Central Drugs Standard Control Organisation

(CDSCO)

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- **Central drug standard control organisation**

1. It comes under ministry of Health and Family Walefare in collaboration with Indian Pharmacopoeial commission Gaziabad.

- CDSCO is working with Pharmacopoeial commission that is as national co-ordinating system.
- The function of CDSCO is to regulate pharmaceutical and medical devices.

- CDSCO has started a national pharmacovigilance program for the protection of health of patients.
- Head office of CDSCO is located in New Delhi and it is directly under control of India government.
- Moreover CDSCO regulate the market authorization of new drug and clinical trail standard.
- CDSCO also keep eye on those drug manufactured outside of India, import registration is also exercised on cosmetic meant for health issue.

Regulatory bodies Associated to CDSCO

1. Ministry of health and family Walefare
2. Indian council of medical association
3. Indian Pharmaceutical association
4. Drug technical advisory board
5. Central drug testing laboratory
6. Indian Pharmacopoeial commission
7. National pharmaceutical pricing authority

Function of regulatory bodies

In Center

1. Check registration and licensing
2. Licence approval for vaccine medical devices biological product & diagnostic agent
3. Any amendments in drug and cosmetic act
4. Participation in WHO organised program
5. To short out banned drug
6. Testing of drug by Central laboratory
7. Grant of licence and NOC
8. Publication of Indian Pharmacopoeia
9. Approval of new drug &clinical trials

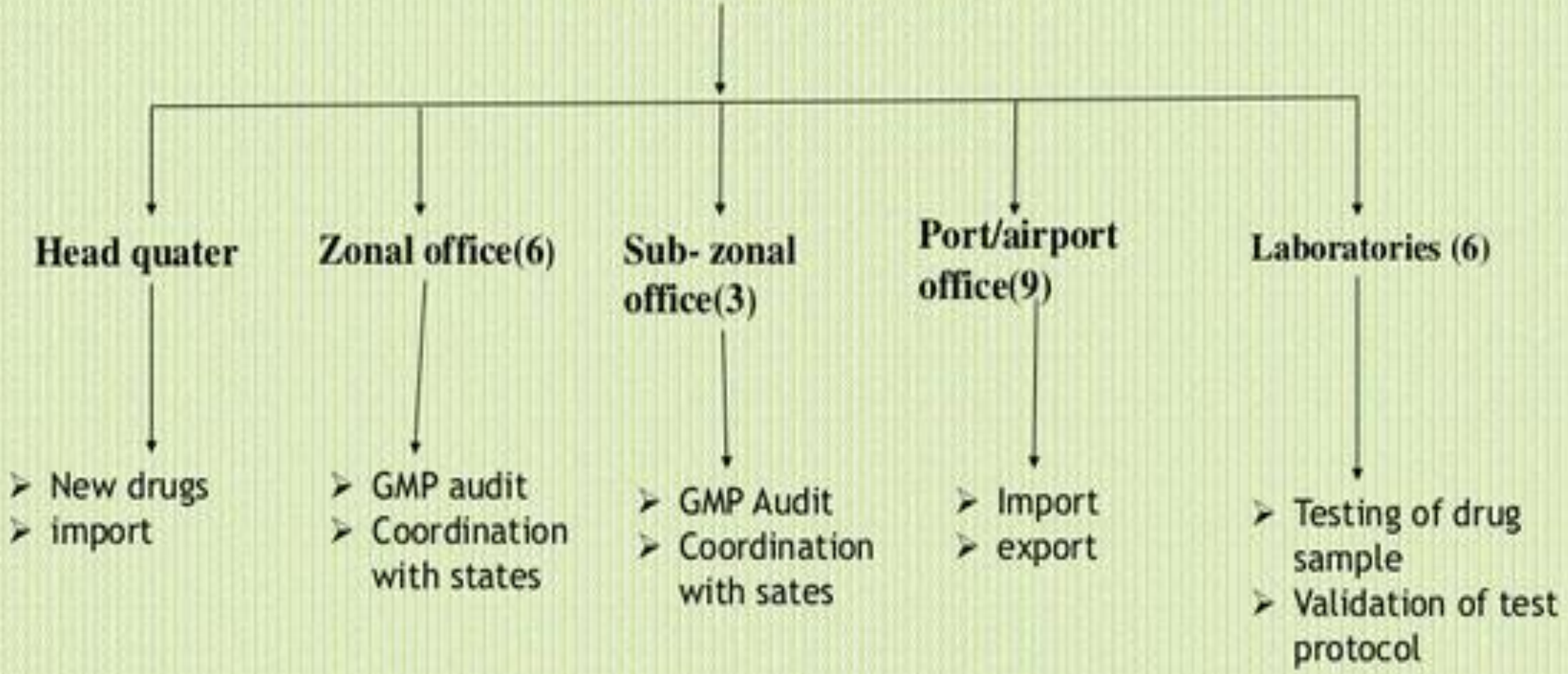
Approval for New Drug

1. New drug can only be marketed if it get permission from drug controller general of India
2. All new drug should be safe effective and must comply the requirements of schedule Y
3. New drug that have combinations,there required marketed data

Function in clinical trials

1. Schedule Y check
2. Prepration of guidelines for grants and permission to conduct clinical trail
3. To grant permission for conducting bioequivalence studies
4. The certificate of pharmaceutical products

Organization Chart



Zonal offices

- These are involved in GMP audits and inspection of manufacturing units of large volume parental, sera, vaccine and blood products.

Mumbai | Kolkata | Chennai | Ghaziabad | Ahemdabad | Hyderabad

Sub-zonal offices

- These centre co-ordinate with state drug control authorities under their jurisdiction for uniform standard of inspection.

Chandigarh | Jammu | Benglore

Port/airport office

- Delhi
- Chennai
- Hyderabad
- Indore port
- Kolkata port
- Mumbai port
- Cochin port
- Vishakapatnam sea-port
- Krishnapatanam sea-port

Laboratories

- CDL(Kolkata)
- CDL(Kasauli)
- CDTL(Mumbai)
- CDTL(Hydrabad)
- CDTL(Chennai)
- RDTL (Chandigarh)
- RDTL(Guwahati)

Drug approval process

SUGAM – online licensing portal

- An online licensing portal of CDSCO to file application for various services like application submission, processing and grant of permission for quick delivery of services.
- **SUGAM Benefits:**
- Applicant can apply license under import and registration division to CDSCO.
- Track the status of application through online.
- Answer back to raised queries.
- Applicant can also upload essential documents for registration , import license and other related activities.