



FSPCA Preventive Controls for Human Food Participant Course

AGENDA

February 25-27, 2019

Monday 1:00 – 5:00 pm / Tuesday - Wednesday 8:00 – 5:00 pm

FDA Long Beach Resident Center – One World Trade Center

4th Floor Training Room - Long Beach, CA 90831

Instructors: Kathy Gombas, Jenifer Kane

Monday, February 25

- 1:00 – 1:30 pm Registration and Sign-in
- 1:30 pm Welcome, Introductions
- FSPCA Course Overview (Kane)
- Chapter 1: Introduction to the course and Preventive Controls & Exercise (Kane)
- Chapter 2: Food Safety Plan Overview (Kane)
- Chapter 3: Good Manufacturing Practices and Other Prerequisites (Kane)
- 4:30 – 5:00 pm Open Discussion/Questions/Expectations for Day 2

Tuesday, February 26

- 8:00 – 8:30 am Sign-in, Questions from Previous Day
- 8:30 am Chapter 4: Biological Food Safety Hazards & Exercise (Gombas)
- Chapter 5: Chemical, Physical and Economically Motivated Food Safety Hazards (Kane)
- Chapter 6 Preliminary Steps in Developing a Food Safety Plan (Gombas)
- Chapter 7: Resources for Food Safety Plan (Kane)
- 12:00 – 1:00 pm Lunch
- 1:00 pm Chapter 8: Hazard Analysis and Preventive Controls Determination (Gombas)
- PCHF FDA Draft Hazards Guide (optional PPT explaining use of Appendix 1) – (Gombas)
- Chapter 8: Exercise (Gombas)
- Chapter 9: Process Preventive Controls & Exercise (Kane)
- 4:30 – 5:00 pm Open Discussion/Questions/Expectations for Day 3

All participants must stay the duration of the course each day to receive a certificate.

Wednesday, February 27

- 8:00 – 8:30 am Sign-in, Questions from Previous Day
- 8:30 am Chapter 10 Food Allergen Preventive Controls Determination & Exercise (Gombas)
Chapter 11: Sanitation Preventive Controls & Exercise (Kane)
Chapter 12: Supply Chain Controls & Exercise (Gombas)
- 12:00 – 1:00 pm Lunch
- 1:00 pm Chapter 13: Verification and Validation Procedures & Exercise (Kane)
Chapter 14: Record-keeping Procedures & Exercise (Gombas)
Chapter 15 Recall Plan (Kane)
Chapter 16 Regulation Overview – cGMP, Hazard Analysis and Risk-Based Preventive Controls for Human Food (Video)
- 4:30 – 4:45 pm Final Questions
- 4:45 – 5:00 pm Foreign Supplier Verification Programs Optional Module (Gombas)

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Instructor Bios



Kathy L. Gombas

Kathy is a recognized food safety expert with over thirty years of experience in the food industry specializing in preventive controls, supply chain management, food safety auditing, and regulatory affairs.

Kathy Gombas was formerly the Senior Advisor for FSMA Implementation with the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN). While at CFSAN, Kathy supported the Agency's Food Safety Modernization Act (FSMA) implementation efforts including the Preventive Controls Regulator Training and launch of FDA's FSMA Technical Assistance Network for industry. Kathy was also lead for the implementation of FDA's Reportable Food Registry. Before coming to CFSAN, Kathy held corporate food safety positions at Dean Foods and at Kraft Foods.

Kathy is currently a member of the Food Safety Preventive Controls Alliance (FSPCA) Steering Committee and co-chair for the International Subcommittee working on industry training, outreach, and technical assistance programs for food companies worldwide. Kathy is an FSPCA Trainer-of-Trainers and Lead Instructor for Foreign Supplier Verification Programs and Preventive Controls for Human Food. Kathy provides food safety consulting services to the food industry.

Kathy graduated from Northern Arizona University with a B.S. in Microbiology.

Instructor Bios



Jenifer Kane, Nobius Food Safety Management

Jenifer Kane is currently President of the Nobius Food Safety Management Company. She has 36 years of experience in the Food Industry, most recently as Sr. Industry Advisor with the International Food Protection Training Institute. Prior to that position, she was Director of Global Quality Auditing for the Kellogg Company. Her Food Safety and Quality career has included various Food Safety and Quality related positions within Nabisco, Planters and Lifesavers, Kraft Foods, and Keebler Companies. Most recently (Kraft, Keebler, Kellogg), Jenifer was instrumental in the development and rollout of global quality system assessments plus the training programs necessary to guide and support audit teams, regional FS&Q support groups, and individual manufacturing site management teams. This international focus on Food Safety and Quality provides the basis of her expertise in identifying and correcting food safety hazards possible within multiple food manufacturing environments. For a period of time in this effort she was based in Germany with Kraft Jacobs Suchard.

Jenifer is an FSPCA Lead Instructor for Preventive Controls for Human Food, Animal food and Foreign Supplier Verification Programs (FSVP) and is a Trainer of Trainer for both the FSPCA Preventive Controls for Human Food and FSVP. This background is key in developing programs and tools in support of training, consulting and guidance within the food industry and in identifying Food Safety and FSMA training needs. She is actively involved in the FSPCA Alliance as the Chair of the Monitoring and Evaluation Workgroup where she has responsibility for addressing FSPCA instructor delivery and course advertising concerns in support of FSPCA curriculum standards.

Jenifer is a graduate of Indiana State University with a BS in Environmental Health and holds an MBA from DePaul University.