

FDA Inspections of Outsourcing Facilities

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FDA /ORA /OMPTO

Inter-governmental Working Meeting on Drug Compounding
September 2017

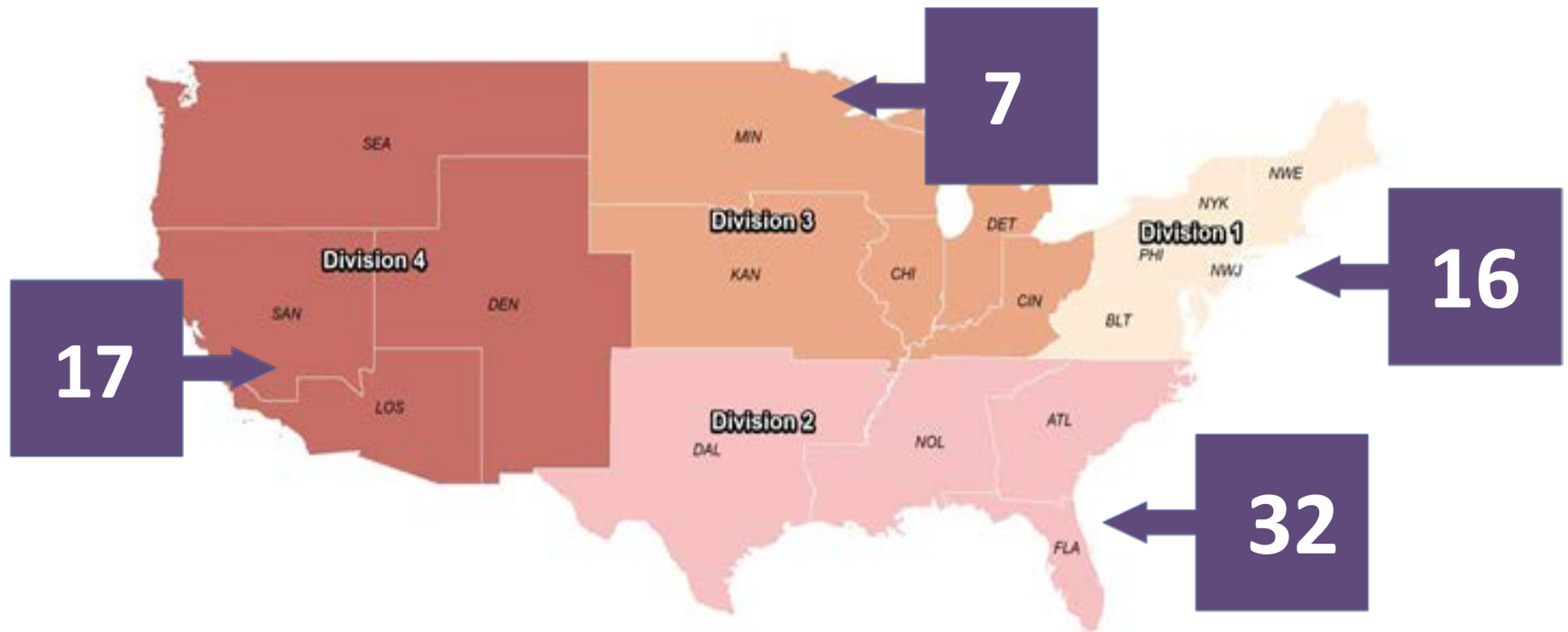
Summary of Presentation

- 503B Registrants: numbers and location
- Inspection stats for 503B and 503A
- 503B Inspection Approach
- 503A Inspection Approach
 - Application of Insanitary Conditions vs GMPs
- FDA Inspection Findings

503B Registrants

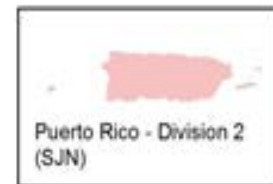
- 72 Registered 503B Outsourcing Facilities
 - 15 NEW registrants in FY17

Number of 503B Registrants per ORA Division

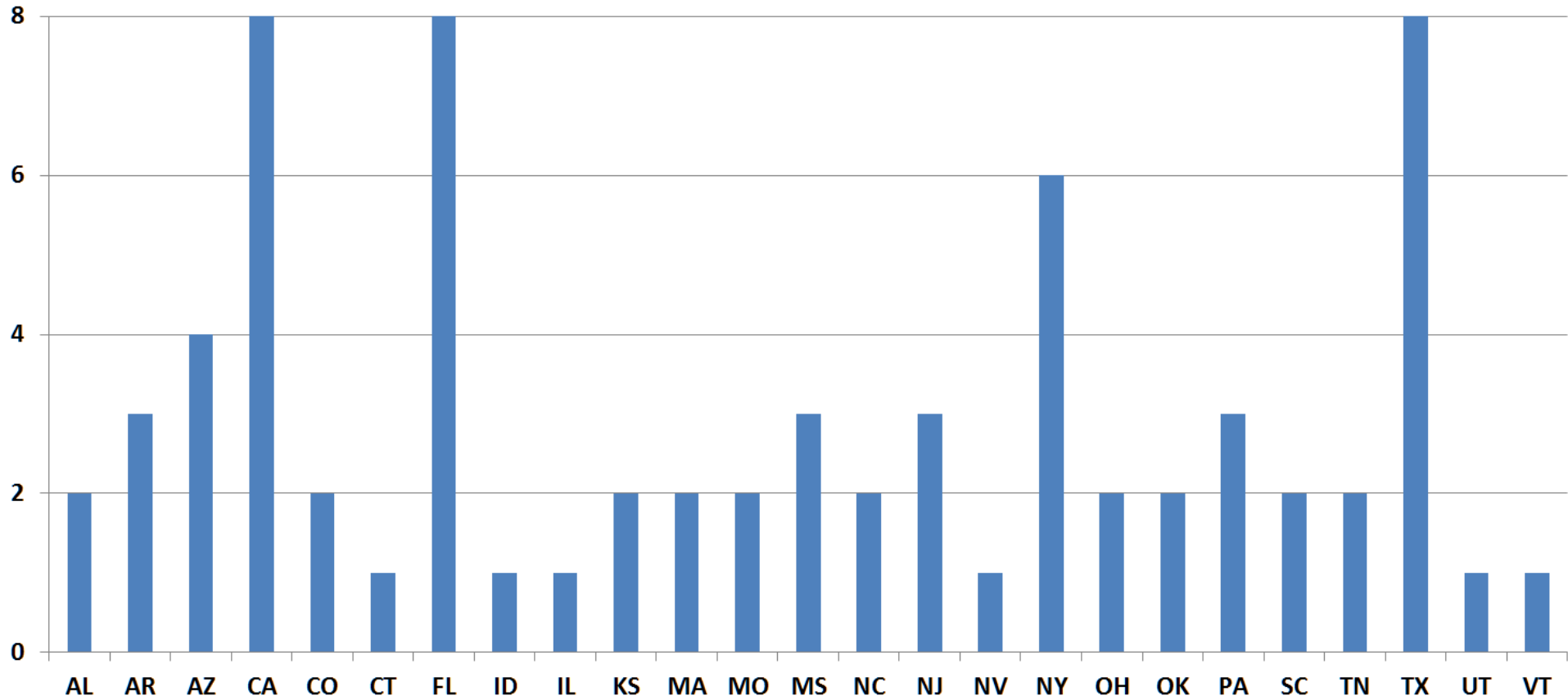


Pharmaceutical Quality Program Divisions

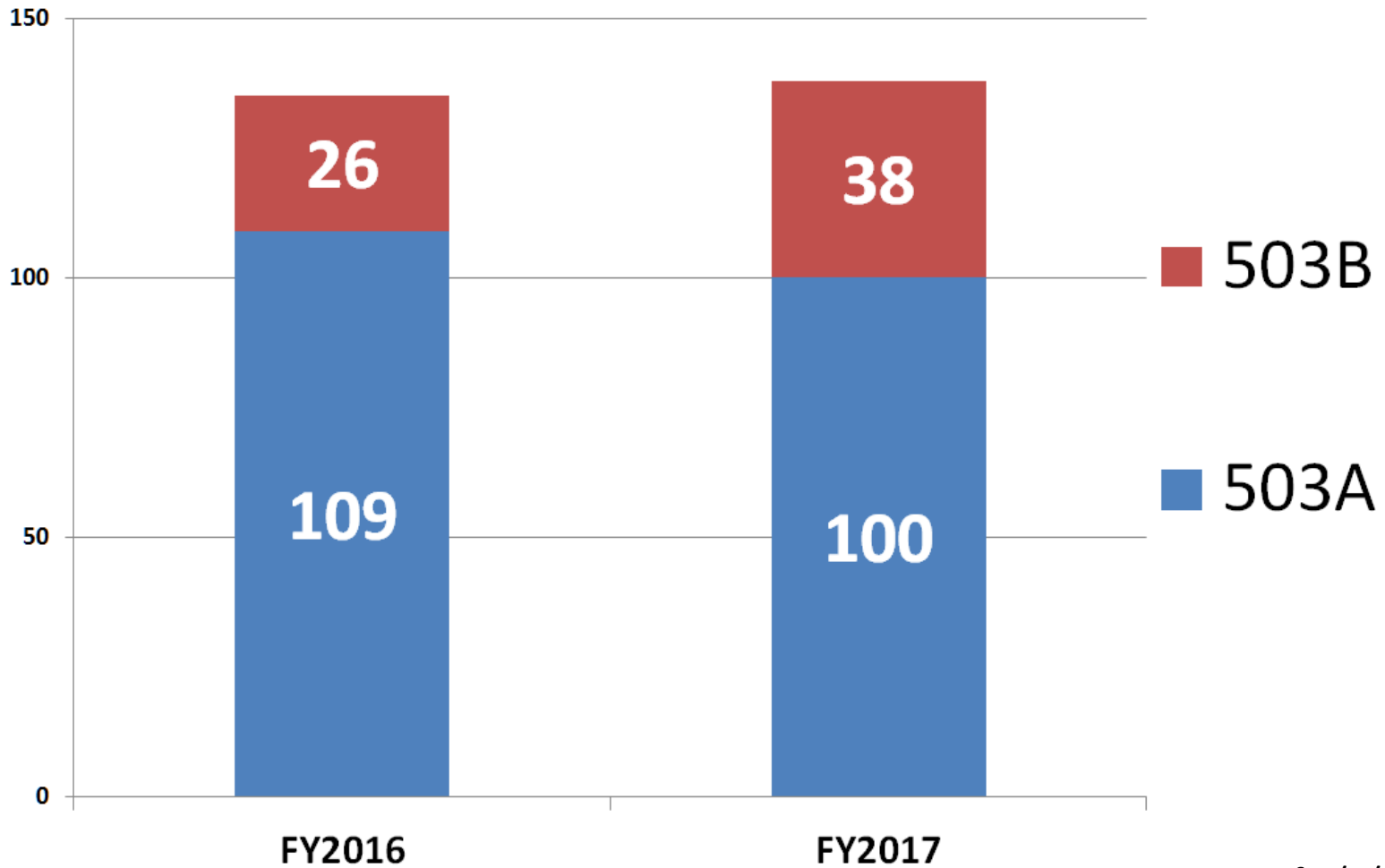
- Division 1 (BLT, NWE, NWJ, NYK, PHI)
- Division 2 (ATL, DAL, FLA, NOL, SJJ)
- Division 3 (CIN, CHI, DET, KAN, MIN)
- Division 4 (DEN, LOS, SAN, SEA)
- FDA Current Districts Boundaries



503B Registrants by State



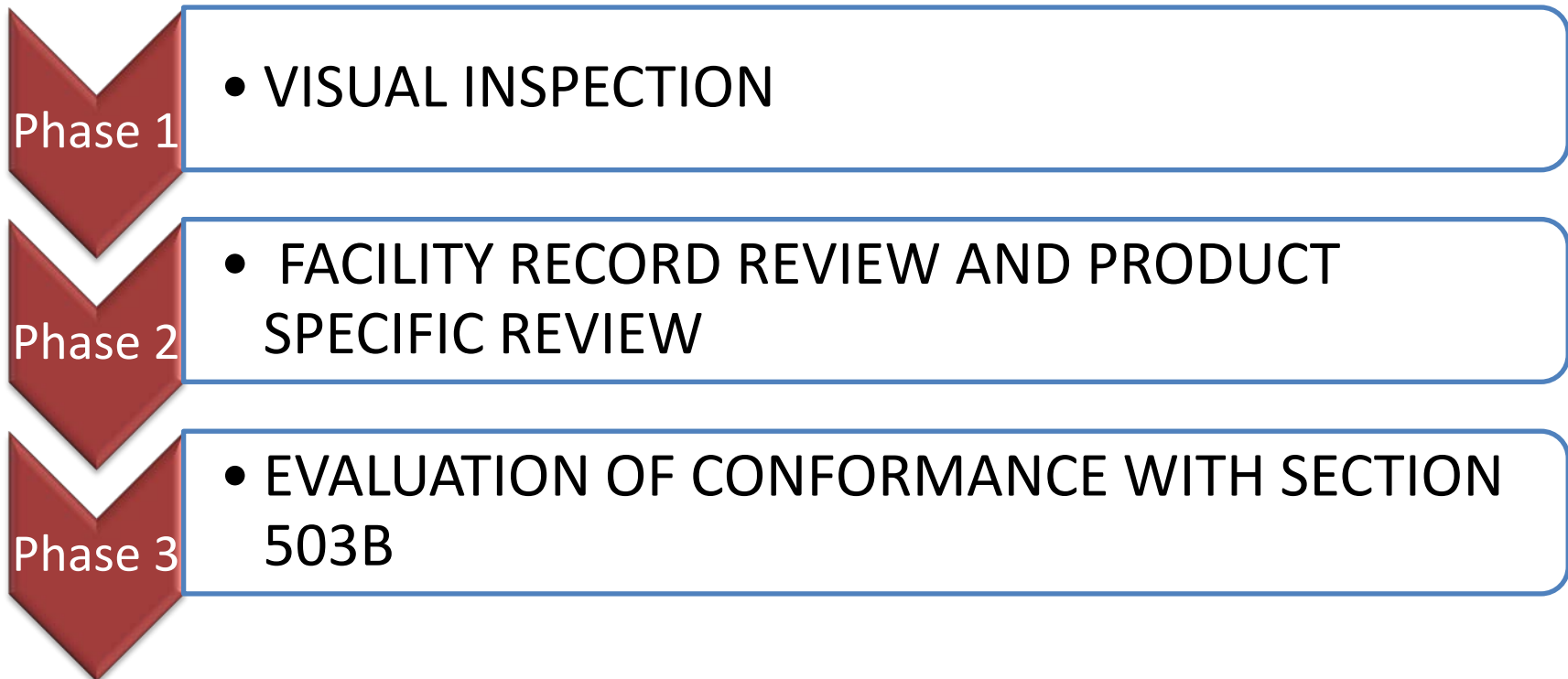
Inspections



503B INSPECTION ASSIGNMENT

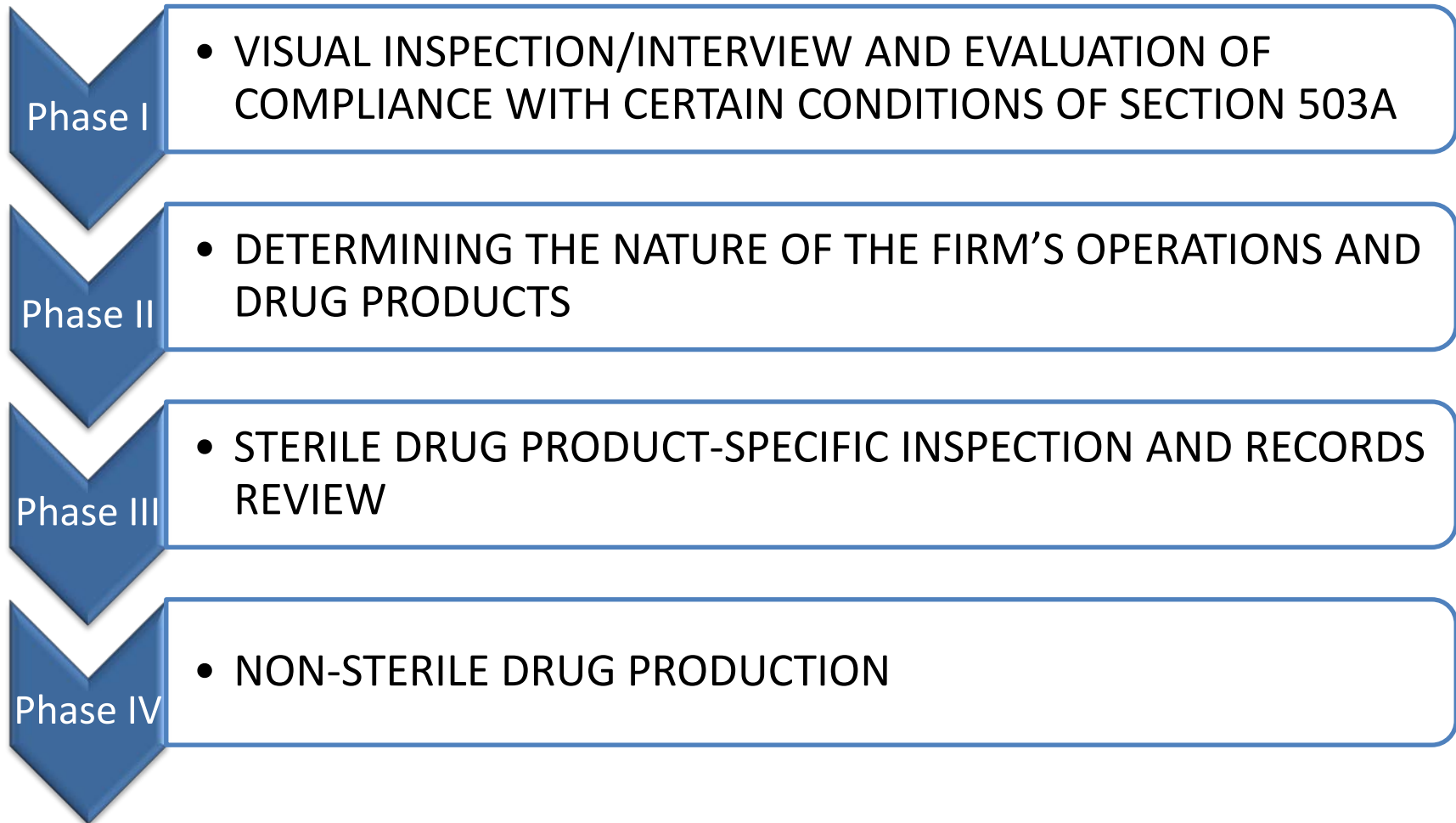
Assignment: Inspectional Coverage

Inspections are conducted as described below:



503A INSPECTION ASSIGNMENT

Part III – Assignment: Inspectional Coverage



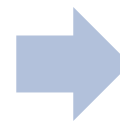
503A Inspection Assignment - Application of Insanitary Conditions

PRELIMINARY ASSESSMENT

Section
503A
compliant?



Patient-specific
prescription for
all
compounded
drug products?



Insanitary
conditions



503A Inspection Assignment - Application of Insanitary Conditions

✓ Does the firm receive patient-specific prescriptions for *all* compounded drug products that it distributed?

YES

INSANITARY CONDITIONS

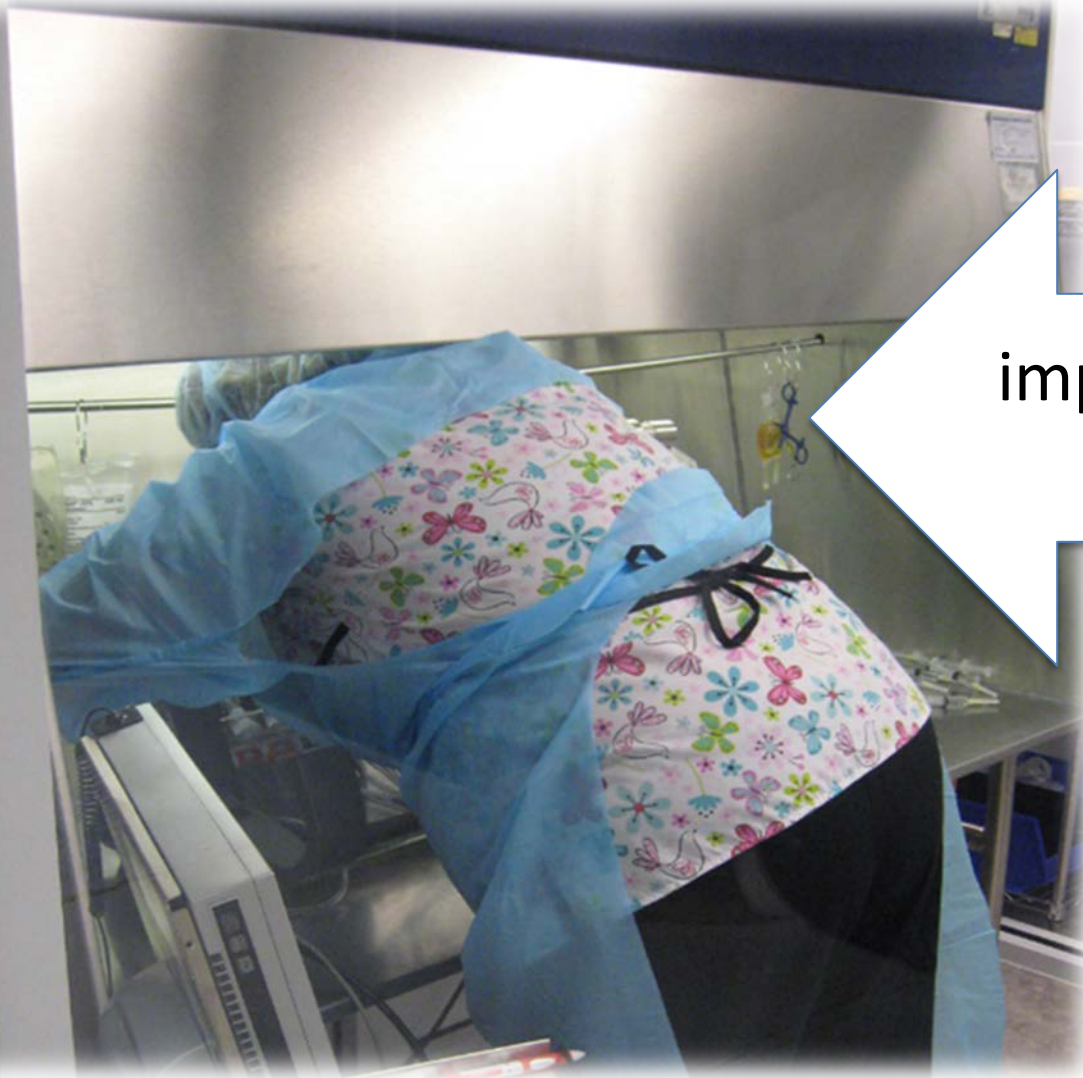


503A Inspection Assignment - Application of Insanitary Conditions

Does the firm receive patient-specific prescriptions for *all* compounded drug products that it distributed?

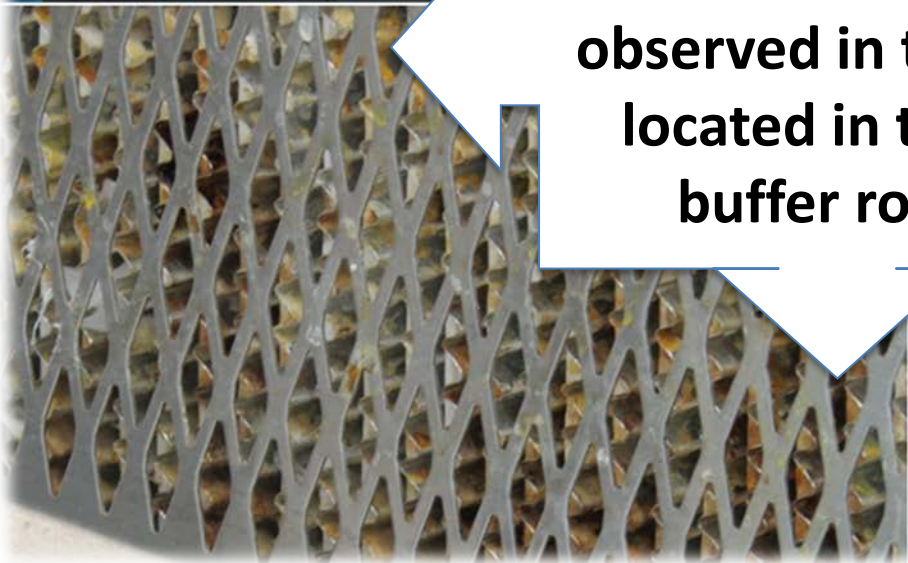
NO

FDA Inspection Findings

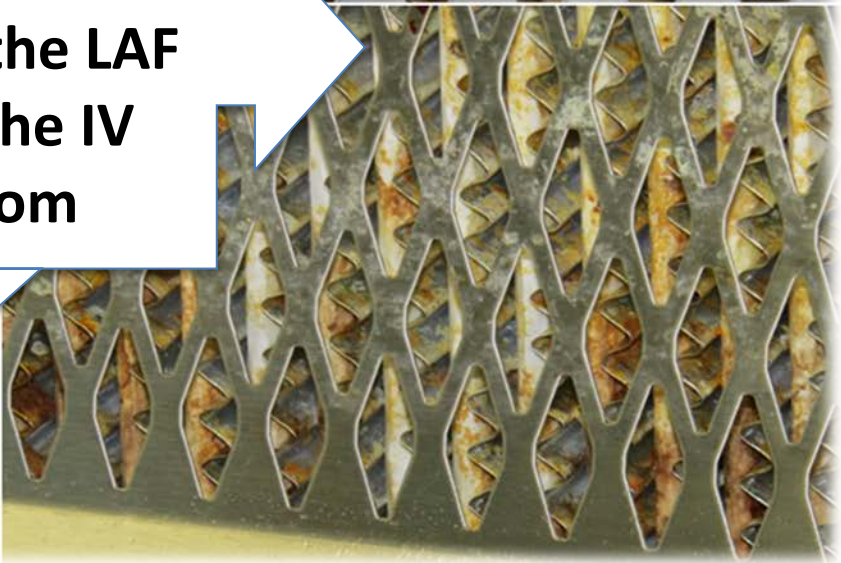


improper aseptic
technique

FDA Inspection Findings



Visible discolored HEPA filters were observed in the LAF located in the IV buffer room



FDA Inspection Findings



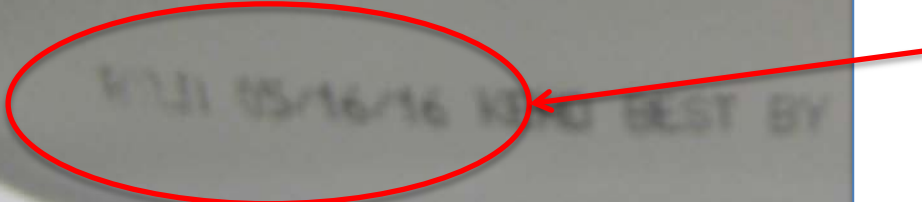
Traps were found on the ground next to the biosafety cabinet. This inspection was initiated because the firm found larvae in their EM

FDA Inspection Findings



➤ **Environmental and Personnel Monitoring:** This plate was read two hours before FDA initiated the inspection. The firm reported 0 cfu. FDA counted 23 cfu.

FDA Inspection Findings



- The water was found to be expired with an expiration date of 5/16/2016.

FDA Inspection Findings



- Insects found on top of the ISO 5 hood within the clean room

FDA Inspection Findings



- ISO 5 glove boxes located in an unclassified space.



QUESTIONS?

