

Enterprise-wide Assessments to Mitigate Food Safety Risks

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Introduce Speakers



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Today's Discussion

1. Something's Not Right
2. Three Key Discoveries
3. Enterprise Risk Assessment
4. Resources
5. Q&A

Something's Not Right



Something's Not Right

We want to shine a light on a big gap in how companies are getting ready for FSMA – and what we all need to do about it.



Consistent Themes Around FSMA

**Something
is not
right...**

- “I have been to training and attended a webinar”
- “We know how to handle audits.”
- “That’s QA’s job to take care of that.”

**We need to change our mindset and not just our
QA Programs**



POLL

Do you think your company is ready for FSMA?

- Yes
- No, but we're close
- No, just no



The Rules of the Game Have Changed



FDA Audits have begun

- Inside intel is that FDA is not happy with FSMA readiness
- They're feeling is industry is taking it business as usual
- Are expecting much more organized Food Safety Plans
- Dangerous implications when grace period ends if industry doesn't step up

Blue Bell Ice Cream

- Serious systemic failure
- FDA investigation/ CDC Database
- Corporate investigation/ Subpoenas went back years!
- DOJ Investigation / Park Doctrine

Three Key Discoveries



Three Key Discoveries

These are the things no one wants to talk about....

1. Food manufacturing processes contain inherent food safety flaws
2. Corporate is **not** thinking about these problems
3. You need to remove the skeletons in your closet

Discovery Number One

Food Manufacturing processes contain inherent food safety flaws

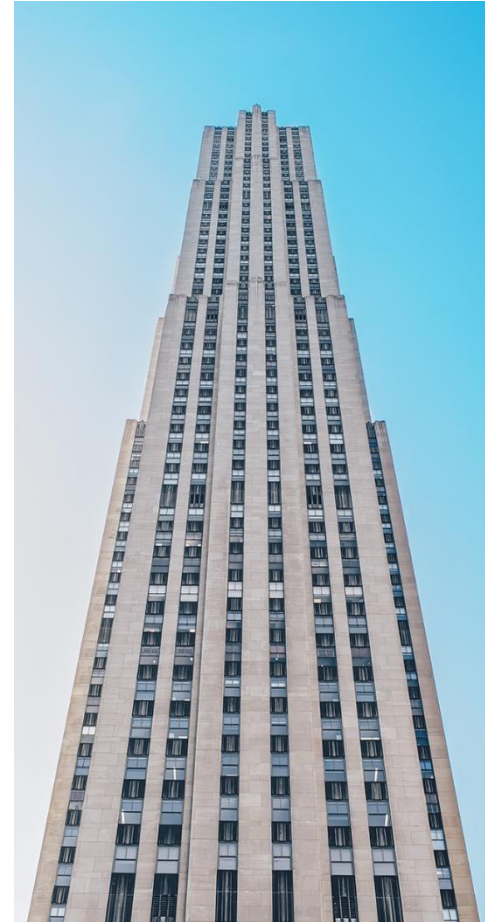
- What products are made?
- Whom do you sell to?
- What is your messaging?
- Are your departments aligned?
 - What is the objective of Procurement?
 - What is the objective of Marketing?
 - What is the objective of Operations?



Discovery Number Two

Corporate is not thinking about these problems

- Current design does nothing to protect you
 - Narrow vs. wide for audits
 - Who is performing evaluation (calibration and expertise)
 - Specialist vs. Generalist
 - Legal/QA/Procurement
- FDA is coming to visit...not just the facilities
 - FDA will be coming to corporate offices
 - Only thing stopping them now is software...which they are fixing
- How can *you* help mitigate this risk?



Discovery Number Three



You need to remove the skeletons in your closet

- The risk is too great to hide them
- Who's providing advice to do this at strategic level?
 - FDA is making templates
 - The story you tell is as important as what you do
- How is your company addressing this new risk?

Wow!
That's a lot
of stuff!

That's what we said, too.

It's scary.

It's overwhelming.

Where do you start?

You need a roadmap, you need a plan.

Enterprise Risk Assessment: The Evolution of Corporate Compliance



What's an Enterprise Risk Assessment?

- Process of planning, organizing, leading and controlling activities of an organization in order to minimize the effects of risk on an organization's capital and earnings
- Enterprise-wide, not plant centric
- Executed by senior-level experts in their functional fields
 - E.g., QA, Legal, Ops
- Strategic approach to identify concerns
 - Understand where risks are in whole company
- Tactical process to solve issues
 - Prioritized plan based on gap assessment

What type of risks are we referring to?





POLL

Which of these risks are you most concerned about?

- Product Recall
- Regulatory Non-compliance
- Pathogen Contamination



Where are the risks?

Company

- Inherent product and process risks
- Geographic locations

Corporate

- Management sponsorship and resources
- Boilerplate programs

Programs

- Adequacy to meet regulatory and audit expectations
- Program verification and validation

Plants

- Plant design, process flow
- Management culture and execution

Records

- Recordkeeping errors
- Deficiency management

A New Approach with Enterprise Risk Management

- Strategic prioritization by function (comprehensive or by desired sections)
 - Corporate
 - Supply Chain
 - Food Safety and Quality Systems
 - Microbial Control
 - Compliance
 - Due diligence approach
- Corrective action and closure
- Risk Reassessments
- Executive view and reporting

What needs to be assessed? (All or Part)

Allergens

REGULATORY

WARNINGS

Environmental
Micro

Complaints **SUPPLY CHAIN**

Audit Management

PRODUCT RECALL

Traceability

sanitation

Swab-A-Thon

CORPORATE/CULTURE

Food Safety Plan

**Non-Conforming
Product**

**Crisis
Management**

Raw Material

dEVIA
TIONS


Finished
Product
Micro


Risk

SUPPLIER RISK

How is the risk assessed?

- Likelihood and Severity Ratings on a scale of 1 to 5
- Risk Assessment Matrix with High, Moderate and Low rankings

Severity 

Likelihood 

	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Severe (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare (1)	1	2	3	4	5

Live Demo: Enterprise Risk Assessment Model

- Strategic summary pages
 - Reporting
 - Company profile
 - Risk assessment
 - Corrective action
- Tactical risk assessment
 - Prioritization based company profile
 - Systematic and Functional approaches

Swab-A-Thon Challenge

- FDA focus on Control of Listeria Monocytogenes
- FDA Inspections – Broad Assessment PC Inspection (500) or Full Preventive Control Inspections (140) to date
- Be proactive to challenge your own operation prior to regulatory actions
- Complete intensified swabbing of all 4 zones to assess effectiveness of Listeria Control Programs
- Be prepared to take corrective actions for positive results
- Improve your environmental control program with better targeted testing
- Manage your results with attorney-client privileges for confidentiality

Post Assessment Action Plan

- Focus on areas of high and moderate risk
- Revise programs as needed to make them more robust
- Mitigate the risks down to acceptable levels
- Reassess periodically to re-evaluate risk levels



POLL

Do you think an enterprise risk assessment would benefit your company?

- Yes
- No
- Maybe



Assess Your Enterprise-wide Risk

Next Steps

- What is your company's risk profile?
- Have you left no stone unturned?
- What is your plan to manage it?
- Will your relationships doom you or enable your success?
- Do you really know your liability?

Next Steps

- Be proactive
- Your CEO and board needs to know, and be engaged
- You've always wanted more resources, here's how you can get them
- Be clear that the rules have changed
- The feeling "we're GFSI certified" does not mean you aren't at risk
- Reminder: FDA will soon be coming to corporate, not just facilities

Resources



Resource: Alchemy Professional Services



Training

HARPC Workshop based on FDA recognized standardized curriculum

- Public courses or on-site
- On-line courses coming soon



Gap Analysis

- On site review to evaluate existing programs, products and facility to new regulatory requirements
- Off site desk top review of existing HACCP Plans comparison to new regulatory requirements



Development

Creation of new Food Safety Plan documentation customized for your products and processes



Reanalysis

- Desk top review of client created Food Safety Plan
- On Site Reanalysis to validate food safety system and written program compliance

Resource: PCQI Blended eLearning Course

No Travel. No Hassle. No Worries.

- New FSMA regulations require that key personnel in charge of managing the Food Safety Plan at a company must be a “Preventive Control Qualified Individual.”
- With the combination of a self-paced eLearning environment and a live virtual instructor led session, this course enables you to become a PCQI on your terms.
- Alchemy’s course features industry best practices developed right on the manufacturing floor by Alchemy Professional Services consultants to ensure you walk away with a comprehensive and complete understanding of the new FSMA requirements.



WHO SHOULD ATTEND

- QA Directors and Managers
- QA Supervisors
- Operations Managers
- SQF/BRC Practitioners and Auditors

Get Started

- ✓ Receive FSPCA Certificate of Completion
- ✓ Learn at your own pace
- ✓ Save time and money

Visit link below to learn more:

<https://academy.alchemysystems.com/product/preventive-controls-for-human-food-blended-elearning-course/>

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Q&A



QUESTIONS?

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