Asia-Pacific Economic Cooperation

Medical Devices 2021

April 6-8, 2021

Interactive sessions on zoom

NB: 1-2 hours of streamed lectures are provided to precede the interactive sessions

Tuesday, April 6: Definitions and Classification

7:00-7:15 PM Introductions and Orientation

7:15-7:45 PM Applying classifications: Case Studies

Moderator: Frances Richmond, PhD, University of Southern California

Presenter: Gerald Loeb, MD, University of Southern California

Discussants: Benson (Chiaoyun) Kuo, PhD, University of Southern California

You Kyoung Lee, MD, PhD, Soonchunhyang University College of Medicine

7:45-8:30 PM Discussion

Wednesday, April 7: Conformity Assessment and Standards

7:00-7:15 PM Introductions and Orientation

7:15-7:45 PM Problems with Conformity Assessment: Case Studies

Moderator: Benson (Chiaoyun) Kuo, PhD, University of Southern California

Presenter: Susan Bain, DRSc, University of Southern California

Discussants: Frances Richmond, PhD, University of Southern California

Keith Morel, PhD, Qserve Group US, Inc.

7:45-8:30 PM Discussion

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Thursday, April 8: Safety, Performance and Risk

7:00-7:15 PM **Introductions and Orientation**

7:15-7:45 PM **Safety, Performance and Risk: Case Studies**

Moderator: Susan Bain, DRSc, University of Southern California

Presenter: Gerald Loeb, MD, University of Southern California

Discussants: Frances Richmond, PhD, University of Southern California

Darin Oppenheimer, DRSc, Medtronic

7:45-8:30 PM **Discussion**

Regulatory Science Symposium

Principles of Global Clinical Research for Medical Devices

Friday, April 9, 2021 / 9am - 3pm Pacific

Asia-Pacific Economic Cooperation | USC School of Pharmacy International Center for Regulatory Science | SC CTSI

9:00 AM PST	**Introduction** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences l Associate Director, DK Kim lnternational Center for Regulatory Science
9:30 AM PST	**Clinical Investigation: Principles from Harmonized Documents** *Maria E. Donawa, MD* President, DONOWA LIFESCIENCE CONSULTING
10:15 AM PST	**Break**
10:30 AM PST	**Good Clinical Practices and ISO 14155** *Danielle Giroud, RN, MBA* Founder, CEO, MD-CLINICALS
11:15 AM PST	**General Discussion**
11:30 AM PST	**Lunch**
12:30 PM PST	**From Clinical Data to Clinical Evidence** *Cheryl Hergert, MPH* Principal Clinical Quality Specialist, Medtronic
1:15 PM PST	**Break**
1:30 PM PST	**Developing Clinical Evaluations** *Evangeline Loh, PhD, RAC (US, EU)* Global Regulatory Manager, Emergo by UL
2:15 PM PST	**Panel Discussion**
2:45 PM PST	**Wrap-Up** *Eunjoo Pacifici, PharmD, PhD* USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences l Associate Director, DK Kim lnternational Center for Regulatory Science

Please complete the course evaluation survey at the end of the symposium to receive a certificate of completion. Hours may be eligible for SoCRA and/or ACRP credit.

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