Swab-a-thon;
How we cooperated with the FDA while still protecting our company

Galloway Company
Jan 15, 2018
Galloway family started dairy farming in 1850’s

Galloway and West families founded a creamery and condensery in Fond du Lac WI in early 1900’s

1932 Ed Galloway invested in Geo. M. Danke Co.

1938 Ed Galloway buys controlling interest

1954 Ownership and name changed to Galloway Company
Galloway Company Founders
Brothers Dick, Ned and John; Father Ed.
Over the Years
Galloway Company Facts

• Third generation family owned and operated
• 97 total employees, 52 production employees
  Teamsters Union
• 136,000 square foot facility (14,000 sq. ft. added in 2015)
• Largest manufacturer of sweetened condensed milk in the country
• Largest manufacturer of dairy dessert mix in Wisconsin - with sales in 38 states.
• Leading manufacturer of specialty dairy beverage bases in the world.
• We are B-2-B - Our products are ingredients for our customers
Sweetened Condensed Milk

- Caramel, candy, confectionary
- Bakery and Pies
- Toppings
Beverage Bases - Non Alcohol Containing
Beverage Bases – Containing Alcohol
Dairy Dessert Mixes and Bases

• Custard Mix (w/ egg)
• Ice Cream Mix (10% butterfat)
• Dairy Desserts and Reduced Fat Ice Cream (<10%)
• Gelato Mix (less butterfat, more dense, warmer serving temp)
• Sorbet
Galloway Food Safety

- GFSI/FSSC 22000 certification since 2012
- Food Safety Team Multi-discipline
- HACCP
  - In place since 1988
  - FSMA compliant
- Training
  - All employees initially & annually
- Environmental swabbing performed weekly
- FDA swab-a-thon March 2017
Food Safety

• FSMA compliance (Food Safety Modernization Act 2011)
  – PCQI trained individuals (Preventive Controls Qualified Individuals)
  – Preventive Controls
    • CCP is pasteurization
    • oPRPs Operational Prerequisite Programs
      » Foreign material filters
      » ABV
      » Allergen –labeling, production & packaging order
      » Sanitation
      » pH
      » Supply Chain
  – Sanitary Transport
  – Intentional Adulteration Mitigation (Food defense & food fraud)
  – Foreign Supplier controls
FDA Inspection Policy

– Started in 2015 working with outside consultant to boost current
– She has 30+ years experience as primary contact leader for any FDA presence with a Global Dairy company with $5 billion sales
– Use expertise when its available, especially for the unknown to start

PLAN
• Upgrade our Inspection Policy to “Global” level experience
• Develop written Plant Policy and Plan
• Do Walk-thru’s to see where to improve/create
• Create guide sheet for Inspection day
• Training plan
FDA Inspection Policy

- Created Do’s and Don’ts list
- Training for front desk staff
- Training for ops and management
- Create “best possible” policy or plan
  - Unknown until “trial by fire”

- Lead person
- Assignments of others
- Back-up people (vacation, absences, travel)
- SME’s
- Keep others away ……loose lips and eyeballs
FDA Inspection Policy

Regulatory Inspection Procedure (FDA / WDATCP)

Our Table of Contents:
1. Purpose
2. Introduction
3. Defined Roles
4. Inspector’s Arrival
5. Opening Conference
6. Plant Tour
7. Closing Conference
8. Follow-Up
9. Reference Section
Defined Roles (all management level)

**Responsible Person** - Ultimate responsibility for Company’s compliance  
**Primary**: President  
**Backup**: Owners

**Regulatory Inspection Escorts (4):**  
*Primary, Secondary, Record Keeper & back up*  
**Primary**: Food Safety Team Leader-QA Director  
**Secondary**: Plant Operations Leader  
**Record Keeper**: Technical Regulatory Affairs Manager-Products  
**Backup**: Technical & Regulatory Affairs Manager / QA Manager

- **Primary roles:**  
  - Face of the Company to the inspector  
  - Take care of side issues and hand them off quickly to get back to the inspection

- **Secondary role:**  
  - Drafts response/ communication back to inspection agency

**Record Keeper role:**  
- Keeps detailed/accurate notes/ minutes of inspection  
- Logs information on samples & swabs and product involved  
- Documents and provides inspectors questions to SME/Responsible person/Attorney  
- Tracks topics/event recorder especially inspectors spoken observations  
- Helps drafting response/ communication back to inspection agency  
- No direct contact with inspector

**Subject Matter Experts (SME)**  
**Not on inspection walk**, Resource only  
- Provide answers to postponed questions  
- Obtains documents requested  
**Primary**: Process Specialist / QA Manager / Operations Leaders  
**Backup**: Technical Regulatory Affairs Manager-Products / Production Schedulers

**Legal Counsel**: Galloway Attorney; Resource for questions regarding inspection actions and follow up
FDA Inspection Policy

In attendance with FDA:
1. Regulatory Inspector
2. Primary Escort—Food Safety Team Leader-QA Director
3. Secondary Escort—Plant Operations Leader
4. Record Keeper—Technical & Regulatory Affairs Manager
5. Secondary Backup—Quality Assurance Manager
6. Responsible Person should NOT attend. Maintain separation.

Galloway’s objectives first meeting
1. Learn the purpose of the inspection (e.g. – routine or response to a customer complaint, etc.)
   a. Comprehensive—covers entire operation
   b. Abbreviated—focuses on critical factors in a Company’s operation, factors that play a major role in whether the Company is in compliance with federal standards.
   c. Directed—conducted in response to a specific problem, e.g. a customer complaint, a history of poor performance
2. Which product/process or areas will be inspected?
3. What is the Regulatory Inspectors background? (food industry, microbiology, dairy, criminal investigations etc)
4. Ask if Regulatory Inspector has any specific questions up front.
5. Advise the Regulatory Inspector of any relevant plant rules (e.g. - no cameras, video recording unit or tape recorders, need to comply with GMP rules, etc.)
   a. FDA does not have a right to take pictures inside the plant (proprietary equipment, distracting to employees etc).
FDA Inspection Policy wording

The DO NOTS of Plant Tours

- Do NOT volunteer documents, records or information. Only answer the question as asked, do not elaborate beyond the question asked.
- Do NOT offer explanations or historical data.
- Do NOT engage in speculation.
- Do NOT respond to baiting comments from Regulatory Inspector such as “something doesn’t appear to comply with regulatory requirements”. **Keep silent unless asked a question.**
- Do NOT allow inspection of offices (not required).
- Do NOT allow Regulatory Inspector to look thru any file cabinets or records storage areas.
- Do NOT discuss business matters near, around or with Regulatory Inspector.
- Do NOT voice opinions, personal views or hearsay (all can be used as evidence later)
FDA Inspection Policy

Confidential Information (see Records)
To the extent possible, confidential information should **not** be disclosed to Regulatory Inspector. When confidential information must be disclosed, the Regulatory Inspector should be advised that the information is confidential and asked to note that fact in their report. Clearly identify confidential and proprietary information by stamping each page provided as “CONFIDENTIAL”.

**Do not** provide or copy this information to FDA

- Financial data (salary information, budgets)
- Processing Records (unless under Bioterrorism act request by form 482c for specific records - not all records)
- Pest control or sanitation company, their name but not the records
- HACCP plan (only that we have a plan)
- Food Safety Monitoring Records (unless under Bioterrorism act request by form 482c for specific records -not all records)
- Customer complaints
- Corrective Actions
- Environmental testing (only that we perform, not where or results)
- Product Quality/test records
- Verification records
- Formulas/Recipes
- Customer lists
- **Personnel**: Regulatory Inspectors should **not** be permitted to examine personnel records or performance appraisals. Upon request, an inspector may be advised of the qualifications of those persons having overall responsibility for quality control and sanitation. For example, a Regulatory Inspector may be advised that the person in charge of quality control has a BS in chemistry plus three years’ experience.
### List of FDA inspection forms – NEVER SIGN any FDA form or Document

<table>
<thead>
<tr>
<th>Number</th>
<th>Purpose</th>
<th>When executed</th>
<th>Read yes / no</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>482</td>
<td>Notice of Inspection</td>
<td>Initial meeting</td>
<td>Yes</td>
<td>FDA required</td>
</tr>
<tr>
<td>482</td>
<td>Sample Collection</td>
<td>Initial meeting and during inspection</td>
<td>Yes</td>
<td>FDA required</td>
</tr>
<tr>
<td>482a</td>
<td>Demand for Records: acidified food EI’s</td>
<td>Initial meeting and during inspection</td>
<td>Yes</td>
<td>FDA required</td>
</tr>
<tr>
<td>482b</td>
<td>Request for Information: acidified food EI’s</td>
<td>Initial meeting</td>
<td>Yes</td>
<td>FDA required</td>
</tr>
<tr>
<td>482c</td>
<td>Notice of Inspection: Request for Records under Bioterrorism rule</td>
<td>Initial meeting and during inspection</td>
<td>Yes</td>
<td>HIGH AWARENESS- Contact LAWYER. When suspicion of adulterated food/bioterrorism, expanded authority to access records</td>
</tr>
<tr>
<td>483</td>
<td>Inspectornal Observations</td>
<td>Exit meeting</td>
<td>Yes</td>
<td>Needs immediate attention/follow up</td>
</tr>
<tr>
<td>484</td>
<td>Receipt for Samples</td>
<td>Initial and during inspection</td>
<td>Yes</td>
<td>FDA required</td>
</tr>
<tr>
<td>463a</td>
<td>Affidavit</td>
<td>Sample collection or exit</td>
<td>No</td>
<td>HIGH AWARENESS- contact LAWYER</td>
</tr>
</tbody>
</table>
**General Inspection:** What is required to be **GIVEN** / **NOT GIVEN** when requested, by law?

<table>
<thead>
<tr>
<th>Item</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records of incoming ingredients or food if REQUEST IS IN WRITING</td>
<td>only provide verbally but <strong>when request is in writing on form 482, it must be specific</strong></td>
</tr>
<tr>
<td>List of products shipped</td>
<td>only provide verbally</td>
</tr>
<tr>
<td>Pesticide use information</td>
<td>only provide verbally</td>
</tr>
<tr>
<td>Product samples</td>
<td>may request; ingredients or finished products made</td>
</tr>
<tr>
<td>Label information</td>
<td>may take pre-printed stock labels</td>
</tr>
<tr>
<td>Labels from production floor</td>
<td>may take pre-printed stock labels</td>
</tr>
</tbody>
</table>
What may be SEEN (SHOWN) / not seen (shown), but DO NOT copy…

<table>
<thead>
<tr>
<th>Consumer complaints</th>
<th>Under bioterrorism rules-YES. A general inspection-NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertinent production equipment</td>
<td>Visible &amp; verbally only, no document or list</td>
</tr>
<tr>
<td>Finished and unfinished materials</td>
<td>Don’t hide but don’t offer</td>
</tr>
<tr>
<td>Food and Drug guarantee from suppliers</td>
<td>Say “Yes we have”, FDA must then ask to see. Okay to show, but NOT copy</td>
</tr>
<tr>
<td>Food Guarantees made by Galloway</td>
<td>Say “Yes we have”, FDA must then ask to see. Okay to show, but NOT copy. Show blank or template; not customer specific</td>
</tr>
<tr>
<td>Records being used in production (such as pasteurization charts)</td>
<td>Charts-YES to current day, No to recipes or formulas or past records</td>
</tr>
<tr>
<td>Containers</td>
<td>If visible, do not volunteer more</td>
</tr>
<tr>
<td>Types of products produced</td>
<td>only provide verbally</td>
</tr>
<tr>
<td>Name of Pest Control service</td>
<td>only provide verbally</td>
</tr>
<tr>
<td>Identity of other inspections (State etc)</td>
<td>Do NOT identify but confirm verbally that we are inspected; by those required by regulation and customer</td>
</tr>
<tr>
<td>Per Centage of products shipped interstate</td>
<td>only provide verbally, broad range %, not specific #</td>
</tr>
</tbody>
</table>
If inspection falls under **Bioterrorism Act rules** then additional information may be accessible to inspector upon written request (form 482c)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturing records</strong></td>
<td>Be shown and receive a copy</td>
</tr>
<tr>
<td><strong>Packaging records</strong></td>
<td>Be shown and receive a copy</td>
</tr>
<tr>
<td><strong>Distribution/shipping records</strong></td>
<td>Be shown and receive a copy</td>
</tr>
<tr>
<td><strong>Incoming ingredient records</strong></td>
<td>Be shown and receive a copy</td>
</tr>
<tr>
<td><strong>Hold records</strong></td>
<td>Be shown and receive a copy</td>
</tr>
<tr>
<td><strong>Importation records</strong></td>
<td>Be shown and receive a copy</td>
</tr>
<tr>
<td><strong>Consumer complaint records</strong></td>
<td>Be shown and receive a copy</td>
</tr>
</tbody>
</table>
**NEVER** entitled to be **SEEN (shown)** or **GIVEN**…

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Company officers names</td>
<td>Never show, “we are privately owned”</td>
</tr>
<tr>
<td>Production figures</td>
<td>Never show, no ranges, highly confidential</td>
</tr>
<tr>
<td>Product cost/pricing information</td>
<td>Never show, no ranges, highly confidential</td>
</tr>
<tr>
<td>Description of manufacturing process</td>
<td>Never show, no ranges, highly confidential</td>
</tr>
<tr>
<td>Quality control records</td>
<td>Never show, no ranges, highly confidential</td>
</tr>
<tr>
<td>Product development records</td>
<td>Never show, no ranges, highly confidential</td>
</tr>
<tr>
<td>Organizational chart-line of authority</td>
<td>Never show, only give next level up from your position</td>
</tr>
</tbody>
</table>
Questions Often Asked By FDA

The following questions often asked by FDA inspectors are best answered by as follows:

- **General operations**: Regulatory Inspector Escort
- **Specific Issues**: SME
- **Document Requests**: Responsible Person

When asked by Regulatory Inspector about problems and Corrective Actions, have a prior plan; Confer between Responsible Person, Regulatory Inspector Escort & Subject Matter Experts, legal counsel before discussing with FDA inspector

Q1. What is expected normal shelf life?
   A1. Based on product. May need clarification. Give general range 30-60, 24-28 days

Q2. What are normal turnover or delivery and service to customer?
   A2. Ask inspector to explain more, clarify? Make inspector tell you want they want.

Q3. What is chain of command?
   A3. Depends, answer one level up

Q4. What is procedure for inspecting ingredient suppliers?
   A4. Risk based. Don’t lock yourself in.

Q5. Do you require pre-ship samples from your suppliers?
   A5. Vagueness. What looking for? Then ok to answer.

Q6. What testing do you do; give an example?
   A6. Ask clarifying questions. Testing is proprietary or not allowed to release that info. Give analytical maybe.

Q7. Do you require certification or actual lab analysis results from suppliers?
   A7. Risk based. Proprietary

Q8. What test: (refers to #7)
   A8. Proprietary

Q9. Would you let me review results?
   A9. Proprietary
Q10. What sanitizers are used?
   What concentration used and how long?
   Where and what chlorine concentration is used?
   Where is Quat used?
   What about iodine?
   A10. Based on recommendations and legal requirements. When as necessary? Be careful not lock yourself in to future use of one sanitizer or application
Q11. What were lot sizes we sampled?
   A11. Approximate, don’t be specific
Q12. What products are produced at plant?
   A12. Only mention what they saw, don’t elaborate to other product or production lines, otherwise proprietary and FDA should mark as such in their notes
Q13. What lines were run during inspection?
   A13. Only mention what they saw
Q14. Would you be able to give me all the items produced and quantities run on the line that samples came from for both days?
   A14. Proprietary
Q15. What analyses is performed pursuant to defect action levels on raw materials?
   A15. Proprietary, if defect level is set (supplier specific) and exceeded, unacceptable-rejected. Supplier testing also
Q16. Can you describe the air conditioning and filters?

Q17. Are all your production areas under positive pressure?
   A17. Dependent on room activity
Q18. Did ‘Linda’ (FDA inspector who visited last year) get samples of all your labels and private labels?
   A18. Check FDA records. “I don’t recall”
Q19. What is your flow pattern of plant personnel and outside personnel?
   A19. GMP and visitor rules followed
Q20. Noticed uniforms; are they provided and cleaned by company?
   A20. Proprietary
Q21. How is “reclaimed” product recycled into product?
   A21. Proprietary. Include pasteurization step
Q22. Are plant and line blueprints available?
   A22. No, Proprietary
Q23. Does hand wash cleaner include a sanitizer?
   A23. Yes
Q24. What is capacity of HTST?
   Who is manufacturer?
   A24. Proprietary
Q25. Do you have a written recall procedure including your people in distribution?
   A25. Yes, See it? NO
Q26. Do you use public storage warehouses?
   A26. Yes. Not given
Q27. Do you do any direct store deliveries?
   A27. Yes, some. Do not disclose names
Q28. Do you have a HACCP program?
   A28. Yes. Includes CCPs and HA and RA
Q29. Is there regular Quality Assurance inspections?
   A29. Yes, as needed based on product & risk factors
Q30. Are there written procedures for testing and methods?
Q31. How is worker training documented?
   A31. Yes, checklists
CFSAN has developed guidance on the specific locations within a firm to collect environmental samples to increase the likelihood of detecting *Listeria monocytogenes* and *Salmonella*. See IOM Exhibit 4-20 and 4-21 and FIELD BULLETIN #30 – FOOD PROGRAM AREA INSTRUCTIONS FOR ENVIRONMENTAL SAMPLING for guidance on environmental sampling/locations for these microorganisms. In addition, please view the training video, “Environmental Sampling” which provides technical and procedural information on environmental sampling.

Environmental sampling, particularly for *Salmonella*, should be considered at manufacturing plants that are typically dry environments where water occasionally wets the area, either intentionally as part of a periodic wet cleaning or inadvertently as the result of leaking pipes or valves or a leaking roof.

Environmental sampling should be initiated as early in the inspection process as possible but should not be performed until supplies, personnel, and plan (walk-
Zone 1 can be raw or pasteurized FCS
Day 1    FDA arrives  
9:20 AM  on a Monday

• Mark notified by receptionist
• FDA is placed in front lobby conference room as per plan
• Mark verbally spreads the word to onsite management

• 10 minute Ops meeting to plan
  – Who is in plant
  – Situation
  – assignments

• Inspection team assembles
• President alerts legal
• Greet FDA at 9:46
Day 1 FDA Meet & Greet

- Three inspectors
- Credentials review
- Introductions
- FDA Plan explained

- Lead previously here for 2008 inspection
- Swabber previously here-unknown
- Helper not here before
Day 1 Inspection Plan

- 482 given to Mark
- 2 days onsite
- 100 *Salmonella* swabs pre-pasteurization
- 50 *Listeria* swabs post-pasteurization

- Explained their process
- Questions asked
  - Employee count?
  - Only location?
- Wanted to take photos
  - Galloway denies
  - FDA upset
  - “Refusal” in record
Day 1  Inspection Plan
-Questions

• Will Galloway place product on hold?
  – no

• Can they have a map?
  – yes

• Can they have a cart for supplies on floor?
  – yes

• Any recent environmental positives?
  – “NO”
  – Last EM Listeria early Oct ’16
  – I didn’t feel that was recent
Day 1 swabbing experience

- Explained mix does not provide any ‘ingredients’ to other lines (SCM, Bev), then only focused on mix floor
- Started 11 AM

- Galloway group
  - Note taker
  - swabbing location identifier
  - Tag-alongs
    - Watch out!!!!
  - Introduce FDA to operators
  - One person answers questions
Day 1 Salmonella

Raw side swabbing, 100 swabs

- Mix floor (raw side)
- 100 *Salmonella* swabs
- Done in 3 hours
- Zones 2 & 3
- No zone 1

- FDA zone 1 could include raw contact since it is product contact
- Tanks, gaskets, pumps
- FDA removes all their own material
Day 1 *Salmonella* Interview Time

- What do we make on mix floor?
- All liquid based?
- Any water based “Ice Pops”?

- Requested list of products made during swabbing
- Hours mix floor runs?
- How many packaging lines?
Day 1 *Salmonella* Interview Time

- Commented that day 2 won’t have many zone 1 since everything is enclosed
- “Skipped intake-but won’t worry about it”

- Requests for records for Day 2 review
  - Sanitation SOP
  - Chemical list requested
  - Concentrations
  - Preventive Controls?
  - Allergen controls?
  - Pest control records
  - Time & sealing records
Day 1 wrap up with FDA

- FDA plans to arrive 9-9:30 AM day 2
- Galloway asks for earlier start, 7-7:30 AM
- Negotiates agreement
  - WHY?
- FDA provides lab sample contact, ID information
- FDA leaves 4 PM
Day 1 Post FDA

- Galloway management on site reviews written notes, FDA comments and plans for day 2
- Galloway knows of day 2 packaging room *Listeria* swabbing plan
- Plans NOT to produce until after FDA swabbing and CIP
Day 2 Listeria

FDA returns—Prep for day

- 7:30 AM start
- FDA asks for product list made today
- Galloway informs of “no-run” plan
- FDA upset
- Contacts district MGR for guidance

- Instructed to continue since already on-site
- Plan is 50 *Listeria* swabs in mix packaging room
- First swab 8 AM
Day 2 **Listeria**
pasteurized side  50 swabs

- Swabs from zones 1, 2 & 3
- Only 2 zone 1 swabs
  - Tank gaskets
- Comments by FDA on some visible concerns noted and corrected
- What temperature is product packaged at?
- 9:39 AM swabs completed
- Only in mix packaging room
- Swabs shipped out
- FDA prepares for records review and questions
Day 2 Interview Time -
3 questions at a time

- Names of Company officers? *
- Number of employees?
- Hours production?
- Sales >$50 MM?
- Retail vs Wholesale %?
- Interstate sales %?
- Out of State ingredients?
- Types of packaging?
- Sizes?
- Labeling info?
- Labels vary?
Day 2 Interview Time - 3 questions at a time

- Milk ## received daily? Where purchased?
- Haulers wash trucks?
- Exteriors? Interiors?
- Do we test raw milk?
- Temperature? TA?
- Antibiotics tested?
- Which?
- Any positive loads?
- Reviewed records
- Pest Control questions*
- Water questions
  - sources
- Testing on water
Day 2 Interview Time-
3 questioners at a time

• Sanitation SOP
• Allergen program
• Recall program
• Mock recalls?
• Finished product testing?
  – What, where, why?

• Any EM hits last two years?
  – Swab types, locations, tests performed, swab while running?
  – See CAs?
    • Never completed this question/answer

• Lunch break
  – GC Contacts legal for EM guidance
Day 2  -legal prep for EM

- Lawyer: Galloway not under FSMA EM rules until 9/17
- Galloway will need to decide how much prior EM to reveal
- What does recent mean?
- Be honest and forthright, not coy, hidden

- Look back two years to see trend
- % + vs % -
- Where happening?
- Are they closed?
- L. sp. vs L.M.s
- Be prepared to show CA work
Day 2 Interview Time - post lunch

- Only FDA lead returns
- Galloway asks learns - No 483s
- Do we segregate allergens?
- Copy of HACCP flows?*
- Reviewed HACCP plan
- Reviewed PCs
  - pre-FSMA complete
- Max HTST run temp?*
  - Only gave/read what is on our CCP SOP
- Top 3 customers?*
  - No
- Top 3 suppliers?*
  - No
Day 2 Interview Time -post lunch

• Review mix HTST charts?
  – Yes
• Milk drivers clean exterior of trucks?
• Do they make own connections?
• Are they secured?
• How tracked?
• How are HTST charts reviewed?
• CIP temp higher than required?
• Back up of charts?
• Job duties those in room?* (gave info)
  – Who they report to?* (gave info)
Day 2 Quick plant walk thru

- Non swabbed areas
  - Evaporator
  - Receiving-Logistics
  - Beverage blending
  - Beverage processing
  - Cooler for egg storage

- Purpose of tanks?
- Where are pasteurizers?
- HTST chart digital display temperature?
- ESL fillers-human contact?
- Pail filling room-Human contact?
Day 2 Quick plant walk thru

• Beverage HTST
• Can FDA see pasteurization indicating thermometer temperature?
• It was covered. Why?
  – Proprietary
• Runs high?
  – Above critical minimum

• Where are eggs/allergens stored?
• Are they pasteurized?
Day 2 Wrap up

- Galloway again inquired if any 483 findings?
  - No only recommendations
- Receipts for swabs
- Contact info for results

- 2 weeks for Hard copy swab result reports
- One month for hard copy inspection report
- Galloway needs to generate e-mail request for earlier swab results
Day 2 Wrap up

- Any “not Negative” results will be confirmed and speciated
- probably DNA/genome sequenced
- Zone 1 or 2 positives should reply with corrective action plan
- FDA not “overly excited” about zone 3 positives
- FDA leaves 1:30 pm
Day 3 Final Day

- Lead inspector returns
- Issues receipt for sample documents
- Requests sign*
- Normally shouldn’t but what you gonna do
- Discusses 8 recommendations/findings
- Galloway informed corrections already happening
- No follow up required to FDA
Outcome and Learnings

- Have a Policy
- Identify teams and player roles
- Practice the plan
- Plan your day
- Be respectful
- Hold ground on important things

- Don’t make them your enemy—they have a job
- Be flexible
  - Understand what you cannot give and what you shouldn’t but maybe do
- Large corporations plans don’t fit small companies
Outcome and Learnings

• Be Friendly
• Be Honest
• But be Cautious
• One speaker or approved speakers that know what to say and what not
• Keep others away

• No extra talking, pointing or visual clues
• Ask FDA questions
• Understand your obligations for their and your next steps
Questions?