



Incorporating FSMA Into the Standards

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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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