Using Shared Facilities for Manufacturing High Potency Finished Drugs

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FDA on Shared Facilities

There shall be separate or defined areas **or such other control systems** for the firm's operations as are necessary to prevent contamination or mixups …

EMA Proposed Updates for Shared Facilities

The outcome of the Quality Risk Management process should be the basis for determining the necessity for and extent to which equipment and facilities should be dedicated to a particular product or product family.

Threshold Values are input parameters for risk assessments

ADE, ADI, PDE




Risk Assessments should address:

- –Mix-up
- –Retention/ Carryover
- –Mechanical Transfer
- –Airborne Transfer

Mix-up

Drugs	Levetiracetam Tablets, USP 500 mg, 500 count bottle, Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 USA, NDC 0378-5615-05	Lot ZLMM12063, Exp March 2014	Class II	Adulterated Presence of Foreign Tablets: Pharmaceutical manufacturer may have distributed foreign tablets in bottles of Levetiracetam Tablets, USP 500 mg.	Mylan Pharmaceuticals Inc.
Drugs	Atrovent HFA Inhalation Aerosol, (ipratropium bromide) 12.9 grams, 200 metered actuations, Rx only, Packaged Exclusively by: Dispensing Solutions, Inc., Santa Ana, CA --- NDC 68258-8952-01, DSI product #8A0947	Lot # F23989, F22311	Class II	Label Mix up; side panel of sticker label applied by Dispensing Solutions Inc. incorrectly indicates product name as Ventolin HFA 90 mcg instead of correctly as Atrovent HFA 12.9 grams Inhalation Aerosol	Dispensing Solutions, Inc

Retention/Carryover

ADE (or PDE)*Batch Size

Maximum Daily Dose

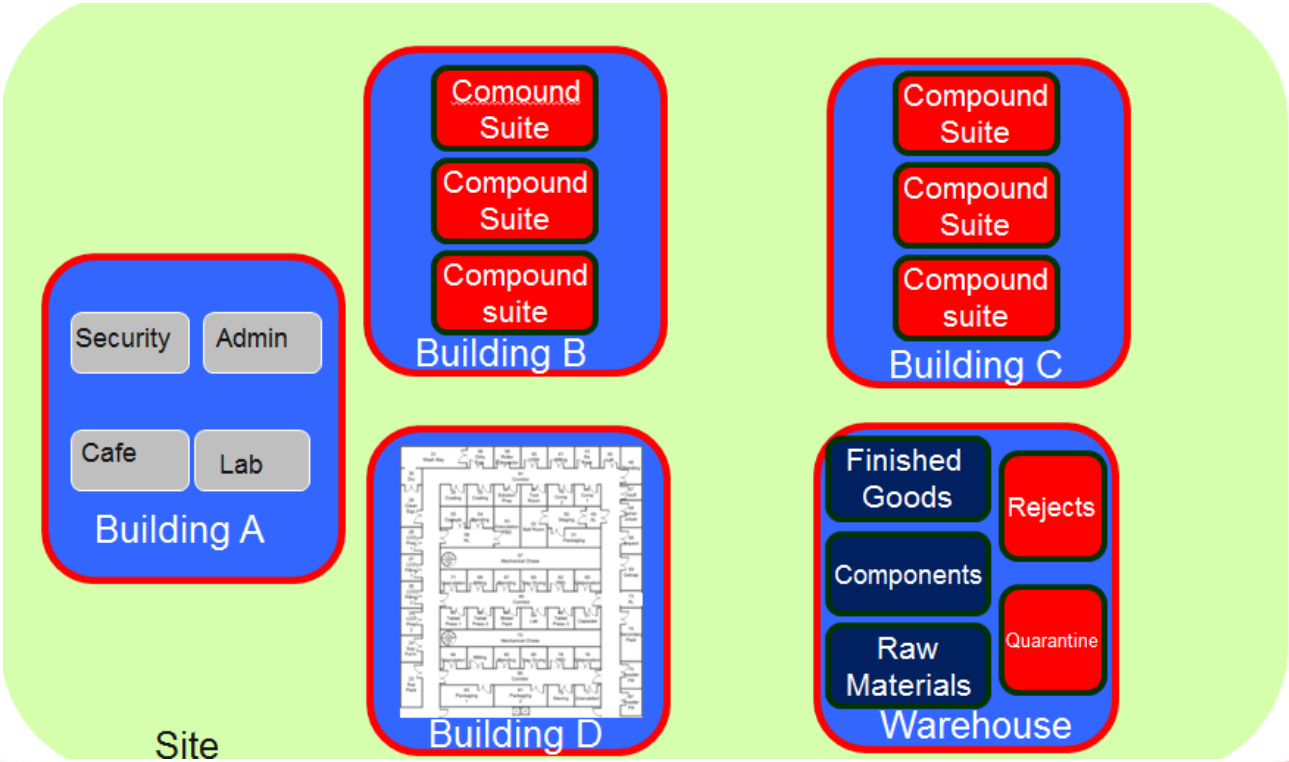



Mechanical Transfer



Airborne Transfer

When are Dedicated Facilities Required?



Thank you

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