



Review of Clean Room Layouts

30th October 2014



**Developing Country Vaccine Manufacturer Association Workshop
at Hotel Lalit, New Delhi**

Safety Connect



Be Safe
Be Alert to Changing Conditions

Agenda

- Vaccine Projects Categorization
- Clean Room Layout Concepts
- Clean Room Partitioning System

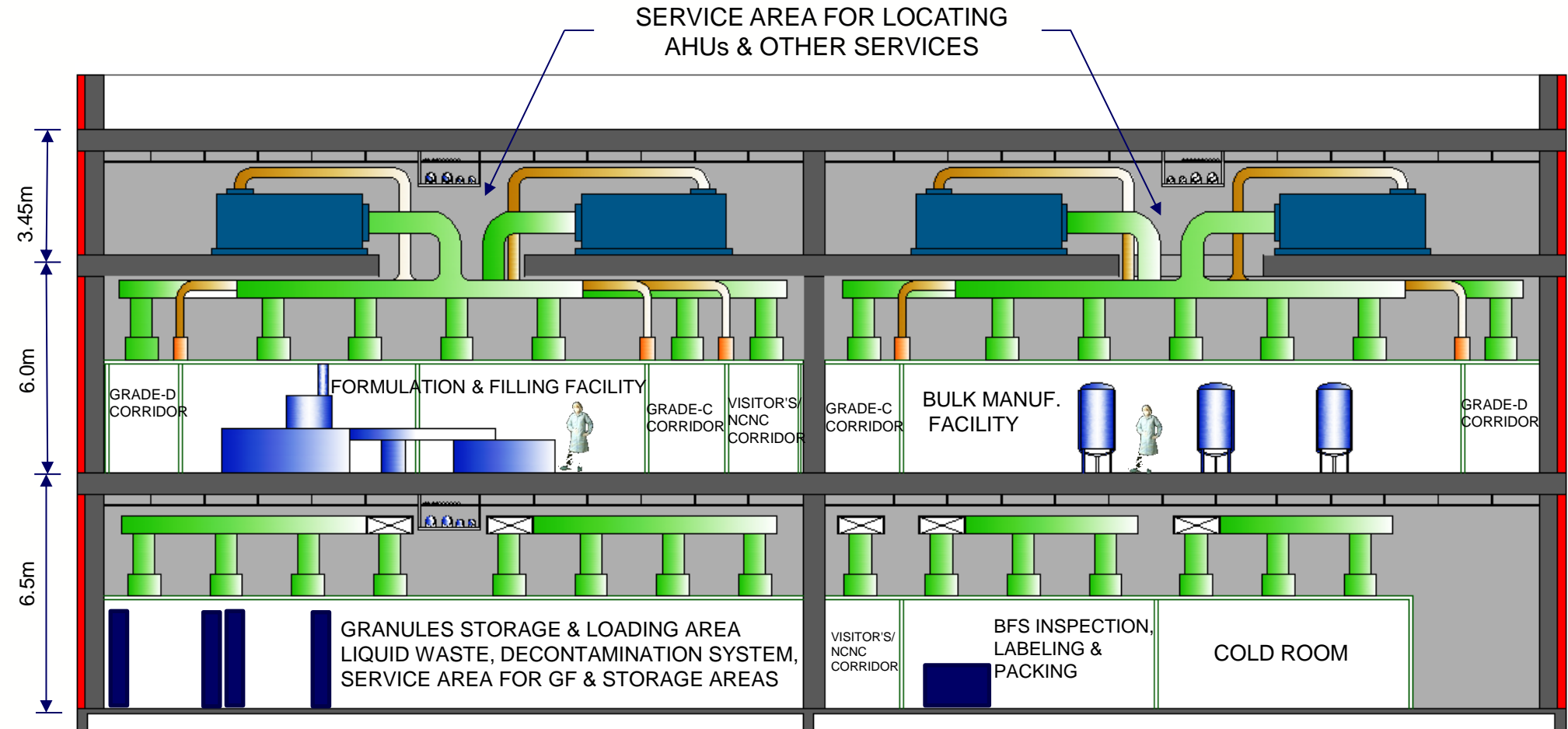
Vaccine Projects Categorization

- Vaccine projects are classified in two categories
 - Bulk Vaccine Manufacturing
 - Formulation, Filling and Packaging
- Associated Quality Control Building
- Warehouse & Storages

Clean Room Layout Concepts

- Conventional Practices
 - G+ 2 Building
 - GF for Utilities, General Services, Labeling, Packing, Storages and Offices
 - FF for Bulk Manufacturing, Formulation and Filing Operations
 - SF for Services (HVAC, Clean Utilities etc.)
- Segregation of Clean & Dirty Corridor
- Unidirectional Flow
- Bi Directional
- Technical Chases to Reduce the Clean Areas

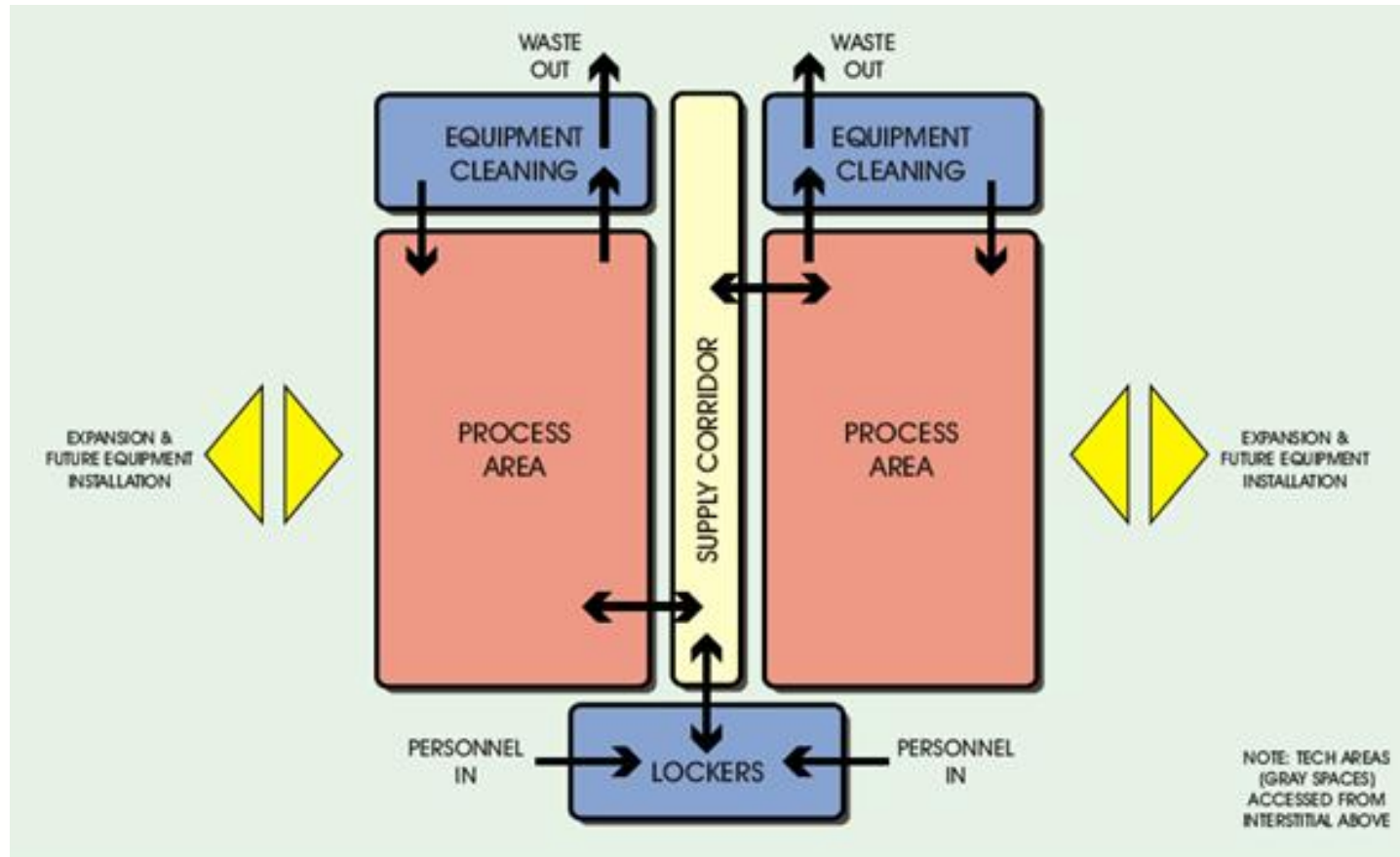
A Sectional View



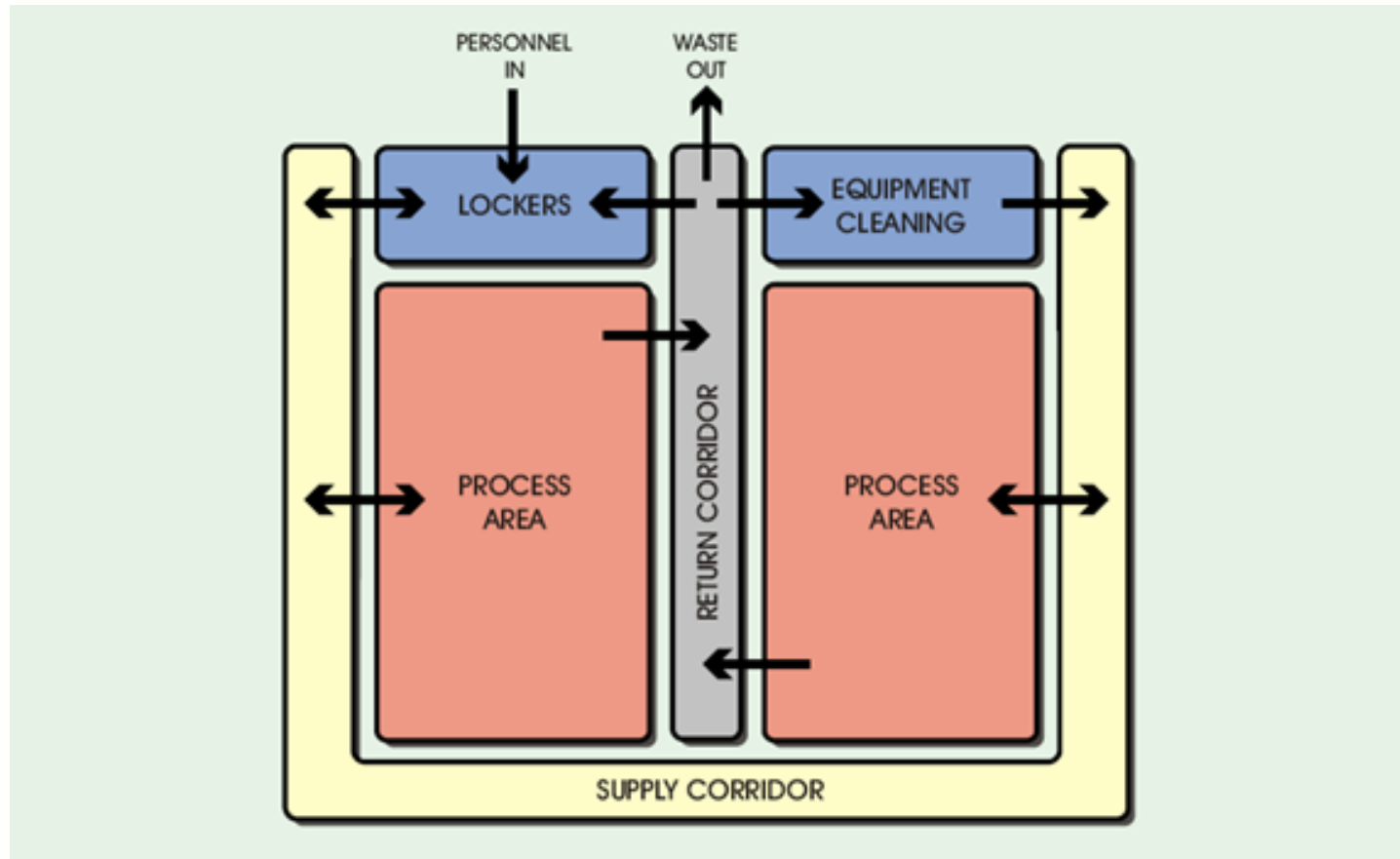
Clean Room Layout Concepts

- Segregation of Clean & Dirty Corridor
 - Unidirectional Flow
 - Bi Directional
- Technical chases to reduce the Clean areas & provide access for maintenance
- Window concepts to reduce clean room area
- Separate personnel, material flow & waste flow
- Use of Isolator to reduce grade of filling area
- Single or Multiple Products running parallel

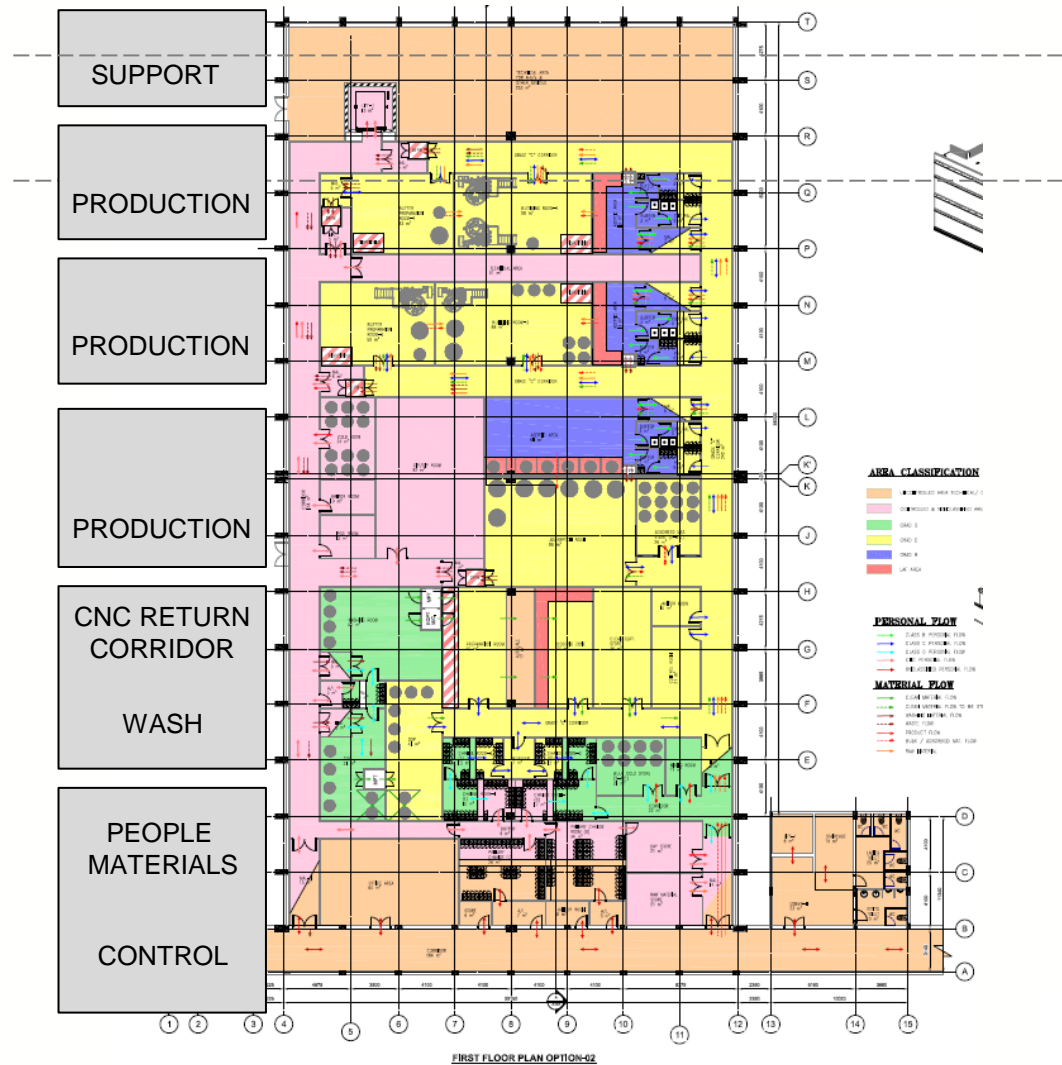
Bi – Directional Flow to and from Process Areas



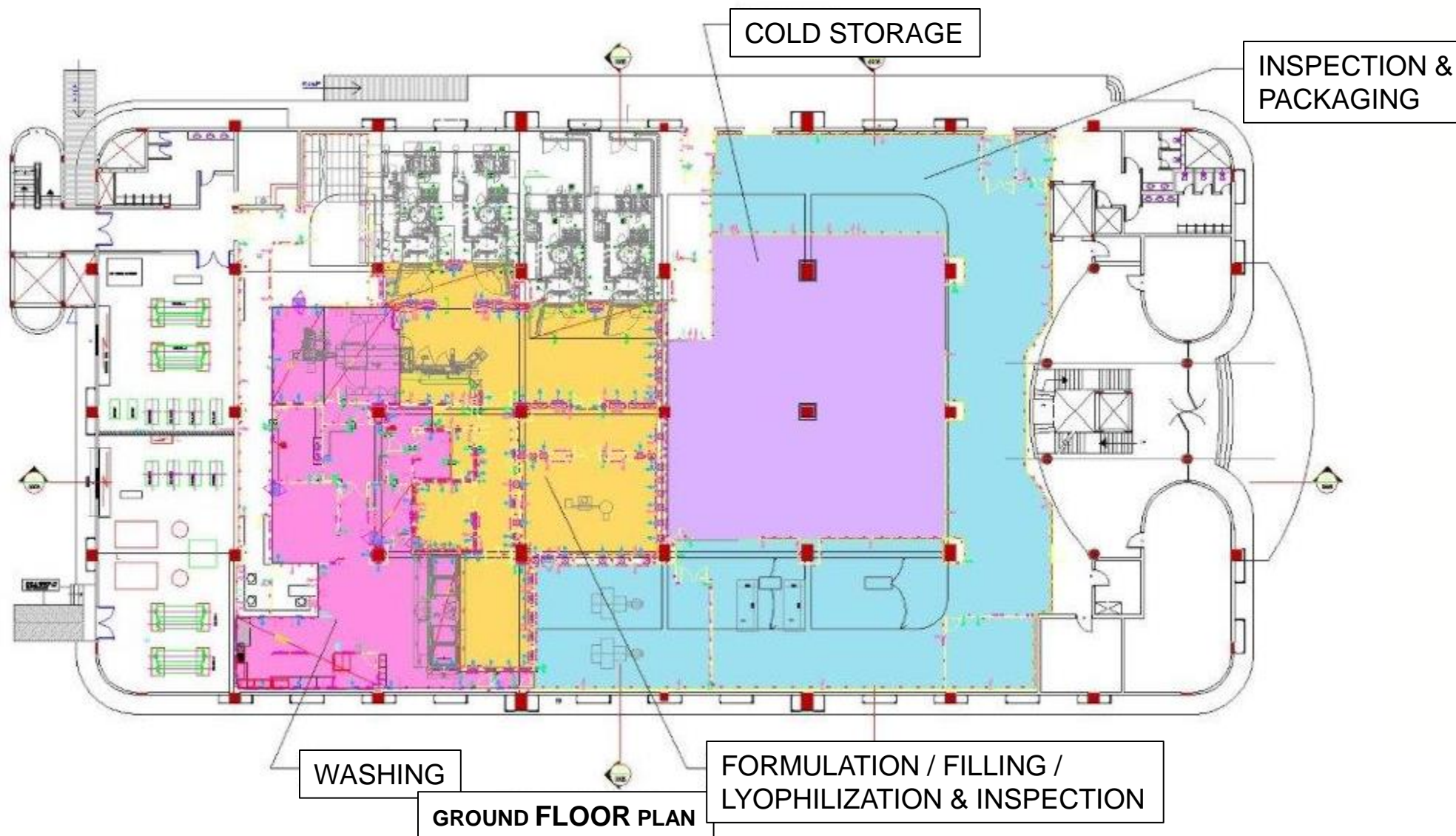
Uni – Directional Flow to and from Process Areas



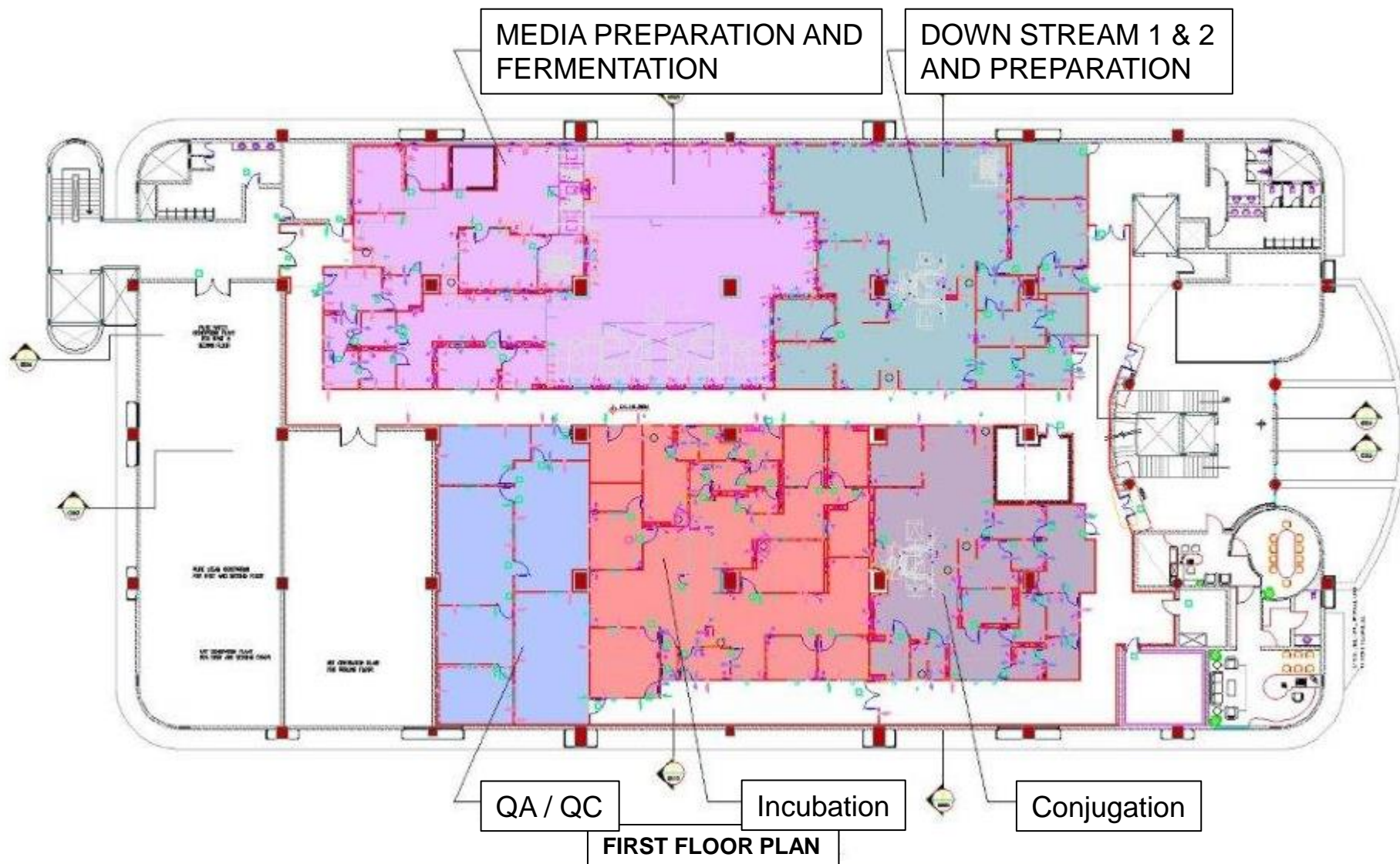
Uni – Directional Flow to and from Process Areas



Typical Fill Finish Layout



Typical Bulk Bio Manufacturing



Clean Room Partitioning System

- Visitors corridors with large view panels to see production area with out entering production suits
- Return air ducts through window panels
- Seamless Vinyl flooring hooked to clean room partitions
- Coving for walls & ceiling

Sterile Fill Finish Line



Sterile Fill Finish Line



Sterile Fill Finish Line



In Conclusion – Things to consider

- Uni-directional or Bi-directional flow
- Technical chases – to reduce clean area/ maintenance access
- Window designs
- Large view panels