So You Got A Positive Now What????





For the People, Animals & Climate of Tomorrow

What do you mean "the sample is positive!"



Credit to Jim Mino Hormel



Now What?

- Make Assumptions
 - Blame the positive on a lab error
 - Blame the positive on poor GMP's
- Avoid the problem
 - Simplify root causes without evidence (loudest voice rules)
 - One time event? Retest until you get a negative
 - Become distracted with superficial fixes e.g.
 - "nuke" the affected area
 - Re-train employees





Now What?

- Our first Impulse is to attack Listeria with everything we have:
 - "Special" Sanitation chemicals
 - Additional equipment disassembly and deep cleaning
 - New (temporary) sanitizer hurdles
 - Restrict employee movement

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How do you solve a crime if you've scrubbed the "crime scene" clean?

You cannot find the root cause and prevent future positives without doing a proper investigation.



VERY IMPORTANT

Celebrate with your team for finding the positive.

Whether you find it or not, Listeria is there. Encourage your teams to meet the risk head on, not avoid it.



Who's responsible?

Seek & Destroy teams are only effective when all departments are involved

- Listeria is **not** "A QA problem"
- Production, Sanitation, Maintenance and QA all have a responsibility in food safety.
- Front line employees can provide invaluable information



Use the Listeria Control Equation as Part of The Problem Solving Approach During S&D

"Spreaders" during Production



A positive finding during Verification Monitoring means that one or more of the control factors in the Listeria Control Equation has failed.

"Shedders" in spite of daily sanitation



Identifying Root Cause

Take the time to understand the environment and processes surrounding the positive.

- TALK TO THE FRONT LINE EMPLOYEES!!! Ask *what has changed*? What is *their* hypothesis?
- Observe production and sanitation (hours, not minutes!)
 - Are procedures being followed as written in the SOP?
- Any unusual activities? Process changes? Special production or equipment repairs? Construction activities?
- Review the Sanitation Schedules. What about Non-daily's?
- History of the Line? Any Listeria Positives or APC fails? What about the surrounding lines/areas?



Identifying Root Cause

Assess the condition of the facility infrastructure and equipment.

- Do you have facility issues? Ceiling leaks? Condensation and moisture issues?
- Sanitary design of the equipment adequate? Can the equipment be disassembled further?
- Is the equipment accessible for cleaning on all sides?

No Hypothesis is off Limits

Don't limit yourself to *"it's never been an issue before"*



Identifying Root Cause

- Test each hypothesis to determine root cause
- Confirm effectiveness of corrective actions will ensure sustainable outcomes with no rework.



Develop Hypothesis for Root Cause



Identifying Root Cause

Remember:

- Root cause hypothesis evolve with sampling results.
- Don't assume the first investigative positive is tied to the contamination source.
- Utilize a variety of sampling tactics including vector and time series sampling.
- Each investigation is unique. Do not be influenced by previous events. There is no set completion time or number of swabs to be taken.



Seek & Destroy Example



Original EMP Sampling Event



VM Program Positive – Ribbon Conveyor Wheels





S&D #1

Main Hypothesis:

Contamination found on the floor mop could have potentially transferred to the R530 ribbon conveyor wheels when designated employees gather the water and potential debris from the floors.

Hypothesis #2:

A fiberglass ladder was located above the positive site and could have dripped down onto the ribbon conveyor wheels where positive results were identified.





Investigative Swabbing #1 Results



Investigative Positive – Equipment Base / Sandwich Parts





Investigative Swabbing #1 Results



Investigative Positive – Under Electrical Box / Ladder

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S&D #2

Hypothesis-

Meat and fat accumulation in and around the sandwich points along the R530 framework acting as a harbourage point for Listeria.







S&D #2

Hypothesis-

Meat and fat was present on the underside of the electrical box located on the R530 conveyor frame. Water from sprayers over the conveyors could have acted as a transfer vector to spread Listeria from these harbourage points to the R530 wheels and ladder.





Investigative Swabbing #2 Results



Investigative Positive – Floor by Ribbon Conveyor





Investigative Swabbing #2 Results



Investigative Positives: Electrical Box Underside Electrical Box Conduit Sandwich Point 1 and 2





Investigative Swabbing #2 Results



Investigative Positives: -Ribbon Conveyor Wheels -Floor under Ribbon Conveyor





S&D #3

Main Hypothesis-

Electrical units identified beside the R530 line had meat harborage inside.







Investigative Swabbing #3 Results





Investigative Positives: -Inside Electrical Box -Inside Conduit





Summary of the Positive Findings

S&D Summary: 3 missions, 41 investigative samples, 12 positive findings. Electrical conduit and boxes replaced and PM revised.



Initial – Wheels / Floor

1st Level – Sandwich Parts

Root Cause - Ladder

2nd Level – Electrical Box / Conduit (Exterior)

Root Cause – Conduit / Electrical Box (Interior)



What would you do differently if you could play the *Seek and Destroy* game again?



Eliminating Root Cause

Destroy **does not** mean "Cleaning the harbourage site"

Destroy means

Eliminate the Harbourage site or mitigate the risk



Eliminating Root Cause

Once you understand what failed (causing your Listeria positive), now you must understand **why** it failed.

- Are there gaps?
- Is your training ineffective?
- Is you plant relying on tribal Knowledge?
- does the plant culture promote preventive/predictive control?



Eliminating Root Cause

Once you understand the *why* you will be able to implement systematic changes to your program and prevent future reoccurrence



Develop Hypothesis for Root Cause

Swab Before Corrective

actions (if appropriate)



If I had read this presentation before our positive event, I would have known to:

• Celebrate the positives.



- NOT clean the "crime scene" before I completed the investigation.
- Use the Listeria equation to focus on the key control factor for brainstorming.
- NOT limit the investigation, challenge the results and keep asking **WHY**.
- Find the source.
- Implement effective and sustainable CA.

