

**Preparing for Inspections
and Audits**

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Why the Concern?

- ▶ FDA required to increase inspections
- ▶ Retailers and other customers requiring audits
 - GFSI schemes
 - Own standards
 - Combinations

**Know the standard against which
you will be audited/inspected**

- ▶ Regulations
- ▶ GFSI benchmarked standards/schemes
- ▶ Customer requirements

Sources of Regulatory Information

Internet

- ▶ FDA - www.fda.gov/food
- ▶ USDA - www.fsis.usda.gov
- ▶ 21 CFR
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
- ▶ FDA Inspection Information
<http://www.fda.gov/ICECI/Inspections/IOM/default.htm>
- ▶ FDA Compliance Policy Guides
<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm>
- ▶ 9 CFR
<http://cfr.vlex.com/source/code-federal-regulations-animals-animal-products-1058>

Further Sources of Regulatory Information

- ▶ Trade Associations
- ▶ List serves
- ▶ Publications
- ▶ Legal consultants
- ▶ Regulators
- ▶ Universities

GFSI

- ▶ Global Food Safety Initiative
- ▶ Sets minimum guidelines for auditable food safety schemes

GFSI Schemes/Standards

- ▶ Bench marked schemes
 - Manufacturing
 - SQF 2000 Level 2
 - Global Standard for Food Safety (BRC)
 - FSSC 22000
 - Synergy 22000
 - Primary Production
 - CanadaGAP
 - Global G.A.P
 - SQF 1000 Level 2
 - PrimusGFS

Within each GFSI scheme

- ▶ HACCP
- ▶ Food Safety Management System
 - Policy
 - Documented system
 - Organization documented
 - Commitment
 - Management review
 - Resource management
 - Document control
 - Specifications
 - Procedures
 - Internal audits
 - Corrective actions
 - Non-conforming product

Within each GFSI scheme

- ▶ Food Safety Management System (cont'd)
 - Product release
 - Purchasing
 - Supplier performance
 - Outsourcing
 - Complaints
 - Serious incident management
 - Calibration
 - Food defense
 - Labeling
 - Traceability
 - Control of inputs

Within each GFSI scheme

- ▶ Good Manufacturing Practices (GMPs)
 - Facility environment
 - Local environment
 - Facility design
 - Fabrication
 - Equipment
 - Staff facilities
 - Physical & chemical product contamination
 - Segregation & cross contamination
 - Materials management
 - Housekeeping, cleanliness, and hygiene

Within each GFSI scheme

- ▶ Good Manufacturing Practices (GMPs) (cont'd)
 - Water quality
 - Waste management
 - Pest control
 - Transport
 - Personal hygiene
 - Training
- ▶ Meet all regulatory and legal requirements

Typical areas of weakness

- ▶ HACCP details and accuracy
- ▶ Validation
- ▶ Management review
- ▶ Specifications (especially services)
- ▶ Internal audit
- ▶ Supplier performance
- ▶ Serious incident management
- ▶ Calibration
- ▶ Fabrication/facilities
- ▶ Training

Organize documentation

- ▶ Know where each document is
- ▶ Organize by the scheme or standard number
- ▶ Address every issue in the standard in your documentation

Attitude

- ▶ Positive
- ▶ Cooperative
- ▶ Responsive
- ▶ Helpful
- ▶ Honest

Potential Benefits

- ▶ What is a successful audit or inspection worth to your company?
- ▶ Will a higher score gain your company anything?

Summary – Audit Preparation

- ▶ Know the applicable standard and regulations
- ▶ Be organized
- ▶ Have clear policies and procedures
- ▶ Effective attitude
- ▶ Know the potential benefits
