



The Architecture of Isolation Technology Based Parenteral Facility Design

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Agenda

- Historical Perspective
- Design Philosophies
- Layout Options
- Architectural Finishes

Historical Perspective Aseptic Clean Rooms

- Grade A/ ISO 5 Suite Design
- Full ‘Space Suit’ Gowning
- Issues
 - Operator Interventions
 - Operator Contamination
 - Expensive to Operate
 - Design Challenges

Historical Perspective RABS

- Addition of a Barrier to Limit Interventions
- Issues
 - Operator Still in Room
 - Maintain Aseptic Room Conditions
 - Expensive to Operate
 - Defending Cleaning Procedures
 - Validating Air Flow
- ‘Ridiculous Attempt Being Sterile’

Historical Perspective Isolation Technology

- Delayed Introduction Due To:
 - Resistance to New Technology
 - 18-Hour VHP Cycle
- Introduction of High Value Bio Products and SKAN's Reduced VPH cycle
- Low Life Cycle Cost
- Preferred Option by USFDA Reviewers

Design Philosophies

Area Classifications

- In Isolator: Grade A/ ISO 5
- In Processing Suite: Grade C/ ISO 8
- Adjacent Processing Suite: Grade D/ C_{un}C
- Capping
 - Potent Product:
In Separate Isolator Compartment with Air Extraction
 - Non-Potent Product:
In Adjacent RABS with Grade A/ ISO 5 Air Supply

Design Philosophies

Gowning

- Unclassified to Grade D/ CunC
 - Remove Street Clothes and Shoes
 - Add Plant Uniform and Plant Shoes
 - Add Hairnet/ Beard Cover
- Grade D/ CunC to Grade C/ ISO 8
 - Add One- or Two-Piece Non-Particulating Suit Gathered at the Wrists
 - Add Shoe Covers, Hairnet/ Beard Cover

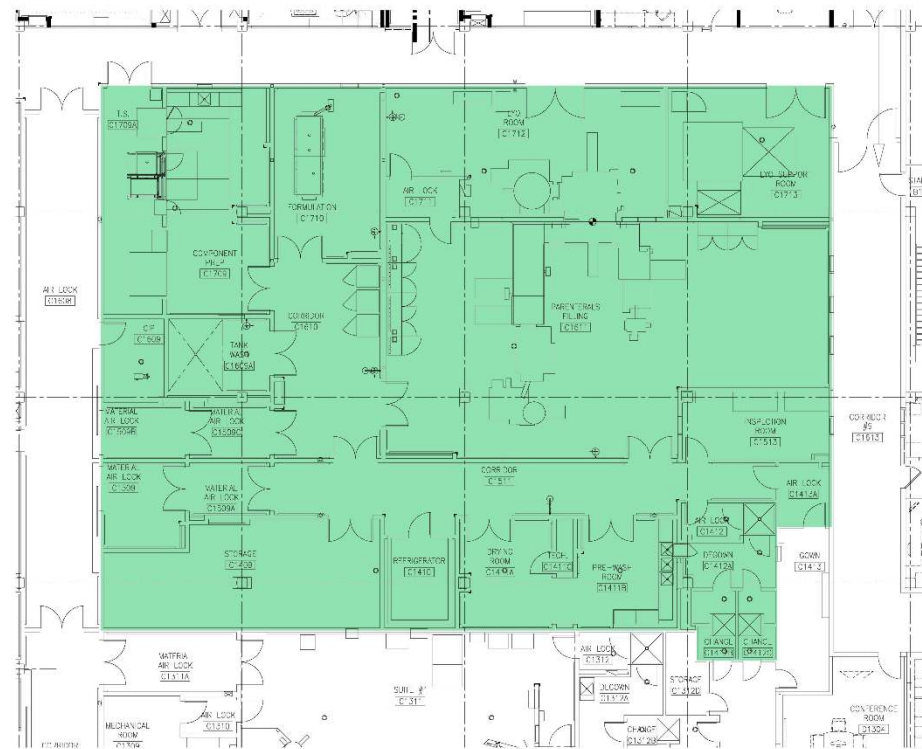
Layouts

GMP Corridor Option

- Enter Suite Through Gowning/ MA/L into GMP Corridor
- All Processing Rooms off the GMP Corridor
- GMP Corridor Positive Pressure to all Adjacent Rooms
- Ideal for Containment of Potent Products
- Uses 30% Less Area than Aseptic Suite and RABS Layouts

Layouts

GMP Corridor Option



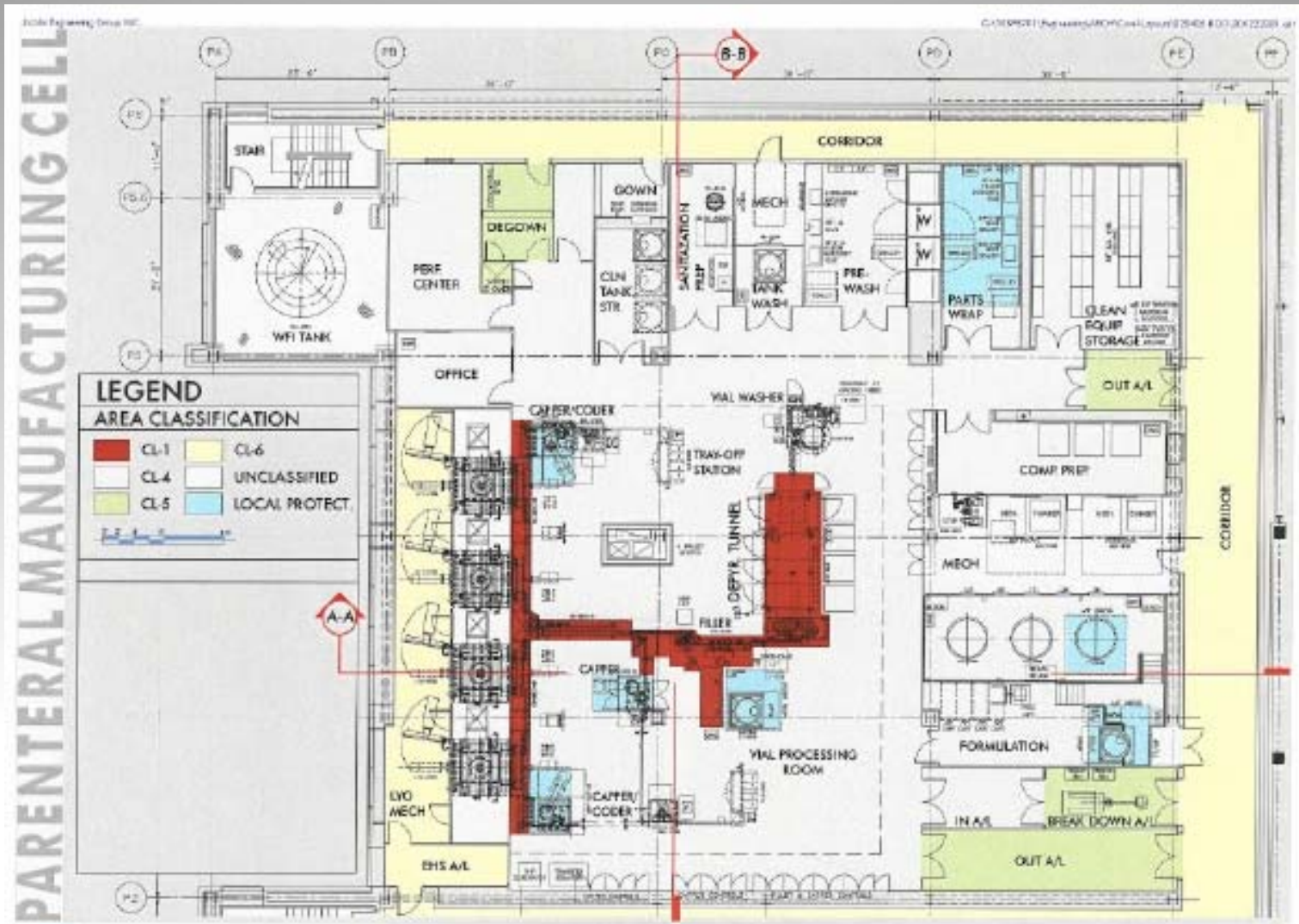
Layouts

Ball Room Option

- Enter Suite Through Gowning/ MA/L into Filling Room
- All Processing Rooms off of Filling Room
- Filling Room Positive Pressure to Gowning/ M A/L, Formulation and Equipment Wash Rooms
- Uses 10% Less Area than GMP Corridor Layout

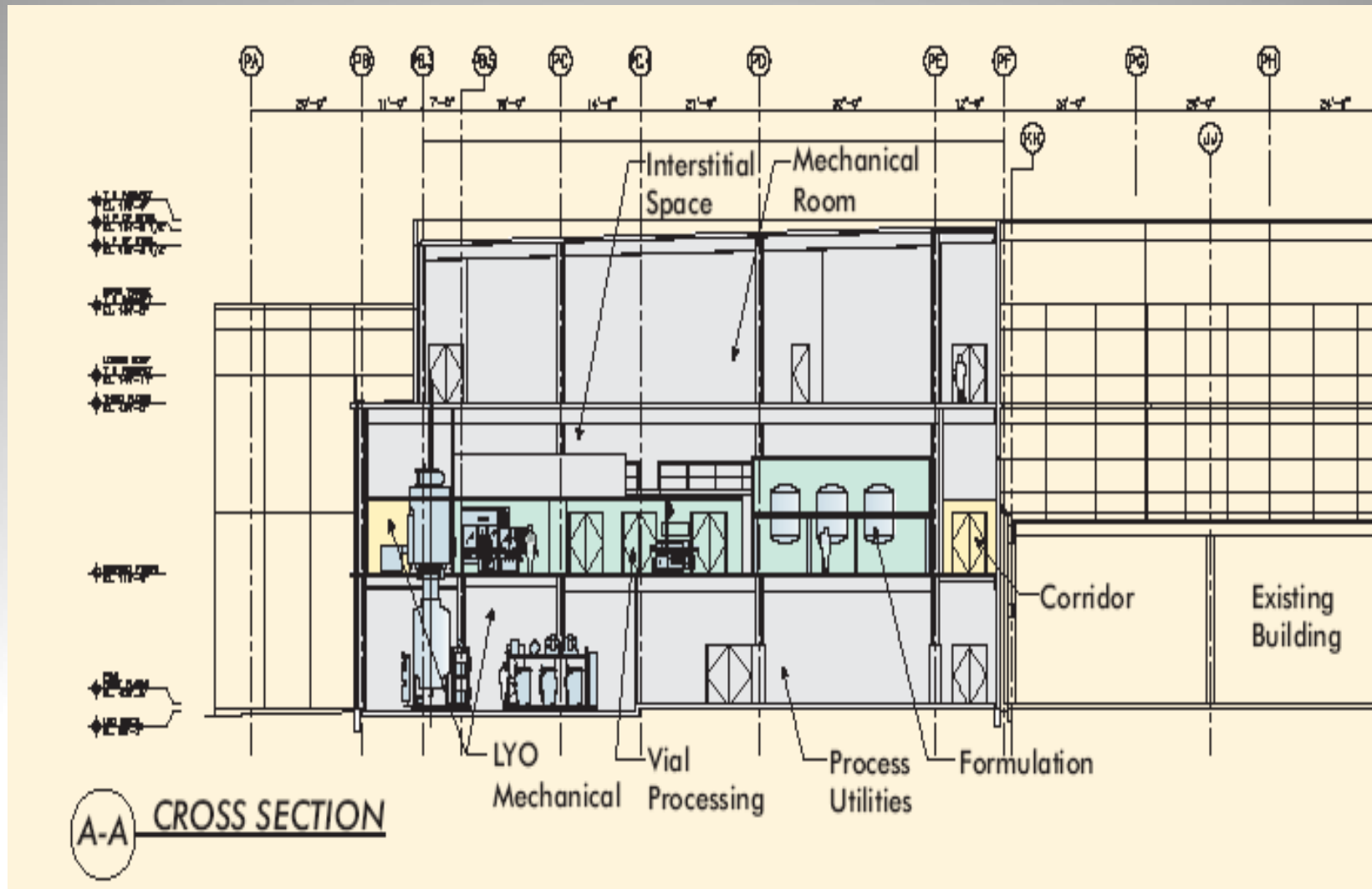
Layouts

Ball Room Option



Layouts

Ball Room Option



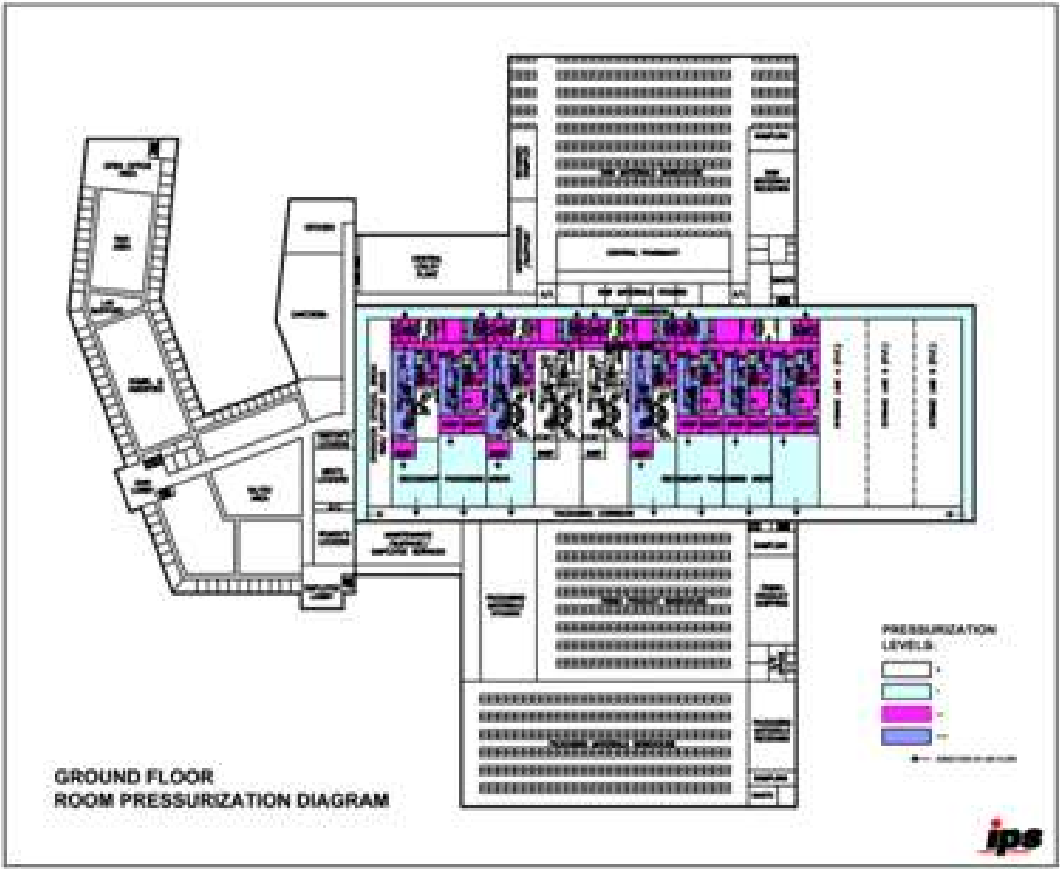
Layouts

Parallel Filling Option

- Similar to GMP Corridor Option but Expanded for Multiple Filling Lines
- Dedicated Parallel Filling and Formulation Rooms with Shared Support Rooms
- Uses 10-15% Less Area than Multiple Ballroom 'Cells'
- Ideal for Unidirectional Material Flow

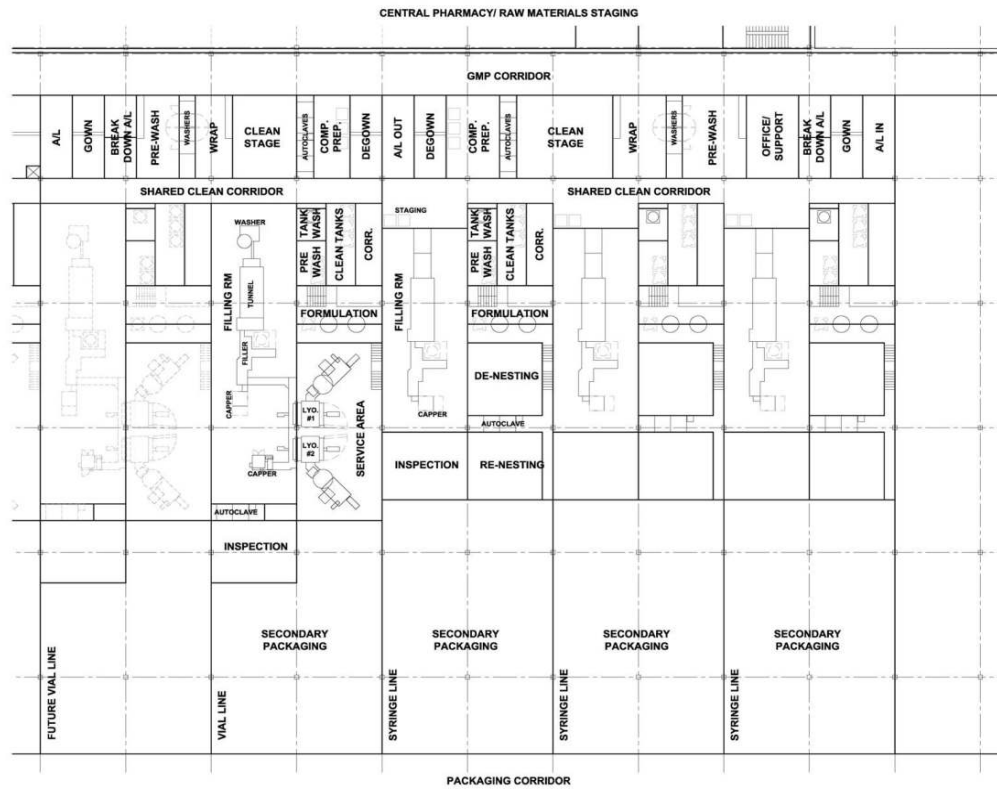
Layouts

Parallel Filling Option



Layouts

Parallel Filling Option



**DETAIL FIRST FLOOR PLAN
MANUFACTURING AND PACKAGING AREAS**



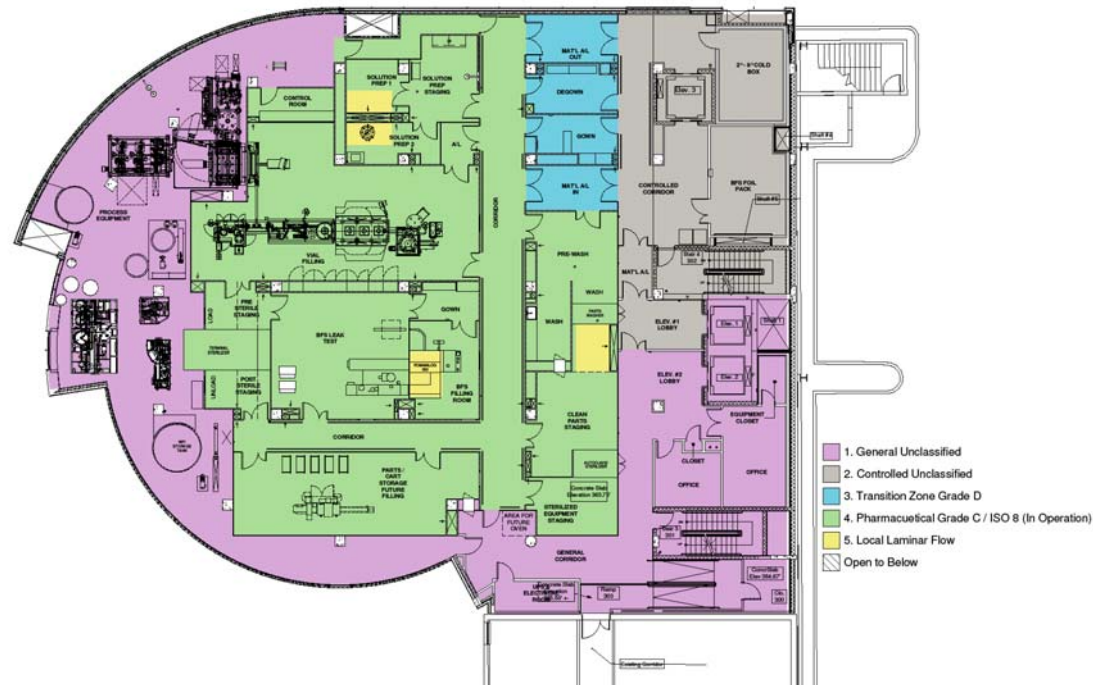
Layouts

Multiple Delivery System Option

- Variation of the Parallel Filling Option using a Variety of Product Delivery Systems
- Leverages Grade C/ ISO 8 for:
 - Isolator Fill Lines
 - Liquid/ Lyo Vials
 - Bulk/ Nested Syringes
 - FFS
 - Terminally Sterilized Fill Lines
 - BFS Fill Lines

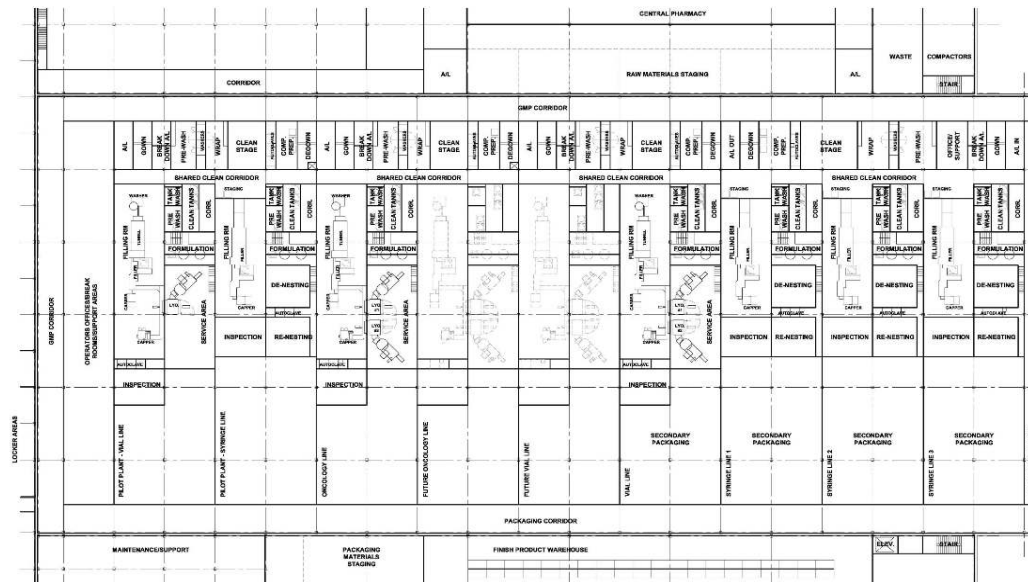
Layouts

Multiple Delivery System Option



Layouts

Multiple Delivery System Option



DETAIL PRODUCTION AREA PLAN

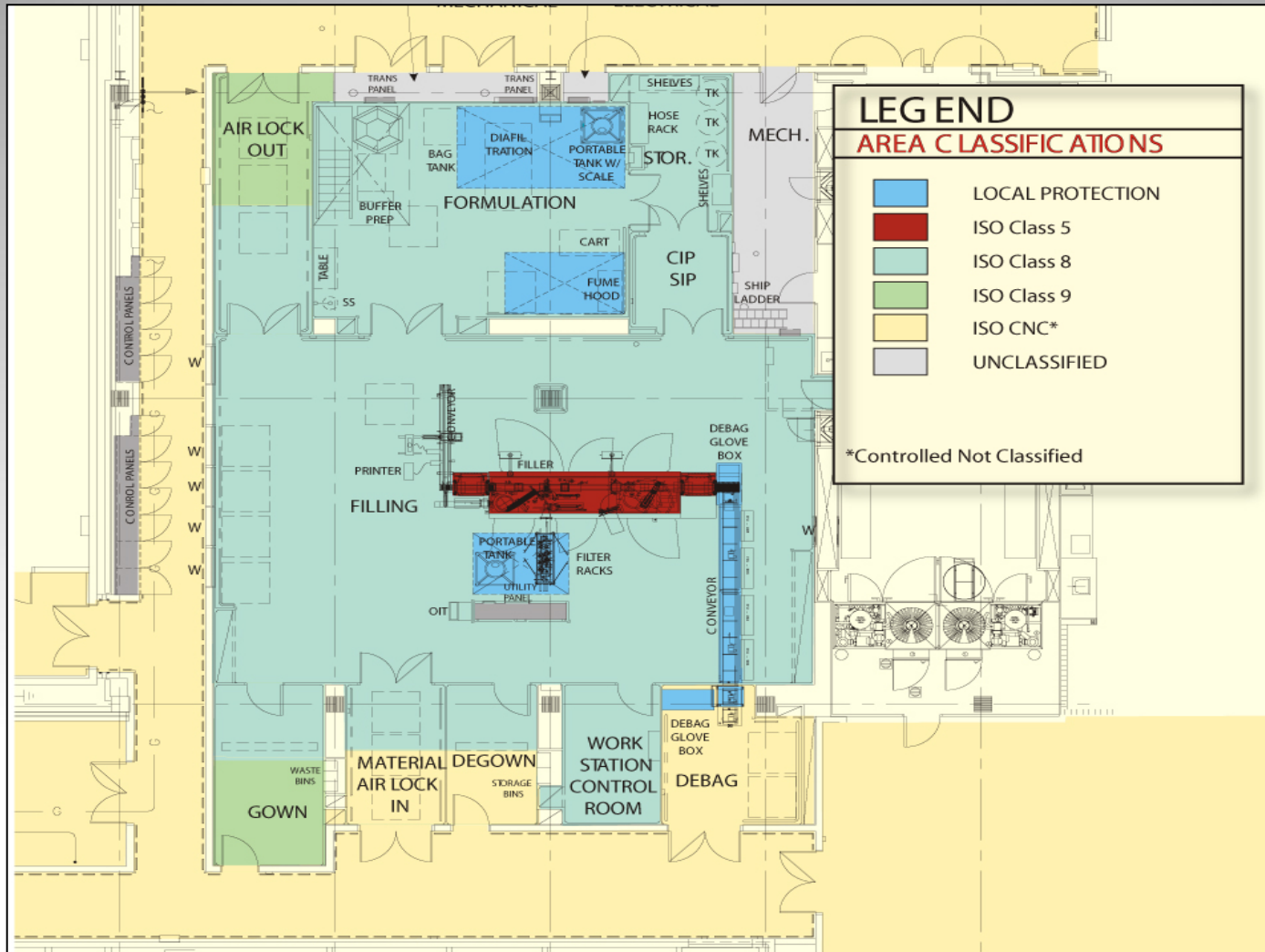
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Layouts

Isolator Renovation Option

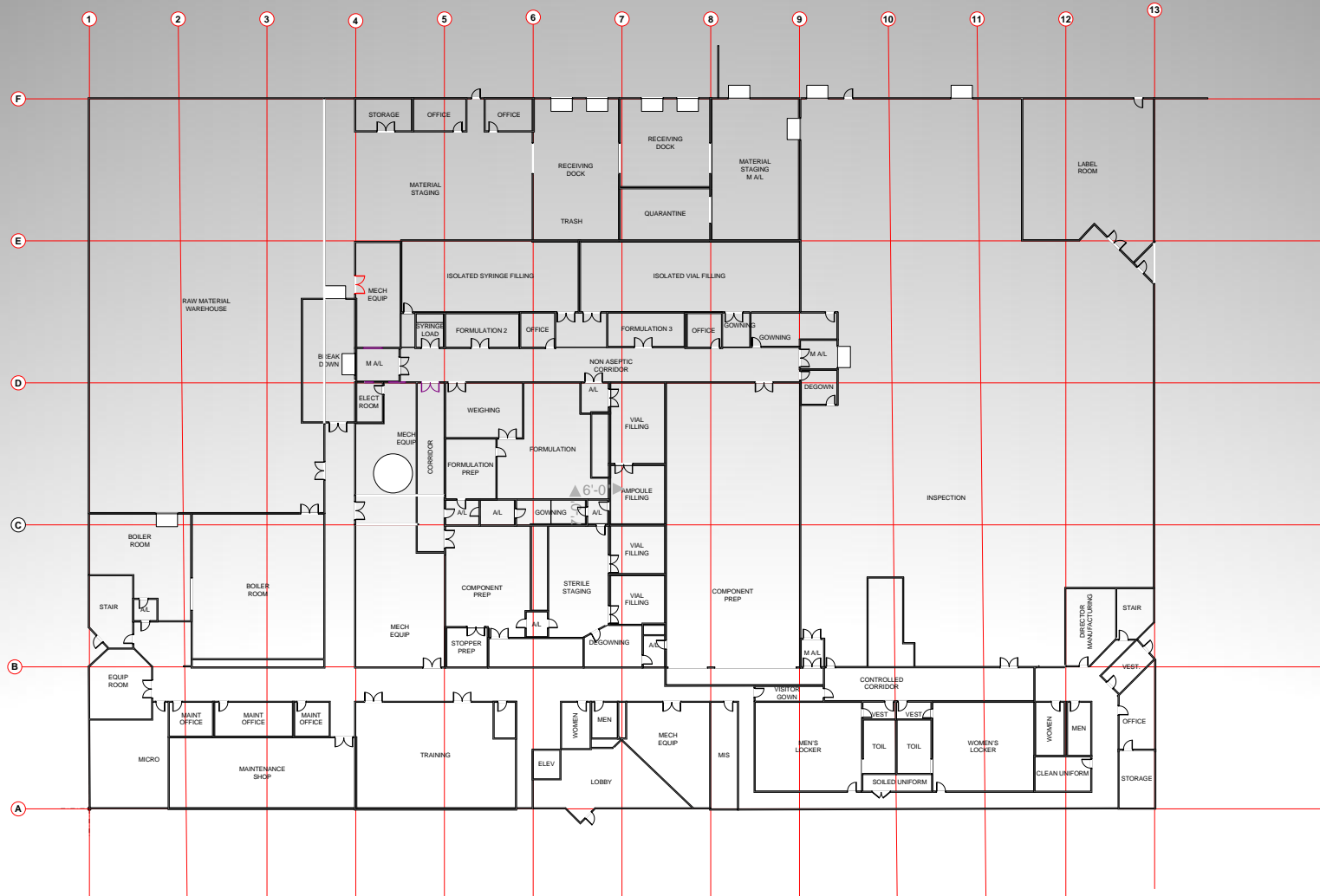
- Leverages an Isolator Filling Room Addition to an Existing Facility with Grade A/B Compliance Issues
- Utilizes Existing Grade C Support Functions by:
 - Replacing the Existing Filler with an Isolated Filler and Reclassifying the Room Grade C/ISO 8 or;
 - Adding a New Isolated Filling Room Adjacent to the Existing Suite

Layouts Isolator Renovation Option



Layouts

Isolator Renovation Option



Finishes

General Requirements

- Surfaces shall be:
 - Monolithic
 - Non-Porous
 - Easily Cleaned
 - Durable
 - Withstand Cleaning Chemicals
- Minimize Caulking
- Eliminate Horizontal Surfaces
- Utilize Coved Corners
- Utilize Flush Door and Window Details

Finishes

Walls and Ceilings

- Stick Built (metal stud, sheet rock, epoxy paint)
 - Issues with Mold Growth
 - Issues with Louvers versus Low Wall Sweeps
 - Requires Repainting
- Modular Panels: MSS, AES, Degard
 - Walkable Ceilings
 - Clean Construction
 - Rapid Integration with Isolators
- Minimize Corners
- Floor-Mounted Stainless Steel Bumpers

Finishes

Floors and Base

- Welded Sheet Vinyl
 - Cost Effective
 - Permanent Surface
 - Issue with Torque from Wheels with Excessive Loads
- Epoxy Based Seamless
 - Top Coat Requires Resurfacing with Wear
 - Quality Variable with Applicator Skill
 - Tends to Discolor with Cleaning Solutions

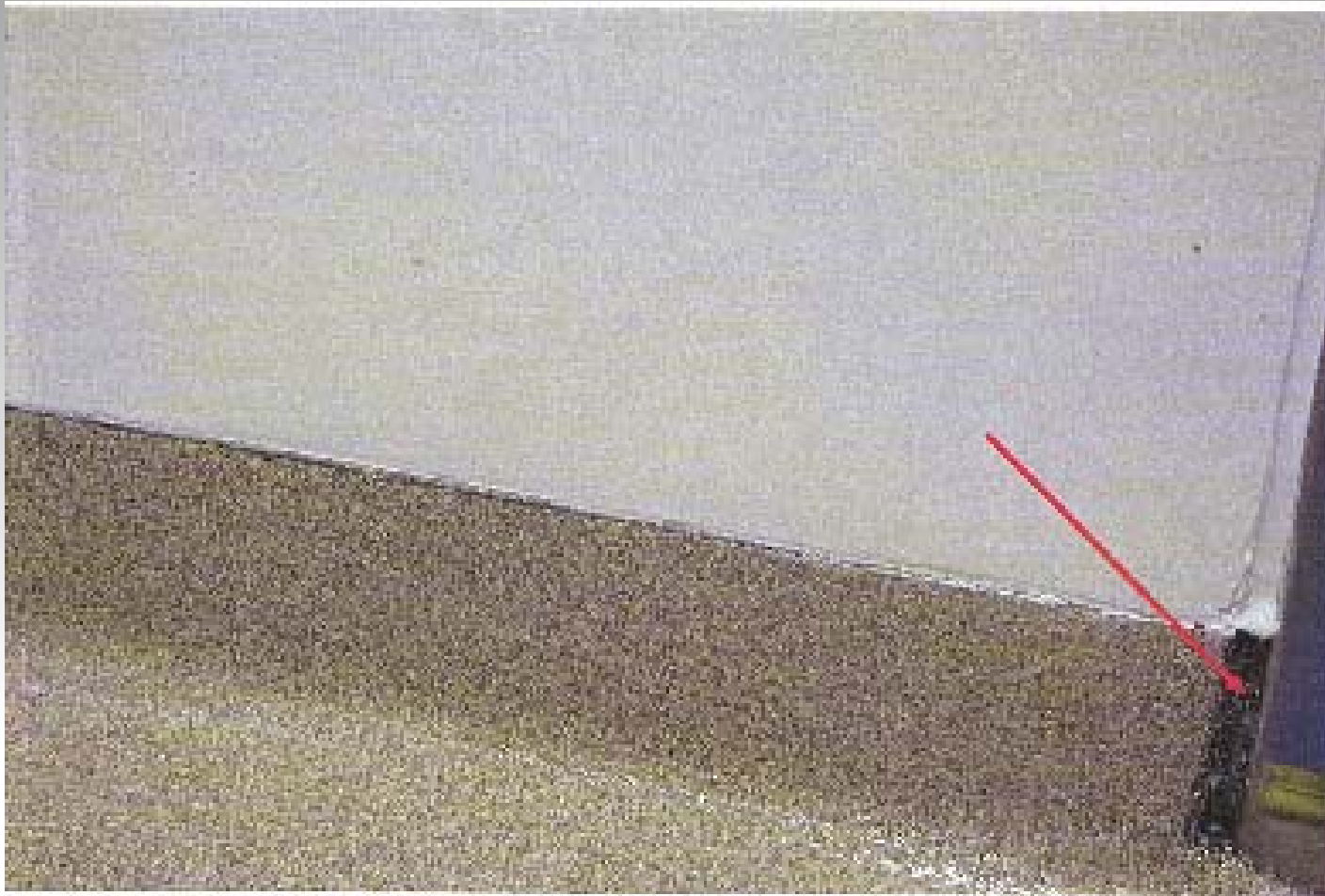
Finishes Color

- Perception of Cleanliness
- Use Cool White Walls and Ceilings
- Use Blue Floors and Doors
- Avoid Warm Whites and Browns
- Modular Wall Companies use Cool White Panels and Blue Doors

Finishes Color



Finishes Color



Conclusion

Parenteral Manufacturing Center

PMC.avi