

PMO, FSMA, and Inspections — Oh My!

Preparing Your Frontline for Success



Holly Mockus, *Alchemy Systems*

Today's Discussion

1. Pasteurized Milk Ordinance (PMO) Background
2. Preparing for Inspections
3. Understanding Learning Types and Training
4. Alchemy Solutions for the Dairy Industry
5. Q&A

Pasteurized Milk Ordinance Background



Pasteurized Milk Ordinance (PMO)

Grade “A” Pasteurized Milk Ordinance (PMO) enacted in 1927

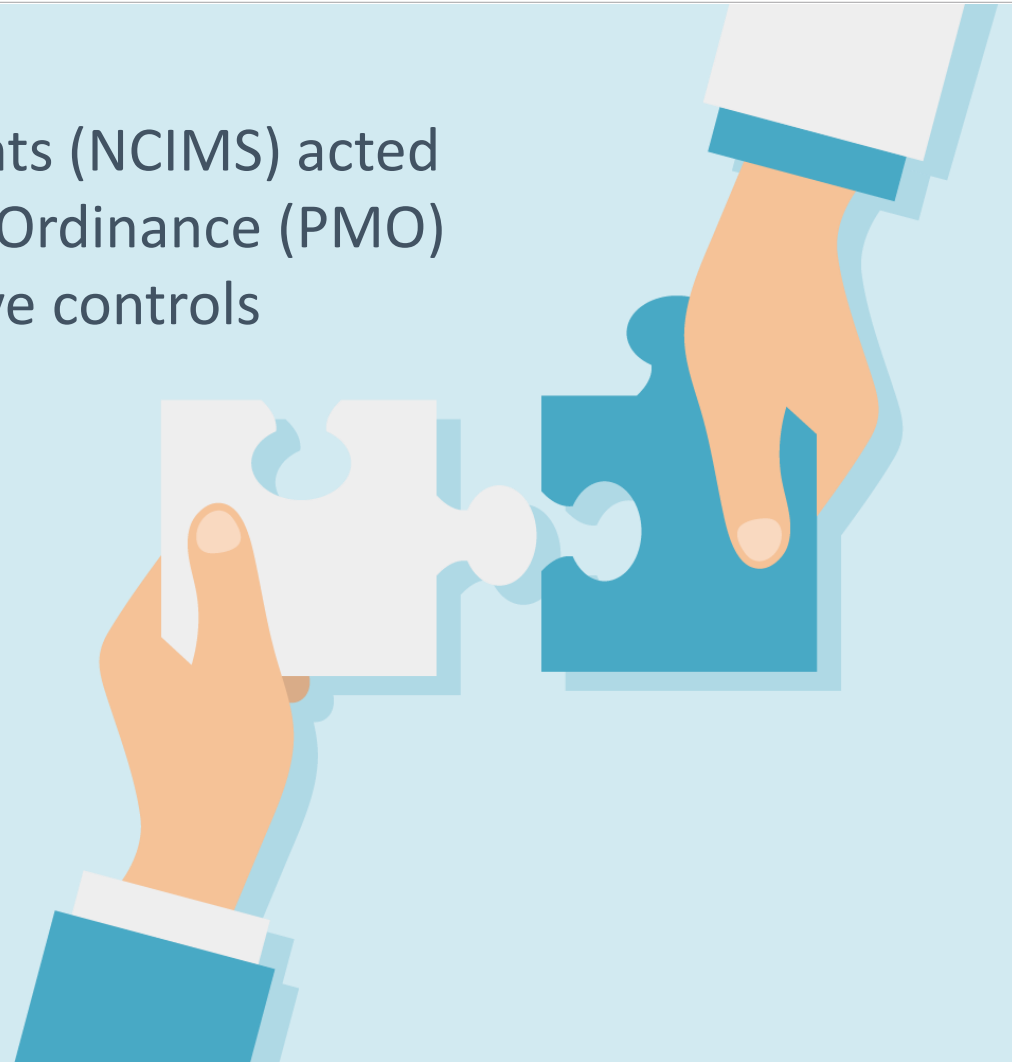
- Established by Food and Drug Administration (FDA) - regulates the production, processing and packaging of Grade “A” milk
 - Includes - fluid milk, cream products, yogurt, cottage cheese, eggnog, buttermilk and many dried dairy products
- Minimum standards and requirements
- Individual states - regulation of Grade “A” milk is usually under State Department of Agriculture or State Health Department
 - States often adopt the PMO standards as a minimum
- Recommendations for revisions or updates in the PMO are put forth by the National Conference for Interstate Milk Shipments (NCIMS)
 - NCIMS - voting representatives from state and local regulatory agencies, nonvoting representatives from the dairy industry and FDA
 - Generally the FDA accepts NCIMS recommendations; incorporates them into the revised PMO

Harmonization

“ National Conference on Interstate Milk Shipments (NCIMS) acted last week to align the Grade “A” Pasteurized Milk Ordinance (PMO) with the regulatory requirements in the preventive controls rule for human food under the Food Safety Modernization Act (FSMA). ”

- Mid May 2017
- New – Appendix T
- Enacted – Fall 2018

<http://www.dairyfoods.com/articles/92296-milk-shippers-group-aligns-the-pmo-with-fdas-rule>





POLL

What is your level of FSMA compliance readiness?

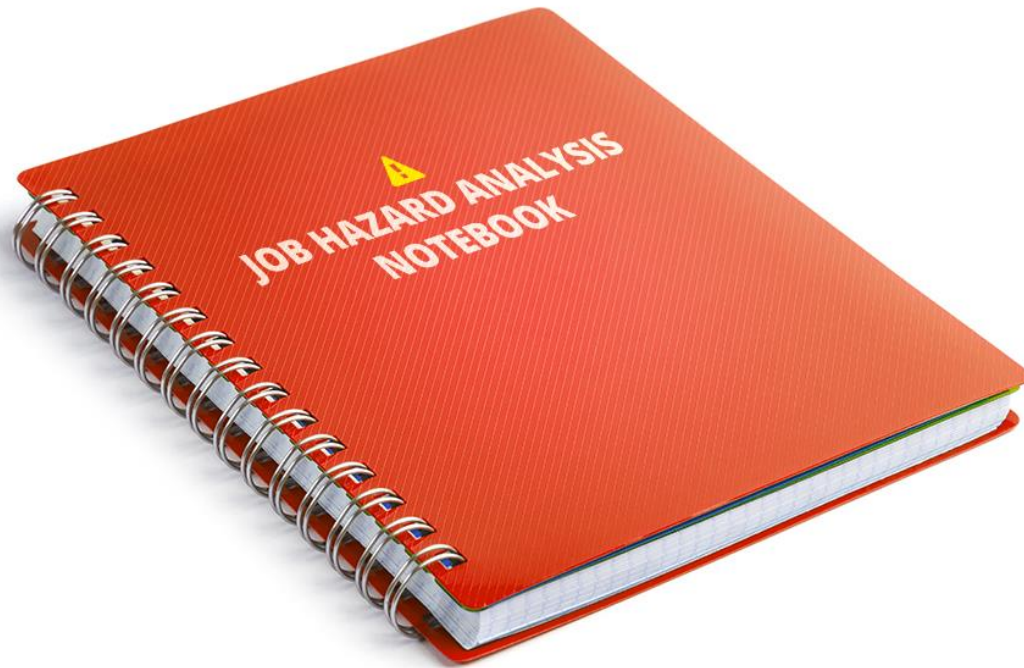
- 76% or more
- 51% - 75%
- 26% - 50%
- Less than 25%



Preparing for Inspections



Big Ticket Item #1



A Written Hazard Analysis

- Raw materials
 - Ingredients
 - Packaging Materials
 - Processing aids
 - Non-food items – utensils, coupons
- Every step in the process
 - Rework, repack, customer returns
- Don't skimp – robust
- Intended use
- Label claims

Hazards

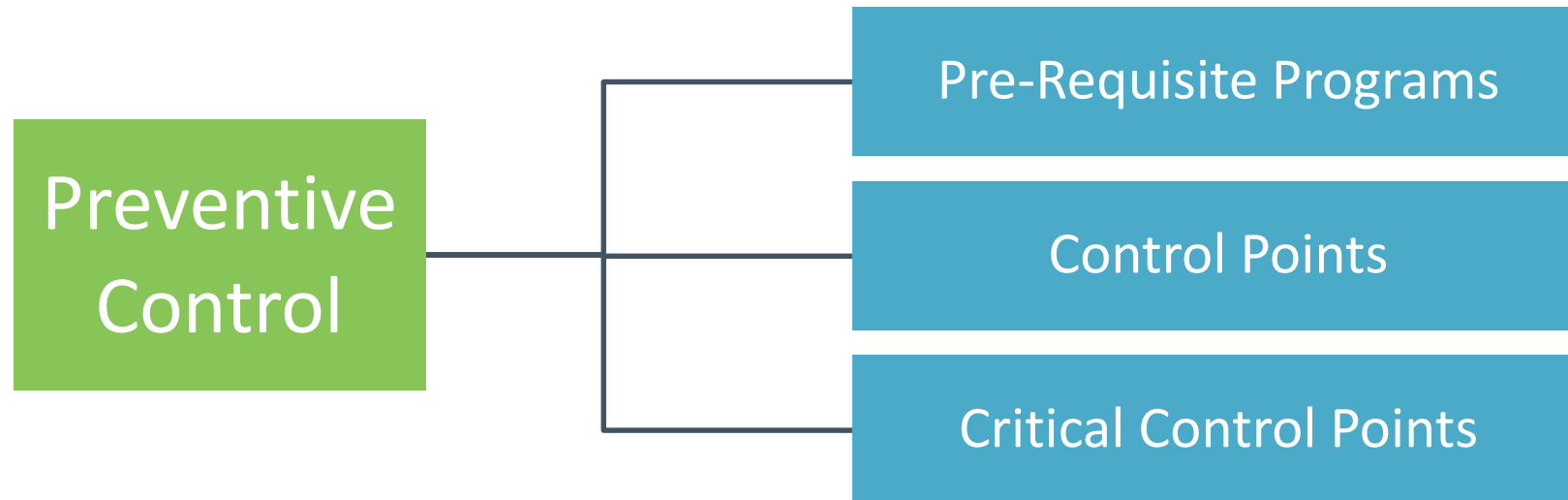
- Biological, chemical, physical and radiological hazards
- Natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives
- Naturally occurring hazards or unintentionally introduced hazards
- Intentionally introduced hazards (including acts of terrorism)



Big Ticket Item #2

Detailed food safety preventive controls for Grade “A” dairy products from potential hazards

- Alphabet soup = PC, CP, CCP, PRP



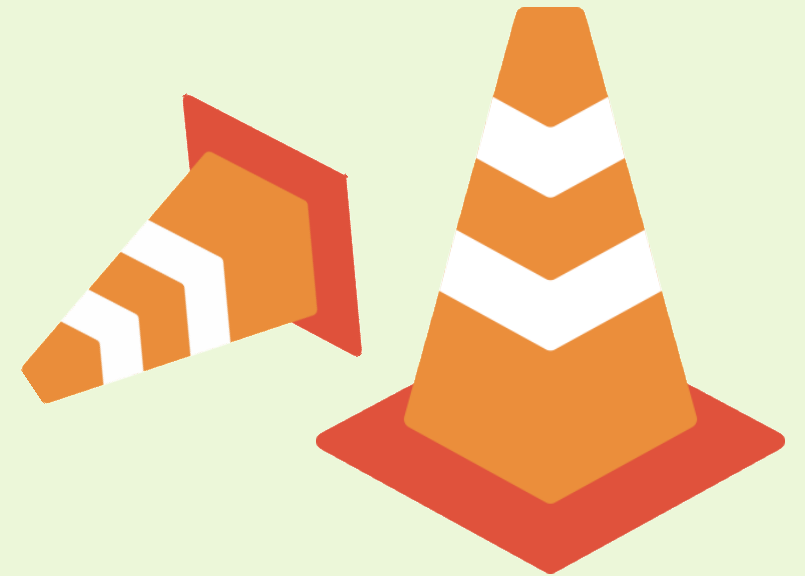
Preventive Controls

- **Must Haves**

- Sanitation procedures at food surface contact points
- Sanitation of utensils and equipment
- Environmental monitoring program (for pathogen controls)
- Hygiene Training
- Food allergen control program
- Recall plan
- Current Good Manufacturing Practices (cGMPs)
- Supplier verification activities

- **Justification needed**

- Definition of 'a lot' throughout the process

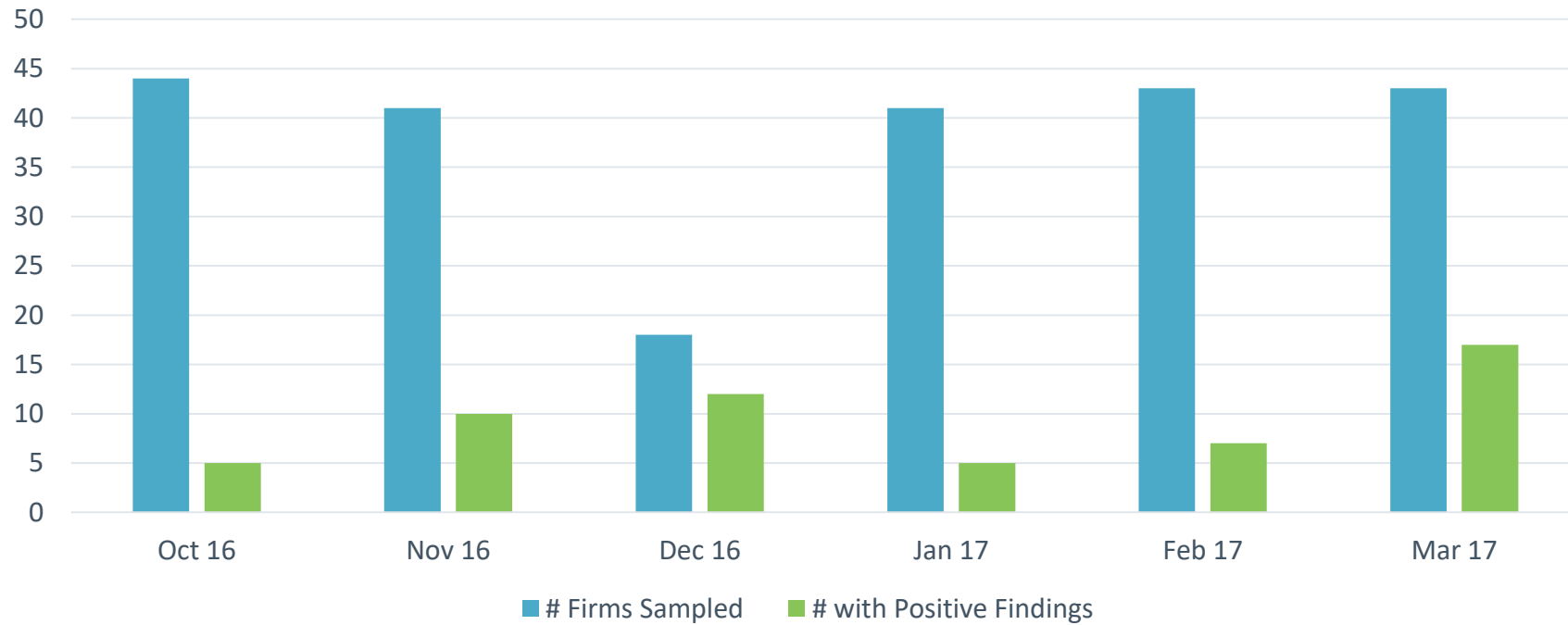


Big Ticket #3

- Testing programs
 - Science based
 - Raw materials
 - Finished product
 - Environmental sampling
- Sampling plans
- Reaction to all results – presumptive too
- Tracking and Trending
- Mapping

Testing

FDA Environmental Sampling



<http://www.achesongroup.com/single-post/2017/06/15/FDA-Updated-Progress-Tracking-Provides-Data-Youll-Want-to-Know>

Testing

FDA Environmental Sampling Since October 2016

- 231** Number of firms that had samples taken
- 57** Number of firms with positive environmental samples
- 14** Recall Recommendations
- 2** Compliance Actions
- 30** Clinical matches to known foodborne illness pathogen

<http://www.achesongroup.com/single-post/2017/06/15/FDA-Updated-Progress-Tracking-Provides-Data-Youll-Want-to-Know>

? POLL

Of the three big ticket items we have talked about — which one keeps you up at night?

- Written Hazard Analysis
- Detailed Food Safety Preventive Controls
- Testing Programs
- All the above



Inspections

- **Food Safety Modernization Act (FSMA)**

- Inspections for compliance will begin after regulators have completed FDA Grade “A” Preventive Controls training
- Expected every 36 months to ensure compliance with the new Appendix T requirements

- **Pasteurized Milk Ordinance (PMO)**

- Traditional quarterly inspections by state regulators to verify compliance with the main parts of the PMO will continue
- To include ‘spot checks’ – example: control of allergen-containing ingredients

Inspections

- **97% of FDA inspectors** have been trained on new preventive controls for human food regulation and are conducting inspections against the Preventive Controls for Human Food regulation.
- **4% of State regulators** have undergone the training and are conducting these inspections.
- **43% of U.S. food industry**, who are subject the PC rule, have successfully completed training conducted by FDA, funded by FDA or using FDA-recognized curricula.

<http://www.achesongroup.com/single-post/2017/06/15/FDA-Updated-Progress-Tracking-Provides-Data-Youll-Want-to-Know>

Oh My!



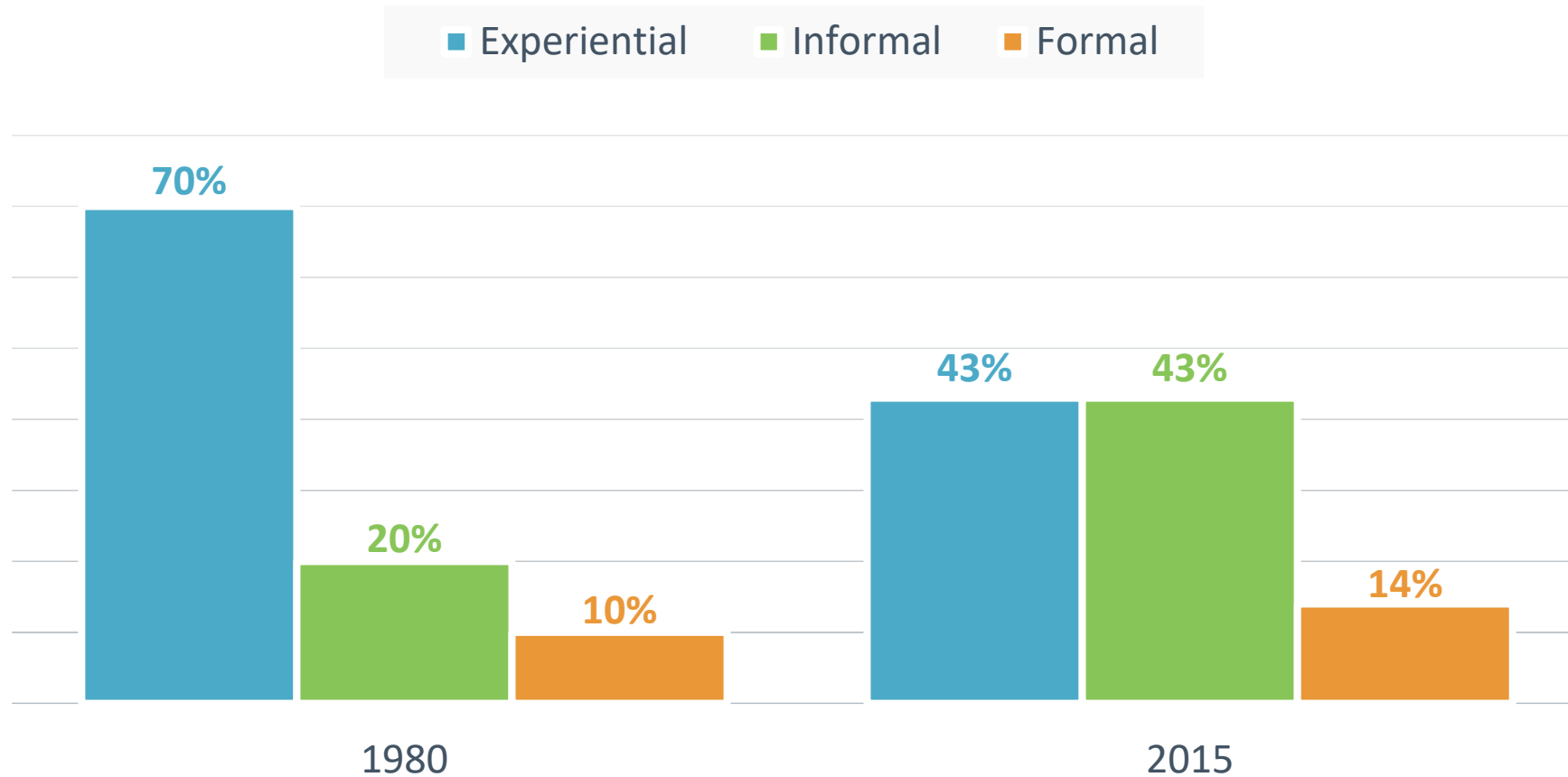
Understanding Learning Types and Training



Learning Types

- **Experiential** - direct experience
 - On the production floor; on the job
- **Formal** - structured
 - Classroom, courses - regardless of how it is delivered
- **Informal** - working with others
 - Referred to as 'Social Learning

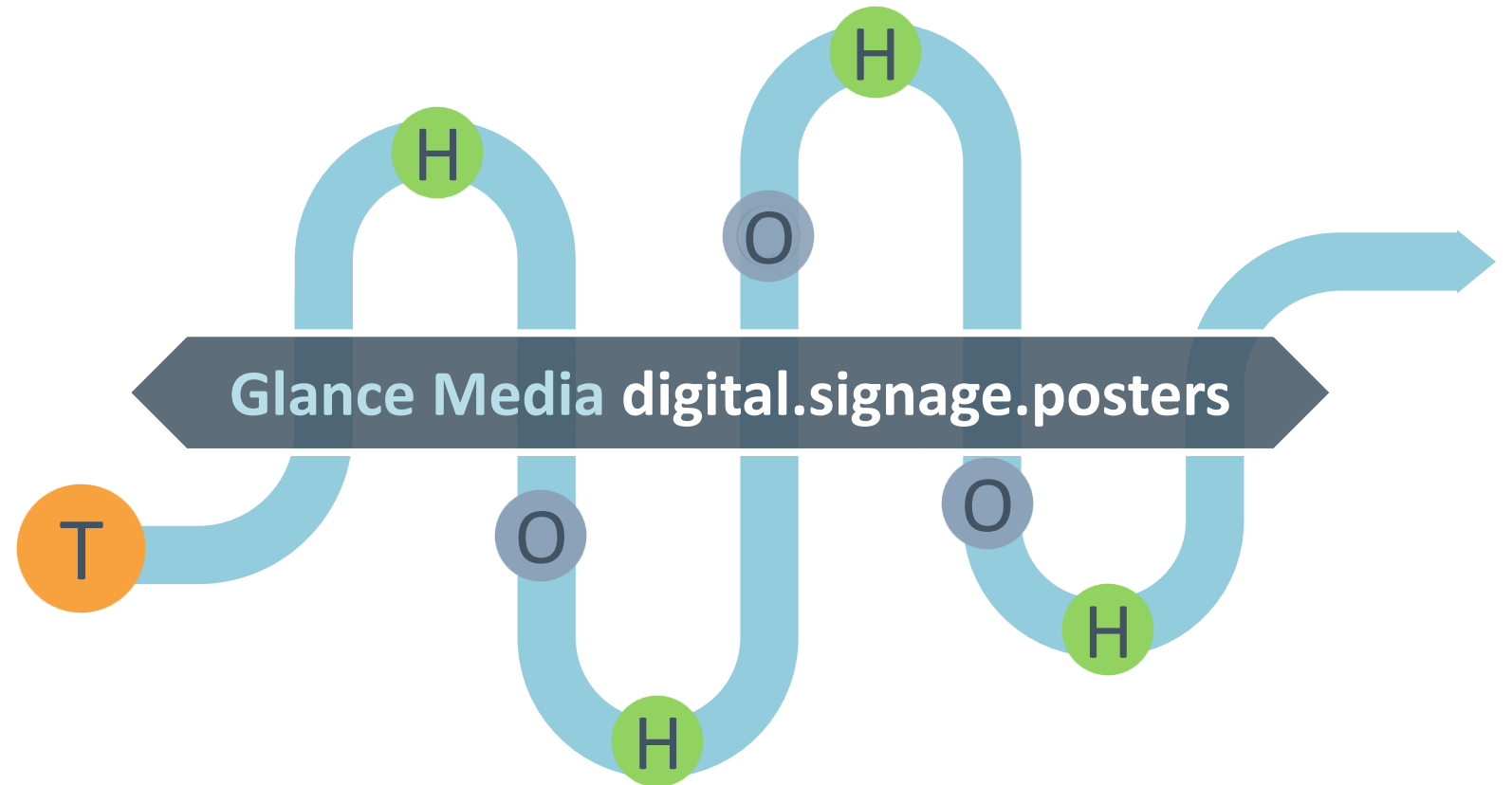
Learning Types



Brandon Hall Group, Measuring the ROI of Informal Learning, December 2015 http://www.brandonhall.com/practice_area_id.php

Training Ecosystem

- T** Training on Topic
- H** Weekly Huddle Talk
- O** Observation



Coaching



VS



Coaching

- **Use every opportunity**
- **Personal**
 - Eye contact
 - Story telling
 - Real life examples
- **Reinforce behaviors**
 - Correction
 - Positives
 - Extinction
- **Build relationships**
 - See, do, teach





*Tell me and I forget.
Teach me and I remember.
Involve me and I learn.*

—Benjamin Franklin

? POLL

How would you describe your current training program?

- Tell me
- Teach me
- Involve me



Alchemy Solutions for the Dairy Industry



Alchemy Solutions – 140 Course Training Library for Dairy

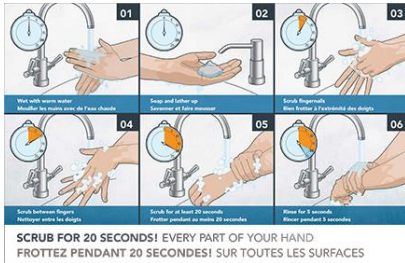
Access hundreds of **multi-lingual courses** on critical **food & workplace safety** topics

- Bacteria Basics
- Bacteria Basics (Metric)
- Controlling Salmonella in Food Manufacturing
- GMPs: Effective Handwashing Techniques
- GMPs: Personal Hygiene – Fluid Products
- GMPs: Promoting Personal Hygiene
- Overview of Preventive Controls
- Preventing Food Contamination
- Understanding Listeria and its Dangers to Food
- Introduction to Pasteurization
- GLPs: Overview of Good Laboratory Practices
- Or create your own!



Alchemy Solutions – Create a Continuous Learning Environment

Huddle Guides



Posters



Workplace Safety

- Lock Out / Tag Out
- Slips, Trips, and Falls
- Pedestrian Fork Lift Safety
- Hearing Protection
- Back Injury Prevention
- Eye Protection
- Repetitive Motion
- Machine Guarding
- GHS Pictograms
- Emergency Evacuation / Response
- Fire Prevention
- Heat Exhaustion
- Bloodborne Pathogens

Food Safety

- Allergens
- Handwashing
- Food Defense
- Pest Control
- Foreign Material Control
- Listeria
- Salmonella
- Environmental Monitoring
- Foodborne Illness
- Personal Hygiene
- Record Keeping
- Water Hose Safety

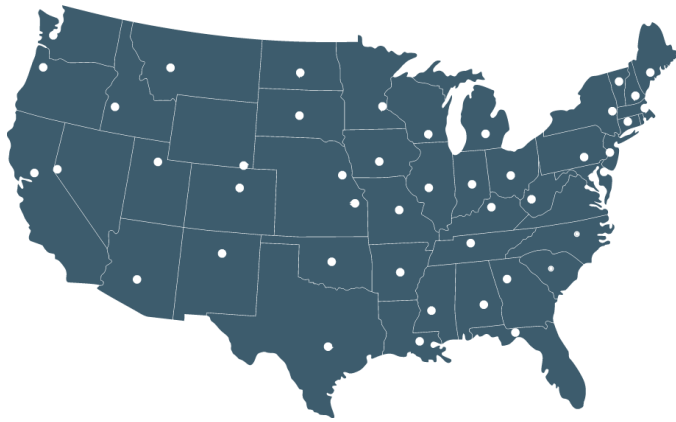
Digital Signage



Coach



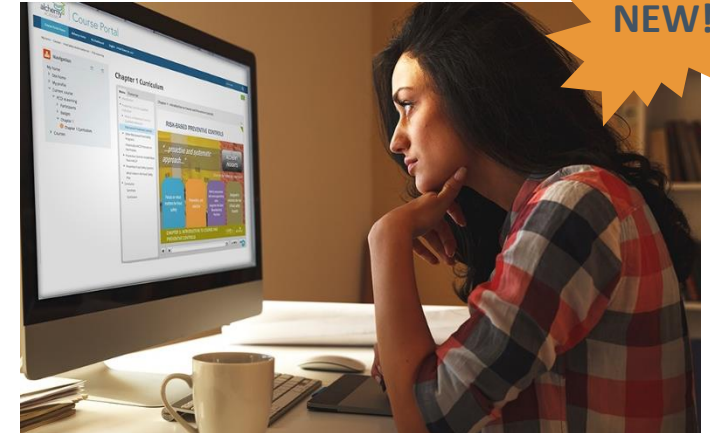
Alchemy Preventive Controls Qualified Individual Training Options



**On-Site Classroom
Across the Country**



**On-Site at
Your Facility**



NEW!

**eLearning on
Your Terms**

Register Here: alchemy.com/food-production/events/preventive-control

Q & A



THANK YOU