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**FoodSafety**  
magazine™

# Strengthening Food Safety

Through Sanitation Validation and Verification

# Audience Poll

1) What is one word that describes a validated sanitation program for you?

2) What is one word to describe your biggest challenge around sanitation validation?

# Learning Objectives

- Distinguish validation vs. verification in sanitation programs
- Design validation/verification plans beyond compliance
- Strengthen programs using gap and risk-based assessments
- Make strategic decisions on organisms, sites, and sampling methods

# Definitions

Validation vs Verification

# Sanitation Validation

## Definition:

- Validation is obtaining and evaluating scientific and technical evidence to demonstrate that sanitation procedures, when properly implemented, are capable of effectively controlling identified hazards.

## In practical terms:

- Proves the cleaning process works before routine use
- Answers: “Will this method control the hazard?”
- Based on science (e.g., literature, challenge studies, environmental data)
- Conducted initially, and when significant changes occur

## FSMA context:

- Required when sanitation is used as a preventive control to significantly minimize or prevent a hazard (e.g., allergen cross-contact, pathogens like Salmonella in low-moisture environments)

# Sanitation Verification

## Definition:

- Verification is the application of methods, procedures, tests, and evaluations to confirm that sanitation procedures are consistently implemented and operating as intended.

## In practical terms:

- Confirms the process is being executed correctly
- Answers: “Did we do it right this time?”
- Includes activities like:
  - Pre-op inspections
  - ATP testing
  - Environmental monitoring (e.g., swabs for indicator organisms)
  - Record review

## FSMA context:

- A required component of Preventive Controls to ensure ongoing control and compliance with the food safety plan.

# Simply!

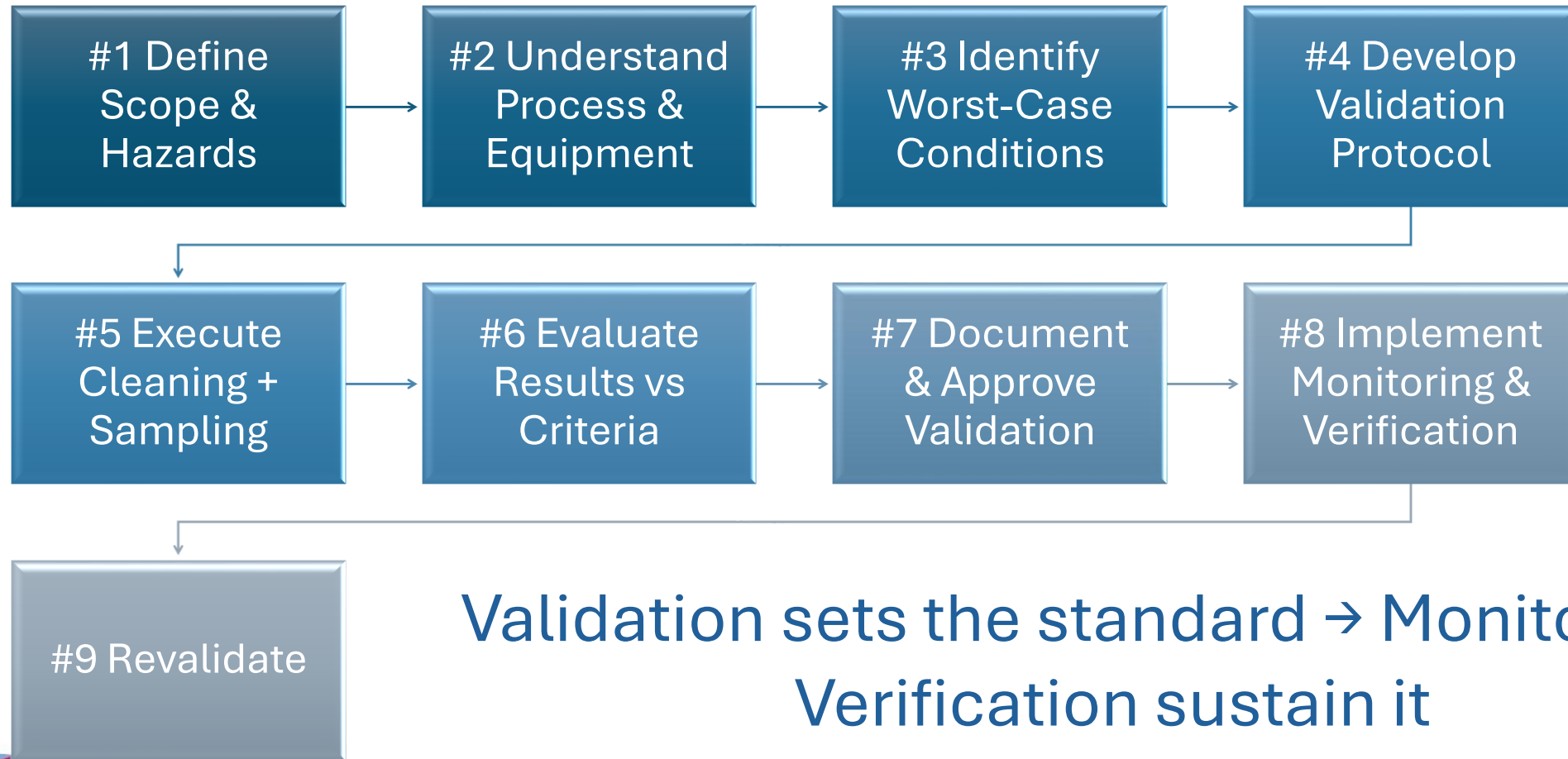
- **Validation = Prove it works**
- **Verification = Prove you did it right**

# Sanitation Validation Program

What is it?

# Validation: Where do I start?

*Identify worst-case conditions*



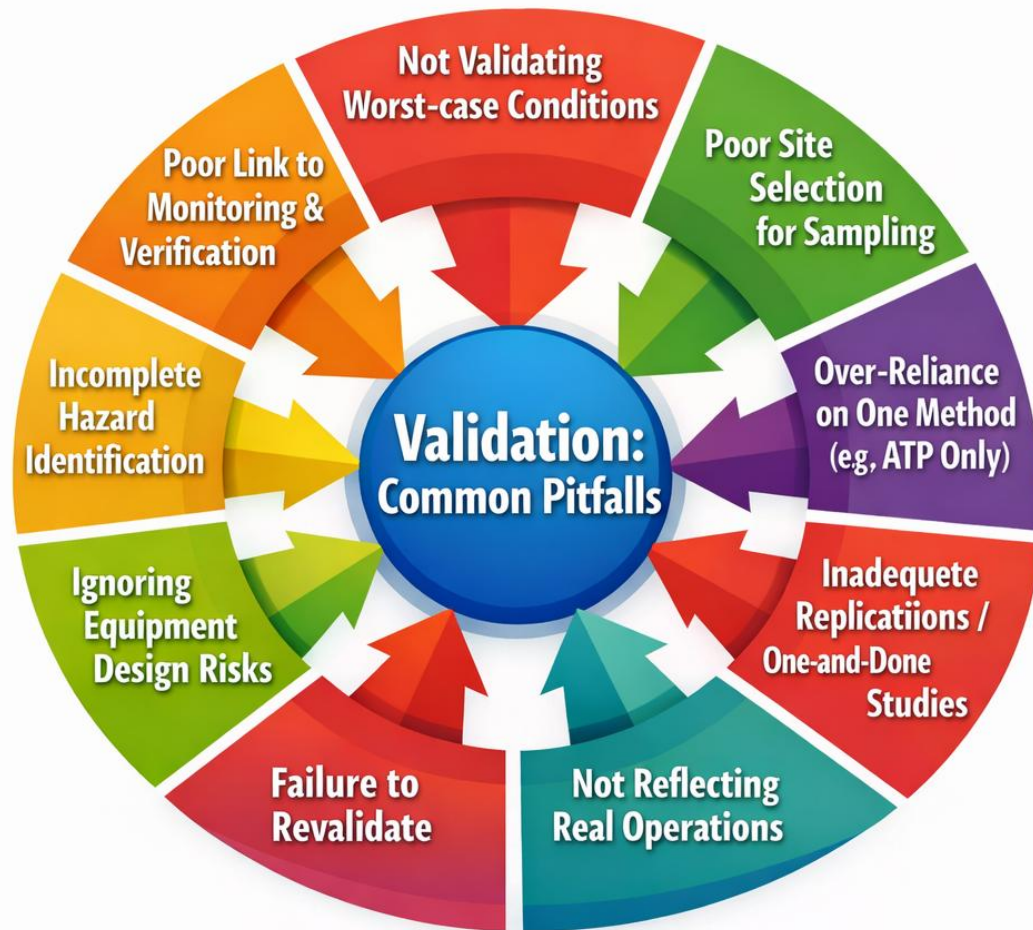
# Validation

Common Pitfalls



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# Validation: Common Pitfalls



**Most failures come down to this:**

- Not testing the right conditions
- Not testing the right places
- Not testing the right hazards

# Validation

Wet vs Dry - Considerations



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Which one is harder to validate,  
wet or dry?

# Dry is harder because:

- You can't “wash away” risk
- Detection is harder
- Margin for error is smaller

# Wet vs Dry Cleaning Validation - Considerations

## Primary Risk

- Wet Sanitation
  - Focus: Microbial control (e.g., pathogens, biofilms)
  - Water = enabler of growth and spread
- Dry Sanitation
  - Focus: Preventing introduction/spread of moisture
  - Water = primary risk (drives pathogen growth like Salmonella)
- Big Shift:
  - Wet = Remove and kill microbes
  - Dry = Avoid creating conditions for microbes

# Wet vs Dry Cleaning Validation - Considerations

## Tools & Methods

- Wet
  - ATP (effective)
  - Microbial swabs
  - Allergen ELISA
  - Chemical residue testing
- Dry
  - Visual inspection (primary tool)
  - ATP (limited usefulness in dry soils)
  - Allergen-specific testing
  - Indicator organisms (selective use)
- Key Pitfall: ATP ≠ reliable in dry environments

# Wet vs Dry Cleaning Validation - Considerations

## Acceptance Criteria

- Wet
  - Often quantitative limits:
    - CFU/cm<sup>2</sup>
    - ATP thresholds
    - Chemical ppm limits
- Dry
  - Often:
    - “Non-detect” for pathogens/allergens
    - Visual cleanliness (critical baseline)
  - May require baseline development due to variability

# Wet vs Dry Cleaning Validation - Considerations

## Worst-Case Conditions

- Wet
  - Dried-on soils
  - Long production runs
  - Reduced chemical concentration/temp
- Dry
  - Product buildup over time (days, weeks, month(s), etc.)
  - Hard-to-clean equipment (dead spots)
  - Inaccessible areas without disassembly
- Dry worst-case = accumulation + inaccessibility

# Wet vs Dry Cleaning Validation - Considerations

## Simple Takeaway

- Wet Validation:
  - “Can I consistently remove and kill hazards?”
- Dry Validation:
  - “Can I remove residues without introducing risk?”

# Validation

Next Level



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# What takes Validation to the next level?

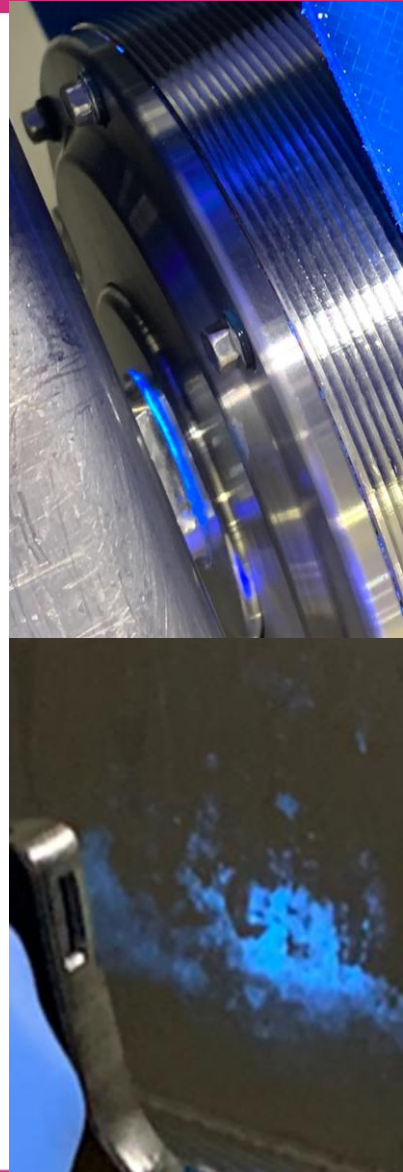
- Hygienic/Operational Design Assessment
  - Mission
    - Eliminate hygienic design and operational weaknesses in the systems, preventing contamination, reducing micro and condensation events.
    - Helping ensure systems meet a defensible standard of hygienic design that protects your products, your consumers, and your brands.
  - Process Includes
    - Failure Modes Effect Analysis (FMEA) format
    - Design, Safety, and Sanitation Criteria
      - Like: construction standards, airflow/pressure controls, interlocks, access/cleanability, and contamination-prevention features.
  - Payoff
    - Reduced micro events, fewer operational interruptions, and standardized hygienic design across site(s).

# What takes Validation to the next level?

- Sampling
  - Making the right choice based on risk and operational processes
    - Micro
    - Allergen
    - Chemical residue
    - **Rinse water samples?**
    - Swabs – which type?
  - What parameters demonstrate good performance?

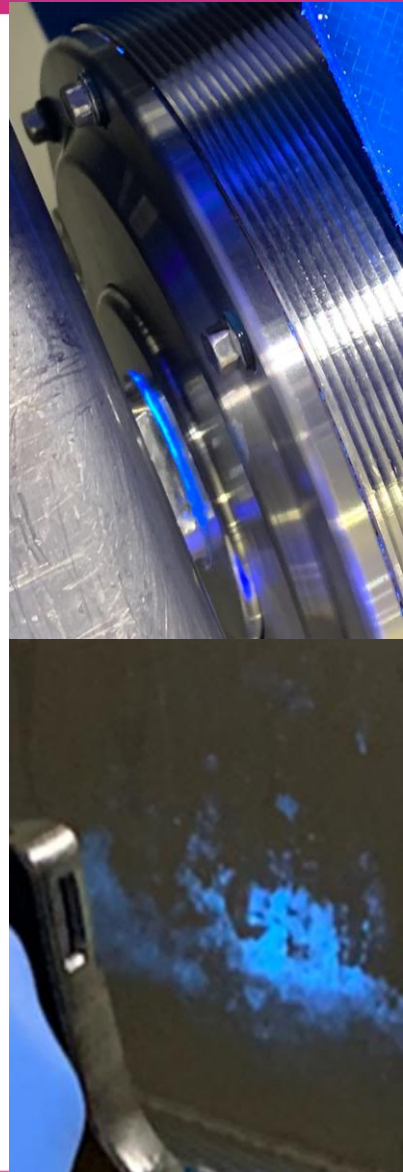
# What takes Validation to the next level?

- Verification
  - Visual – **UV light** – ATP – Micro/Allergen Swab
    - Many organic compounds (proteins, fats, microbial metabolites) fluoresce under UVA
    - Clean surfaces show minimal fluorescence
    - Biofilms and residues appear as glowing patches, streaks or films



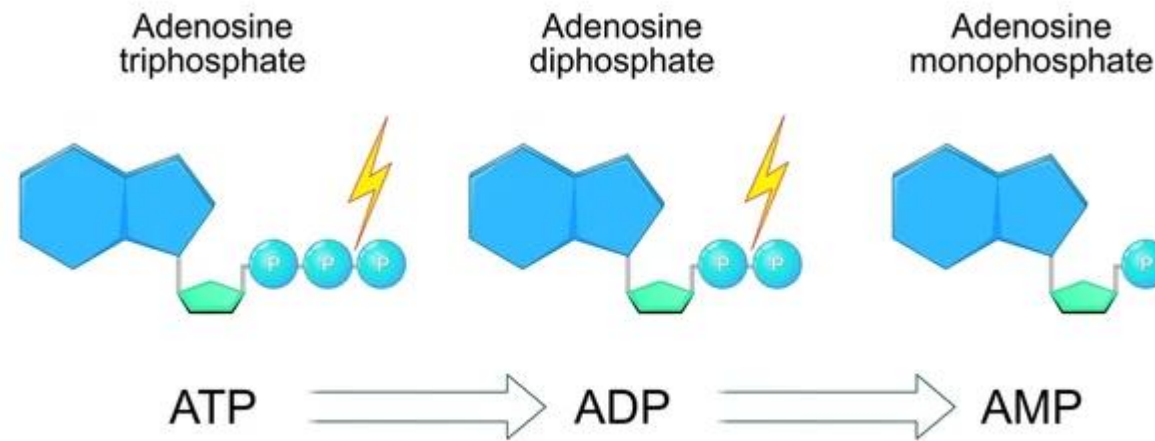
# What takes Validation to the next level?

- Verification
  - Visual – **UV light** – ATP – Micro/Allergen Swab
    - Applications:
      - Sanitation verification after CIP or manual wash-downs
      - Routine inspections in hard-to-clean areas like seals, joints, drains, and filler heads
      - Training tool for sanitation staff, showing where residues remain
      - Early detection of biofilm hotspots before they cause contamination
    - Advantages
      - Fast → real-time feedback, no incubation required
      - Portable → easy to carry across production lines
      - Non-destructive → no need to swab first
      - Cost-effective → more affordable than molecular methods



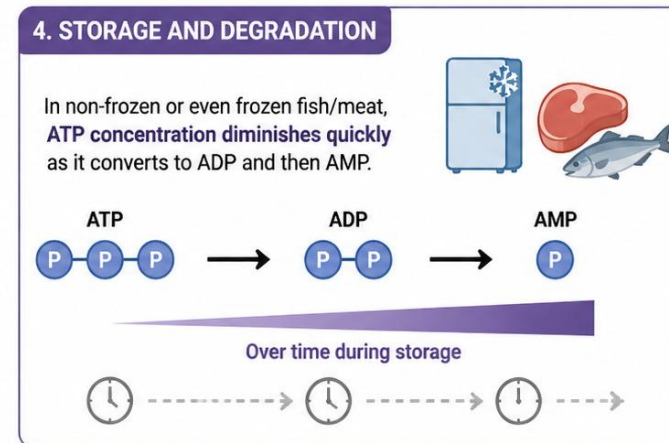
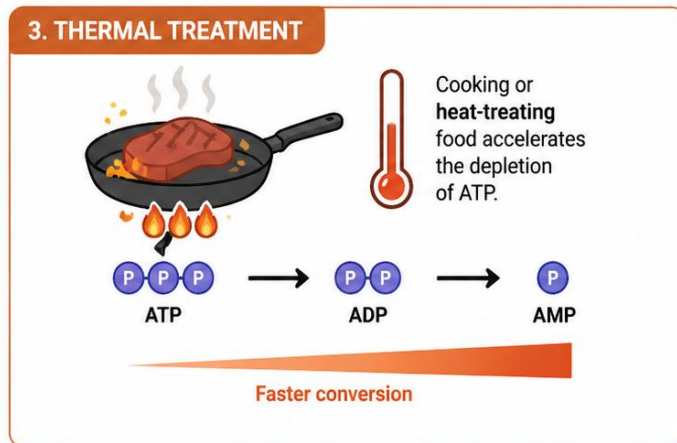
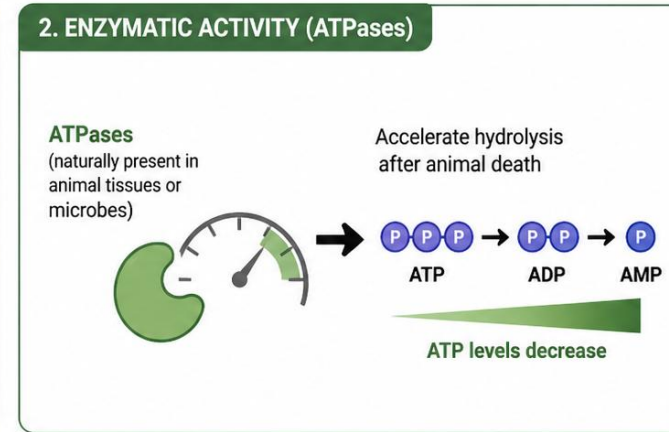
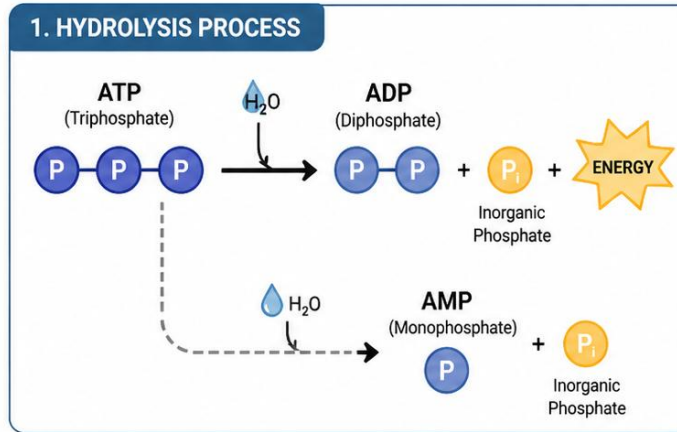
# What takes Validation to the next level?

- Verification
  - Visual – UV light – **ATP** – Micro/Allergen Swab



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# What takes Validation to the next level?



# What takes Validation to the next level?

- Verification
  - Visual – UV light – **ATP** – Micro/Allergen Swab

Should we consider adding a testing system that covers all 3?  
ATP+ADP+AMP or “A3”

# Validation

Interactive Exercise

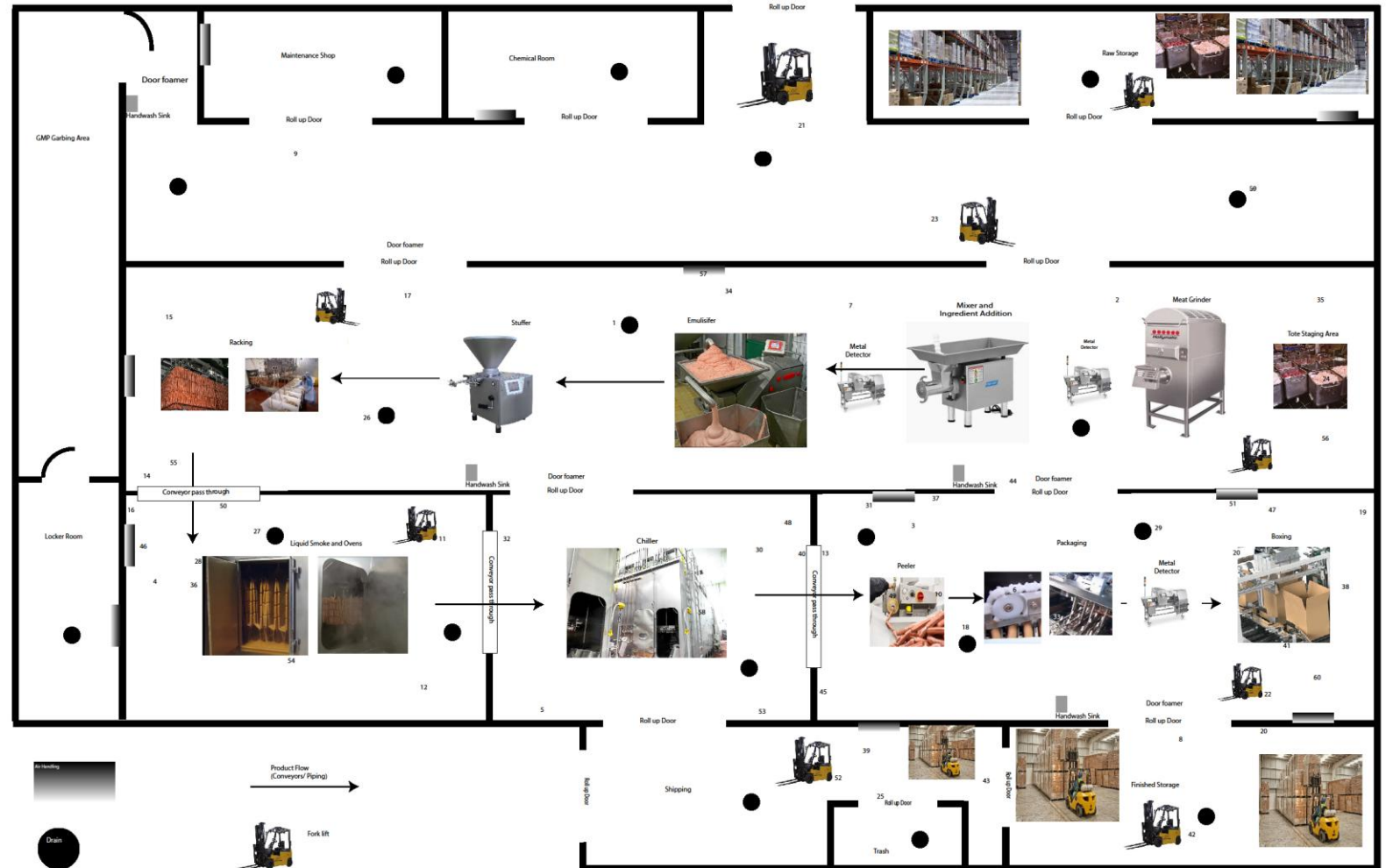


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# Interactive Exercise: Map Your Control to the Framework

## Objective:

- Apply validation & verification concepts to a real scenario
- Make risk-based decisions on sampling, tools, and limits



# Interactive Exercise: Map Your Control to the Framework

## Instructions:

- Each table is assigned:
  - A control (Sanitation or Allergen Changeover)
  - A plant zone (Pre vs. Post; Allergen vs. Micro risk)
- Use your game board to:
  - Select swab locations
  - Identify risks and hotspots
- **Your Task** (20 min):
- Work as a team to complete the worksheet:
  - Validate the process
  - Define verification methods
  - Select tools, tests, and limits
  - Decide what success looks like
  - **Plan actions if things fail**

# Interactive Exercise: Map Your Control to the Framework

## Debrief (5 min):

- Share 1 key decision
- Share 1 challenge or “watch-out”

“Right risk → Right location → Right method → Right decision”

# QUESTIONS?

Thank you!



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