

Validation Workshop: Aseptic Processing and Filling

June 9 -12, 2025, Focus on Key Aspects and Hands-On Experience

AGENDA

Monday Afternoon – June 9

Nelson Hall of Food Science, Room 1195

- 12:00 pm Registration
- 12:30 pm Welcome and Introduction
- 1:00 pm Aseptic 101 *(Dr. Dharmendra Mishra)*
- 1:45 pm Master Validation Plan
(Dr. Dharmendra Mishra)
- 2:45 pm Refreshment Break
- 3:00 pm Environmental Monitoring Program
(Dr. Bruce Applegate)
- 4:05 pm Kinetics of Spores *(Dr. Bruce Applegate)*
- 6:00 pm Dinner on your own

Tuesday Morning – June 10

Nelson Hall of Food Science, Room 1195

- 8:00 am Validation of UHT and A tank
(Dr. Dharmendra Mishra)
- 9:30 am Refreshment Break
- 9:45 am Package & Pre-sterilization Lab - Team 1
Microbiology Lab- Team 2
Aseptic Tank Temp. Distribution - Team 3
Spoilage Diagnosis Lab - Team 4
- 12:00 pm Lunch (provided)

Tuesday Afternoon – June 10

Nelson Hall of Food Science, Room 1195

- 1:00 pm Filler Sterilization Validation
(Mr. Corpus Perez)
- 2:30 pm Refreshment Break
- 2:45 pm Package & Pre-sterilization Lab - Team 2
Microbiology Lab- Team 3
Aseptic Tank Temp. Distribution - Team 4
Spoilage Diagnosis Lab - Team 1
- 5:30 pm Dinner Social (provided)

Wednesday Morning – June 11

Nelson Hall of Food Science, Room 1195

- 8:00 am Aseptic Packaging Qualification and Validation
(Dr. Dharmendra Mishra)
- 9:30 am Refreshment Break
- 9:45 am Package & Pre-sterilization Lab - Team 3
Microbiology Lab- Team 4
Aseptic Tank Temp. Distribution - Team 1
Spoilage Diagnosis Lab - Team 2
- 12:00 pm Lunch (provided)

Wednesday Afternoon – June 11

Nelson Hall of Food Science, Pilot Plant

- 1:00 pm Validation Requirements – FDA
(Dr. Glenn Black)
- 2:30 pm Refreshment Break
- 2:45 pm Package & Pre-sterilization Lab - Team 4
Microbiology Lab- Team 1
Aseptic Tank Temp. Distribution - Team 2
Spoilage Diagnosis Lab - Team 3
- 5:30 pm Dinner Social (provided)

Thursday Morning – June 12

Nelson Hall of Food Science, Room 1195

- 8:00 am Inoculated Pack Lab *(All teams)*
- 9:00 am Sterile Barriers Validation *(Mr. Corpus Perez)*
- 10:00 am Refreshment Break
- 10:15 am Practical Aspects of Manufacturing
(Dr. Jairus David)
- 11:15 am Mock FDA Filing *(Mr. Corpus Perez)*
- 12:00 pm Workshop Evaluation and Feedback
- 12:30 pm Workshop Adjourns

Laboratory Programs: Philip E. Nelson Hall of Food Science Building – Pilot and Research Laboratory Facilities

Note: Workshop attendees will be assigned to one of four groups. Your assigned group will participate in the sessions indicated.



Food Entrepreneurship and
Manufacturing Institute

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Workshop Faculty and Instructors

Dharmendra Mishra Associate Professor of Food Science and Director, Food Entrepreneurship and Manufacturing Institute (FEMI) at Purdue University. His expertise includes thermal processing, mathematical modeling, aseptic validation, and parameter estimation. He works closely with commercial food manufacturers and provides operational guidance and design training courses for the workforce and has trained over 1800 food industry professionals and government regulatory inspectors. He also works with entrepreneurs (over 100 cases) to develop their products and scale-up to commercial production.

Glenn Black Associate Director of Research of the Division of Food Processing Science and Technology (DFPST) in the office of Food Safety within CFSAN/FDA. DFPST is jointly located with the Institute for Food Safety and Health at the National Center of Food Safety and Technology (NCFST) and is responsible for providing management, budget oversight, and supporting food safety-related research related to food processing and safety.

Bruce Applegate Professor of Food Science at Purdue University. His current research consists of both an applied and fundamental focus using molecular approaches to develop platforms for the detection of pathogenic bacteria in matrices and examining problematic foodborne bacteria (pathogens/spoilage) associated with processing, survival, inactivation, and dissemination.

Jairus David Consultant and expert on food preservation science, food safety and quality. His industrial experience spans family-owned small companies and large corporations—highly regulated baby foods, infant formula, consumer-packaged goods, and food service. Jairus has worked with the food industry in developing microbiology and thermal processing food safety objectives and compliance for canning and aseptic processing for over 38 years.

Corpus Perez Aseptic Process & Packaging Process Authority with specialized expertise in validation of aseptic processing and packaging systems with more than 2 decades of experience. He is also an expert in hot fill hold processing & packaging, microbiological validation testing, and troubleshooting spoilage diagnosis for complex liquid food and beverage processing systems.

Subhashis Chakraborty Extension Research Administrator and Regulatory Specialist at the Dept. of Food Science, Purdue University. His experience spans more than 11+ years in the food and beverage industry through industrial work, training, auditing, and consulting.

Kelsey Budreau Pilot Plant Manager at the Dept. of Food Science, Purdue University. She coordinates daily activities in the department's 9,500 sq. ft. modular space dedicated to food manufacturing research and education. Kelsey supports department research, training for student courses and industry, and pilot scale R&D trials for industry through the Food Entrepreneurship and Manufacturing Institute (FEMI).

Ben Paxson Purdue Food Science Academic IT Specialist. He determines short and long-term goals for the management and expansion of the departmental network and is responsible for the design and implementation of new features of the network and manages the department's servers. Additionally, Ben acts as the IT lead on several projects within the department including aspects related to Computer Integrated Manufacturing in our Pilot Laboratory, the development of technology based educational tools, and the creation of applications for specific research needs.

Graduate Student Assistants and Workshop Staff

Allison Kingery, Allison Brown, Amandeep Singh, Athira Syamala, Audrey Searing Hettel, Halak Mehta, Rahul Kamath, Harneel Kaur, Matthew Kittaka, Vinoothna Ramisetty, Manoj Sawale, Xiang Cheng, and Dept. of Food Science Undergraduate Assistants.