Good Cleanroom Design & Construction Practice

Presented by Gordon Farquharson
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Good Design & Construction Practice – Cleanrooms

• ISO Link to Annex 15 of the PIC/S GMP Guide.
• Some new energy saving considerations.
• Practical tips – the devil is in the details.
ISO 14644-4 :2001 and NEW 2018

2001

- Adequate space.
- Specify ISO cleanliness class.
- Clean construction protocol.
- Avoid cracks, crevices, and uncleanable areas.
- Impervious, non-shedding surfaces.
- Coved junctions.
- Guidance on air changes/hr for non-UDF.
- Design review and testing fits with old Annex 15.

2018 new aspects

- Generally updated.
- Air change rates guidance removed; source strength of contaminants and ventilation effectiveness principles included.
- Energy saving measures identified.
- URS added to link to new Annex 15 PIC/S GMP guide.
Every Cleanroom is a “Prototype”!!

- Process & Product has unique features
- The host building and its environment are unique
- The equipment configuration and layout is unique
- The project team is unique

**BUT**

All cleanrooms use common components and techniques
Cleanrooms are very different!

Cleanroom technology applied to API manufacture
Cleanrooms are very different!
1. Exclusion of the external environment.
2. To create the class of cleanliness and environmental conditions required for the process by dilution or displacement of the contamination generated.
   • To maintain ISO cleanliness Classes (1-9), or GMP Grades (A-D).
3. Containment of hazards arising from the process.
5. Control and management of Material & Personnel flows and procedures by way of planning and layout of the suite.
Configuration of Clean Rooms
Design Layout

Planning and layout requirements are not defined in GMPs or Cleanroom standards.

The expectation however, is quite clear. The layout and planning should ensure the following:

1. Effective segregation between the external environment and the classified space.
2. Well managed materials and personnel flow.
3. Segregation spaces of different grade or class.
Don’t Underestimate the Impact of the Process Equipment
The Potential of Closed Process Equipment

- CIP/SIP
- Vacuum
- Uncontrolled area
- Classified area
- Heating cooling
Designing for Adaptability

- Loose fit - enables changes with minimum disruption
- Consider modular design
- Clean construction protocol ISO 14644-4
- External access for maintenance
- Service chases
Corridors and Working Spaces
Remember Maintenance of Technical Systems
Construction of clean rooms

Some images from MRC Systems & Clestra
Basic Construction Methods

GMP doesn’t mandate any specific approach.

1. “Stick-built”. In-situ construction

<table>
<thead>
<tr>
<th>Masonry + gypsum applied plaster + applied finish</th>
<th>Finish options:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Sheet PVC</td>
</tr>
<tr>
<td></td>
<td>• Sprayed elastomeric paint</td>
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<tr>
<td></td>
<td>• Epoxy paint</td>
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</tbody>
</table>

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<tr>
<th>Gypsum or calcium silicate board + closing of joints + applied finish</th>
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2. Pre-fabricated, pre-finished cleanroom wall & ceiling panel systems

<table>
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<th>Options</th>
</tr>
</thead>
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<tr>
<td>• Mild steel painted</td>
</tr>
<tr>
<td>• Stainless steel</td>
</tr>
<tr>
<td>• GRP – Glass reinforced polyester</td>
</tr>
<tr>
<td>• Phenolic sheet</td>
</tr>
</tbody>
</table>
Choosing the Preferred Option

**Cost**
- Shouldn’t always be at the top of the list.
- Remember you should be considering >20 years life.

**Local sourcing**
- Materials
- Labour to install
- Technical support

**Construction environment**
- Clean/dirty - Dry/wet

**Project lead times and decision making**
- Have to make decisions early for pre-fabricated
- Have longer to cogitate for stick-built

**Modification and relocation requirements**
- Is the systems compatible with development and evolution of the business operations?

**Repair**
- In house / Local resources
- Vendor dependent
Other Attributes of The Construction System

Ceiling:
- Suspended
- Bridging on walls
- Walk-on

Low level return air ducts:
- In wall construction
- Double wall required
- Plant on surface

Services in walls:
- In wall thickness
- In a service pod on wall
- In a service chase
Masonry System
- Masonry walls
- Concrete ceiling
- Hard plaster (gypsum)
- Door frames set into the wall structure
- Applied epoxy paint to walls
- Thin epoxy floor finish
Gypsum Board and Frame System

- Metal frame
- Calcium silicate or Gypsum board attached
- Joints taped
- Finish applied – this case a glass reinforced polyester resin.
GRP Cleanroom Panel System
Picture courtesy of MRC Systems Ltd
Typical Metal Panel System
Floor Channels...
Ceiling Channels...
Walk-on Ceiling…
Single or Double Glazing...
Doors Swing Slide Powered...
1. Swing doors should close with air pressure.
2. Often need to work with electromechanical interlock systems
3. Doors should be self closing (soft close to avoid pressure shocks).
5. Powered doors
   • Becoming more common
   • Ensures optimum open/close rate
   • Can help avoid hand contact
6. Sliding doors
   • OK
   • Ensure cleanroom style
   • Avoid floor tracks
   • Ensure top track cleanable
Door Options

- Hinged
- Horizontal sliding
- Vertical roller door
Advantages of Sliding Doors

- Saves space (in particular in clean corridors for Grade C & D areas).
- No wind effect when opening & closing.
- More convenient for moving materials & equipment (pallets, IBCs).
- Less susceptible to mechanical damage.
- More convenient for large openings.
- Can be part opened.
Disadvantages of Sliding Doors

- Sometimes greater cost than double leaf swing door.
- Top track needs periodic inspection.
- Not good for dusty rooms – should be on clean corridor side.
Doors in OSD Application - With Airlock

- Clean process corridor
  --

- Process Room
  +

- Process Room
  +

+++

++

+ +

++

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Doors in OSD Application – Without Airlock

Clean process corridor

Process Room +

Process Room +
Sliding Doors in OSD Cleanroom

Example MSD Singapore
Sliding Door Details

- Very important to choose specialist good supplier.
- Essential Top track, door leaf, and bottom guide.
Single Door Width
Insulated Sliding Doors – Cold Room
GRP Sliding Doors
Glass & Low Leakage Sliding Doors
Door Leakage

- Generally some leakage is OK.
- Should be estimated and allowed for.
- If cleanrooms are too airtight, pressure balancing and pressure stability become problematic.
- Example – SP 30 +/- 3 Pa
Sheet materials adhered to floor:

- PVC sheet (lowest cost)
  - Adhered to floor.
  - Seams welded
  - Cove former to walls
- Tacky mats
  - Permanent
  - Peel-off
Cleanroom Flooring (2)

**Applied screeds**

1. Epoxy (thin self levelling)
   - Available in ESD/static dissipative and conductive versions.

2. Polyurethane (thin self levelling)
   - Some uses the natural power of silver to fight bacteria, and
   - Available in ESD/static dissipative and conductive versions.

3. Epoxy terrazzo (thick)
   - recycled granular material.

4. Tiles
   - Ceramic (chemical plants)
   - Epoxy
   - Terrazzo
Cleanroom Flooring (3)

Cleaning

1. Classified cleanrooms
   • Surface swabbing with mops and controlled disinfectant materials.
   • Routine hygiene and cleanliness monitoring
2. Non-sterile manufacturing
   • Machine cleaning preferred
   • Periodic housekeeping controls.
Equipment Integration

- Space for the equipment.
- Integration with the room fabric.
- Maintenance access.
- Room Pressure barriers.
• Room Pressure barriers.
• Impact of equipment on room pressure due to air in-flow (loss) into the equipment.
Thank you for your time.
Questions?

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