

Preventive Controls Implementation Strategies

<http://www.fda.gov/fsma>

**FDA FOOD SAFETY
MODERNIZATION ACT**



THE FUTURE IS NOW

FSMA Phase 2 Implementation

Preventive Controls Workgroup
Key Approved Strategies

Introduction

- Inspection Approach
- Regulatory Strategy
- Regulator Training
- Information Technology (IT)/Observation Corrective Action Report (OCAR)
- Technical Assistance for Regulators

Inspection Approach

- No “one size fits all” approach
- Systems based; not observation focused
- Large firm structure may lend itself to evaluating:
 - Adequacy of overarching food safety programs relative to the Food Safety Plan that are developed and managed at the corporate level
 - Implementation of the Food Safety Plan at the facility level
- CGMP before HRBPC (Animal Food)
- Two-tier feasibility study (Human Food)

Regulatory Strategy - Domestic/Foreign

IMPLEMENTATION

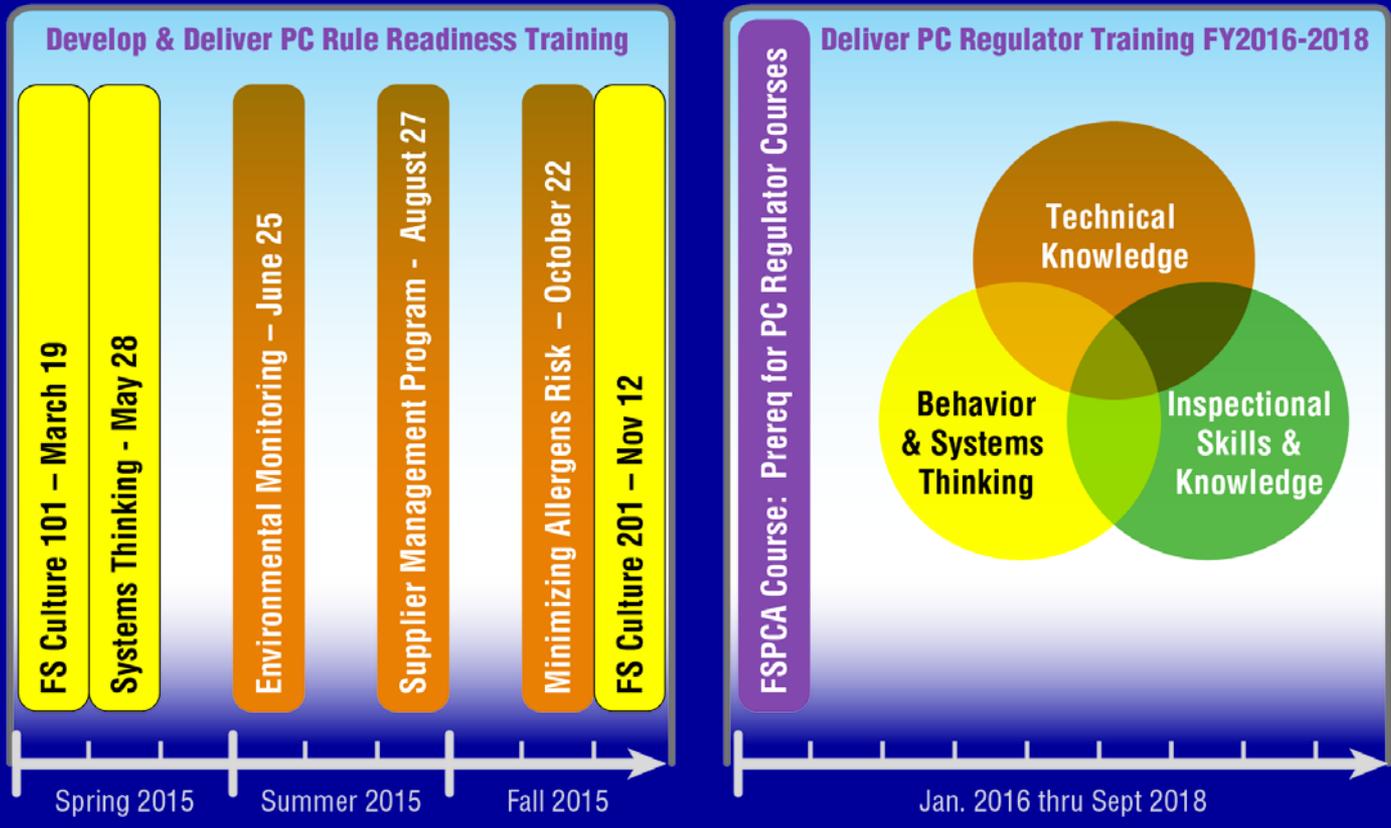
Focus on:

- Achieving compliance through prompt voluntary corrective action
 - Offer industry incentives for corrective action and compliance (e.g. 483 concept; facility risk)
- Rank violations according to public health outcome
 - Minor, major, critical
 - To inform classification (NAI, VAI, OAI)
 - To inform follow-up verification activities – FDA/State
 - To inform work planning

Regulatory Training

- FDA/State regulators will attend Food Safety Preventive Controls Alliance training with industry
- Regulators will also attend regulator-specific training
- Regulator training will include:
 - Technical Knowledge
 - Inspection Skills and Knowledge
 - Behavior and Systems Thinking

PC Training Plan: FY15 PC Rule Readiness Plan & FY 15-18 PC Regulator Plan



Behavior & Systems Thinking Technical Knowledge FSPCA Training Inspection Skills & Knowledge





2015 Sessions

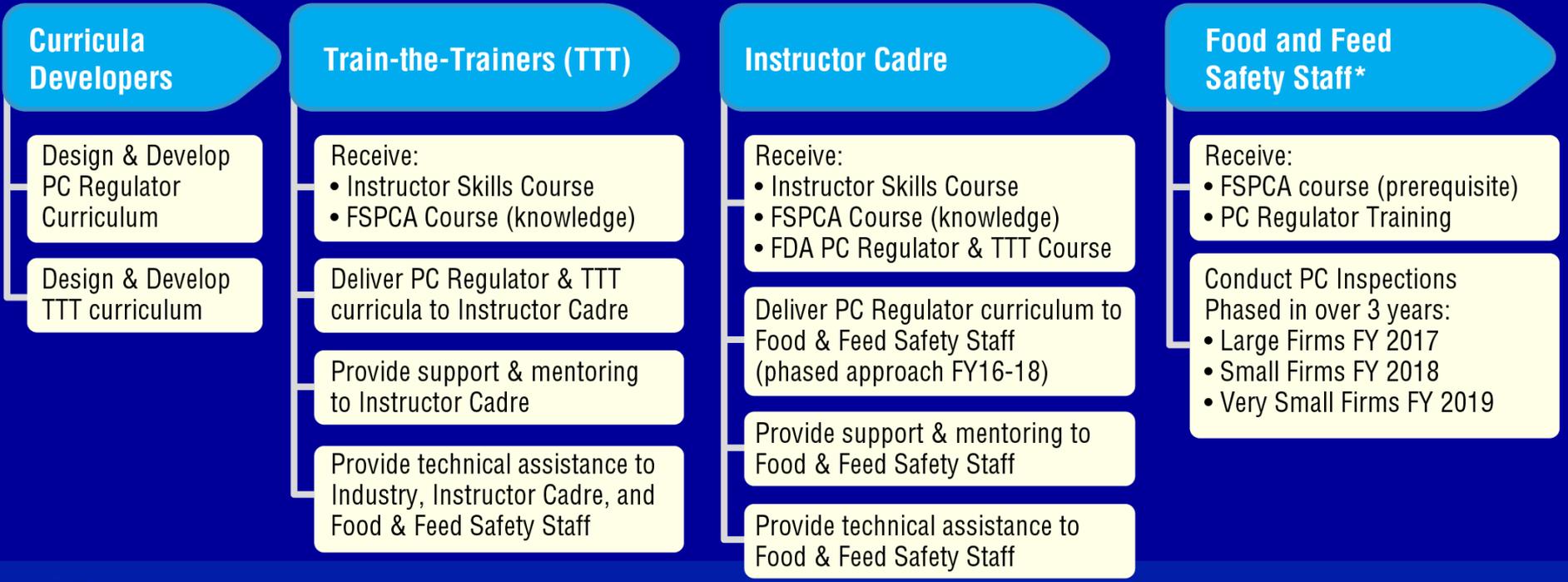
- Food Safety Culture 101 – March 19
- Systems Thinking – May 28
- Environmental Monitoring - June 25
- Supplier Management Program- August 27
- Minimizing Allergens Risk - October 22
- Food Safety Culture 201 – November 12

Events for sharing industry best practices
& FDA perspectives



Development and Delivery Model

Objective: To develop and deliver PC Regulator & Train-the-Trainers (TTT) curricula
 Curricula Developers, TTT, and Instructor Cadre will include experts from ORA/CFSAN/CVM/States
 FSMA Training Workgroup established Selection Criteria for Curricula Developers, TTTs and Instructors



Includes FDA investigators, supervisors/managers, compliance officers, Subject Matter Experts, Technical Experts, and state inspectors



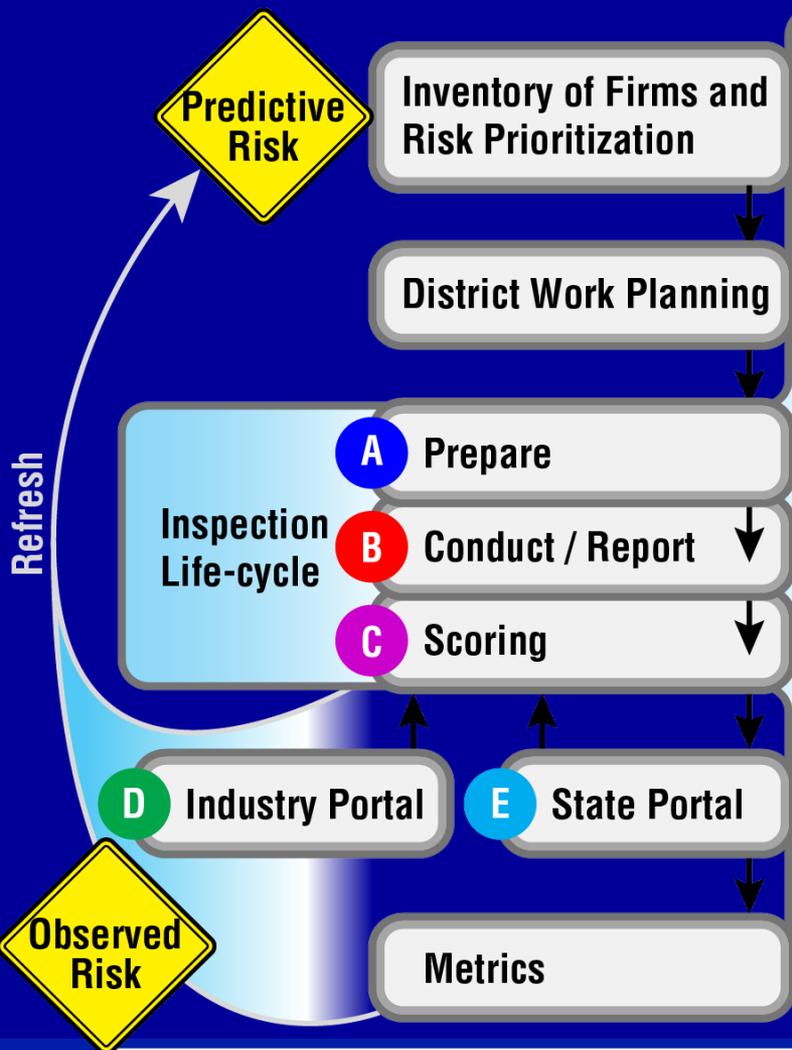
IT and OCAR

OCAR = Observation and Corrective Action Report

- One stop - inspection preparation, reporting, and compliance follow-up reporting platform
- Report = structured data
- State and Industry Portal

Inspection Life-Cycle with OCAR

IMPLEMENTATION



- A Prepare**
Food Safety Staff Resources:
- Firm History
 - Compliance Data
 - Sampling Results
 - RFRs
 - Recalls
 - Consumer Complaints
 - Resource Library
 - Special Instructions / Assignments
 - Guidance Documents
 - Links for Training Videos
 - FACT Sheets
 - List of SME's

- B Conduct / Report**
Inspection Reporting:
- Intelligent Questionnaire (Data Collected in a Structured Format)
 - Minimize the Reporting Burden, Increasing Efficiency
 - Guide Inspection, Lending Focus and Consistency
 - Improve Data: Risk Intelligence and Compliance Patterns
 - Facilitate Data Trending/ Metrics
 - Efficient Generation of Inspection Reports
 - Inspection Report (from IQ)
 - Observation/Discussion/FDA 483 [if applicable]
 - Corrective Action Report (CAR) [if applicable]

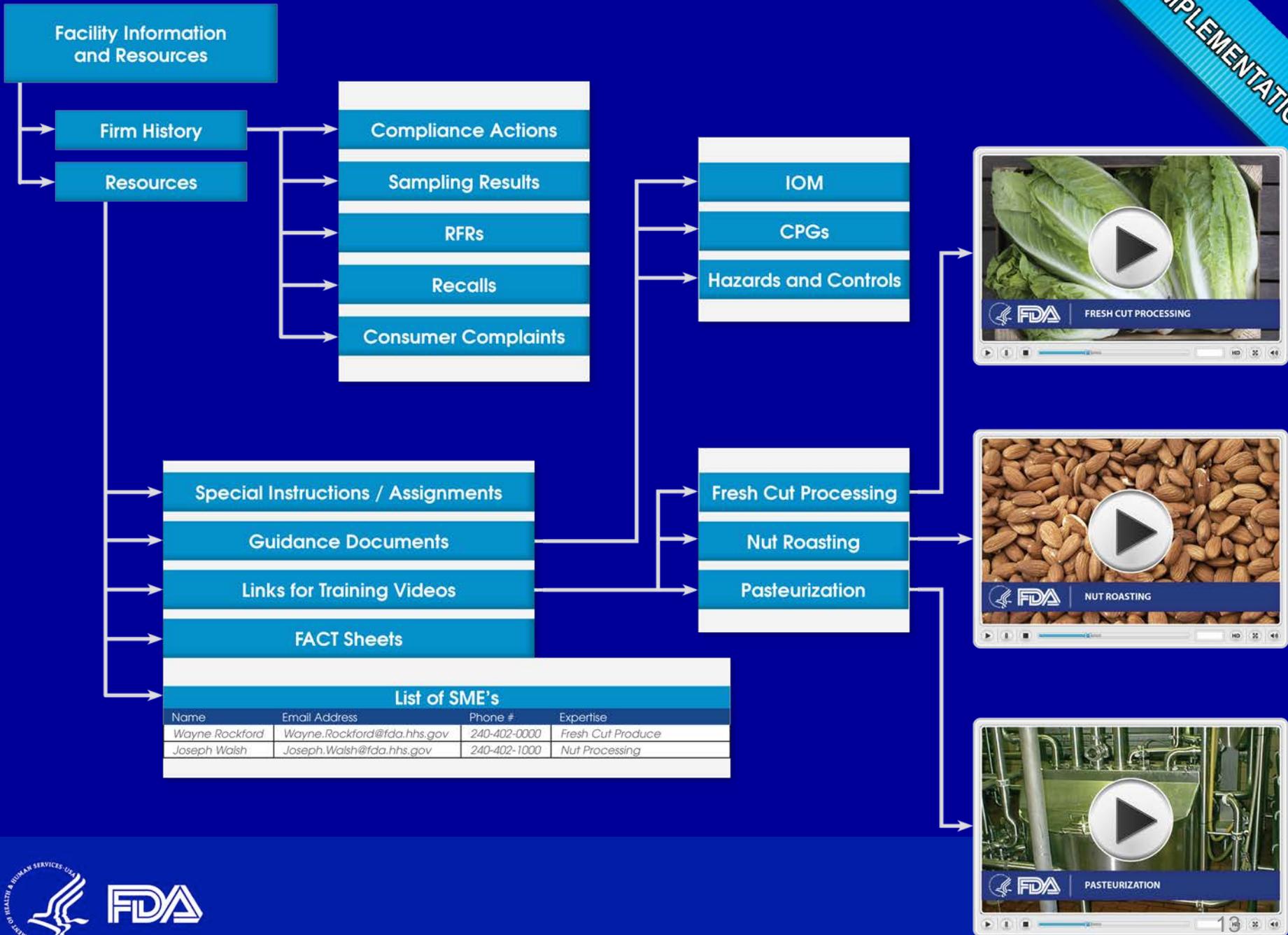
C Scoring

- D Industry Secure Access Portal:**
- Access Inspection Reports and Sampling Results
 - Corrective Action Submissions

- E State Secure Access Portal:**
- Access to: **A B C**
 - Posting Inspection Reports and Sample Results

Technical Assistance for Regulators

- **Guidance Documents**
- **Internal technical network** to provide consistent sources of technical assistance
 - Infrastructure – FDA and State Field Staff through Subject Matter Experts
 - Knowledge Management System
- **Resource Library**



List of SME's			
Name	Email Address	Phone #	Expertise
Wayne Rockford	Wayne.Rockford@fda.hhs.gov	240-402-0000	Fresh Cut Produce
Joseph Walsh	Joseph.Walsh@fda.hhs.gov	240-402-1000	Nut Processing

Thank You For Your Attention!