

## Guidance 114 Preventing Cross Contamination

- Processing areas at negative pressure with respect to adjacent rooms;
  - Air handling systems designed to prevent cross contamination;
  - Suite dedicated equipment;
  - Suite dedicated sampling/dispensing area;
  - Use of airlocks;
  - Suite dedicated clothing and shoes; and
  - Decontamination of containers and other articles prior to removal from isolated area; and
- Dedicated Manufacturing Facility Required: beta-lactams (e.g., cephalosporin, penicillin). There is no cross-flow of exposed materials or personnel between the dedicated facility and other facilities
  - Dedicated Manufacturing Facility aspects include, but are not limited to:
    - Dedicated building with dedicated entrances and exits for personnel and materials;
    - Dedicated utility systems, including air handling;
    - Dedicated personnel (i.e., no cross flow with other personnel after entry to the area);
    - Dedicated materials (i.e., no cross flow after entry to the area); and
    - Dedicated laboratories.
4. Precautions should be established and maintained to ensure that cross contamination at product exposure points (e.g., open hatch charging or sampling, packout, heel scraping) is prevented from overhead equipment and piping. Consideration should be given to such precautions, including, and are not limited to, the following items:
- Booth or canopy over tank hatch openings;
  - Isolators (e.g., glove boxes);
  - SOPs defining conditions under which vessels can be opened;
  - Periodic inspection of overhead piping and ducts to ensure that there are no leaks, condensation, flaking of paint and/or insulation that might fall into vessel openings;
  - Drip pans under HVAC units or cold surfaces to collect or contain condensation; and
  - Facilities designed with minimal overhead ducts and piping.
5. Equipment should be located so that cross contamination between production operations undertaken in a common area is prevented.
6. Ovens, Dryers, Autoclaves and Similar Equipment should contain only one open, exposed RM, API, intermediate, in-process material, medical device or drug product at a time.
7. Airflow Patterns should not present a cross contamination risk. Air handling systems should be designed to prevent cross contamination of exposed product, components, or production areas.