

# Good Regulatory Practices.

Documentation

Licenses

Renewals

e-governance

Drugs  
Medical devices

- ① community pharmacy
- ② Wholesale "
- ③ Hospital "
- ④ Pharma Manufacturer
- ⑤ Export
- ⑥ Import.
- ⑦ Inspection

① Community pharmacy



Retail pharmacy

Allows the public access to their medications  
& advice about their health.

① Documentation

Medical stores / pharmacies

Have to maintain

Various records as per

Drugs & cosmetic Act 1940.

① Correspondence with Licensing Authority.

② Licenses:

③ Inspection Record

④ Registered pharmacist.

- ⑤ Purchase record of drugs.
- ⑥ Sale records of drugs.
- ⑦ Prescription Register
- ⑧ Schedule - H<sub>1</sub> Register.
- ⑨ NDPS Record
- ⑩ Record of expiry drugs.
- ⑪ Record of Ns a drugs.

## ⑫ Licenses

Retail sale : 20F

Whole sale : 20G.

## Blood Bank :

⇒ collection center of donated blood.

⇒ Blood Bank — section of a hospital where blood products are stored & properly tested to reduce the risk of transfusion related ADR.

Function under the supervision of a licensed physician, a transfusion Medical Specialist as a blood Bank Medical officer.

State Drug controller → license  
Approved by DCGI  
Regulated by Drugs & cosmetics Act

## Requirements :

① General.

⇒ Location & surroundings.

⇒ Building

⇒ Health, clothing & sanitation of staff.

② Accommodation.  $100^2\text{m}$  /  $50^2\text{m}$

↓  
operations

↓  
preparation

separate rooms.

## Places

Approval private

government

Sufficient technology

## Duration

< than 12 weeks - 1 RMP suggestion.

20 weeks - 2 RMP suggestion.

## Circumstances.

⇒ < than 12 weeks.

⇒ Pregnant woman.

⇒ child (seriously handicapped).

⇒ More than 20 weeks

Abuse.

Failure of contraceptives,