Review of Clean Room Layouts

30th October 2014
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
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

- Cold Storage
- Inspection & Packaging
- Washing
- Formulation / Filling / Lyophilization & Inspection
- Ground Floor Plan
Typical Bulk Bio Manufacturing

FIRST FLOOR PLAN

MEDIA PREPARATION AND FERMENTATION

DOWN STREAM 1 & 2 AND PREPARATION

QA / QC

Incubation

Conjugation

FIRST FLOOR PLAN
Clean Room Partitioning System

- Visitors corridors with large view panels to see production area without 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
In Conclusion – Things to consider

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