NECAFS
Preventive Controls
February 2021
Objectives

- FDA Program Alignment Overview
- OHAFO Structure
- PC Inspections Overview
FDA Program Alignment
2017

• Alignment by FDA Regulated Product
• Organization no longer based on Geography
Old Geographic Districts
BLT-DO

Maryland
District of Columbia
Virginia
West Virginia
Old Geographic Districts

NWE-DO

Connecticut
Maine
Massachusetts
New Hampshire
Rhode Island
Vermont
Old Geographic Districts

NYK-DO – New York

NWJ-DO – New Jersey
Old Geographic Districts

PHI-DO

Delaware
Pennsylvania
Program Division
Office of Human and Animal Food

HAFE-1
MA, ME, NH, NY, RI, VT

HAFE-2
DE, MD, NJ, PA, VA, WV,
District of Columbia
HAFE-1
Management

• Ronald Pace, Program Division Director
• Lori Holmquist, Director of Investigations
• CDR Catherine Beer, Director of Compliance
HAFE-2
Management

• Randy Pack, Program Division Director
• CDR Martin Guardia, Director of Investigations
• Vacant, Director of Compliance
Preventative Controls
21 CFR 117
Inspections

• Who Conducts FDA Inspections
• Number of Inspections Conducted
• Inspection Coverage
PC Inspections
Who conducts the Inspections

- FDA Inspections
- State Contract Inspections
- Training
## FY19 and FY20 Preventative Control Inspection Counts

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Preventative Controls
21 CFR 117

• Subpart A: General Provisions
• Subpart B: Current Good Manufacturing Practice (old part 110)
• Subpart C: Hazard Analysis and Risk-Based Preventive Controls
• Subpart D: Modified Requirements
• Subpart E: Withdrawal of a Qualified Facility Exemption
• Subpart F: Requirements Applying to Records That Must be Established and Maintained
• Subpart G: Supply-Chain Programs
Limited Scope
PC Inspection

- Subpart A Training Requirements
- Subpart B cGMP
- Subpart F
Limited Scope
PC Inspection

A brief review and assessment of required preventive controls:

• Sanitation Controls
• Food Allergen Control
• Process Controls
Full PC Inspection

• All Subparts of 21 CFR 117
• Hazard Analysis