Inspections of Sterile Drug Compounding Facilities

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Inspections

- For-cause inspections
  - After receiving reports or complaints about serious adverse events related to drugs
  - When states request our assistance
- Surveillance inspections
  - Firms we were aware of that produced sterile drugs
  - Risk-based model
    - Serious adverse event reports
    - Historical inspection data
    - Reports of product quality problems

Inspections

- Visual Inspection/Interview
  - Aseptic Technique
  - Potential for Mix-ups
  - Process and Facility Design
  - Environmental and Personnel Monitoring
  - Product Inspection
  - Equipment, Containers, and Closures

Inspections

- Determining the nature of the Firm's Operations and Products
  - Nature of Firm's Activities
  - Product and Process Risks
  - Complaints and Recalls
  - Supply Chain of Exported Drugs

Inspections

- Product-Specific Inspection and Record Review
  - Excessive Beyond Use Dates with no data
  - Methods of Sterilization
  - Equipment, Containers, and Closures
  - Record Review Facility Wide

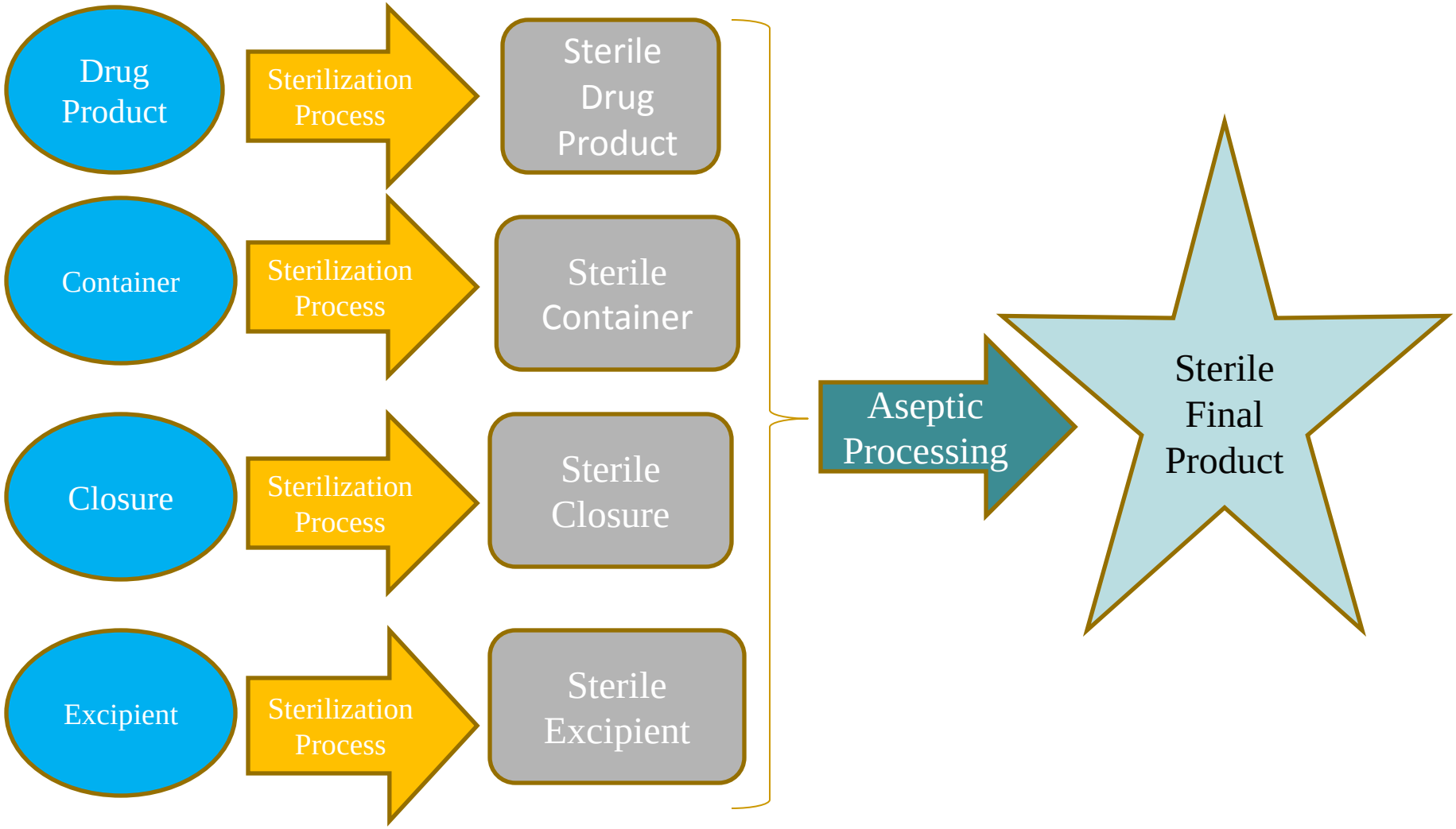
State & FDA Collaboration

- Transparency between States and FDA
- Risk model built on information sharing
  - Focus on evaluating surveillance & enforcement – using existing authorities
  - Refusals
  - Warrants

State & FDA Collaboration

- Over 75 FDA/State Joint Inspections
- 3 Administrative Warrants issued

Expectations for Sterile Inspections



Observations

Inspectional observations (**FDA 483s)** for insanitary conditions are made when in the investigator's judgment, conditions or practices observed, indicate that a drug products may have adulterated because it has been *prepared, packed, or held* under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.

Observations

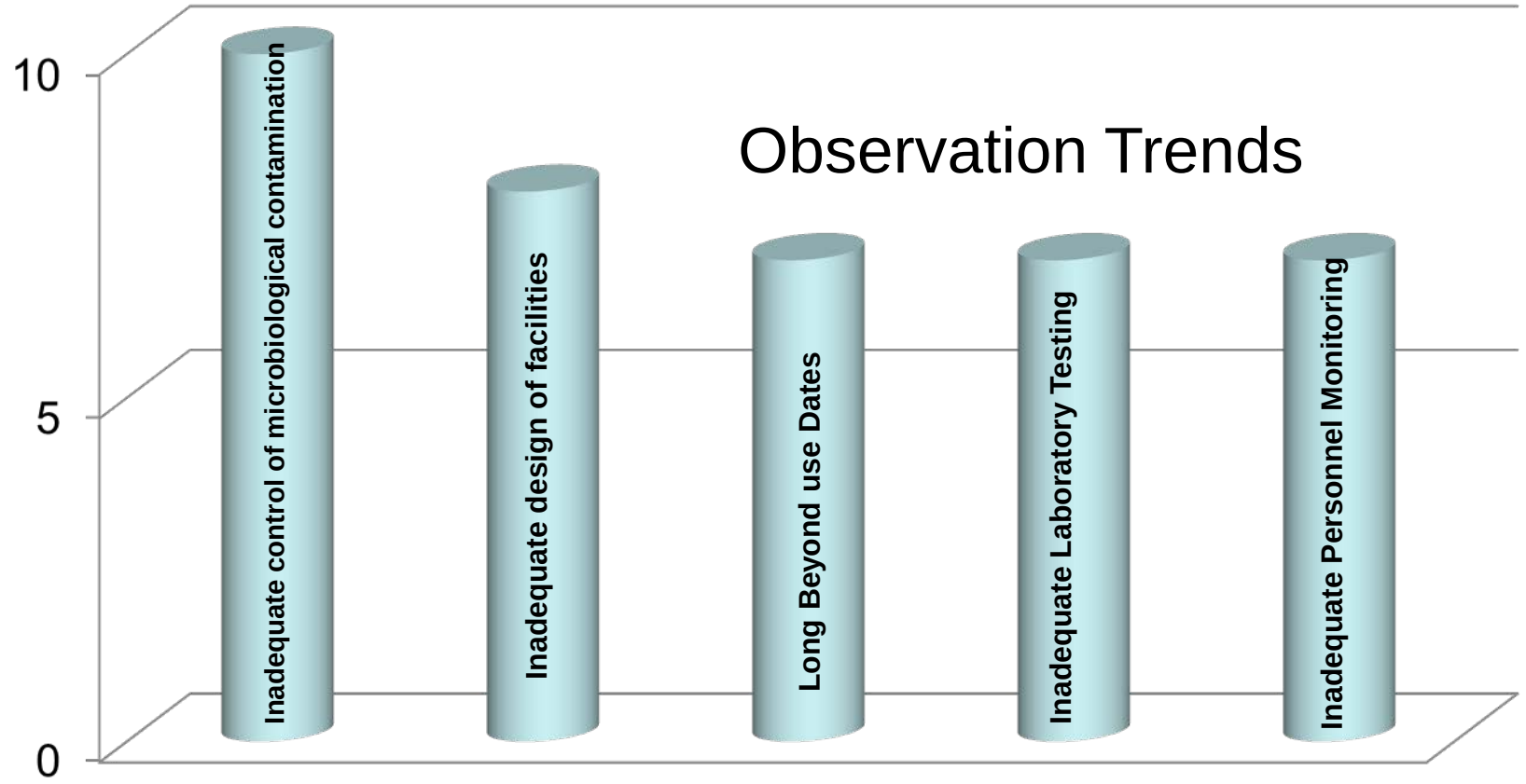
Residue in Weigh Station Hoods

Aspergillus niger (mold) in finished product of CA Gluconate

Inspection Outcomes

- Reasons for Product Recalls
  - Lack of sterility assurance
  - Unreliable testing results
  - Outbreak
- Some cases – cessation of sterile processing

Inspection Overview



http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm339771.htm

- Next Steps
  - Continue to collaborate with state authorities in for-cause, surveillance and follow-up inspections of compounding pharmacies.
  - Evaluate outsourcing facilities for compliance and ability to produce sterile drug product and requirements set forth in 503B

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