



GRAS Essentials for Developers & Formulators

Virtual Workshop

Agenda

Day 1: Introduction to FDA Generally Recognized as Safe (GRAS)

- Review the FD&C Act – Additives
- Review the FD&C Act – GRAS
- Review FDA Regulations and Criteria for GRAS Determinations
- The Role of Scientific Evidence in GRAS

Day 2&3: GRAS Assessments

- Real-World GRAS Determinations Case Studies
- Close looks at several successful notifications and FDA response letters
- Interactive Group Exercises
- Group evaluation and discussion of example notifications
- What you need to consider as an ingredient developer/supplier
- What you need to consider as an ingredient user/product formulator

Day 4: International Regulations and the Future

- Part 1 = International Regulations and Novel Foods
- Part 2 = The Future / What may be changing

Meet the Instructor



Steven Gendel, PhD
Principal at Gendel Food Safety LLC

Steven Gendel is an internationally recognized expert on food safety, food allergens, GMPs, safety assessments for new food products, and food policy and regulation. He has over 30 years of experience working to use new approaches and advanced technology to protect public health.

Dr. Gendel spent over two decades advancing science and policy in the FDA Center for Food Safety and Applied Nutrition. He was the first FDA Food Allergen Coordinator and contributed to the creation of agency policies, guidance documents, and regulations.

Dr. Gendel holds a BS in Chemical Engineering and a PhD in Cell and Developmental Biology. He has advanced training in risk assessment, food law, HACCP, and Preventive Controls. He works in the Washington DC area.