Welcome!

Validation and Verification of Processes

Session 11

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Chicago, IL

Solutions *for* TODAY
Planning *for* TOMORROW

May 6-9, 2019 | Rosemont, IL
Donald E. Stephens Convention Center

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Session Description and Objectives

- Validation and verification processes are critical and often complementary components of a good food safety plan Validation is a subset of verification, which is one of the key required element of the FSMA preventive control regulations.
- This session will discuss key aspects of validation and verification in context of industry practices and regulatory compliance.
- We would like to make this session as interactive as possible. So Questions and comments are welcome

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Speakers

- Purnendu C. Vasavada, University of Wisconsin-River Falls. Validation and Verification: Fundamental Concepts
- Alvin Lee, Institute for Food Safety and Health, Illinois Institute of Technology, Chicago, IL. Validation and Verification of Thermal and Non-thermal Processes- key considerations
- Larry Keener, International Product Safety Consultants, Seattle, WA., Validation and Verification of processes- Industry Perspective

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LET'S GET STARTED

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Validation and Verification: Key Concepts

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Objectives

- To define and discuss Verification and Validation
- To discuss Verification requirements for FSMA Preventive Controls for Human Food (PCHF).
- To discuss role of Preventive Control Qualified Individual (PCQI) for verification and validation

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Why Validation and Verification ?

- The successful implementation of HACCP requires validation
- Meat and poultry regulations requires Validation of the Adequacy of HACCP plans - *"Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis.…"*
- HACCP Principle 6: Establish verification procedures
- Juice HACCP rule requiring a 5 log reduction in microorganisms is interpreted in FDA guidance as requiring process validation

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Why Validation and Verification ?

- FSMA Preventive Controls regulations requires Validation of Process Preventive Control to support that measures such as sterilizing, pasteurizing, cooking, freezing, controlling pH, or controlling a_w taken to destroy or prevent the growth of undesirable microorganisms are adequate to prevent adulteration
- Part of the role and responsibilities of the Preventive Controls Qualified Individual (PCQI)

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Validation - Definition

- Validation - “Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.” – 21 CFR 117.3
- Validation - That element of verification focused on collecting and evaluating scientific and technical information to determine whether the Food Safety Plan, when properly implemented, will effectively control the identified hazards-

- NACMCF

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Verification - Definition

- Verification - “The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.” – 21 CFR 117.3
- Are the controls in the Plan actually being properly implemented in a way to control the hazard?
- Are we doing things right?

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Distinguishing Verification and Validation

- Verification activities are done to determine whether the food safety plan is being implemented as required (*i.e.*, whether you are doing what you said you were going to do)
- Validation is done to determine whether the food safety plan is working to control the significant hazards (*i.e.*, whether you are doing the right things)
- **Validation is a subset of verification activities**

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Validation: Factors to Consider

- Food safety hazards of concern identified
- Food formulation
- Established process / changes to current process
- Established controls and parameters
- Equipment (age, design, controls, sanitation, maintenance, calibration)
- Regulations and Preventive Control programs
- Published data and Industry data

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Validation Procedures

- Validation may include:
  - Using scientific principles and data
  - Use of expert opinion
  - Conducting in-plant observations or tests
  - Challenging the process at the limits of its operating controls
- Performed or overseen by a Preventive Controls Qualified Individual

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Validation Information Sources

- Peer reviewed scientific literature
- FDA Hazards Guides
- Dairy Hazards and Controls Guide
- Validated microbial modeling programs
- Trade association guidance
- Internal and external scientific studies
- Cooperative extension websites for many universities

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Validation Frequency

- Before the Food Safety Plan is implemented (ideally) or Within the first 90 calendar days of production or
- Within a reasonable timeframe with written justification by the preventive controls qualified individual
- When a change in control measure(s) could impact efficacy
- When reanalysis indicates the need

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FSMA : Changing paradigm

The FSMA shifts the food safety focus away from reaction and response and toward prevention, so that prudent preventive measures can be built into all parts of the Food Safety Management System.

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FSMA Preventive Controls for Human Food

- FSMA – Hazard Analysis and Risk-Based Preventive Controls (Part 117, Subpart C) requires a Written Food Safety Plan including:
- Hazard analysis, Preventive controls, Monitoring, Corrective actions and corrections
- Verification procedures
- Supply-chain program
- Recall plan

FDA FOOD SAFETY MODERNIZATION ACT

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FSMA PC HF Verification Procedures

- A facility is required to conduct verification activities, as appropriate to the facility, food and nature of the preventive control and its role in the facility's food safety system, including:
- Validation of preventive controls*
- Verification of monitoring and corrective actions
- Calibration of process monitoring and verification instruments
- Product testing, environmental monitoring, Records review
- Reanalysis of Food Safety Plan

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Potential Verification Procedures

- Process verification
- Allergen verification
- Sanitation verification
- Supply-chain verification
- System verification
- Validation of effectiveness
- Checking equipment calibration
- Targeted sampling and testing
- Environmental monitoring
- Label review
- 2nd and 3rd party audits
- Record review
- Food Safety Plan reanalysis

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FSMA PC HF Verification

- Flexibility for the facility to not validate other preventive controls with a written justification based on factors such as the nature of the hazard, and the nature of the preventive control, and its role in the facility's food safety system.
- Validation is not required for all controls. e.g. verification not required for certain preventive controls (i.e., food allergen controls, sanitation, supply-chain controls, and the recall plan)
- May be useful to validate some sanitation-related controls, e.g., How long a processing line can run between cleaning, Allergen controls for complex equipment

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Product testing and environmental monitoring

- Product testing and environmental monitoring are possible verification activities, but, only required as appropriate to the food, facility, the nature of the preventive control, and the preventive control's role in the facility's food safety system.
- In some cases neither product testing nor environmental monitoring may be appropriate. e.g. product testing or environmental monitoring in facilities that pack or hold produce raw agricultural commodities (RAC) that are rarely consumed raw, such as potatoes

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Validation Frequency

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Verification Record Review

- Verification records, including calibration, product testing, environmental monitoring and supplier program records, Reviewed in a reasonable time
- All monitoring and corrective action records must be reviewed within seven (7) working days from the time they were created. Preferably, prior to release of product
- Performed or overseen by a Preventive Controls Qualified Individual
- ***When issues are identified during the review, corrective action is required***

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Food Safety Plan Reanalysis

- A food safety system changes with time
- Periodic reanalysis must be done to verify that the whole system works
  - At least every three (3) years
  - Significant change in product or process
  - New information becomes available about potential hazards associated with the food
  - Unanticipated problem
  - Preventive control ineffective

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Reanalysis Includes:

- Verifying that the Food Safety Plan, including the hazard analysis, is still accurate
- Reviewing records to identify trends and verify that the Food Safety Plan is being followed
- To be done /supervised by a PCQI

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Preventive Controls Qualified Individual

- PQCI - Must have successfully completed training in the development and application of risk-based preventive controls (At least equivalent to that received under a standardized curriculum recognized as adequate by FDA)
- be otherwise qualified through job experience to develop and apply a food safety system.
- More than one PQCI may be involved in various aspects of FSP

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PCQI - Role and Responsibilities

- PQCI’s role and responsibility :
  - Preparation of the food safety plan
  - Validation of the preventive controls
  - Review of records
  - Reanalysis of the food safety plan

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Summary

- Validation and Verification are necessary and important part of Food Safety Assurance
- Validation will effectively control the identified hazards
- Verification demonstrates that the Food Safety Plan is properly implemented by those involved

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Summary

- FSMA PCHF Final Rule requires Verification of Preventive Controls as a part of Preventive Control Management Components
- Verification activities are conducted at a frequency identified in the Plan
- Reanalysis is conducted as needed and at least every 3 years
- Validation is overseen by a PCQI.

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PCHF Implementation

- Expect FDA to require process validation to support preventative control validation and evidence that measures such as sterilizing, pasteurizing, cooking, freezing, controlling pH, or controlling a_w taken to destroy or prevent the growth of undesirable microorganisms are adequate to prevent adulteration
- Expect increased #s of 483s for violations

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Validation and Verification: A Practical, Industry-driven Framework Developed to Support the Requirements of the Food Safety Modernization Act (FSMA) of 2011

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http://www.iit.edu/ifsh/resources_and_tools/pdfs/preventive_controls_white_paper.pdf

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Acknowledgment

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- You- the audience!

THANK YOU !!

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