

The Healthcare Nutrition Council presents “A Medical Foods Workshop: Science, Regulation and Practical Aspects”, co-sponsored by the American Society for Nutrition

### Workshop Objective

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

#### Day 1

Tuesday, August 13

#### **8:30 - 9:30am: Opening Session**

- Introductions & Workshop Objectives
  - Speakers: Sarah Ohlhorst, American Society for Nutrition and Madeline Jurch, Healthcare Nutrition Council
- Medical Foods: Challenges and Opportunities
  - Speaker: Tim Morck, Spectrum Nutrition LLC
- The Current Regulatory Framework of Medical Foods
  - Speaker: U.S. Food and Drug Administration (*invited*)
- Learnings from the 2018 NASEM Workshop on Examining Special Nutritional Requirements in Disease States
  - Speaker: Barbara Schneeman, UC Davis

#### **9:30 - 10:45am: From Essentiality to Quality of Life: Assessing “Distinctive Nutritional Requirements” in Different Clinical Contexts**

- The Role of Nutrition in Managing a Disease
  - Speaker: Sarah Ohlhorst, American Society for Nutrition
- Improving Clinical Outcomes: Immunonutrition and Surgery
  - Speaker: Dr. Juan Ochoa, Geisinger Medical Center
- The Role of Mode of Delivery and the Patient Spectrum (Long Term Care to ICU)
  - Speaker: Susan Lessar, Winchester Medical Center
- Malnutrition and Gastrointestinal Impairment in Meeting Patient Nutritional Needs
  - Speaker: Dr. Mark DeLegge, Medical University of South Carolina
- The Role of Clinical Guidelines in “Distinctive Nutritional Requirements”
  - Speaker: Ainsley Malone, American Society of Parenteral and Enteral Nutrition
- Q&A with Speakers

#### **10:45 - 11:15am: Coffee/Tea Break**

#### **11:15am - 1:10pm: 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
  - Speakers: Patsy Brannon, Cornell University
- Current Regulatory and Legal Context on Modification of the Diet Alone
  - Speaker: 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
  - Speakers: Dr. Eric Kossoff, Johns Hopkins Medicine (Intractable Epilepsy); Dr. Osama Hamdy, Harvard Medical School (Spectrum of Diabetic Patients); and Alison Steiber, Academy of Nutrition and Dietetics (End-Stage Renal Disease)
- Practicality of the Usage of Medical Foods to Assure Compliance and Meet Nutritional Requirements: Patient Perspective
  - Speaker: Laura Wingate, Crohn’s and Colitis Foundation
- Q&A with Speakers

**1:10 - 2:10pm: Lunch** *(provided)*

**2:15 - 3:15pm: International Perspective on Patient Foods Intended for the Dietary Management of a Disease or Condition**

- Foods for Special Medical Purposes (FSMP) in Europe
  - Speaker: Basil Mathioudakis, former European Commission – DG SANTE' *(invited)*
- Canadian Modernization of Division 24
  - Speaker: Genevieve D'Annunzio, Abbott Laboratories
- Q&A with Speakers

**3:15 - 4:45pm: New Types of Evidence and Product Innovation: From Patient Needs to Product Design and Development**

- Moderator: Sarah Ohlhorst, American Society for Nutrition
- Panelists:
  - Dr. Peggi Guenter, American Society of Parenteral and Enteral Nutrition (ASPEN's Research Value Proposition Project)
  - Dr. Satya Jonnalagadda, Abbott Nutrition (Product Design Considerations)
  - Dr. Krysa Araujo Torres, Nestle Health Science (Research & Evidence Development)
- Q&A with Panelists

**4:45 – 5:00pm: Wrap-Up and Adjourn**

- Madeline Jurch, Healthcare Nutrition Council

**Day 2**

Wednesday, August 14

**8:30 - 9:00am: Review of Workshop Objectives and Learning from Day 1**

- Speakers: Madeline Jurch, Healthcare Nutrition Council and Sarah Ohlhorst, American Society for Nutrition

**9:00 - 10:30am: Differentiating Foods for Special Dietary Uses and Medical Foods**

- The Current FDA Regulation around Foods for Special Dietary Uses
  - Speakers: U.S. Food and Drug Administration *(invited)* and Jessica O'Connell, Covington & Burling
- Concepts around Differentiating Medical Foods and FSDU
  - Speakers: Jena Rostorfer, Abbott Nutrition, and Alexandre Biella, Nestle Health Science
  - Panel Discussion (Reflections on Medical Food and FSDU concepts)
    - Panelist: Xin Tao, Hogan Lovells
    - Panelist: Barbara Schneeman, UC Davis
    - Panelist: Tim Morck, Spectrum Nutrition
- Q&A with Panelists

**10:30 - 12:00pm: Final Panel on Learnings from the Workshop and Actionable Next Steps**

- Moderator: Tim Morck, Spectrum Nutrition
- Panel Discussion and Q&A with Panelists
  - Panelists: Ann Yaktine, National Academies of Science, Engineering and Medicine *(invited)*; Joan Bishop, Oley Foundation; Barbara Schneeman, UC Davis

**12:00 - 12:15pm: Closing**

- Speakers: Madeline Jurch, Healthcare Nutrition Council and Sarah Ohlhorst, American Society for Nutrition