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PPT Presentation

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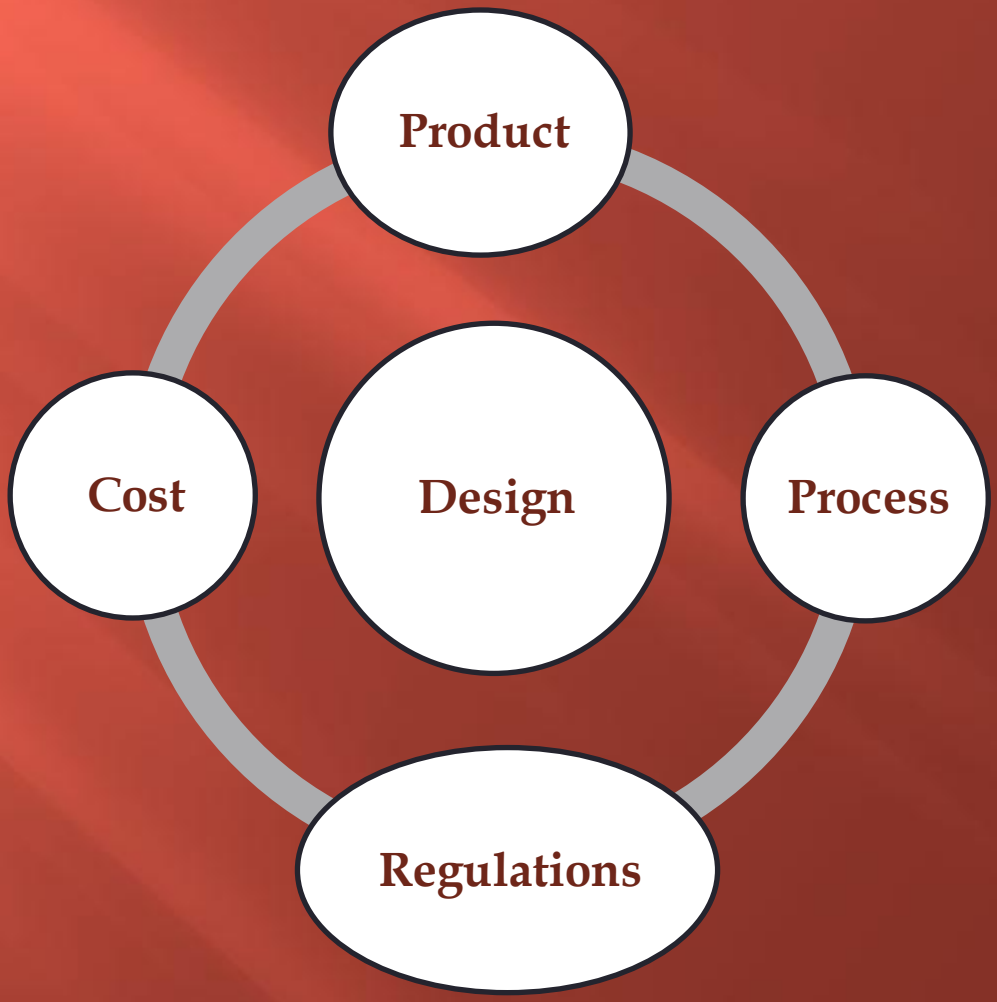
DESIGN OF MODERN PHARMACEUTICAL FACILITIES (OSD)

CONCEPTS & REGULATORY PHILOSOPHY:

- Comply with cGmps and concerned authorities requirements.
- Design should be based on detailed consideration of product and process.
- Flexible space with a capability of expansion.
- Cost effective construction with economic maintenance and energy.

DESIGN ELEMENTS



Product consideration

- **Deep analysis of the product characteristics.**
- **Product forecast.**
- **Evaluate Facility flexibility:**

  single/multiple dedicated/multiple for use .
- ***Risk assessment and impact on design* (ICH Q9)**

1-PRODUCT CHARACTERISTICS (RISK)	DESIGN IMPACT (RISK CONTROL)
1- Light sensitive	-Closed process and special lighting system.
2- Hygroscopic	- Low humidity conditions is required especially during exposure of product.
3-Staining materials	- Dedicated equipment. - Cleaning systems (CIP).
4- Toxicity	- Handling precautions. - Dedication - HVAC requirements.
5- Flammable ingredients	- Separate store and explosion proof arrangements.

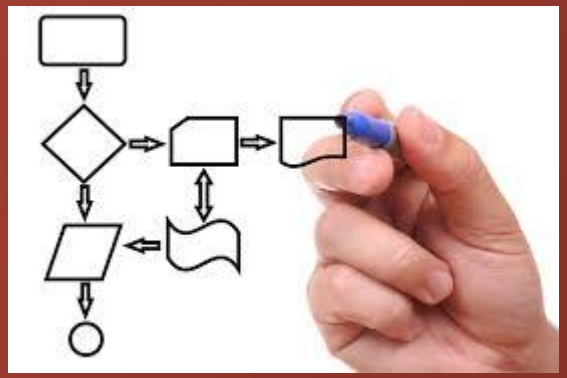
2- CAPACITY & RATIONALIZATION	IMPACT ON DESIGN
1- Product forecast.	▪ Capacity and technology of equipment. ▪ Staging and storage area.
2- Product volume compared to total site forecast.	▪ Equipment specs. ▪ Dedication (Equipment or area) in case of special conditions required and high % of forecast (e.g. Low RH%).
3-Estimation of quantities of starting and packaging materials.	▪ Storage area (No. of pellets and degree of store technology). ▪ Size of sampling and weighing area.

CONCULSION:

Based on analysis of products and forecast we can evaluate:

- Special operating and storage requirements.
- Required dedication of equipment or area.
- Degree of technology and capacity of equipments required.

PROCESS CONSIDERATION



- **PROCESS MAP:**

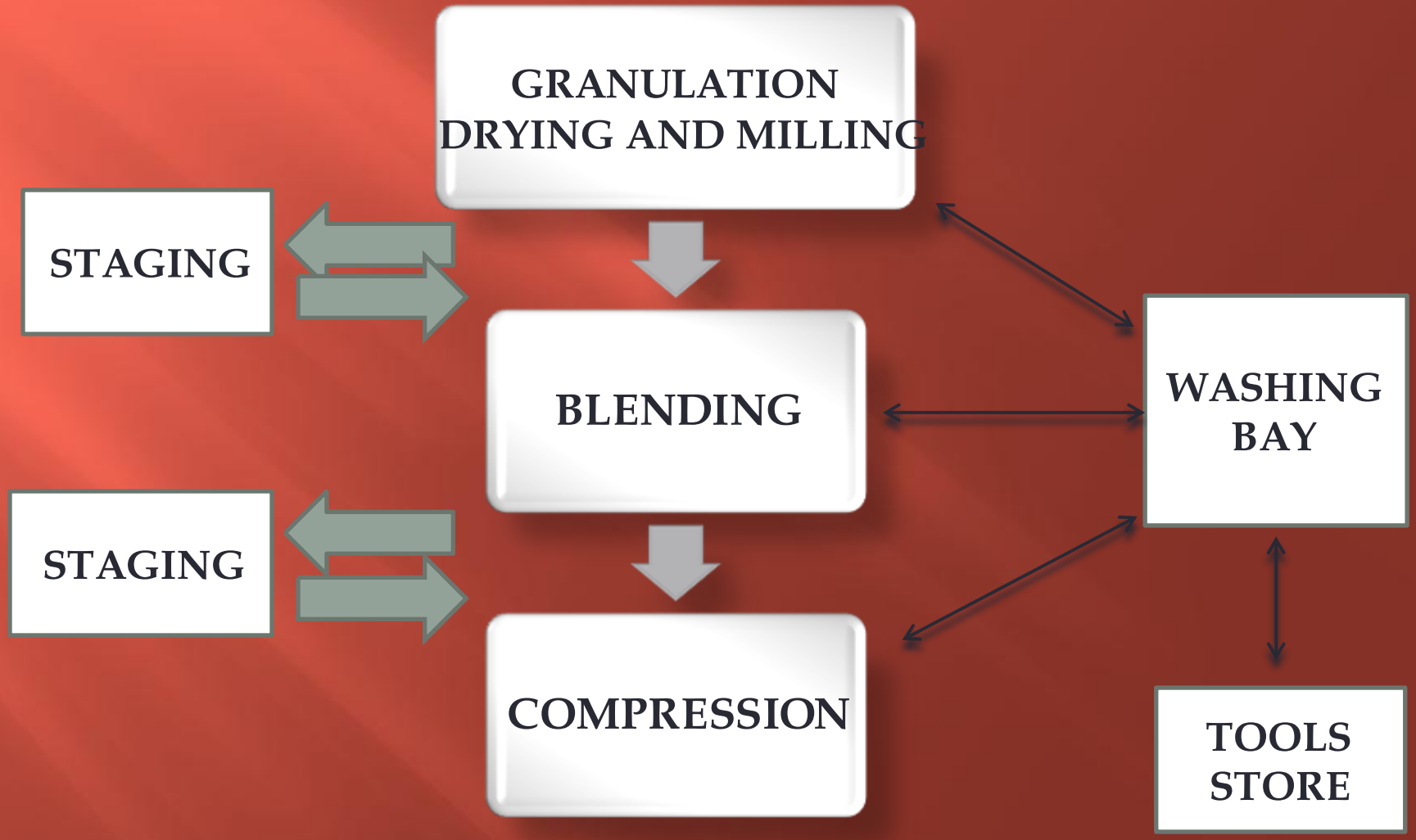
Shows a simple sequence of process steps.

- **FUNCTIONAL PROCESS MAP:**

Detailed map includes the process, its organization as well as inter-relationships within the production .

SIMPLE PROCESS MAP

DETAILED PROCESS MAP



EQUIPMENT LAYOUT

- Defines precise room sizes and access routes
- Blocks of rooms are assembled based on necessary adjacencies and process requirements

LEAN CONCEPTS

- **Aim:**
- **Increase the utilization ratio of the equipments.**
- **reduce waste of human resources and equipment resources.**
- **Simulation Elements of the System:**
- **Arrival of the material, the leaving of the material, waiting times, status of machines, overall machine process time….**
- **Simulation results of the different layout schemes verify the rationality and superiority of the final lean facility layout**

LEAN CONCEPTS

- Minimize the waiting time of a machining task.

  (Rationale of blender and coating machines capacity)

- Point out the bottleneck procedure and bottleneck equipment.

  (No. and capacity of blistering machines)

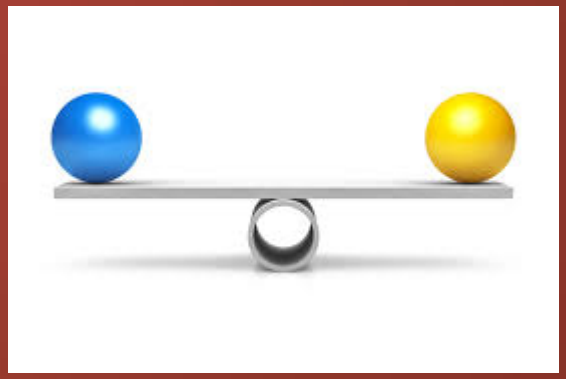
- Reduce the transfer distance of the work pieces.

  (Sequential and logical flow)

CONCLUSION

- Critical parameters and operating conditions are specified to control risks (e.g. cross contamination and mix up).
- List of equipment per each area and supporting services is prepared.
- Warehouse areas for format and spare parts .
- Quality of walls, ceilings and floors.
- Ventilation technology (recirculating air, fresh air, laminar flow).
- Type and quality of utilities (Water, compressed air, nitrogen, steam)

COST CONSIDERATION



- Classify areas according to level of protection required.

  e.g. store area vs. production area

- Optimum utilization of available facilities and technology degree.
- Current cost vs. life cycle cost.

  Example: Cost of closed processing operations.

Closed processing	Equipment	HVAC	Other utilities	Area cleaning
	↑	↓	↓	↓

REGULATORY CONCEPTS

- **EU, FDA, PIC/S, WHO Regulations.**
- **Local authority requirements.**
- **Environment and occupational health and safety requirements.**

FACILITY DESIGN

1- FACILITY LOCATION

- ✓ **Surrounding area and airborne particles.**
- ✓ **Ease of transport and distribution**
- ✓ **Climatic factors.**
- ✓ **Availability of energy sources.**
- ✓ **Available land space.**

2- FACILITY COMPONENTS

WAREHOUSE

PROCESSING

PACKAGING

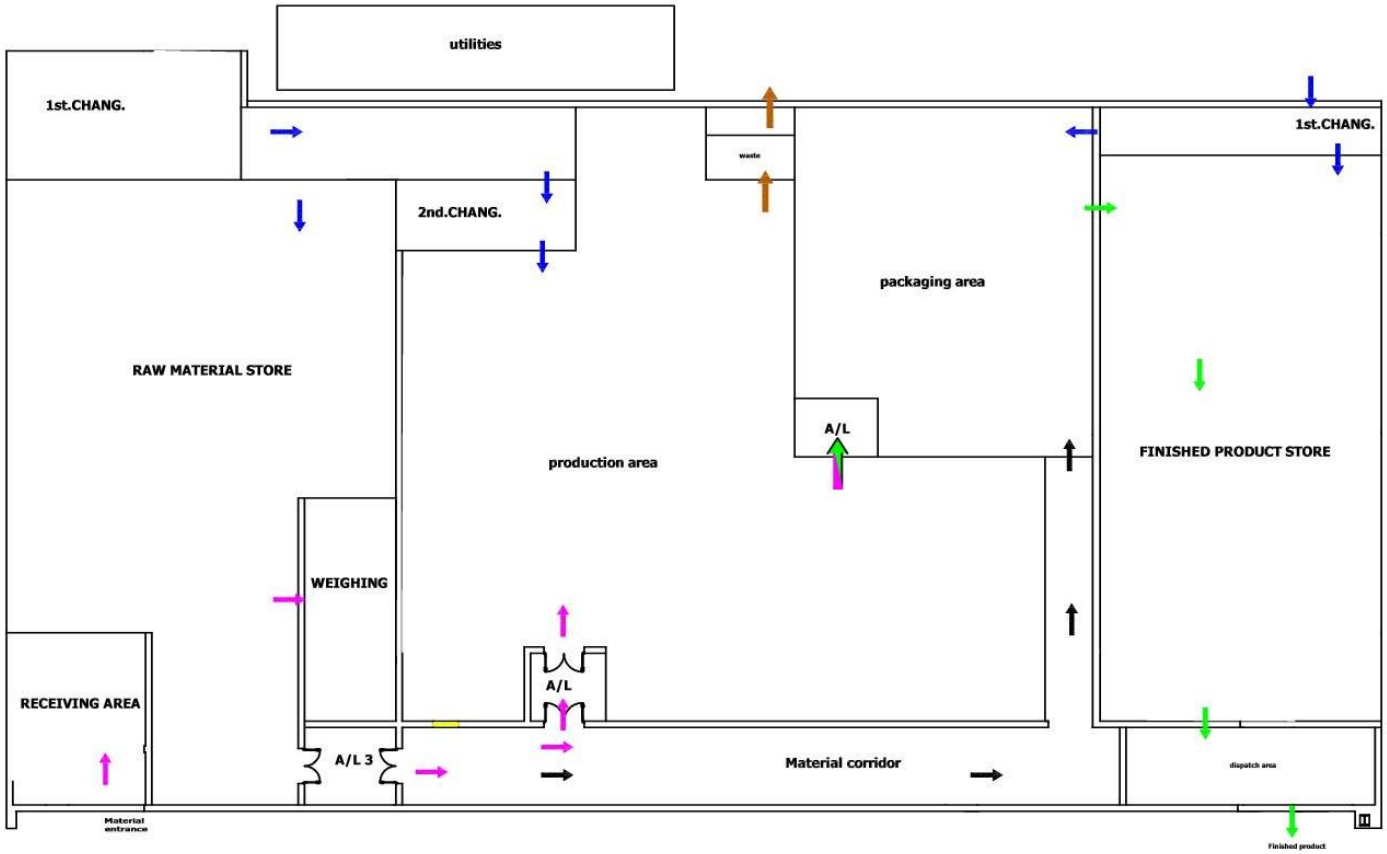
QUALITY AREA

UTILITIES AND SERVICES

3- FACILITY LAYOUT

Facility layout must be an integrated design that satisfies the following:

- **Equipment layout requirements**
- **Maintenance access requirements**
- **Personnel flow**
- **Material flow**
- **Waste flow**



workers flow

starting material and primary packaging material flow

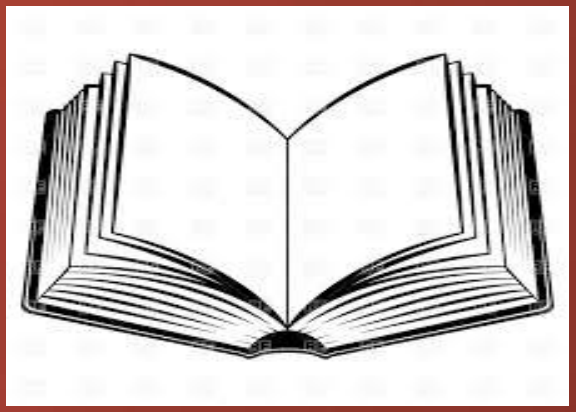
secondary packaging material flow

product flow

semi finished flow

waste

4-ROOM BOOK



- Useful document in which all data relevant to the room can be compiled.
- Together with the layout, the room book presents the specification of a room.
- Basis of qualification.

4- ROOM BOOK

Room name	Code	Length	Width	Height	Area	Volume	Temp	RH%	Class	Light Load	Power Load KW	Steam	Load air volume	No of air change	Compressed air	No. of persons
Blending																
Compression																

UTILITIES

- URS
- Risk assessment
- Functional specification
- Control strategy
- Detailed drawing

COMMON MISTAKES

1-Insufficient capacity of warehouse

- Specify inventory level (Company policy).
- Quarantine time.
- Production extension.

2-Under sizing of area

- Space for movement and equipment access.
- Extra space for portable items brought into the room, such as material container.
- Space for mechanical and electrical equipment panels.

COMMON MISTAKES

3-Insufficient staging area

- **Take in consideration production plan (No. of shifts, machine capacity, campaign size…).**
- **Waiting time for analysis.**

4-No space for Future extension

5-No tool store

COMMON MISTAKES

6- Under capacity of AHUs

- Thermal load calculation (No. of persons, machines, lighting...).
- Duct connections (air flow).
- Actual capacity of AHU motors.
- Dehumidifier capacity (different seasons).

Thank You

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