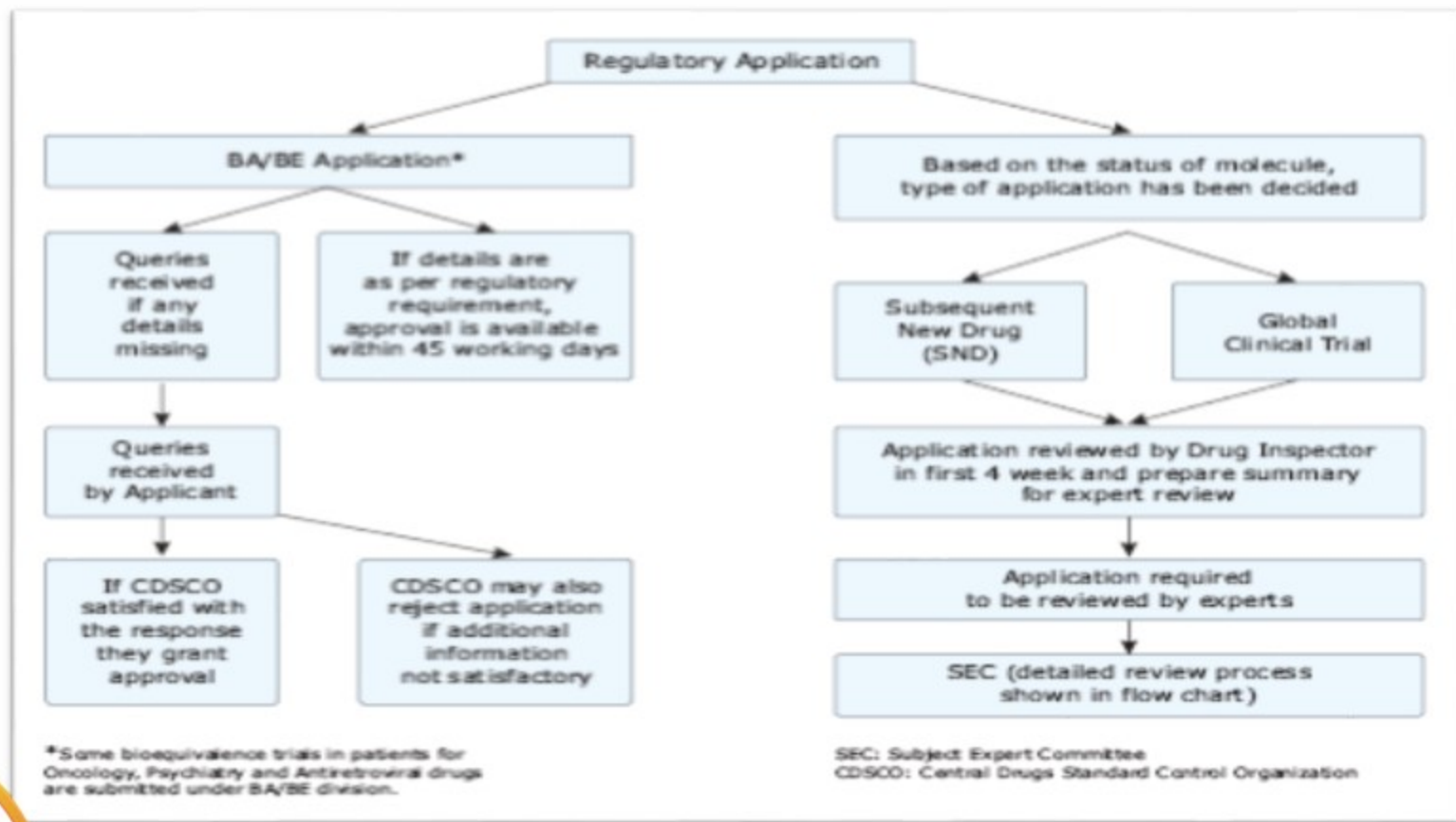
CDSCO: Supporting foundations

Indian Pharmacopoeial Commission (IPC)

IPC is an Autonomous Institution under the Ministry of Health & Family Welfare, Govt. of India dedicated for setting of standards for drugs, pharmaceuticals and healthcare devices/ technologies etc besides providing Reference Substances and Training.



Clinical Trial Approval Process of New Drugs In India



References

- Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. 30/06/18,
<http://www.cdsc0.nic.in/forms/contentpage1.aspx?lid=1423>

