DESIGN OF MODERN PHARMACEUTICAL FACILITIES (OSD)
COMPLIES & 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
- Cost
- Design
- Process
- Regulations
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)
<table>
<thead>
<tr>
<th>PRODUCT CHARACTERISTICS (RISK)</th>
<th>DESIGN IMPACT (RISK CONTROL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- Light sensitive</td>
<td>- Closed process and special lighting system.</td>
</tr>
<tr>
<td>2- Hygroscopic</td>
<td>- Low humidity conditions is required especially during exposure of product.</td>
</tr>
<tr>
<td>3- Staining materials</td>
<td>- Dedicated equipment.</td>
</tr>
<tr>
<td>4- Toxicity</td>
<td>- Cleaning systems (CIP).</td>
</tr>
<tr>
<td>5- Flammable ingredients</td>
<td>- Handling precautions.</td>
</tr>
<tr>
<td></td>
<td>- Dedication</td>
</tr>
<tr>
<td></td>
<td>- HVAC requirements.</td>
</tr>
<tr>
<td></td>
<td>- Separate store and explosion proof arrangements.</td>
</tr>
<tr>
<td>2- CAPACITY &amp; RATIONALIZATION</td>
<td>IMPACT ON DESIGN</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>1- Product forecast.</td>
<td>Capacity and technology of equipment.</td>
</tr>
<tr>
<td></td>
<td>Staging and storage area.</td>
</tr>
<tr>
<td>2- Product volume compared to total site forecast.</td>
<td>Equipment specs.</td>
</tr>
<tr>
<td></td>
<td>Dedication (Equipment or area) in case of special conditions required and high % of forecast (e.g. Low RH%).</td>
</tr>
<tr>
<td>3- Estimation of quantities of starting and packaging materials.</td>
<td>Storage area (No. of pellets and degree of store technology).</td>
</tr>
<tr>
<td></td>
<td>Size of sampling and weighing area.</td>
</tr>
</tbody>
</table>
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 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

GRANULATION
DRYING AND MILLING

BLENDING

COMPRESSION
• Defines precise room sizes and access routes.

• Blocks of rooms are assembled based on necessary adjacencies and process requirements.
• **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
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)
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)
• 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.

<table>
<thead>
<tr>
<th>Closed processing</th>
<th>Equipment</th>
<th>HVAC</th>
<th>Other utilities</th>
<th>Area cleaning</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>↑</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
</tbody>
</table>
• 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
Facility layout must be an integrated design that satisfies the following:

- Equipment layout requirements
- Maintenance access requirements
- Personnel flow
- Material flow
- Waste flow
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.
<table>
<thead>
<tr>
<th>Room name</th>
<th>Code</th>
<th>Length</th>
<th>Width</th>
<th>Height</th>
<th>Area</th>
<th>Volume</th>
<th>Temp</th>
<th>RH%</th>
<th>Class</th>
<th>Light Load</th>
<th>Power Load KW</th>
<th>Steam</th>
<th>Load air volume</th>
<th>No of air change</th>
<th>Compressed air</th>
<th>No. of persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blending</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
UTILITIES

- URS
- Risk assessment
- Functional specification
- Control strategy
- Detailed drawing
1-Insufficient capacity of warehouse
   o Specify inventory level (Company policy).
   o Quarantine time.
   o Production extension.

2-Under sizing of area
   o Space for movement and equipment access.
   o Extra space for portable items brought into the room, such as material container.
   o Space for mechanical and electrical equipment panels.
3-Insufficient staging area
   o Take in consideration production plan (No. of shifts, machine capacity, campaign size...).
   o Waiting time for analysis.

4-No space for Future extension

5-No tool store
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

Presented by:
Ahmed Salah Abu shoukka
Technical director of Copad Pharma