



ANNUAL EVENT AND EXPO

Understanding GRAS and Product Development Workshop

Saturday, July 13, 2024

Room: Gold Coast

Time	Topic	Instructor
8:00 – 8:05 AM	Welcome & Introductions	All Instructors
8:05 – 8:15 AM	Overview of GRAS Concept and It's Implications/Importance in the Food Industry	Steven Gendel, PhD
8:15 – 9:15 AM	An introduction of FDA's Food Ingredients Regulation Programs <ul style="list-style-type: none"> Historical perspective and evolution of federal food and drug regulations GRAS ingredients and GRAS notices 	Kaiping Deng, PhD
9:15 – 10:30 AM	Criteria for GRAS Determination (What are the factors/evidence) <ul style="list-style-type: none"> In-depth exploration of the criteria for a substance to be considered GRAS 7 Parts of a GRAS Notification Safety assessment principles and methodologies 	Steven Gendel, PhD
10:30 – 10:40 PM	BREAK	
10:40 – 12:00 PM	Interactive Session: Case Studies (Chemicals) <ul style="list-style-type: none"> Illustrating non-successful GRAS determination Illustrating successful GRAS determination 	Steven Gendel, PhD
12:00 – 1:00 PM	LUNCH – Crystal Ballroom B	
1:00 – 2:00 PM	The Role of Scientific Evidence in GRAS Assessment	Steven Gendel, PhD
2:00 – 2:15 PM	BREAK	
2:15 – 3:15 PM	Differences Between Organisms, Enzymes, and Chemicals (GRAS notices)	Steven Gendel, PhD
3:15 – 4:00 PM	Case Studies (Organisms & Enzymes)	Steven Gendel, PhD
4:00 – 4:30 PM	Audience Q&A	
4:30 – 6:00 PM	HAPPY HOUR & NETWORKING EVENT – The Living Room	

Please note that the schedule, including instructors, topics, and times are approximate and subject to change.

Sunday, July 14, 2024

Room: Gold Coast

Duration	Topic	Instructor
8:00 – 8:15 PM	Recap of Day 1 & Audience Q&A	Steven Gendel, PhD
8:15 – 9:00 PM	International Perspectives on GRAS and Novel Foods <ul style="list-style-type: none">• A comparative analysis of GRAS and Novel Foods regulations in different countries• Considerations for global product development and market access	Steven Gendel, PhD
9:00 – 10:00 AM	FDA Enforcement Tools <ul style="list-style-type: none">• 483, FSVP, warning letters, Import alerts	Steven Gendel, PhD
10:00 – 10:15 PM	<i>BREAK</i>	
10:15 – 12:00 PM	Thinking GRAS from the POV of a Product Developer & User <ul style="list-style-type: none">• Product Developer: Developing a new substance (Daily Harvest case study/Tera flour)• User: Using the new substance	Steven Gendel, PhD
12:00 – 1:00 PM	<i>LUNCH – Crystal Ballroom B</i>	
1:00 – 2:00 PM	Challenges and Opportunities in GRAS Determinations <ul style="list-style-type: none">• Addressing emerging issues and evolving regulatory landscape• Strategies for overcoming challenges in the GRAS determination process• Opportunities for innovation in the food industry	Craig Llewellyn, PhD
2:00 – 4:00 PM	GRAS and You: What's on Your Plate?	Steven Gendel, PhD
4:00 – 4:30 PM	Post-Workshop Wrap Up and Review	Steven Gendel, PhD

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