GFSI Audit Readiness & FSMA:
What You Need to Know

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Welcome to the OnTrak with FSMA Webinar Series

GFSI Audit Readiness & FSMA: What You Need to Know

Objective:

- To educate new and established food and beverage companies and business ventures that on the path of GFSI Audit Readiness and meeting the requirements of the FDA's FSMA (Food Safety Modernization Act).
- Incorporate FSMA compliance with GFSI Audit Readiness for both new and established companies.

Target Industries:

- Food & Beverage Manufacturers, Processors
- Food Packaging Manufacturers
- Retail (Grocery) and Wholesale Food Companies
- Food Distribution, Warehousing and Logistics Companies
- Food Traders, Agents, Brokers and Importers

7 Government FSMA Programs

- Preventive Controls Human Food
- Preventive Control Animal Food
- Foreign Supplier Verification Program
- Third Party Auditor Accreditation
- Produce Safety
- Sanitary Transport
- Food Defense

FDA FOOD SAFETY
MODERNIZATION ACT

Programs Start Dates/Deadlines

Rule	Final Rule Deadline	Compliance: Non Small	Compliance: Small	Compliance: Very Small
PC Human Food	8/30/2015	1 year	2 years	3 years
PC Animal Food	8/30/2015	1 year	2 years	3 years
FSVP	10/31/2015	6 months after PC final rules become effective	2 years after PC final rules become effective	2 years after PC final rules become effective
Produce Safety	10/31/2015	2 years	3 years	4 years
Sanitary Transport	3/31/2016	1 year	2 years	n/a
Food Defense	5/31/2016	1 year	2 years	3 years

- Very Small: Less than $1million in sales
- Small: Less than 500 employees

Global Food Safety Initiative (GFSI)

- Initiative created in 2000 by a global industry partnership with these objectives:
  - Reduce food safety risks by delivering equivalence and convergence between effective food safety management systems
  - Manage cost in the global food system by eliminating redundancy and improving operational efficiency
  - Develop competencies and capacity building in food safety to create consistent and effective global food systems
  - Provide a unique international stakeholder platform for collaboration, knowledge exchange and networking

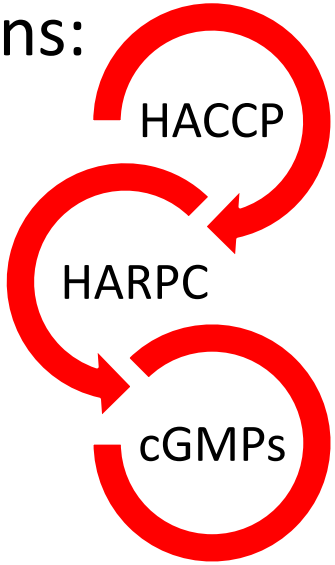
GFSI Recognized Standards

- Most utilized in the US by food and beverage companies
  - SQF
    - Level 2
    - Level 3
  - BRC (British Retail Consortium)
    - Global Food
    - Packaging
    - Distribution, Others
  - IS0/FSSC22000
    - Beverage companies

FSMA Food Key Requirements

Implement a food safety system which contains:

- Hazard Analysis (HACCP)
- Preventive Controls (HARPC)
  - Oversight and Management
  - Validation
- Current Good Manufacturing Practices (CGMPs)



Creating your GFSI-Based Food Safety Management System with FSMA Compliance

- Timing: Reconcile deadlines per FSMA requirements and annual GFSI initial and re-certification audits
- Supplier Controls: Food Defense as intentional adulteration in addition to a traditional GFSI approach.

GFSI Standard-specific Considerations for FSMA

- **SQF:** A more comprehensive validation of process controls and a documented process for corrective action
- **BRC:** Escalate to a preventive control for practices that the standard may control via pre-requisite programs
- **FSSC22000:** Defined as Operational Pre-requisites (PRPs)
- Not all require validation per FDA

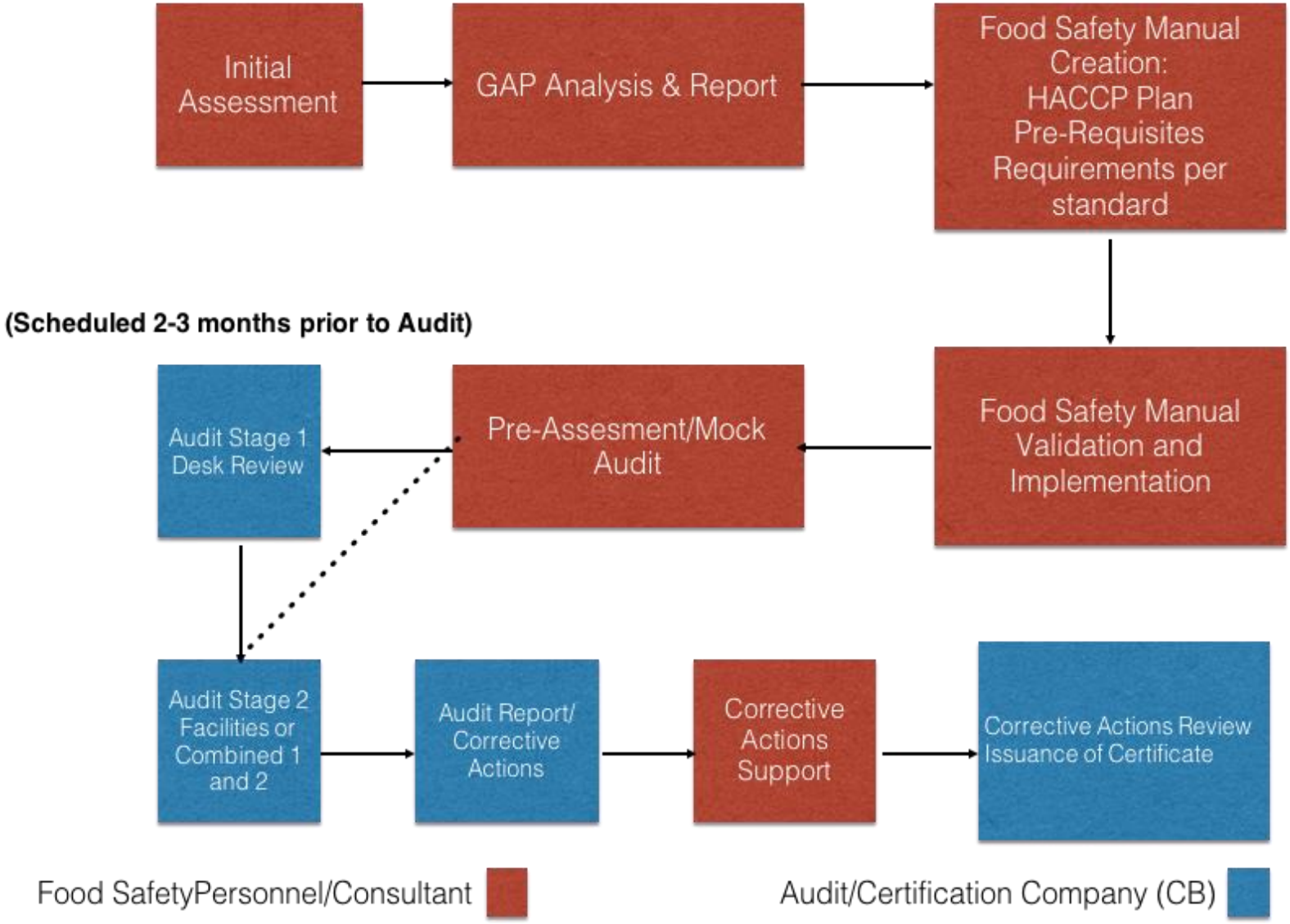
FSMA and GFSI: Key Differences

- FSMA's focus on Hazard Analysis of **Risk-based Preventive Controls** (HARPC) vs. GFSI-focused HACCP.
- A food safety program in compliance with a GFSI audit covers most of the FSMA requirements except **intentional adulteration.**

FDA FOOD SAFETY MODERNIZATION ACT

GFSI Global Food Safety Initiative

Initial Audit/Certification Readiness Process



Getting Started: Initial Assessment/GAP

- Details where the facility is vs. where it needs to be to be ready for the selected food safety audit standard.
  - A food safety Consultant (or internal food safety personnel) will assess the location and review:
    - » The existing food safety/quality documentation in relation
    - » The production and storage facilities
  - A documented report stating your current status and what is needed to implement or improve the FSMS.

Review and/or Creation of Documents

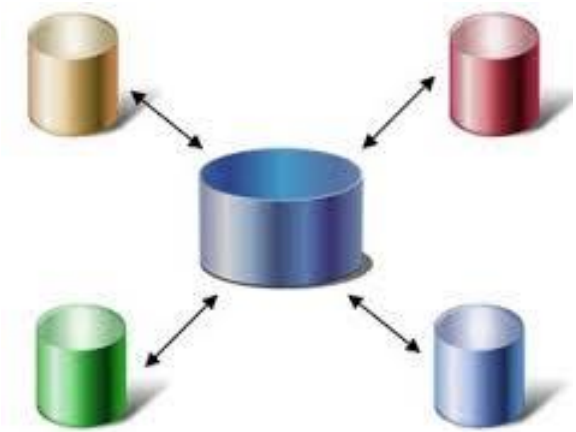
HACCP Plan

- Pre-requisites
  - GMP
  - SSOP
  - Records

Food Safety Manual

- Modules
- Additional documentation

Get Documents into a Centralized Management System



- Food Safety Manuals
- HACCP Plans
- Supplier Verification Data
- Management of all compliance matters
- Tracking/Tracing of all materials and finished products.
- For single or multiple operating sites

Audit/Certification by Certification Body (CB)

- Documentation Audit (remote or on-site)
- Facilities Audit (on-site)
- Audit Report and Corrective Actions
- Surveillance Audits scheduled (if needed)
- Re-Certification the following year/period

Utilization of 3rd Party Consultants for Audit Support

- On-site consultant at time and for duration of audit
- Post audit corrective actions (CARs)
- Help with surveillance audits and annual re-certification efforts

QSPS Consulting LLC

- QSPS Consulting can guide you through the process of developing your FSMA-compliant Food Safety Management System
  - Over 32 years combined experience in food safety audits and food safety consulting
  - Experienced across all food and beverage categories and most utilized GFSI compliance standards.

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Questions?