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Presented by:

D.L. NEWSLOW & ASSOCIATES, INC.

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Food SafetyTech

Effective Change Management for a Strong Food Safety Management Systems

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The Key Points of Ensuring Safe, Controlled, and Compliant Transitions. The webinar will explore discuss developing and maintaining an effective program.

Excellence based on Experience

Debby Newslow

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President·Owner·Consultant·AuditorTrainer·Speaker·Author

Debby is President of D.L. Newslow & Associates, a leading food safety and quality management consultant. She has over 30 years of food safety experience.

Education & Credentials:

Holds a Food Science & Technology degree from the University of Florida. She brings hands-on experience from T.G. Lee Foods and Coca-Cola's Minute Maid Division.

Career Highlights:

Debby leads consulting, auditing, and training programs that strengthen food safety and quality systems. With decades of industry experience, published works, and the prestigious Bronson Lane Award, she is recognized for elevating standards across several food & quality sectors.

Effective Change Management

What is Change Management?

Management of Change or **Change Management** is about dealing with the technical side of change, often seen in a manufacturing or industrial setting, but it can be applied anywhere.

Effective Change Management

Why Change Management Matters!

Change management matters far more than most people realize. It's core to solid Food Safety Management Systems, yet it is consistently one of the most overlooked elements. Today, we're breaking down the foundational principles every organization needs to follow. Changes to your products, processes, equipment, materials, or personnel can seriously compromise food safety if they're not properly managed. We'll walk through those core principles and connect them directly to what regulators and your industry expect from you

Objectives

- **Explain the core principles of Change Management:** identification, communication, and evaluation of changes
- Apply a **structured, risk-based approach** to assessing changes consistent with FSMA Regulations, GFSI schemes, and FDA expectations
- Define **roles, responsibilities, and documentation requirements** including record control, approval workflows, and pre-implementation verification
- **How to Integrate Change Management** into the broader FSMS: preventive controls, PRPs, HACCP plans/programs, and continuous improvement
- Recognize how this fits in **modern regulatory and industry developments:** digital traceability, data-driven decisions, updated certification standards, and how we elevate the importance of disciplined Change Management.

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What is Change Management

The Foundation Every Strong FSMS Is Built On

Defining Change Management in the Context of Food Safety

- **Change Management = a systematic, documented approach** to identifying, evaluating, approving, implementing, and verifying changes
- Not just operational change, it is a food safety function
- Applies to changes in:
  - Products and formulations
  - Processes and procedures
  - Equipment and facilities
  - Raw materials, ingredients, and packaging
  - Personnel (key roles and responsibilities)
  - Suppliers and contract services
  - Labels and specifications
  - Food safety plans themselves

Why is Change Management So Often Overlooked?

- Viewed as a "quality" or "operational" issue, not a food safety risk
- Changes happen fast; food safety review is an afterthought
- No formal trigger system to flag when a review is required
- Responsibility not clearly assigned
- Lack of cross-functional communication
- "We've always done it this way" mindset
- **The bottom line:** Unmanaged change is one of the leading root causes of food safety failures

The Real Risk: What Happens Without Change Management?

- Hazards introduced without assessment
- Critical Control Points (CCPs) become ineffective without anyone realizing it
- Prerequisite programs fall out of alignment
- Training gaps create errors at the line level
- Documentation does not reflect actual practice
- Regulatory non-compliance, including potential FDA enforcement action
- **Real consequences:** Recalls, consumer illness, audit failures, regulatory citations

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The Five Core Principles

What Every Effective CM Program Must Have, Without Exception

The Five Core Principles of Effective Change Management

- **Identification -** Recognizing when a change has occurred or is planned
- **Communication** - Ensuring the right people know, before it happens
- **Risk-Based Evaluation** - Assessing the food safety impact
- **Roles & Responsibility** - Assigning qualified individuals with authority
- **Documentation & Records** - Evidence that it was done right

Principle 1: Identification

- Every organization must have a **defined trigger system** for identifying changes
- Both **planned changes** (new equipment purchase) and **unplanned changes** (emergency supplier switch) must be captured
- Identification responsibility must be assigned, it cannot be assumed

- Examples of commonly missed triggers:
  - Supplier reformulation of an ingredient
  - Seasonal changes in raw materials
  - Personnel changes in key food safety, quality, and operational roles
  - Maintenance modifications to equipment
  - Software or automation updates affecting monitoring systems

Principle 2: Communication

- Change must be communicated **before implementation,** not after
- Cross-functional communication is essential:
  - Quality / Food Safety Team
  - Operations and Production
  - Maintenance and Engineering
  - Procurement and Purchasing
  - HR (for personnel-related changes)
  - Regulatory and Compliance
- Communication must be **documented:** who was notified, when, and what was shared
- Silence is not approval

Principle 3: Risk-Based Evaluation

- Every change from simple to complex must be **evaluated through a food safety lens**
- Key questions to answer before any change goes live:
  - Does this introduce a new hazard or increase an existing one?
  - Does this affect any CCP or critical limit?
  - Does this impact any prerequisite program?
  - Are current verification and validation activities still adequate?
  - Does this require a food safety plan reanalysis? *(21 CFR 117.170)*
- Risk assessment must be **documented** with the outcome recorded
- Assessment must be performed or overseen by a **PCQI or qualified individual**

Principles 4 & 5: Roles, Responsibility & Documentation

Roles & Responsibility:

- Assign a **qualified individual** with both competence AND authority
- FSMA is explicit: the PCQI must perform or oversee the reanalysis *(21 CFR 117.170(e))*
- Define who initiates, evaluates, approves, implements, and verifies
- Approval must occur **before** the change is operative

Documentation & Records:

- Records are **not optional:** they are evidence
- Must include; change description, risk assessment, approval, implementation date, training completed, verification results
- Records must align with the organization's **record control program**
- Retained per regulatory and scheme requirements

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The Change Management Process Step by Step

Nine Steps That Turn Good Intentions into Documented, Verifiable Results

The Change Management Process:
A Structure Workflow

Step 1
Identify the change (planned or unplanned)

Step 2
Notify the food safety team and relevant functions

Step 3
Evaluate the food safety risk (hazard analysis, CCP/PC/PRP impact)

Step 4
Determine if food safety plan reanalysis is required

Step 5
Obtain approval from qualified individual, prior to implementation

Step 6
Train/Educate affected personnel before go-live

Step 7
Implement the change

Step 8
Verify effectiveness after implementation

Step 9
Document every step and retain records

Step 3-4 Evaluating the Change Before it Goes Live

- **Food safety impact assessment must happen FIRST:** not during or after implementation
- Key evaluation areas:
  - Hazard analysis: new biological, chemical, physical, or radiological hazards?
  - Impact on CCPs, critical limits, and monitoring procedures
  - Impact on allergen controls
  - Impact on environmental monitoring program
  - Impact on supplier verification activities
  - Impact on labeling and specifications
- If the change creates a **reasonable potential for a new or increased hazard** → food safety plan must be revised ***(21 CFR 117.170(d))***
- If **no revisions needed** → document the basis for that conclusion

Step 5–6: Approval and Training Before Go-Live

Approval

- Written approval by a qualified individual is required **before** the change is operative
- No workarounds, no "we'll document it later"
- Approval workflow should be defined in your CM procedure

Training/Education

- Affected employees must be **trained/educated before the change takes effect**
- Training is not just "here's the new SOP", it must include the **WHY**
- Document: who was trained, what they were trained on, when, and verification of understanding
- Remember: Training without education is just a procedure, people need to understand the food safety reason

Step 8: Verifying Effectiveness

- Implementation is not the finish line, **verification confirms the change worked as intended**
- Verification activities may include:
  - Observation of the new process
  - Review of monitoring records post-implementation
  - Environmental swabbing (if applicable)
  - Product testing (if applicable)
  - Internal audit of the changed activity
  - Employee interviews or behavioral observation
- Verification results must be **documented**
- If the change did not achieve the intended outcome → corrective action required

Record Control: The Documentation Standard

- Change Management records must be **identified, controlled, and retained** per the organization's record control program
- Minimum records for each change:
  - Change request / description
  - Food safety risk assessment / evaluation
  - Determination: plan revision required or not (with justification)
  - Approval signature and date
  - Training records
  - Implementation date
  - Verification records
  - Any corrective actions taken
- Records demonstrate compliance: to auditors, to regulators, and in the event of a recall or outbreak investigation
- **GFSI schemes, FDA, and FSMA all expect these records to be audit-ready**

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Regulatory & Industry Framework

FSMA, FDA, GFSI (SQF, BRCGS, and FSSC 22000, Primus, etc.): They All Expect This from You.

Regulatory & Industry Landscape: Change Management is Now Required

- Change Management is no longer best practice, **it is a regulatory and scheme requirement**
- Key frameworks covered in this section:
  - FSMA - **21 CFR 117.170** - Reanalysis Rule
  - FSMA **Section 204-** Food Traceability Rule *(compliance: 2028)*
  - FDA New Era of Smarter Food Safety
  - **BRCGS Issue 9** *(in force: February 2023)*
  - **FSSC 22000 Version 6** *(all audits against v6 since April 2024)*
  - **SQF Edition 10** *(auditable: January 2, 2027?)*

FSMA: 21 CFR 117.17: Reanalysis Requirements

- Facilities must conduct a **full food safety plan reanalysis at least every 3 years**
- **Must also conduct reanalysis whenever:**
  - A significant change creates a reasonable potential for a new or increased hazard *(the change management trigger)*
  - New information about potential hazards becomes available
  - An unanticipated food safety problem occurs
  - A preventive control or the food safety plan is found ineffective
- Reanalysis must be **completed before the change is operative** (or within 90 days with written PCQI justification)
- **PCQI must perform or oversee** the reanalysis
- If reanalysis reveals no revision needed → **document the basis for that conclusion**

FSMA Section 204: Food Traceability Rule

(Compliance Date: January 20, 2026 - Already in Effect)

- Requires **Key Data Elements (KDEs)** maintained for **Critical Tracking Events (CTEs)**
- Foods on the **Food Traceability List (FTL)** are subject to these requirements
- Information must be provided to FDA **within 24 hours** upon request
- **CM connection:**
  - Any change to systems, suppliers, processes, or records affecting traceability **must be evaluated**
  - Changes to digital recordkeeping or traceability platforms require CM review
  - Cross-functional approval needed: systems must stay aligned with KDE/CTE requirements
  - Organizations that lack structured CM will struggle to maintain traceability accuracy

FDA's New Era of Smarter Food Safety

- Four core elements: all linked to disciplined Change Management:
  - **Tech-enabled traceability:** systems changes require Change Management review
  - **Smarter tools and approaches:** automation, digital monitoring, AI-assisted decision making all introduce change risk
  - **Stronger food safety cultures:** Change Management is a cultural behavior, not just a procedure
  - **More deliberate engagement with consumers and communities** - transparency depends on controlled, documented processes
- FDA's message: **proactive, data-driven, risk-based management** - exactly what Change Management delivers
- Companies that rely on reactive approaches will fall behind

BRCGS Issue 9: Pre-Change HACCP Validation Required

- **HACCP and food safety plans must be validated PRIOR to any changes that may affect product safety:** not after.
- This creates a **formal pre-implementation review gate** that must be embedded in your Change Management process.
- **If a site introduces a new ingredient, modifies a process, or changes equipment without validating its HACCP plan first → that is a non-conformance**.
- What auditors will look for:
  - Evidence that HACCP validation occurred **before** recent operational changes
  - A CM process with a documented trigger for HACCP review
  - Validation records for non-CCP control measures and PRPs
  - HACCP coverage for traded products if applicable
- Root cause analysis is now **mandatory**, not recommended.

FSSC 22000 Version 6: Change Management Elevated *(All Audits Against Version 6 Since April 2024)*

- Version 6 explicitly requires a **product design and development procedure** that includes change management
- Organizations must show food safety systems **actually control risk in day-to-day operations** - from product development and equipment purchase to handling
- **CM was integrated throughout the system. Areas specifically linked to CM:**
  - **Allergen management plan** - must be reviewed at least annually or after significant incidents or changes
  - **Environmental monitoring** - risk-based, with trend analysis and clear triggers for review when changes occur
  - **Food safety culture** - must be measured and improved; Change Management is a cultural behavior
  - **Quality objectives** - now mandatory; changes must be evaluated against quality as well as safety parameters
- Version 6 was no longer tolerant of a purely formal approach - systems had to demonstrate real-world control. Version 7 (May 2026) continues the emphasis on effective Change Management Programs.

SQF Edition 10: Change Management Is Now a Standalone Clause (2027)

- **Change management is now its own standalone clause** in SQF Edition 10
- All changes to the following must follow a **documented change-control procedure:**
  - Product formulations
  - Manufacturing processes
  - Ingredients, packaging, and labels
  - Equipment
  - Specifications for ingredients, packaging, chemicals, processing aids, and finished products
  - Contract services
  - Food safety plans

cont. on next slide

SQF Edition 10: Change Management Is Now a Standalone Clause – Continued

- **What auditors will look for:**
  - A formal Change Request Form with risk assessment, approval signatures, and verification steps
  - Evidence that no change went live without documented review and approval
  - Training records tied to each change
- **SQF Practitioner must be a facility employee:** consultants may advise but cannot serve as the accountable practitioner

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Integrating Change Management Into Your FSMS

What the Regulations and Schemes Are Now Requiring, and Why It Matters.

Change Management and Your Food Safety/HACCP Program

- The food safety plan/program is a **living document -** changes must keep it current
- Change Management Triggers that directly impact Food Safety/HACCP
  - New or modified process steps
  - New raw materials or suppliers
  - Equipment changes at or near CCPs
  - Changes to monitoring methods or frequencies
  - New scientific information about a hazard
- When a change affects a CCP: **revalidate the critical limit and monitoring procedure before going live**
- Update the Food Safety/HACCP Programs or document in writing why no revision was needed
- **BRCGS Issue 9 and FSSC 22000 v6 both require pre-change validation -** not post-change correction

Change Management and Prerequisite Programs (PRPs)

- PRPs are the **foundation** of your FSMS - they are also impacted by change
- Change Management must evaluate PRP impact for:
  - Sanitation and hygiene program changes
  - Pest control changes (provider, program, chemicals)
  - Allergen control changes
  - Supplier changes
  - Equipment changes affecting cleaning procedures
  - Facility modifications
- PRPs must reflect **current operations** - not how the facility operated three years ago
- Cross-reference CM decisions with your PRP master list
- **GFSI schemes audit PRPs against current reality** - misalignment may be a finding.

Change Management and Continuous Improvement

- Change Management is not just a control - it is an **engine for continuous improvement**
- Effectively managed changes generate data:
  - Trends in the type and frequency of changes
  - Root causes that triggered unplanned changes
  - Verification outcomes that reveal system weaknesses
  - Training gaps identified during CM review
- This data feeds **management review** - and drives strategic decisions
- **PDCA connection:**
  - **PLAN**: Design the change and evaluate risk
  - **DO:** Implement with training in place
  - **CHECK:** Verify effectiveness
  - **ACT:** Correct, improve, update the system
- Organizations that treat Change Management as a compliance checkbox miss the continuous improvement opportunity

Building or Strengthening Your CM Program: Where to Start

- **Step 1: Conduct a GAP assessment:**
  - Do you have a documented Change Management procedure?
  - Does it cover all change types (product, process, equipment, personnel, suppliers)?
  - Is responsibility clearly assigned to a qualified individual?
  - Are records complete and audit-ready?
- **Step 2: Define your trigger list:**
  - What categories of change automatically require Change Management review?
  - Who has the authority to initiate a Change Management request?
- **Step 3: Design your Change Management form and workflow:**
  - Change request → risk assessment → approval → training → implementation → verification → record retention
- **Step 4: Train/Educate your team:**
  - Not just QA - Operations, Maintenance, Purchasing, HR, and Management must understand CM expectations
- **Step 5: Integrate Change Management into management review:**
  - Review Change Management data as a standing agenda item

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Top Management Full Involvement is Essential!

Change Management in food safety collapses quickly when top management isn't fully engaged

Why Change Management Fails Without Top Management Involvement

- No authority behind process
- Competing Priorities override safety
- Lack of cross-functional alignment
- Insufficient resources
- Cultural drift

Why Top Management Fails So Often

- They underestimate the risk
- They assume QA "has it handled"
- They lack visibility
- They don't understand regulatory accountability
- They are disconnected from daily operations

Fixes That Actually Work

- Executive Training
- Formal change control workflow
- Leadership participation in management review
- Cross-functional change committee
- Cultural reinforcement
- Resource commitment

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In conclusion

Key take-a-ways and more…

Key Takeaways!

- Effective Change Management is **non-negotiable** - regulatory and GFSI schemes now require it explicitly
- Every change - simple or complex - must be **evaluated for food safety impact before implementation**
- Responsibility must be assigned to **qualified individuals with real authority**
- **Documentation is evidence** - records must be complete, controlled, and retained
- Change Management must be **integrated into the FSMS** - not treated as a standalone procedure
- Modern challenges (digital traceability, automation, supply chain complexity) have made **disciplined Change Management more critical than ever**
- **The goal is not paperwork - it is protection:** protecting products, consumers, your brand, and your team
- Must have Top Management support

Thank You!

Thank you for joining us today!

Moderated Q&A to follow. Please submit questions in the chat.