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SIPS

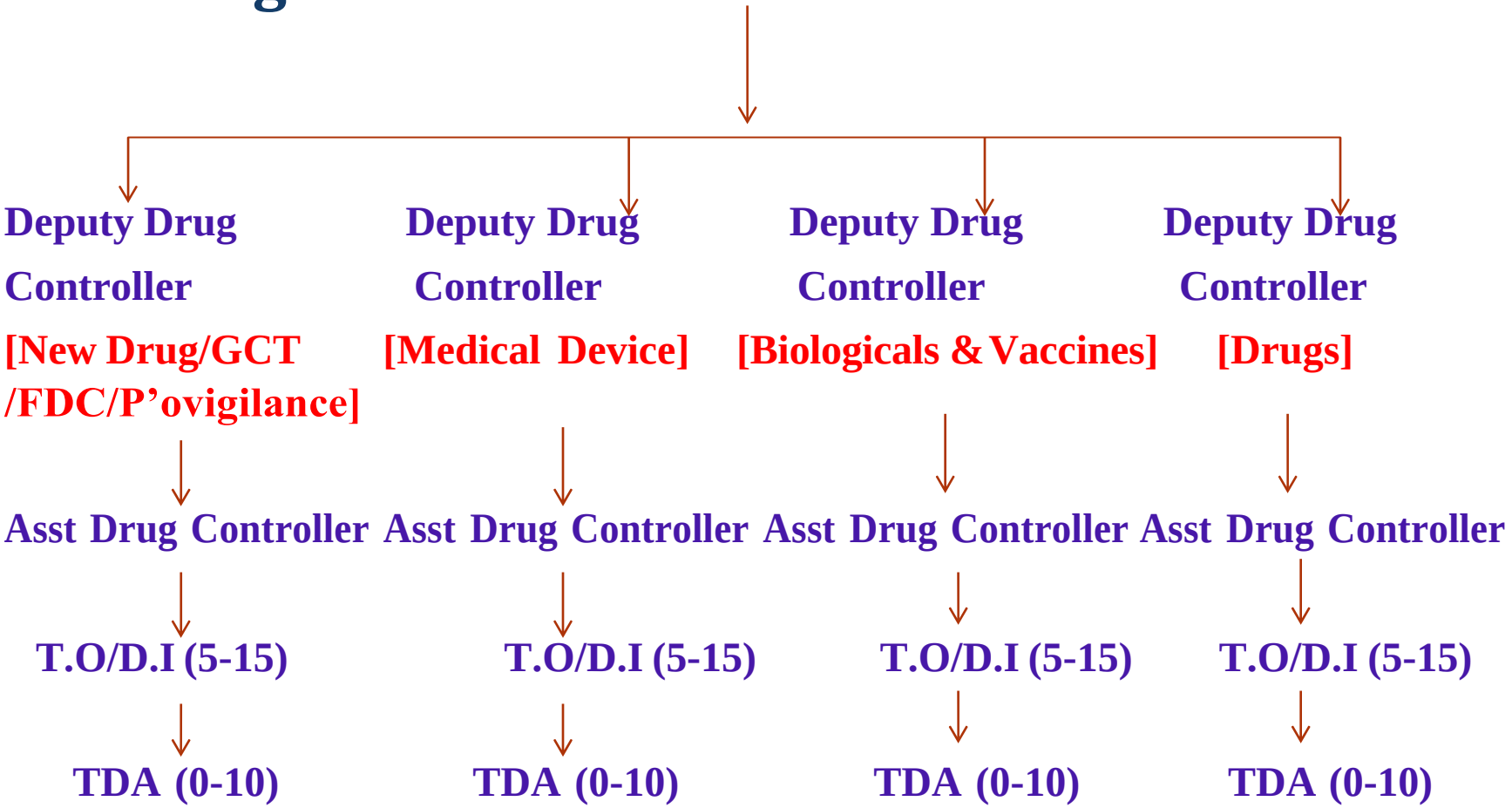
DRUG REGISTRATION

DRUG REGULATION SYSTEM IN INDIA

Drug Controller General of India is the head of Central Drug Standard Control Organization , which regulates Devices & Drugs in India.

TR Challan: Fees of 1500 USD is required for site registration and 1000 USD for registration of each product.

Drug Controller General of India



FLOW CHART FOR REGISTRATION

LEGAL DOCUMENTS

Documents To be submitted by Indian agent

- **Form 40-** It should be signed and stamped by Indian agent.

Documents To be submitted by Manufacturer

- **POA-** Power of attorney should be Appostilised or Consularized from Indian embassy of the country of origin, and should be co-jointly signed by both the parties i.e Manufacturer and Indian Agent.
- **Schedule DI & DII-** They should be signed and stamped by Manufacturer (Need not to be notarized)

REGULATORY DOCUMENTS

- Notarized Plant Registration Certificate
- Notarized Manufacturing & Marketing License
- Notarized Free Sale Certificate
- GMP Certificate Notarized
- COPP Notarized
- Whole Sale License (20B & 21B) of Indian Agent

Technical Documents

A) Plant master file: Should include the following points.

- Sketch of the Plant
- Profile of the company
- Organogram of the Company
- Plant & Machinery
- Hygienic & Sanitary measure details
- IQPQDQOQ
- HAVAC System
- MEN MATERIAL MOVEMENT

B). Device master file: Should include the following points.

- Manufacturing process/Flow Chart
- Quality Assurance procedures/process controls
- Final product testing report
- Functionality Test protocol and report
- Sterilization process and validation report
- Stability data
- BA/BE Study Report and Toxicological data

Post marketing Surveillance- It is the part of Device Master File, should include following points:

- Procedures for distribution of records
- Complaint handling.
- Adverse incident reporting
- Procedure for product recall

C). LABELS AND INSERTS

- Product labels should show the address of

  Drug Name & Ingredients, Manufacturer,Importers Address, provision for import licence No. Mafg. Date, Expiry Date, Lot No.

- Product inserts

PROCESSING PROCEDURE

After ensuring all documents correctly as per the requirements of FDA, they are submitted. It generally takes about 2-3 months to scrutinize these documents by Technical Data Associates/Drug inspectors of CDSCO and during this period clarification if any, required by them are answered and thereafter we get the Registration Certificate (RC) in Form 41.

IMPORT PROCESSING

After getting the registration certificate from CDSCO, the Indian agent is now import the products from the manufacturer. Following documents are further required to get Form 10 (Import license).

- **Form 8**
- **TR Challan- (Rs 1000 for Ist product then Rs 100 for each additional product)**
- **Form 9**
- **Copy of Wholesale License (Indian agent)-Notarized**
- **Copy of Registration Certificate-Notarized**

TIME LINE FOR IMPORT LICENSE

The Importer (Indian agent) is not authorized to import the products from foreign manufacturer unless he obtains Import license (Form 10) form CDSCO.

It generally takes about one month to scrutinize these documents by Technical Data Associates/Drug inspectors of CDSCO and during this period clarification if any, are required by them are answered and thereafter the importer gets the Import license.

For Import license application TR Challan of Rs 1000 for Ist product then Rs 100 for each additional product is required.

THANK YOU