Harmonizing Medical Device Regulation

October 12-13, 2023

CHP 140, HSC Campus, USC

Thursday, October 12

8:30 **Introductions and Orientation**

Moderator: Larry Liberti, PhD, University of Southern California

8:45 **What defines a medical device? Who are the players from manufacturer to clinic?**

Chiaoyun Kuo. PhD, University of Southern California

9:15 **Principles of Medical Device and IVD Classification**

Frances Richmond, PhD University of Southern California

10:00 **Break**

10:15 **Essential Principles of Medical Device Safety and Performance**

Frances Richmond, PhD, University of Southern California

11:30 **Panel Discussion**

Moderator: Larry Liberti, PhD, University of Southern California

Participants: TBA

12:00 **Hosted Lunch**

1:00 **Designing Development Programs under the Essential Principles**

Gerald Loeb, PhD, University of Southern California

Workshop: Active Devices: an example of the application of Essential Principles.

Gerald Loeb, PhD, University of Southern California

2:45 **Break**

3:00 **Risk Management: Principles and Examples**

Darin Oppenheimer, DRSc, BD Technologies

3:45 **Environmental and Human Factors**

Nozomi Yagi, MAS, Infraredx

Friday, October 13

Moderator: Chiaoyun Kuo

9:00 Essentials of Conformity Assessment- lecture and workshop

James Wabby, MHMS, Abbvie

10:30 Break

10:45 In vitro diagnostic devices

You Kyoung Lee, MD, PhD, SCH University

12:00 Hosted Lunch

1:00 Audits and the MDSAP program

Susan Bain, DRSC, USC

2:00 Break

2:15 Principles of Labeling

Sai Tatavarty, MSc, Abbott Diabetes Care

3:00 Workshop: Conformity Assessments and Audits

Susan Bain, DRSC, University of Southern California

3:45 Panel discussion

Moderator: TBA