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Preventive Controls Inspections in Minnesota

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1:00PM

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Association of Food & Drug Officials

AFDO

Founded 1896

FDA U.S. FOOD & DRUG ADMINISTRATION

Adoption of the Regulations

- Federal Regulations adopted by reference (in MN Statute)

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Staff Training

117 Modernized GMPs

- **FDAs 117 Modernized GMP Webinar**
  - **All staff at the time attended live (July 2016) or reviewed at a later date**
  - **Required for new-hires as part of their Basic Training (MFPRS)**
- **Additional mGMP conducted by our staff in November 2016**
- **Revised GMP Training in Basic Training Plan**

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Staff Training

117 Preventive Controls Training

- Added to our Training Plan as Advanced
- All current staff have completed PCQI course (prereq)
- FD 254 – Regulator Training
  - One lead inspector accepted by FDA to be part of the National Training Cadre – completion of FD 254 and additional train the trainer courses
  - One additional lead inspector attended 254 in Aug 2017
  - Two additional staff at training now, 4 more attending in June 2018
- OJE or Joint Inspection

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Staff Training

Who should conduct Preventive Controls Inspections?

- All (trained) staff?
- Select staff? Identify skills needed
  - Attention to detail
  - Systems based thinking
  - Problem solving
  - Tenacity

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Inspections

- Electronic Inspection System updates

  New inspection types/standard orders (based off turbo citations)

  - 117 GMP Inspection Subp B & F
  - Add on inspection for 117 Subp C & G

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Inspections

- 117 GMP Inspections started January 2017
  - About 160 conducted in 2017
- Preventive Controls Inspections (Subp C/G) started fall 2017
  - Two completed so far, additional 4 under the contract, state inspections

PC Inspections

- Challenges
  - Resource intensive
  - Determining if appropriate controls were in place
  - Required inspectors to do a lot of independent research
  - Plants also had products under USDA inspection
  - No ‘phone a friend’

PC Inspections

Inspection time

#1 – Two staff – 35 hrs each in-plant and writing the state report; additional travel time; additional 10-15 hrs to write FDA Contract Report and document exhibits

#2 – Two staff – 30-35 hrs each in-plant and writing; additional travel time; additional 10-15 hrs write FDA Contract Report and document exhibits

Both inspections were at firms that were prepared and there were few regulatory issues.

Std 8 Resource Assessment

Manufacturing/Processing & Warehouse Inspections						
Risk Level	**Licenses**	**Yearly Inspections**	**Hours**	**FTEs**	**Hours per Inspection**	
High	292	321	4352	4.2	**13.55**	
Medium	608	466	4019	3.9	**8.63**	
Low	725	435	2153	2.1	**4.95**	
Total				**10.2**		

FDA Contract Inspections						
Risk Level	**Licenses**	**Yearly Inspections**	**Hours**	**FTEs**	**Hours per Inspection**	
High	54	54	2916	2.8	**54**	
Medium	108	108	6577	6.4	**60.9**	
Low	132	132	1254	1.2	**9.5**	
Total				**10.4**		

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PC Inspections

- Keys to success
  - Planned for sufficient time to do it right
  - Have/use resources provided
  - Reference examples in the PCQI and FD254 course
  - Ensure relevant docs requested early
  - Do the walk-though and see the food safety plan before the hazard analysis is conducted; may need to do additional walk-throughs
  - Asking the right questions of the firm
  - Risk Communication to the firm when deficiencies are found

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Outreach

- MN Food Safety and Defense Task Force sponsored PCQI Courses
- MDA Fact Sheets – General FSMA and 117 specific
  - Handed out to all firms during inspections

What do we know?

- Small firms are not ready
  - Experience with industry indicates they are trying but not there yet
  - Challenges with hazard analysis and determining controls
  - Some firms lacked awareness of a new regulation

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Next Steps

- Determination on staff training
- Preventive Controls inspections for all state inspections
- Fine tune inspection procedures
  - 1 or 2 inspectors
  - Proficiency, efficiency

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