Incorporating FSMA Into the Standards

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1:00-1:45
Standard 1

- MN Statutory Provision that adopts the CFRs by reference
  
  All regulations in effect in Minnesota
Standard 2

• Training Plan updated to reflect Part 117 GMP inspections
  - Updated our in-house training to incorporate 117 language (vs 110) for new-hire training
  - Conducted 117 classroom training for existing staff
  - Modernized GMP Inspections
  - Webinar FD800R/L
  - Bridge course – FD190W101
Standard 2

• Training Plan updated - Preventive Controls (Full Scope) added as an Advanced/Specialized Inspection Type
  - PCQI Course
  - Pre-course joint inspection(s) if available
  - FD 254 PC for Human Food
  - Two Post Course joint inspections (one as observation, one as lead) and One Evaluation prior to conducting independent inspections
  - One 1 Yr post-approval joint inspection
Standard 3

• Inspection Procedures & Contract Inspection SOP updates
  - Updated to reflect 117
  - Added full scope inspection procedures
    - Includes: Resources to be provided, records to review, language for contract inspection report template
Standard 3

• Updated/Added Standard Orders to Electronic Inspection System for all 117 Subparts
  ❖ Base 117 GMP Inspection (Subp A, B, D, F)
  ❖ Add-On Inspection (Subp C, G and other specialized inspections)

• Modifications to documentation of ‘comments’
Standard 6

- Reassessing existing policies as to when a Reinspection and Follow up inspection are to be done to better align with FDA planned follow up and make best use of resources
Standard 7

• Developed guidance documents for industry to answer basic questions and direct to more detailed information from FDA
• Conducted outreach at industry/association meetings – in particular where Produce and PC regulation might both apply
Next Steps (short term)

• Sanitary Transportation Inspections – Training, Inspection Procedures
• Update Inspection Report Audits to reflect new orders being cited based on the inspection type (full scope PC vs cGMP)
• Resource assessment with addition of full scope PC inspections
Contact Information

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