CLEMENS
FOOD GROUP

NAMI Virtual Conference 09-11-20

Back to Basics: Validation

Outline

CLEMENS FOOD GROUP

- This is an overview of the regulation, learnings and frequent industry issues with validation. This is not an in-depth review of each element of the validation process.
- Validation takes time and capital – including people capital.

In the Next Slides - -

- Relevant Regulation and the Types of Validation
- Validation, Verification and Calibration
- Why we have validations and some Common Validation Topics
- Support for Validation Studies
- Practical HACCP
- Validation Upkeep
- Summary of the validation
- Networking

Relevant Regulation

CLEMENS FOOD GROUP

- **9 CFR § 417.4 - Validation, Verification, Reassessment.**
- (1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.
- (2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:
  - (i) The calibration of process-monitoring instruments;
  - (ii) Direct observations of monitoring activities and corrective actions; and
  - (iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.
- (3)
  - (i) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.
  - (ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment

Electronic Federal Code of Regulations -
https://ecfr.io/Title-9/
Specifically to Validation -
https://ecfr.io/Title-9/Section-417.4

Types of Validation

CLEMENS FOOD GROUP

- Scientific or Technical Based – used for reference
  - A peer reviewed scientific journal
  - A documented challenge study
  - Other Industry data

- In-House data
  - Validation studies performed on the current process

Validation, Verification and Calibration

CLEMENS FOOD GROUP

- Validation - is what we do, going to work. Is it going to achieve the outcome that we desire and require? Is your HACCP system is designed and capable to eliminate hazards or reduce them to a safe level.
  - Cook a food to a particular temperature because we want to make sure that there is no harmful bacteria remain. To validate the temperature chosen, we could refer to legislation, scientific journals or other data that supports the cooking temperature we have selected will kill the harmful bacteria.
- Verification - the things we do to see if we are actually doing what we say we are going to do. It consist of ongoing activities to determine if the HACCP system is working effectively.
  - In the above example, with the temperature to kill the harmful bacteria, we would check or verify that the food was actually reaching that temperature.
- Calibration – the Accuracy of the equipment that is used in the monitoring of the verification

The Why…

CLEMENS FOOD GROUP

- The establishment is responsible for all aspects of developing and implementing the HACCP plan including validation of the adequacy of the process that insures **all food safety hazards** are under control.
- Beside the regulatory requirement - - *Validation* is needed to ensure that your establishment is producing **safe** products for the consumer.

Some Common Validations

CLEMENS FOOD GROUP

- Some Common validations are temperature (chilling / cooking) and antimicrobial (wash / spray).
- Temperature:
  - Product size variation – thin to thick
  - Chilling vessel variation – front to back top to bottom
  - Unit defrost cycles
  - Equipment decline post validation
- Antimicrobial:
  - Running multiple sprays *during* validation
  - Concentration (PPM / %) range *during* validation
  - Dwell time range *during* validation
  - Recording other factors during validation

Support for Validation

CLEMENS FOOD GROUP

- Budget – these can be expensive
  - Break them into fiscal years
  - Summarize your data for ongoing validation
  - Hire temporary help
  - Colleges in your region
- Process Authority – IEH, FSNS, Eurofins, Hanson Tech, etc…are examples of organizations that can assist in validation studies.
- Scientific Articles – these can be used to support the theory but need to be backed up by in-house validation to prove it works.
- Other Industry studies – Match your process, can be used similar to Scientific Articles for *support*.

Practical HACCP

CLEMENS FOOD GROUP

- Engage the Food Safety Team!
  - Maintenance / Trades
  - Operations Upper Management
  - Carcass Sales
  - Process Engineers / Industrial Engineers
  - Lab Personnel
  - Quality Team

  Benefits -
    - Process Improvements
    - Plant By In
    - Education
    - Team Building

Validation Upkeep

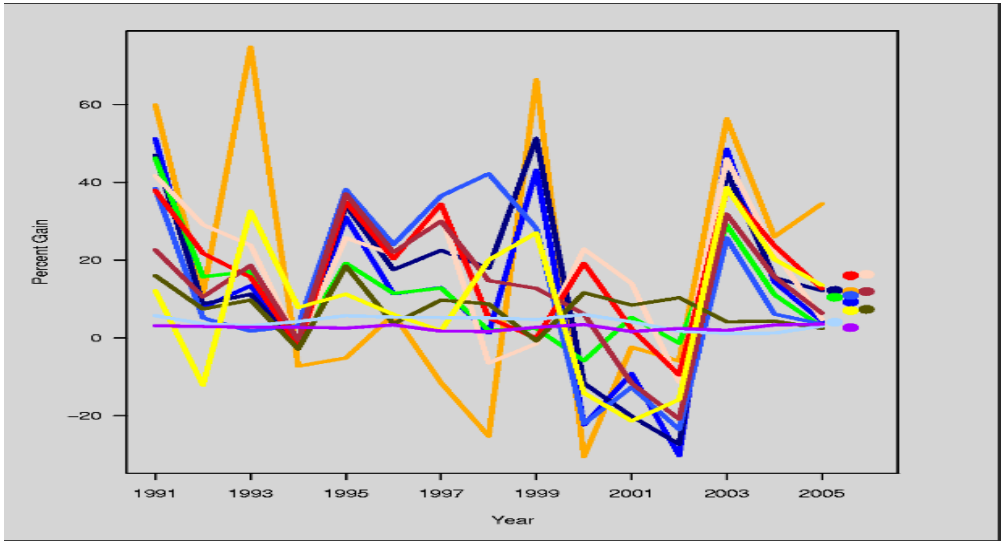
CLEMENS FOOD GROUP

- Examples that the Validation needs to be redone
  - Annual
    - Break into Fiscal Years – don't overwhelm the system / people
    - Strategically Schedule for the year
  - Process Changes –
    - Speed
    - Size of Product
    - Volume
    - New Technology
  - Critical Limit Changes
  - Regulation changes

Summary of the Validation

CLEMENS FOOD GROUP

- The work has been done…
- Data – Understand where it came from and how it was gathered.
  - Stats – these can be tricky
  - Misleading tables and charts



Summary of the Validation

CLEMENS FOOD GROUP

- White Paper – 1 to 2 pages that sums up the validation for personnel that are not familiar with your process.
  - Be mindful that depending on the reader the white paper may not be the end of the conversation (HACCP Tech versus and EIAO).
- Know your process and how the validation supports your decisions. Why did you do what you did.
  - Capture in the Decision Making Document or White Paper

Networking

- The Industry is a small world – don't be afraid to ask for help.
- Use the Industry Groups
- Supplier Reps can be a great resource
- Peers

TIM STRITTMATTER
VP FOOD SAFETY AND QUALITY ASSURANCE

CLEMENS FOOD GROUP
2700 CLEMENS ROAD | HATFIELD, PA 19440
P 215.368.2500 ext 8217 C 267-377-5655
E Tstrittmatter@clemensfoodgroup.com
clemensfoodgroup.com