Welcome

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From HACCP to HARPC – What's Best-In-Class and How to Get There

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Agenda

- Overview HARPC proposed rule

- Comparing HACCP to HARPC

- HARPC and GFSI

- Benefits of adopting HARPC today

- CCPs & PRPs – key differentiators

- How to get from HACCP to HARPC

- How technology can support a robust program while creating ROI

Definitions

HARPC:

Hazard Analysis Risk-based Preventive Controls

HACCP:

Hazard Analysis Critical Control Points

Let's Discuss

What do you consider "preventive" in your operation?

Status of the HACCP Program - CCPs?

The role of your PRP programs?

Let's identify 15 PRP programs that are preventive

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FSMA ... FDA Food Safety Modernization Act of 2011

http://www.fda.gov/food/foodsafety/fsma/ucm247548.htm

> *"Building A New Food Safety System Based Upon Prevention"*
> *-FDA*

Comparison of Laws

Old Law

- Reactive
- U.S.-centric
- Focused toward on-market products

New Law

- Proactive
- Global Implications
- More *PROCESS/PREVENTION* oriented
  - Early identification of risk
  - Supplier emphasis
  - Increased communication

FSMA = Enhanced FDA Enforcement Power

- Increased Access to Records
- Facility Registration (Strengthened)
  - ➢ Biennial Renewal & Suspension Authority

- **Hazard Analysis Risk-Based Preventive Controls (HARPC) Plan**

- Authority to Collect Fees
  - ➢ For Re-inspection And Food Recall
- Food Transportation (pending)
- Intentional Adulteration (pending)
- Mandatory Food Recall Authority
- Targeting of Inspection Resources Based Upon Risk

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Overview of HARPC Rule

- FDA Food Safety Modernization Act (FSMA) of 2011
  - ➤ Build a new food safety system based upon prevention (FDA)
- FSMA Sec. 103:
  - ➤ Hazard Analysis and Risk Based Preventative Controls (HARPC)
  - ➤ Facilities required to implement a written HARPC plan

Elements Of The HARPC Plan as Specified in FSMA Sec. 103

- Evaluating the hazards that could affect food safety

- Specifying the preventive steps, or controls, that will be put in place to "significantly" minimize or prevent the hazards

- Specifying how the facility will monitor the effectiveness of these controls to ensure that they are working

- Maintaining routine records of the monitoring

- Specifying what actions the facility will take to correct problems that arise

- Re-analysis requirements

FDA Proposed HARPC Rule - 2013

- *Current Good Manufacturing Practice and Hazard Analysis and Risk- Based Preventive Controls for Human Food, Proposed Rule* [78FR11 (January 16, 2013), Pages 3646-3824]

  ➢ http://www.gpo.gov/fdsys/pkg/FR-2013-01-16/html/2013-00125.htm

  ➢ Comment Period Closed in November 2013

  ➢ Had been expanded from September 2013

General Aspects of Proposed Rule

Proposed Provisions of HARPC Plan

Proposed Revision Of The Existing *Current Good Manufacturing Practices (CGMPs)* (21 CFR Part 110)

Part 117, *"Current Good Manufacturing Practice And Hazard Analysis And Risk-based Preventive Controls For Human Food."*

HARPC Plan – Additional Comments

- **HARPC Intended to be Science and Risk-Based**

  ➢ Only where necessary to prevent hazards to public health

  ➢ Not required (or may have modified requirements) for certain low risk activities

- **HARPC Intended to Be Flexible**

  ➢ Facilities may develop preventive controls that fit their products and operations, as long as they are adequate

    - **To significantly minimize or prevent all food safety hazards that are reasonably likely to occur**

Looks Like HACCP, Smells Like HACCP, But.....

Is HARPC just HACCP Without Saying "HACCP"?

If it Looks Like HACCP … Smells Like HACCP … What's the Difference?

HACCP ELEMENTS

- Foundation & Prerequisite Programs → Hazard Analysis → Critical Control Points (CCPs) → Critical Limits → Monitoring → Corrective Actions → Verification → Recordkeeping

HARPC ELEMENTS

- Hazard Analysis → Preventive Controls → Monitoring → Corrective Actions → Verification → Recordkeeping
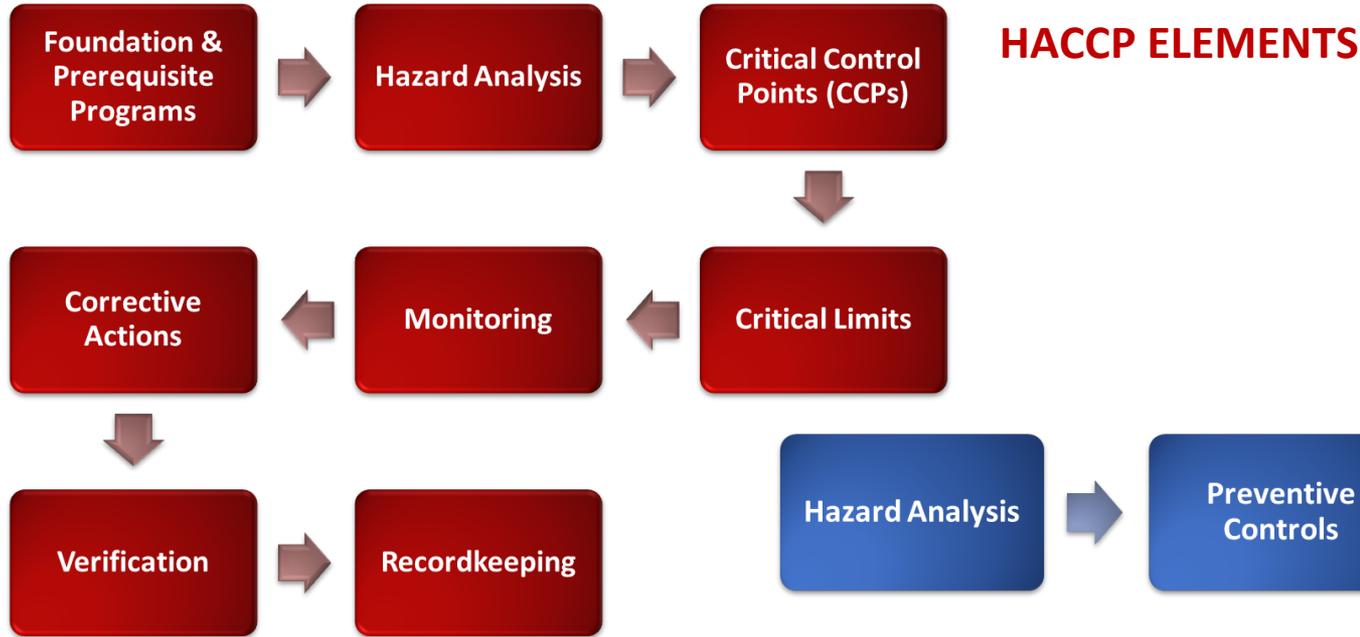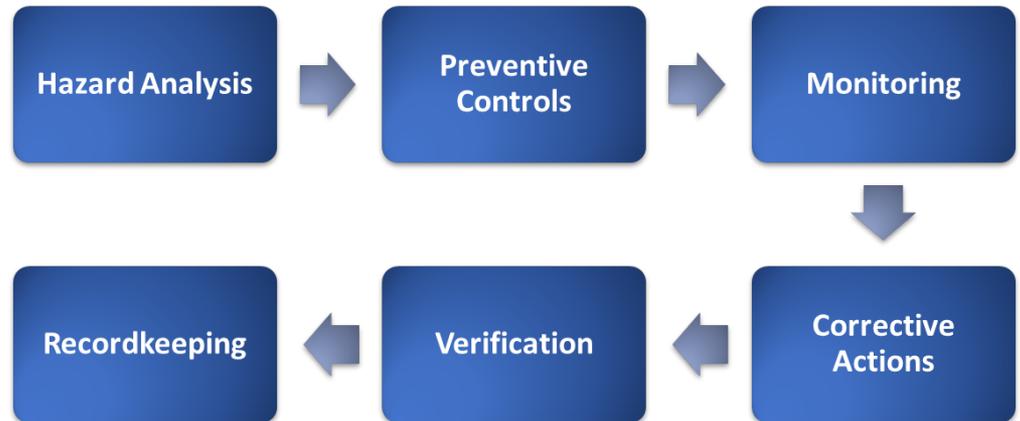
Comparison HARPC & HACCP – Who Implements?

HACCP	HARPC– Proposed
HACCP Team -	**"Qualified Individual"** -
Key Individuals Trained or Otherwise Qualified by Experience **FDA HACCP -- "Recognized Curriculum"** **Training Documented**	**Specialized Training in Implementing Risk-based Preventive Controls or Qualified by Experience** **"FDA Approved Curriculum"** **Training Documented**

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Comparison HARPC & HACCP – Hazard Analysis

HACCP	HARPC– Proposed
Elements -	**Elements** -
Hazard Identification **Hazard Evaluation (Risk Assessment)**	**Hazard Identification** **Hazard Evaluation (Risk Assessment)**
Hazards-	**Hazards**-
Biological **Chemical** **Physical**	**Biological** **Chemical** **Physical** **Allergens** **Radiological**

# Hazard Analysis – Under Proposed HARPC Rule

- Hazards
  - Allergens and Radiological Agents Listed as Separate Categories
    - **These would be under "Chemical" in HACCP**
- "Risk-based" and "Risk Assessment"
  - Considerable Discussion in the Proposed Rule

HACCP Hazard Analysis

- **Importance and Emphasis of Risk Assessment in Hazard Analysis**
  - ➤ Considerable Variation in Food Industry HACCP Plans
    - **Many HACCP Plans Stop at Hazard Identification**
  - ➤ Has Had More Emphasis in Codex HACCP Than US

Risk Assessment in HACCP Hazard Analysis – Historical Look
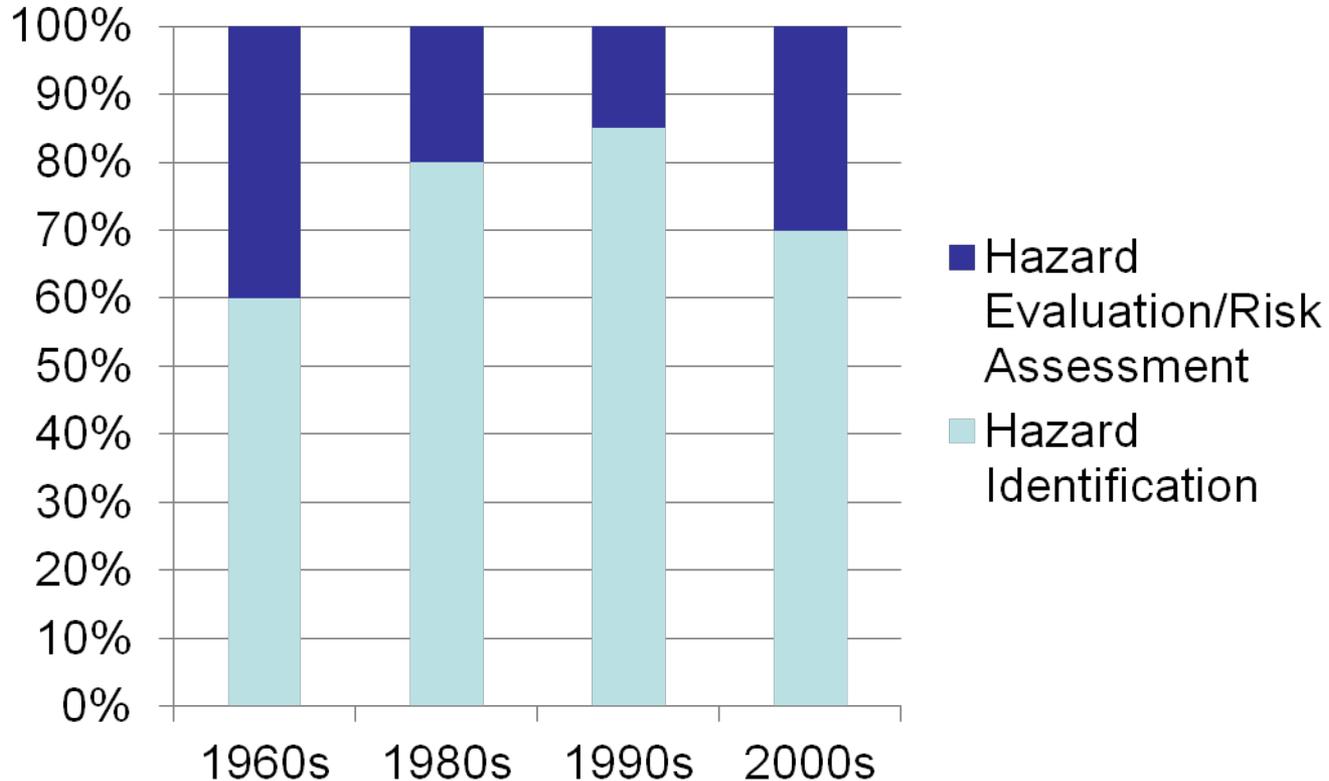
Note: Estimates based upon opinion of an aging professor

Point Being..

Additional emphasis on "Risk Assessment" is needed

HARPC Preventive Controls – Proposed

- Must be Identified and Implemented
  - ➤ Includes Both CCPs and Non-CCPs
- May Include (where appropriate)
  - ➤ Process Controls
  - ➤ Food Allergen Controls
  - ➤ Sanitation Controls
  - ➤ A Recall Plan

Discussion Note in Proposed Rule

- **FDA** *Recognizes Supplier Verification Programs As "Risk Based" Preventive Controls*
  - **Seeking Comments**

HACCP Control Measures …
Prerequisite Programs (PRPs) vs. Critical Control Points (CCPs), The Time Honored Debate

Relative Emphasis of HACCP PRPs and CCPs – Historical Look
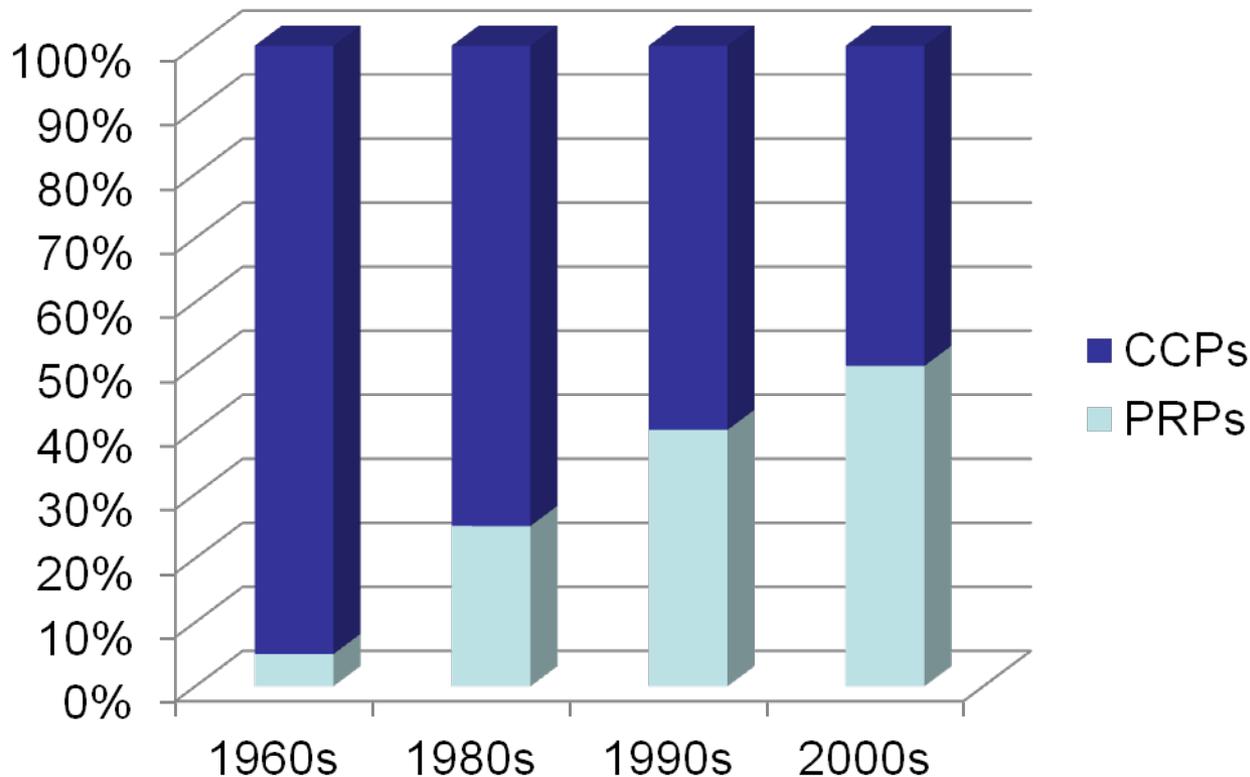
Note: Relative values are subjective estimates based upon opinion of an aging professor.

HACCP Sanitation Programs

- Written SSOPs
- FDA HACCP – Shall Include SSOPs for
  - ➢ Water Safety,
  - ➢ Food Contact Surfaces,
  - ➢ Prevention Of Cross Contamination,
  - ➢ Maintenance Of Hand-washing & Toilet,
  - ➢ Protection From Contamination,
  - ➢ Proper Labeling, Storage, & Use Of Toxic Materials,
  - ➢ Control Of Employee Health,
  - ➢ Exclusion Of Pests

HARPC Sanitation Programs - Proposed

- ## Written SSOPs For:

  - ➢ Procedures For The Cleanliness Of Food-contact Surfaces, Including Food-contact Surfaces Of Utensils And Equipment.

  - ➢ Environmental Programs for Pathogens
    - *Listeria Monocytogenes* & *Salmonella*
    - **Allergens**

  - ➢ Prevention Of Cross-contamination

  - ➢ Calibration Of Equipment Used To Monitor Or Verify Preventive Control Parameters

Control Measures – Summary

HACCP	HARPC – Proposed
Critical Control Points (CCPs)	**Preventive Controls**
Based Upon Decision Tree Must Have Definable and Realistic Critical Limit Which can be Monitored and Verified	**Include CCPs and "Non-CCPs"** **Include Sanitation Programs (SSOPs)**
Prerequisite Programs (PRPs)	

Required as Foundation to HACCP
    Include Sanitation
    Programs (SSOPs)
 	
May be used to Control Hazards when Impractical to Identify as CCP	

Critical Limits

HACCP	HARPC– Proposed
CCPs -	**Preventive Controls** -
Critical Limit Required for Each CCP Identified	**Not Required for All Preventive Controls**
Prerequisite Programs (PRPs)-	
Varied Critical Limit Not Always Definable	

Monitoring

HACCP	HARPC– Proposed
CCPs-	**Preventive Controls** -
Must be Monitored	**Required** **To Provide Assurance That Preventive Controls Are Consistently Performed**
Prerequisite Programs (PRPs)-	
Varied **If Controlling Hazard -- Should Be Monitored**	

Corrective Actions

HACCP	HARPC– Proposed
CCPs-	**Preventive Controls** -
When Deviation From a Critical Limit **Correct Problem and Minimize Reoccurrence** **Prevent Unsafe Product From Entering Market**	**Required Regardless of Whether Critical Limit Defined or Not** **Correct Problem and Minimize Reoccurrence** **Prevent Unsafe Product From Entering Market**
Prerequisite Programs (PRPs)-	
Varied **If Controlling Hazard -- Should Have Appropriate Corrective Actions**	

Proposed HARPC Corrective Actions – Additional Comments

If Corrective Action Not Identified, Or If Controls Found To Be Ineffective

Re-evaluate Food Safety Plan And Modify As Needed

Verification

HACCP	HARPC– Proposed
Verification	**Verification**
To Assure That System is Operating as Planned	**To Assure Consistent Implementation of Food Safety Plan**
Includes Validation to Assure That Identified Hazards are Being Controlled	**May Include Validation**
What to Verify	**What to Verify**
All CCP Activities	**Effectiveness of Preventive Controls**
HACCP Plan/System	**Frequency Varied With Activity**
PRPs -- as Appropriate	
Frequency Varied With Activity	

Verification

HACCP	HARPC (Proposed)
Frequency	**Frequency**
When Process System Significantly Changes	**When Process System Significantly Changes**
Whenever Deviation Occurs	
At Least Annually	**Every 3 Years**

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HARPC Verification – Discussion in Proposed Rule

- FDA Seeking Comment On Potential Verification Activities Including:

  - ➢ Environmental Testing Programs

  - ➢ Customer And Other Complaints

  - ➢ Mock Recall

Recordkeeping

HACCP	HARPC– Proposed
Hazard Analysis	**Hazard Analysis**
Must Have Documentation	**Documentation Required**
CCPs-	**Preventive Controls -**
CCPs, Critical Limits, Monitoring, Corrective Actions, Verification Documentation	**Preventive Controls, Monitoring, Corrective Actions, Verification Documentation Required**
Prerequisite Programs (PRPs)-	**HARPC Plan**
Documentation Varied **Documentation as Deemed Appropriate and Necessary**	**Documentation Required**
HACCP Plan & HACCP System	
Must Have Documentation	

Proposed HARPC Documentation

- Must be Maintained for 2 years
  - ➢ 6 months available on site

- May be Electronic
  - ➢ See 21CFR11
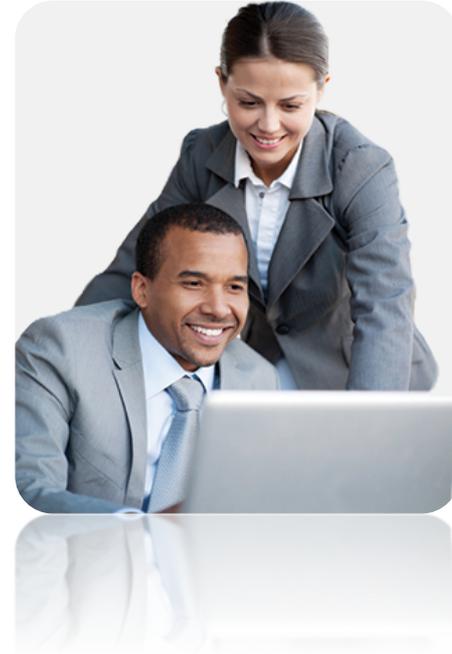
Proposed HARPC Plan – Additional Comments

- **More Emphasis on HACCP-Like Prerequisite Programs, Including:**
  - Monitoring
  - Corrective Actions
  - Verification
  - Documentation
- **May Have More Emphasis on (Still Pending)**
  - Environmental Sanitation For Microbiological and Allergen Control
  - Recall and Traceback
  - Supplier Verification Programs

Who Has A Crystal Ball?

Will My Current HACCP Plan Be In Compliance? It Depends...

- How Strong Is Your Hazard Analysis?
- How Strong Is Your Risk Assessment?
- Is It Based Upon Current Science?
- How Strong Are Your Prerequisite Programs?
- How Strong Is Your Verification?
- How Good Are Your Records?

Let's discuss

What are you doing now that is preventive?

What could you do better?

How could you do it better?

What is your biggest concern when discussing "preventive controls"?

HARPC and Third Party Food Safety Programs?

- Brief General Discussion of Global Food Safety Initiatives in Proposed Rule (Appendix Section II)
- Will PRPs Under These Programs Comply?

Agenda

- Overview HARPC proposed rule

- Comparing HACCP to HARPC

- HARPC and GFSI

- Benefits of adopting HARPC today

- CCPs & PRPs – key differentiators

- How to get from HACCP to HARPC

- How technology can support a robust program while creating ROI

We'll Discuss

- Compliance concerns
- Food Safety Chain Management System (FSCMS) automation
- Support for 6 key components of FSMA Food Safety Plan
- ROI

Key Concerns – HARPC & Overall FSMA Compliance

- Resources
- Making sure programs are current & followed
- Trending, risk assessment
- Documentation, documentation, documentation
- Audits, audits, audits

Answer? Automation.

Automating the Key Components of a FSMA-Ready Food Safety Plan

Written facility- and product-specific plan

Assess risks that are reasonably likely to occur

Create Preventive Controls for risks

Frequently monitor – verify, validate

Documented corrective actions

Re-analyze anytime there's a breach
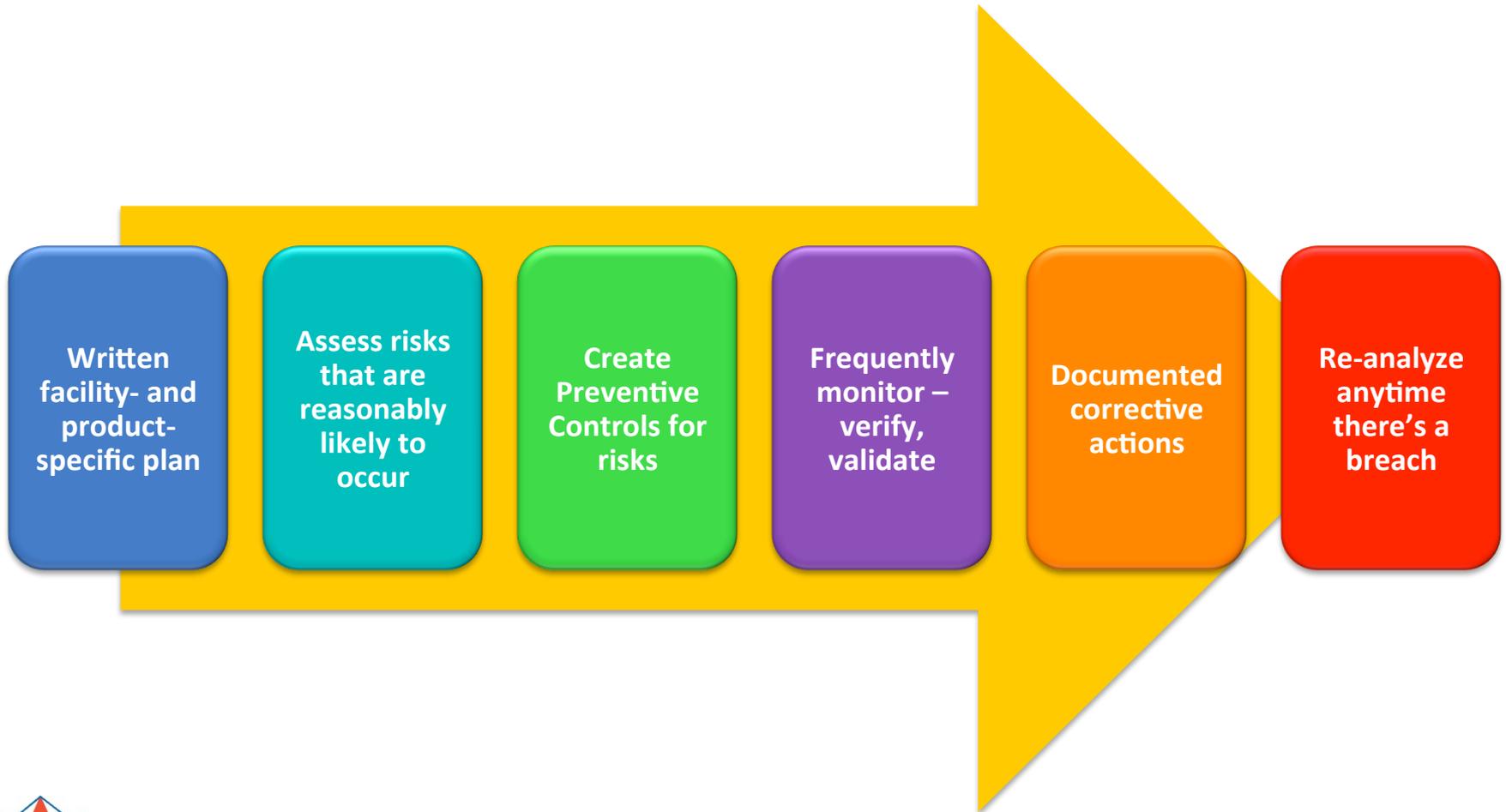
Food Safety Chain Management System (FSCMS) – Automate, Streamline & Improve FSQA

- *Designed to help enforce – and document – Food Safety & Quality Assurance at all points along a company's supply chain … for what comes in, what you do with it, and where it's going next*

- Helps ensure FSQA program workflow, processes, documentation

- Creates central repository FSQA data for trending, assessments, reporting, audit readiness

- *Saves time, saves money and creates operational efficiencies that help your members and their supply chain participants:*

  - *Enforce* safety & quality compliance
    - ✓ **Regulatory (USDA, FDA/FSMA, CFIA), GFSI, internal programs, customer**
  - *Eliminate* manual processes and errors
  - *Prevent* withdrawals, rejections and recalls
  - *Prepare* for audits "on-demand" at the click of a mouse
  - *Protect* market value and brand

How Does an FSCMS Work?

1 Requirements Set Up in System

- Regulatory (FDA, USDA, CFIA)
- GFSI
- Customer Specs
- Internal

1 Food Safety Plans & Data Sources

- Supplier Docs
- Approved Vendor Programs
- Forms
- HACCP/HARPC Plans
- Data From Equipment
- The "P's" SOPs, GAPs GMPs, etc
- Internal/External Labs LIMS
- PRPs i.e. Sanitation Programs

2 Workflow Engine:
- Workflow
- Task Scheduling
- Notifications

3 Verification Engine:
- Realtime Analysis
- Realtime Alerts

4 Central Repository:
- All Forms
- All Results
- All CAPAs
- All Time/Date Stamped

1 Say what you do
2 Do what you say
3 Ensure it works
4 Make sure that it's documented

Home · Sample Testing · Reporting

Accessible, Actionable Data for Trending, Continuous Improvement

Regulatory, GFSI, Customer Supplier & Internal Compliance – *On-Demand Audit Readiness*

Peace of Mind Knowing Your FSQA Programs are Being Followed & You're in Compliance

Written Specific Plan

| Written facility- and product-specific plan	Assess risks that are reasonably likely to occur	Create Preventive Controls for risks	Frequently monitor – verify, validate	Documented corrective actions	Re-analyze anytime there's a breach

- Unlimited number of specifications, Prerequisite Programs (PRPs), Preventive Controls (PC)
- Can be identified by product/plant
- Task scheduler with auto-alerts
- Supplier compliance

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Risk Assessment

| Written facility- and product-specific plan | Assess risks that are reasonably likely to occur | Create Preventive Controls for risks | Frequently monitor – verify, validate | Documented corrective actions | Re-analyze anytime there's a breach |

- All FSQA test results, COAs, supplier documentation accessible from central repository
- Realtime analysis, trending and alerts helps identify risks

Create Preventive Controls

Written facility- and product-specific plan → Assess risks that are reasonably likely to occur → **Create Preventive Controls for risks** → Frequently monitor – verify, validate → Documented corrective actions → Re-analyze anytime there's a breach

- Set up all PRPs such as sanitation, allergen control, preventive maintenance, training, etc.

- Benefit from same auto-scheduling, realtime assessment and alerts

Monitor, Verify, Validate

| Written facility- and product-specific plan | Assess risks that are reasonably likely to occur | Create Preventive Controls for risks | **Frequently monitor – verify, validate** | Documented corrective actions | Re-analyze anytime there's a breach |
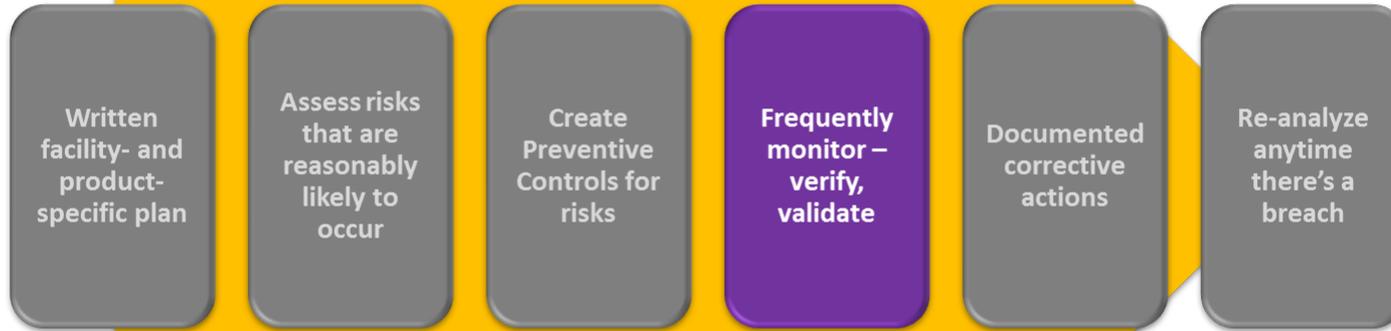
- Mobile data capture and assessment – field/plant
- Information from suppliers, labs, equipment – even during transportation
- Again, task scheduler – ensures monitoring is verified
- Realtime analysis against specifications
- Realtime alerts on deficiencies and omissions
- All time/date stamped in central repository for reporting

Documented Corrective / Preventive Actions

| Written facility- and product-specific plan | Assess risks that are reasonably likely to occur | Create Preventive Controls for risks | Frequently monitor – verify, validate | Documented corrective actions | Re-analyze anytime there's a breach |

- Alerts ensure that CAPAs identified at earliest point possible
- Before/after digital photos
- And because all data is in the central repository, respond on-demand to FDA, 3rd party, customer inquiries and inspections

Re-Analysis and Action

Written facility- and product-specific plan	Assess risks that are reasonably likely to occur	Create Preventive Controls for risks	Frequently monitor – verify, validate	Documented corrective actions	Re-analyze anytime there's a breach

- Upstream/downstream/internal visibility
- Traceability, root cause analysis
- Additionally:
  - Benchmarking
  - Scorecards
  - Continuous improvement
  - Improve cost of goods made

GFSI Automation

- Automate management of all documents, records

  ➤ Forms, PRPs, SOPs, more

- Electronically ensure document and version control

- Access, organize all required audit programs, forms, records "on-demand"

- Automatically schedule required tasks

  ➤ Auto-notifications, escalating alerts for non-completion or   non-conforming results

- Realtime data dashboards for trending, continuous improvement

- Automate approved vendor programs

Bottom-Line ROI

- Time and labor
- Reduce cost of non-conformance
- Reporting and analysis
- Audit readiness
- Risk mitigation

For More Information

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