Chapter 5

(Indian Regulatory Requirements)

1. Central Drug Standard Control Organization (CDSCO):

- It is the National Drug Regulatory Authority of the Government of India.
- CDSCO exercises regulatory control over the Quality of drugs, cosmetics and notified medical devices in the country.
- It is the Central Drug Authority for discharging functions under the drugs & cosmetic act.
- The function of CDSCO is to protect and promote public health in India.
- CDSCO initiates in framing of rules, regulations and guidance documents to match the contemporary issues in compliance with the requirements of Drugs & Cosmetics act 1940 and rules 1945.
- CDSCO facilitates in uniform implementation of the provisions of the drugs & cosmetics act 1940 and rules 1945.

2. State Licensing Authority [FDA]:

- Food & Drug administration (FDA) is a law enforcement agency.
- Responsibility of enforcement of the prevention of Food Adulteration Act, 1954.
- The regulations are implemented by the following independent sections:

✓ Drug section

✓ Food section

✓ Food & drug control laboratories

- For the drug section, following acts are implemented by the administration;

✓ Drugs & Cosmetics Act 1940 & rules there of 1945.

✓ Drug & magic Remedies (objectionable advertisements) Act 1954.

✓ Drug Price (Control) Order, 1995.

✓ Narcotic drugs & psychotropic Substance Act, 1985.

✓ Poison Act 1919.

- The major objectives of FDA are:

✓ To ensure safety, purity & quality of drugs.

✓ To prevent consumers from self-medication.

✓ To ensure availability of drugs at authorized prices.

✓ To avoid irrational combinations.

✓ To prevent misuse of narcotic drugs.

✓ To prepare policy regarding drug matter.

3. Certificate of Pharmaceutical Product [COPP]:

- Certificate of pharmaceutical product (COPP) is a certificate issued in the format recommended by the World health Organization (WHO).
- It is needed by the importing country when the product in question is intended for registration or renewal of registration with the scope of commercialization or distribution in that country.
- Certification has been recommended by WHO to help undersized drug regulatory authorizes or drug regulatory authorizes without proper quality assurance facilities in importing countries to assess the quality of pharmaceutical products as prerequisite of registration or importation.
- The COPP will be issued by zonal/sub zonal officers on behalf of Drugs Controller General of India after inspection and satisfactory clearance by CDSCO officers as per WHO-GMP guidelines.

4. Regulatory Requirements and Approval procedure of New drugs in India:

- When a company in India wants to manufacture/import a new drug, it has to apply to seek permission from the licensing authority (DCGI) by filing in Form 44 also submitting the data as given in Schedule Y of drugs and cosmetics act 1940 and rules 1945.
- A pharmaceutical company seeking FDA approval to sell a new prescription drug must complete a five–step process:

✓ Discovery/Concept

✓ Preclinical Research

✓ Clinical Research

- ✓ FDA Review
- ✓ FDA post-market safety monitoring.

Learning Outcome:

1. To learn the different Central and State Indian drug Regulatory agencies.
2. To understand the Regulatory requirements and Approval process of new drugs in India.

Important questions:

[Two marks Questions]

1. Define CDSCO.
2. What is COPP?
3. What is DCGI?

[Five marks Questions]

1. What are the objectives of CDSCO?
2. What is the role of state FDA?
3. Discuss certificate of pharmaceutical product in detail.

[Ten marks Questions]

1. Explain the regulatory requirements and approval procedures for new drugs inIndia.