This medical foods workshop will aim to foster a dialogue on the regulatory framework of medical foods in the U.S. by discussing topics such as distinctive nutritional requirements, modification of the diet alone, usage under medical supervision, and clinical guidelines.

TUESDAY, AUGUST 13

8:00–8:30 AM  
Breakfast (provided)

8:30–9:30 AM  
Opening Session

  Introductions & Workshop Objectives  
  Sarah Ohlhorst, American Society for Nutrition  
  Madeline Jurch, Healthcare Nutrition Council

  The Current Regulatory Framework of Medical Foods  
  Dr. Tim Morck, Spectrum Nutrition

  Learnings from the 2018 NASEM Workshop on Examining Special Nutritional Requirements in Disease States & Looking Ahead  
  Dr. Barbara Schneeman, UC Davis

9:30–10:45 AM  
From Essentiality to Quality of Life: Assessing “Distinctive Nutritional Requirements” in Different Clinical Contexts

  The Role of Nutrition in Managing a Disease  
  Sarah Ohlhorst, American Society for Nutrition

  Improving Clinical Outcomes: Immunonutrition and Surgery  
  Dr. Juan Ochoa, Geisinger Medical Center

  The Role of Mode of Delivery and the Patient Spectrum (Long Term Care to ICU)  
  Susan Lessar, Winchester Medical Center

  Malnutrition and Gastrointestinal Impairment in Meeting Patient Nutritional Needs  
  Dr. Mark DeLegge, Medical University of South Carolina

  The Role of Clinical Guidelines in “Distinctive Nutritional Requirements”  
  Ainsley Malone, American Society of Parenteral and Enteral Nutrition

10:45–11:15 AM  
Coffee/Tea Break

11:15 AM–1:10 PM  
Practical Aspects for Meeting Distinctive Nutritional Requirements through Modification of the Diet Alone

  Modification of the Diet Alone in the Context of Medical Foods’ Traditional Focus  
  Dr. David Cockram, Cockram Consulting

  Current Regulatory and Legal Context on Modification of the Diet Alone  
  Jessica O’Connell, Covington & Burling

  Practicality of the Usage of Medical Foods to Assure Compliance and Meet Nutritional Requirements: Healthcare Providers Perspectives on Three Disease States  
  Dr. Eric Kossoff, Johns Hopkins Medicine (Intractable Epilepsy)  
  Dr. Osama Hamdy, Harvard Medical School (Spectrum of Diabetic Patients)  
  Dr. Alison Steiber, Academy of Nutrition and Dietetics (End-Stage Renal Disease)

1:10–2:10 PM  
Lunch (provided)

2:15–3:15 PM  
International Perspective on Patient Foods Intended for the Dietary Management of a Disease or Condition

  Foods for Special Medical Purposes (FSMP) in Europe  
  Basil Mathioudakis, former European Commission—DG SANTE

  Canadian Modernization of Division 24  
  Genevieve D’Annunzio, Abbott Laboratories

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2:15–3:15 PM  
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Q&A with Speakers

Q&A with Speakers
3:15–4:45 PM

New Types of Evidence and Product Innovation: From Patient Needs to Product Design and Development

Scientific Basis for Products & Clinical Perspective
Sarah Ohlhorst, American Society for Nutrition

ASPN’s Research Value Proposition Project
Dr. Peggi Guenter, American Society of Parenteral and Enteral Nutrition

Patient Needs & Product Design Considerations
Dr. Satya Jonnalagadda, Abbott Nutrition

Product Research & Evidence Development
Dr. Krys Araujo Torres, Nestlé Health Science

Q&A with Panelists

4:45–5:00 PM

Wrap-Up and Adjourn
Madeline Jurch, Healthcare Nutrition Council

10:30 AM–12:00 PM

Final Discussion & Panel on Learnings from the Workshop and Actionable Next Steps

Summary of Workshop Key Findings & Key Issues Uncovered—Panel Moderator
Dr. Tim Morck, Spectrum Nutrition

Panel Discussion—Reactions to Workshop Summary, Remaining Questions & Looking Forward
Joy McVey Hugick, Oley Foundation
Madeline Jurch, Healthcare Nutrition Council
Dr. Alison Steiber, Academy of Nutrition and Dietetics
Dr. Peggi Guenter, American Society of Parenteral and Enteral Nutrition
Dr. Barbara Schneeman, UC Davis

Q&A with Panelists

12:00–12:15 PM

Closing
Sarah Ohlhorst, American Society for Nutrition
Madeline Jurch, Healthcare Nutrition Council

WEDNESDAY, AUGUST 14

8:00–8:30 AM

Breakfast (provided)

8:30–9:00 AM

Review of Workshop Objectives and Learning from Day 1
Sarah Ohlhorst, American Society for Nutrition
Madeline Jurch, Healthcare Nutrition Council

9:00–10:30 AM

Differentiating Foods for Special Dietary Uses and Medical Foods

The Current FDA Regulation around Foods for Special Dietary Uses
Jessica O’Connell, Covington & Burling

Concepts around Differentiating Medical Foods and FSDU
Jena Rostorfer, Abbott Nutrition
Alexandre Biella, Nestlé Health Science

Panel Discussion—Reflections on Medical Food and FSDU Concepts
Xin Tao, Hogan Lovells
Dr. Barbara Schneeman, UC Davis
Dr. Tim Morck, Spectrum Nutrition

Q&A with Panelists

HNC is an organization representing the manufacturers of nutrition support products, specifically enteral nutrition (EN) formulas, parenteral nutrition (PN) solutions, supplies and equipment. HNC member companies are committed to improving health by advancing policies that address and raise awareness of nutrition and its impact on patient outcomes and healthcare costs. This includes promoting nutritional screenings, diagnoses, assessments, and appropriate and timely clinical nutrition interventions while maintaining patients' access to specialized nutrition support products and services throughout the continuum of care. For more information about HNC, please visit healthcarenutrition.org.

ASN is a not-for-profit scientific, professional society with more than 6,500 members working in academia, clinical practice, government and industry in more than 75 countries around the world. ASN currently reaches over 36 million people annually with the highest quality nutrition information. For more information about ASN, please visit nutrition.org.