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Implementation of the Preventive Controls for Human Foods Rule

New York State Department of Agriculture and Markets

Division of Food Safety and Inspection

Andrew M. Cuomo
Governor

Richard A. Ball
Commissioner

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Adoption of Regulation

- The Department elected to adopt the entire regulation (21 CFR 117) with the exemption of subparts D & E, through the consensus rule making process
- We received no objections
- Regulation was published in the State Register on June 21, 2017
- Adoption of the rule enables the Department to conduct inspections covered by the Preventive Control for Human Food rule under New York State jurisdiction

Implementation

- Devised a 'information collection' worksheet for inspectors to:
  - Understand the size of the universe i.e. how many facilities in New York are affected by the rule
  - As a mechanism to create awareness around the new rule
  - To provide outreach on the rule (FDA PC 'At-A-Glance' document)
  - To understand the 'gap' between current processes/practices and actual regulation
- Additional resources *are* needed to bring small/medium facilities into compliance – Cornell University *Institute for Food Safety*

Implementation *cGMP only*

- Using FDA GMP 'cross-walk' document - reviewed and compared differences between existing reg (21 CFR 110) and current reg (21 CFR 117 subpart B)
- Devised a training presentation as a mechanism to train inspectors on the differences
- Provided this training in-person to all inspectors across the state
- Prior to in-person training required all inspectors to complete online class (FD-8000r)
- Updated and rolled out inspection worksheet to include new requirements
- Updated inspection database to include new requirements
- Using FDA 'citations' draft document – updated enforcement/compliance tools

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Implementation *Next Steps*

- Training
  - Provide PC regulator training to inspectors across the state
  - Devise a list of PC – SMEs. SMEs will supplement PC regulator training by providing training to all remaining staff and providing hands-on on the job 'experience' training
- Create a specialty inspection worksheet to include all PCHF requirements
- Update inspection database to include new specialty PCHF inspection requirements
- Identify high-risk facilities and determine based on risk, compliance history and recalls, etc what the appropriate frequency will be to perform full PC inspection
- Determine what additional resources are needed (staff, IT, etc)
- Timeframe? *Years…*

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Challenges

Infrastructure

- Funding is unavailable
- Training is limited
- Guidance is lacking
- Enforcement tools are unavailable
- Do we have skilled people?
- Do we have people?

Uniformity

- No coordination for implementation of PC rule
- Working groups have not been formed
- No forum to learn from each other
- 50 different methods of conducting PCHF inspections, compliance, etc.

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NY-CA-FDA Training Pilot (FD-180/FD152)

Problem

- × Model was in-person training only
- × Limited seats available
  - × Did not allow for long-term sustainability or training consistency among inspectors
- × State travel restrictions
- × Student waivers received (to avoid seasoned inspectors having to take the course) were inconsistent

Solution

- ✓ Offer FDA classes at New York academic institute
- ✓ Create process for states to designate their own trainer and offer training themselves
- ✓ FDA classes hosted at NYS offices
- ✓ Create a process for a student to receive a ‘waiver’ from taking the class
- ✓ Exploring waivers for (state) training class equivalents
- ✓ Virtual hosting of training

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Solutions

Infrastructure

- Availability of funding
- Expand training pilot to all courses
- Insight into creation of guidance
- Formation of working groups to aid in the *uniform* implementation of the rule

Uniformity

- MFRPS alliance to form forum for working groups to report into
- Forum to be the conduit that works and communicates *with/between* States and FDA
- Forum to provide higher level feedback to AFDO and NASDA

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Questions?

Thank You!

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