TOPIC: A BRIEF INTRODUCTION TO GMP

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INTRODUCTION

- GMP: Good manufacturing practice
- It is a practice that ensures that products are consistently produced and meet the required specifications of standard quality.
- It is designed with an aim to minimize the risk of contamination in pharmaceutical products.
- Schedule M of Drug and cosmetic act 1940 lays the standards for GMP.

REQUIREMENTS RELATED TO GMP

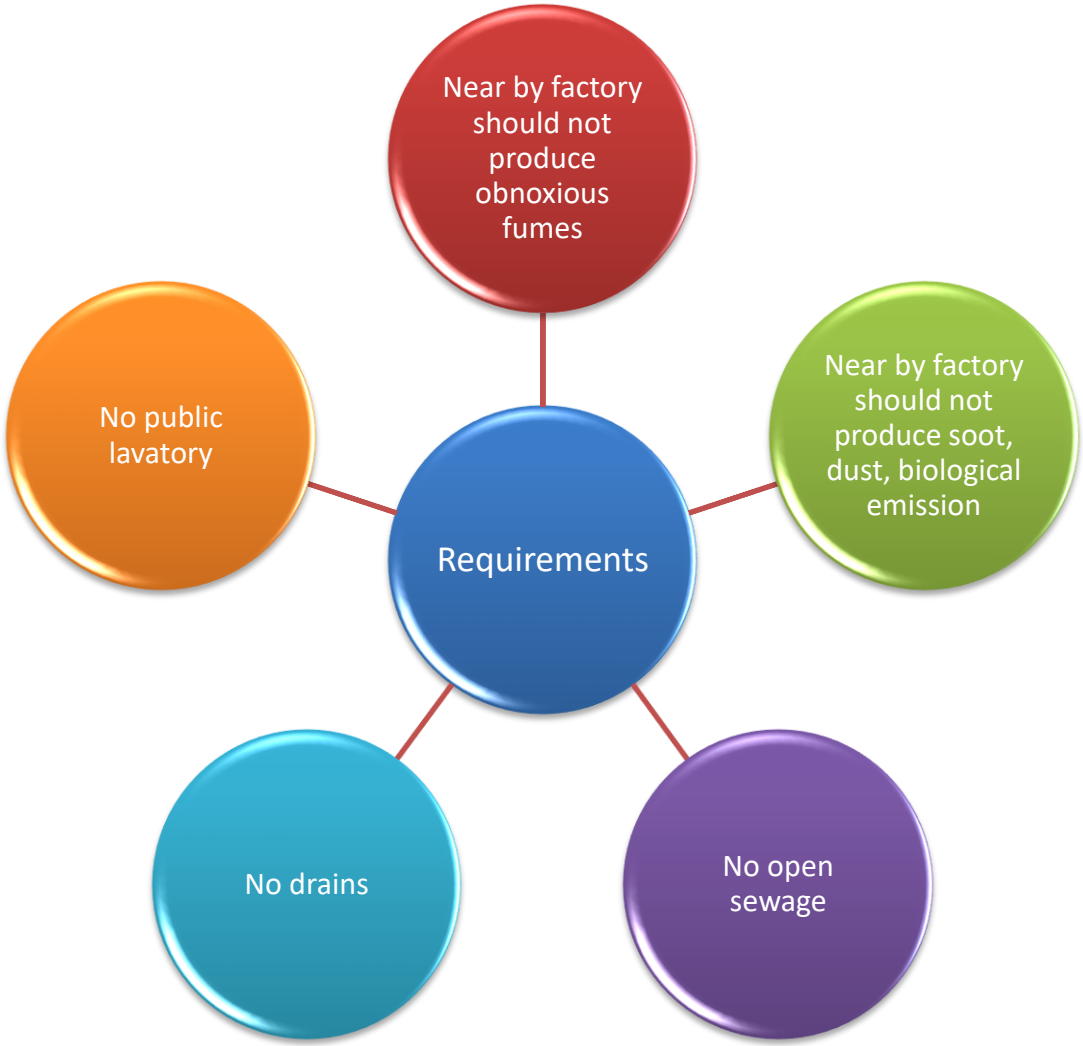
Requirement related to surroundings

General requirements for pharmaceutical plants

Requirement related to various departmental areas

Requirement related to special products

REQUIREMENTS RELATED TO SURROUNDING OF PLANT



GENERAL REQUIREMENTS FOR PHARMACEUTICAL PLANT

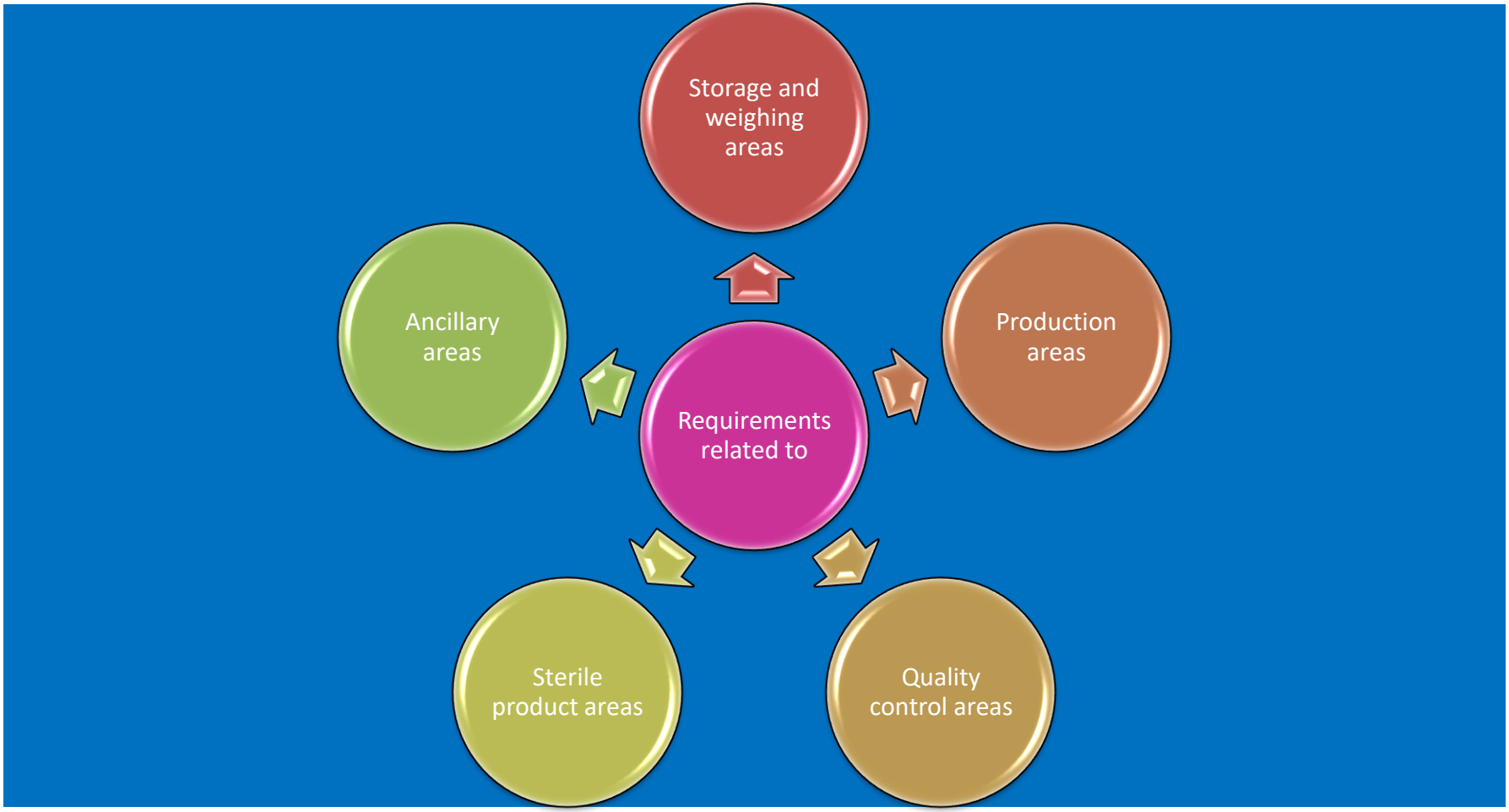
- Plant should be located, constructed, adapted and maintained to suit all operations.
- The layout should minimize the risk of contamination and cross- contaminations.
- The plant should always be in clean and sanitized condition.
- Should have good state of repair.
- SOPs should be maintained for cleaning, disinfection and sanitization.

- Plant should have following facilities

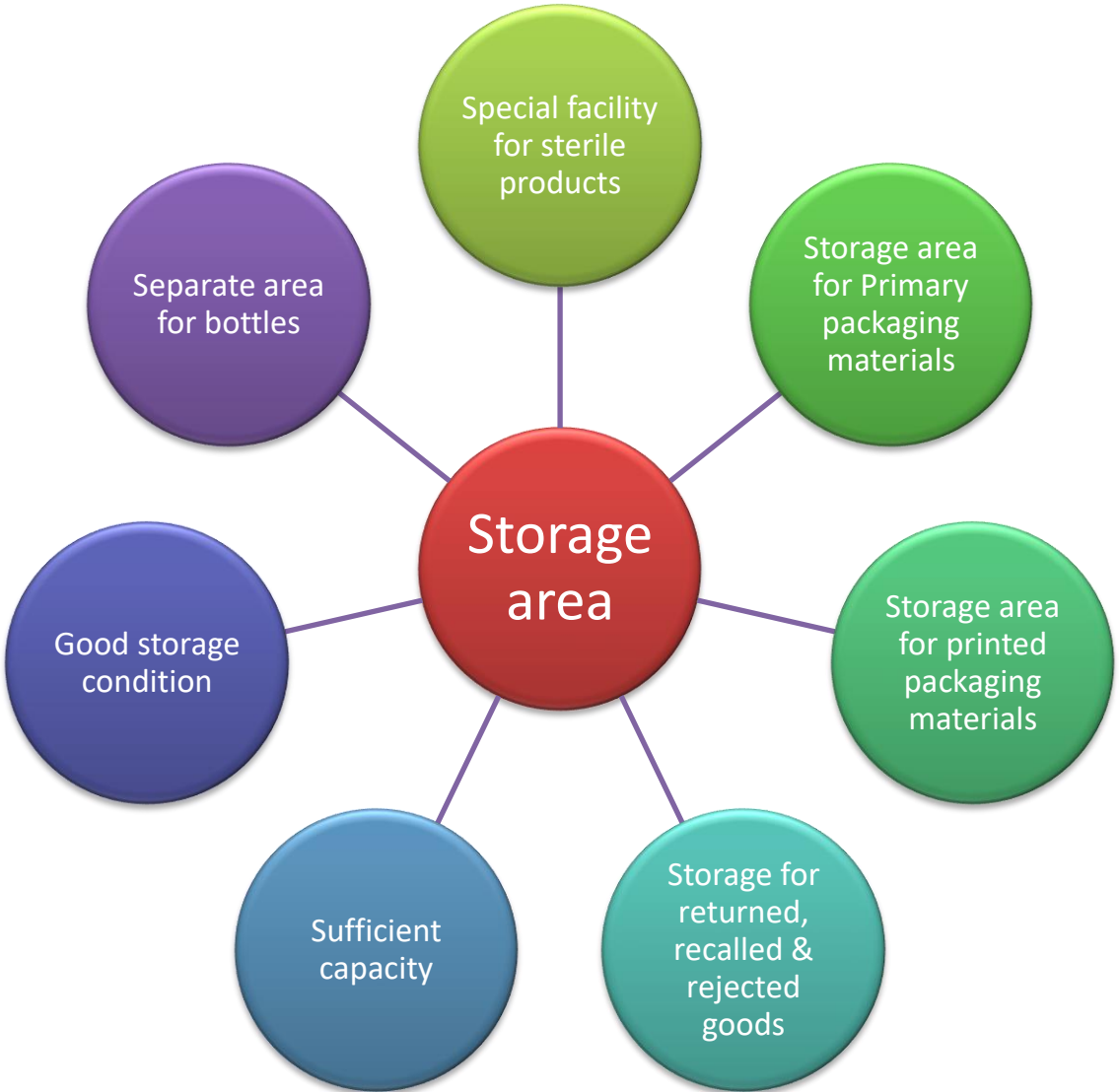
a. Electric supply
b. Lighting
c. Temperature
d. Humidity
e. HVAC: heating ventilation and air conditioning.

- Avoid entry of crawling and flying insects.
- Avoid entry of unauthorized people.
- Remove waste material on continuous basis.

REGUALTORY REQUIREMENTS RELATED TO VARIOUS DEPARTMENTS



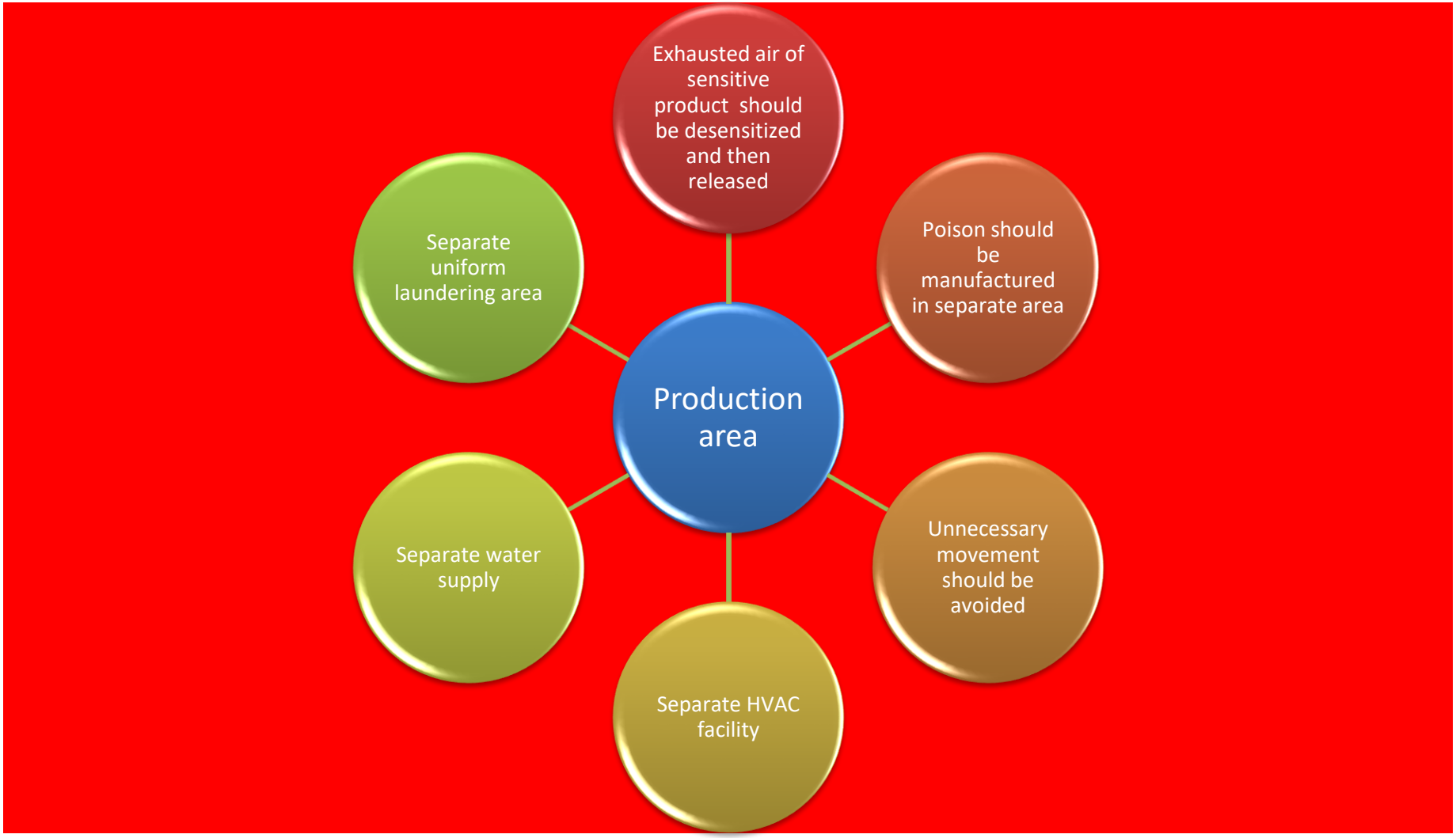
STORAGE AREA



WEIGHING AREA

- There should be separate weighing area for starting material and estimation of yield
- Dust control provisions should be followed

PRODUCTION AREA



QUALITY CONTROL AREA

- QC lab should be separate from production area.
- Lab should have facilities for biological , microbiological or radioisotope tests as required.
- Should have sufficient floor space to avoid intermixing.
- Storage space for sample, reference standard and records.
- Separate room for instruments to protect them against electrical interference, vibrations, contact with moisture etc.

STERILE PRODUCTS AREA

- Aseptic area for all operations.
- All exposed surfaces should be smooth, impervious and unbroken.
- Dust control provisions should be adopted.
- False ceiling on roof.
- Sinks and drains should be avoided.
- Changing rooms should have airlocks.
- Hand washing facility in changing room.
- Airlocks should not be opened simultaneously.
- HEPA filters for supply of purified air
- Laminar air flow bench for aseptic processing
- Air should have positive air pressure.
- Warning system to indicate failure of air supply.

Tab: Recommended limits for microbial contamination

Grade	Air sample, CFU/m3	Settle plates(dia. 90mm) CFU/4hours	Contact plates (dia. 55mm)CFU/plate	Glove-print 5 fingers CFU/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	NA
d	200	100	50	NA

ANCILLARY AREA

- Rest rooms, refreshment rooms and smoking areas should be separate from other area.
- Changing room facility should be provided.
- Separate area for maintenance work shop.
- Animal house should be well isolated from other areas and should have separate entry.