CLEANING VALIDATION, VERIFICATION AND MONITORING

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DEFINITIONS: CLEANING VERIFICATION, MONITORING AND VALIDATION

- **Past** - Verification – has the process been working as designed?
  - A planned event looking at historical information
- **Present** - Monitoring – is the process working now? Failure = re-clean
  - Real-time observations wherein failures can be corrected before production starts
- **Future** - Validation – is the process, when followed, capable of delivering predictable and desired results? Minimizes variability
  - A formal, written process = Sanitation Standard Operating Procedure (SSOP)

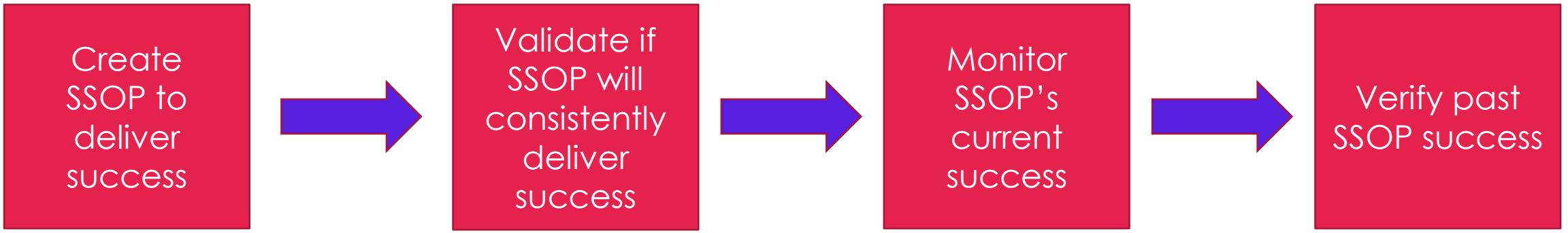
See: Foodsafetymagazine.com

CLEANING VALIDATIONS – WHAT THEY ARE AND WHAT THEY ARE NOT

- Cleaning validations **<u>are</u>**:
  - Validation of a formal, written SSOP
  - Demonstration of repeatable, acceptable results achieved when the SSOP is followed as written
  - Designed to validate the SSOP against the "worst case scenario", e.g.:
    - Hardest to clean product
    - Hardest to clean places
    - Longest possible run-time
    - Different people performing the SSOP
- Cleaning validations **<u>are not</u>**:
  - The evaluation of an individual's performance
  - A study of efficiency or process improvement

CLEANING VALIDATION, MONITORING AND VERIFICATION PROCESS

THEN



WHAT MAKES A GOOD CLEANING VALIDATION?

Four things:

1. Cleaning success criteria must be decided upon **BEFORE** starting validations (Why clean + How clean):
   - Visual (usually?)
   - ATP? What passing limits?
   - Micro? Which one(s)? Limits?
   - Allergen cross-contact controls and removal?
   - Aligned with identified HACCP risks, finished goods specifications, label claims, any customer and regulatory requirements, etc.
2. Creating an SSOP that describes the success criteria and the detailed activities to get to the success

WHAT MAKES A GOOD CLEANING VALIDATION (CONT.)?

3. Observing the SSOP being performed
   - If the SSOP is not followed as written, **STOP**. Adjust the SSOP or the performance and start over.
   - If the procedure is followed as written, then evaluate if the results meet the success criteria.
   - If the SSOP was followed and the results meet the success criteria, then the trial has been a success.
4. Conduct more than one trial (one is a lousy sample size)
   - Nestlé requires 3 consecutive successful trials to prove repeatability and predictability

WHAT MAKES A GOOD SSOP?

- Mutually agreed upon success criteria
- Adequate detail to minimize variability
  - **Safety** equipment and processes needed (PPE & LOTO)
  - **Tools and equipment** needed and their management
  - **Cleaning chemicals** and concentrations (aligned with label directions)
  - **Step-by-step procedures** from start to finish (**DETAIL!!!**)(Think of a cooking recipe)
  - **Pictures/Videos**(visual standards) of
    - Hard to reach places
    - What is the expectation for visual clean (what "good" looks like)
  - **"Watch-outs"** and special call-outs
  - **Who to contact** and what to do if there's a problem with following the SSOP

OTHER THOUGHTS …

- Cleaning validations have no expiration date unless something "significant" changes with equipment, product or cleaning process
  - Management of change process
  - Factory food safety team
- Cleaning verifications are typically a planned annual event to ensure
  - The process has been under control and
  - The SSOP is still being followed as written
- Besides looking at historical data, consider
  - Including one successful trial of the original cleaning validation
  - Watch the SSOP being performed!

OTHER, OTHER THOUGHTS …

- Allergen cleaning validations, as mentioned yesterday, are an extension of cleaning validations.
- Allergen cleaning validations = routine cleaning validations + additional success criteria and process considerations
  - Additional success criteria and considerations:
    - Acceptable levels of allergenic residues on food contact surfaces
    - Processes that include emphasis on preventing allergen cross-contact
      - Dedicated cleaning equipment
      - Color-coding
      - Avoiding overspray and water drainage to other areas
      - Dust control
      - Increased scrutiny on visual cleanliness, etc.

SUMMARY

- Validations are of the SSOP (**Critical point**!)
- Validations determine if an SSOP, when followed as written, will deliver the mutually agreed upon success criteria
- Validations should always be against the "worst case scenario". **Try to make it fail!** If you don't, Murphy's Law will!
- Validation hinge upon an SSOP having sufficient detail to minimize variability in performance and results
- SSOP's should have details such as
  - Pictures/videos
  - Descriptions of all the processes
  - What to do if one cannot perform the procedure as written
  - Descriptions of what "good" looks like

Q&A