MEDICAL FOODS WORKSHOP:

## Science, Regulation and Practical Aspects

AUGUST 13-14, 2019 WASHINGTON, DC

# Workshop Agenda

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

**Q&A** with Speakers

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)

### Practicality of the Usage of Medical Foods to Assure Compliance and Meet Nutritional Requirements: Patient Perspective

Laura Wingate, Crohn's and Colitis Foundation

### **Q&A with Speakers**

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

**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

### **ASPEN'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

### **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

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



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