

# How Compliance Uses WGS Data?

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# WGS Applications

- Determine close relationships with pathogens in FDA regulated foods and manufacturing environments:
  - Environmental Samples
  - Finished Product Samples
  - Clinical isolates
- FDA Recall data shows the top 2 reasons for a product recall
  - Allergens- Misbranding
  - Pathogens in RTE Foods (*Salmonella*, *Listeria*)

# WGS Applications

- Additional insight into pathogens in manufacturing environments:
  - Resident strains in the environment
  - Cross contamination from environmental contamination to finished product
- Undetected outbreaks
  - Sporadic microbial contamination during processing

# Environmental Microbial Risk

- Facilities not controlling the pathogen risk in processing environment.
  - Ineffective sanitation programs
    - Cross contamination
    - Condensate/ high pressure hoses/ etc.
    - Bad equipment design to effectively clean/ sanitize
    - Product flow (“pretzel flow” vs hygienic design)
      - State of the art cleaning procedures won’t fix underlying problem
- Preventable with environmental monitoring programs and verification procedures



# Options to Consider

- Encourage voluntary corrective actions
  - Voluntary Recall
- Collaboration with our State and Local counterparts
- Enforcement tools:
  - Warning Letter
  - Regulatory Meeting
  - Injunction
  - Seizure
  - Administrative Detention
  - Suspension of Food Facility Registration
  - Mandatory Recall



# Case Study

# What Happens Next?

- FDA will be outward reaching/ sharing what we know
  - Conversation about the signal (result)
  - Provides a signal for industry as well
- What environmental monitoring program do you have?
- What corrective actions (ex. A root cause analysis, etc.) are done in the event a positive may be found?
  
- If you have zero data of your own- may suggest a different conversation from FDA
  - FDA may conduct swabbing
    - Different then the places we are already out swabbing

# Next Steps

- If you have zero/ minimal data of your own- may suggest a different conversation from FDA
  - FDA may conduct swabbing
    - Different then the places we are already out swabbing
- If cleaning/ sanitation inadequate- different conversation
- Prevention through supplier controls
  - Know your contract manufacturers, ingredient suppliers, and how they control the risk.



# Managing the Risk

- We expect you to find it
  - It's about what happens next!
    - Look in Zone 1/ food contact surfaces
    - Find and fix
    - Reacting to Zone 2, 3, and 4s before it gets into Zone 1
- It is doable!
  - # of success stories where firms have strong EMP and operating in control
  - It's all about the data

