



Welcome

OnTrak with FSMA: A Webinar Series

Hosted by: ReposiTrak[®]

Presentation by: The Acheson Group



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Trusted Brand Protection



The Proof of Compliance is in Your Recordkeeping



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JULY 14, 2015

Presentation Outline

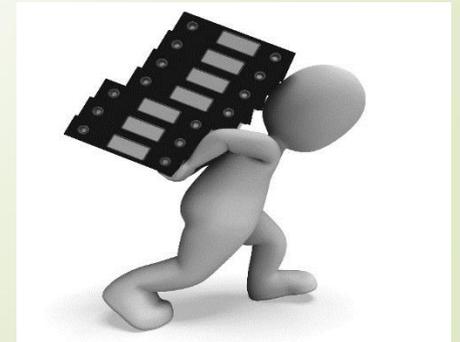


- What is the reason for maintaining records?
- Document Control Requirements
- Document Control Elements
- Recordkeeping Requirements
- Record Retention Requirements
- Risks Associated with Poor Recordkeeping
- Leveraging Technology to Manage Risk
- Developing a Compliant Recordkeeping Program

What is the reason for maintaining records?

- To document how the food was handled and labeled to ensure that it was not adulterated or misbranded.
- To validate process controls in place
- To establish traceability
- Prevent regulatory non-compliance

**No record of documentation?
It never happened!**



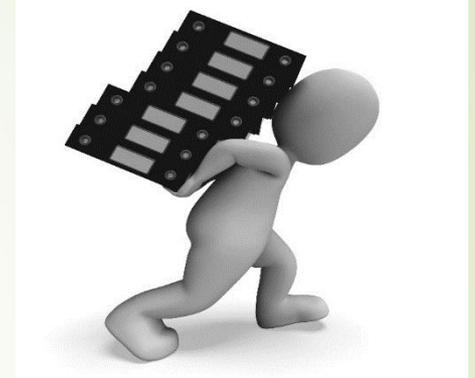
Document Control Requirements

- Designate a location for recordkeeping documents
- Authorize a person to approve new documents or make changes to existing ones including keeping document revisions if necessary
- Develop a procedure for handling obsolete documents
- Create a record retention policy for each type of record: training, quality, production, HACCP, etc.
- Generate a Master list of documents



Document Control Elements

- Recorded in pen
- Document identification number
- Title of document
- Date document was created
- Date document was revised
- Revisions made at the date of the revision
- Authority that approved the document
- Stored in a manner to protect from environmental exposure for the length of document retention.



What approach is Best-in-Class?

- **Inactive Approach:**
 - Collecting data without reviewing
 - Collecting data without trending
- **Proactive Approach:**
 - Defining Key Performance Indicators that allow the operation to measure current performance against the industry standards
 - Collect data to trend how the operation is performing as part of the continuous improvement objectives
- **Reactive Approach:**
 - Paper data is only actionable after it has been reviewed by a human. This can take hours, days or weeks therefore there is a LAG in time for it to be actionable.
 - Waiting until an issue has occurred such as a product that is out of specification before implementing documentation to prevent non-compliance



Record Retention Requirements

- **How long must a facility retain records onsite?**
 - At least 2 years after the date they were created unless otherwise declared by federal agency. If facility is governed by multiple agencies then documents would be retained for the term that is the longest to meet compliance.

- **Are there exceptions to retaining records onsite 2 years?**
 - Records beyond 6 months may also be stored off-site **IF** they can be readily accessed within 24 hours upon request of the regulatory agency.



FSMA: Recordkeeping Requirements

A **written** Food Safety Plan is required and should include the following components:

- Hazard Analysis including identification and evaluation
- Preventative Controls
- Procedures for monitoring the implementation of preventative controls
- Corrective Action procedures
- Verification procedures
- Recall Plan

Records are required as documentation to confirm that the following has occurred

- Monitoring of Verification & Validation procedures
 - Corrective Action procedures
 - Review of Prerequisite program records
 - Training records as relevant to food safety and the “qualified individual”

Recordkeeping Requirements

HACCP vs. HARPC

HACCP

- **Written Food Safety Plan**
 - Written Hazard Analysis including identification and evaluation
 - Written Preventative Controls
 - Written Procedures for monitoring the implementation of preventative controls
 - Written Verification procedures
 - Written Recall Plan
- **Documented Corrective Actions**
- **Documented Verification Activities**
- **Documented Training for the “qualified individual”**

HARPC

- **Documented Monitoring of Preventative Controls**
 - Process Controls
 - Food Allergen Controls
 - Sanitation Controls
 - Environmental Monitoring Program
 - Current Good Manufacturing Practices
- **Documented Supplier Program**
 - Supplier Approval and Verification Program

Risks Associated with Poor Recordkeeping

- Data that is recorded on paper has the potential to be:
 - Lost or Misplaced
 - Damaged due to the facility environment
 - Illegible or incomplete creating a risk in the ability to effectively perform a trace
- Operations are vast with a lot of moving parts and multiple facilities:
 - Data may not be reviewed leading to a greater risk of regulatory non-compliance
 - Record keeping may be inconsistent across the network of operations
 - Data collected may be incomplete or inaccurate
- Audit Preparation with Paper Data:
 - It takes time to physically collect the required documents for the audit
 - Preparation often requires going to multiple sources or departments for documentation
 - The chain of custody has the potential to be lost
- Paper data is not “actionable data”

INABILITY TO PROVIDE REQUIRED DOCUMENTATION IN A TIMELY MANNER TO THE REGULATORY AGENCY WILL RESULT IN DISCIPLINARY ACTION

- ▶ Case Study: “Bad Record Keeping Practices”



Leveraging Technology to Manage Risk (1)

- ▶ Leveraging technology to capture data allows your data to work for you:
 - Digital data is real-time data – as soon as it is recorded you can respond to it making it “actionable”.
 - Digital data can be trended automatically without the need of additional resources these trends may be the early indicator you need to see a “crisis in the works”.
 - Digital data allows facilities to share data among facilities as a best in practice approach to respond to issues as a method of “harmonization”.



Leveraging Technology to Manage Risk (2)

- ▶ Leveraging technology to capture data ROI:
 - Digital data gives time back to the operation by allowing the people that review data to spend their time on other functions rather than reviewing data.
 - Digital data encourages an effective Quality system by allowing you to perform the root cause analysis in a timely manner and CAPA to reduce non-compliant product.
 - Digital data can reduce the amount of time spent conducting a recall therefore leading to a more efficient traceability.



Corporate Drivers for Leveraging Technology

- Record Keeping on Paper has an associated cost
 - Toner, Ink, Paper, Printers, File Cabinets, Storage Rooms for those files, Data entry clerk
- Reviewing Paper data steals time from your bottom line
 - Whether it is recording data on the production floor or in the office the time spent on data entry accumulates quickly. That time is valuable.
- Digital data decreases the amount of time spent preparing documentation
- Provides a rapid response to customers on outbound documents.
- Allows data to be recorded consistently across the network of operations
- Creates a system for efficient Quality operations
 - Root Cause Analysis / Corrective Action Preventative Action / Traceability

Proper recordkeeping and documentation will provide regulatory compliance even in a bad situation

- Case Study: “Good Recordkeeping Practices”



Developing a Compliant Recordkeeping Program

- Identify what records are required for regulatory compliance for your operation.
- Know the record retention requirements for your company if different from the industry standard.
- Develop a documented “document control” system for recordkeeping compliance.
- Train all employees on the importance of recordkeeping no matter how limited their exposure to records may be.
- Conduct periodic self-audit for record compliance to ensure that records are complete, accurate and maintained.
- Challenge record retention during your “mock recall” activities by electing items manufactured greater than 60 days prior to activity.

Develop a Compliant Recordkeeping Program by Leveraging Technology

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- Get buy in from senior management at the top all the way down for implementing a compliant program by leading by example. “These senior leaders are ultimately the ones who may have to testify in court on records that are incomplete, illegible or do not exist.”
- Overwhelmed with paper data and recordkeeping transition from paper data “silos” to a digital data “domain”.
- Choose a digital platform that will work for your operation not all operations are the same.
- If you are shopping for technology talk to your customers and suppliers about the technology platforms that they are using it is possible that you can integrate the data when it comes to their products creating “harmony”.
- Remember: People do not respond well to rapid change. You may consider the best approach is to implement in stages rather than all at once. Find a pace that will best suite the need of the operation.

Thank You!

