Medical Devices…and More

April 30-May 2, 2019

CHP 140, HSC Campus, USC

Tuesday, April 30

9:00-9:20 **Introductions and Orientation**

9:20-10:00 **What is a medical device? Who are the players?**

Frances Richmond, PhD, University of Southern California

10:00-10:15 **Break**

10:15- 10:45 **Introduction to Essential requirements**

Frances Richmond, PhD, University of Southern California

10:45-11:30 **The Central Role of Risk Management**

Darin Oppenheimer, DRSc, Merck

11:30-12:15 **Panel Discussion**

Hosted Lunch

1:00-1:45 **Role of Standards**

Keith Morel, PhD, Qserve Group

1:45-2:30 **Design Controls for Safety and Performance**

Gerald Loeb, PhD, University of Southern California

2:30-2:45 **Break**

2:45-3:15 **Chemical, Physical and Biological Properties**

Michael Yartzoff, MS, Edwards Life Sciences

3:15-3:45 **Combination products**

Nayan Patel, MS, Amgen

3:45-4:30 **Environmental and Human Factors**

Nishchay Gupta, Genentech

Wednesday, May 1

9:00- 9:45 **Infection and Microbial Contamination**

Susan Bain, DRSc, University of Southern California

9:45-10:30 **Active medical devices**

Gerald Loeb, PhD, University of Southern California

10:30-10:45 **Break**

10:45-11:30 **In vitro diagnostic devices**

Arul Sterlin, MRSc, Abbott

11:30 -12:00 **Workshop**

Hosted Lunch

1:00- 1:45 **Essentials of Conformity Assessment**

Frances Richmond, DRSc, University of Southern California

Susan Bain, DRSc, University of Southern California

1:45-2:15 **Audits and the MDSAP program**

Michael Chan, US FDA

2:15-2:30 **Break**

2:30-3:30 **Labeling**

Dawn Fowler, Masimo

3:30-4:30 **Panel discussion**

Day 3: Field Trip

9:15 **Depart for Irvine**

10:30-12:00 **Tour of Edwards Life Sciences**

12:00-1:00 **Lunch**

1:00-3:00 **Optional field experience**

6::00 **Meet transportation to Gala**

6:30-9:30 **Gala**

Day 4:

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

Regulatory Science Boot Camp:

Clinical Trials with Medical Devices

Friday, May 3rd, 2019
9:00am - 4:00pm

USC-HSC John Stauffer Pharmaceutical Sciences Center Room 112 (PSC 112)
1985 Zonal Avenue | LA, CA 90089

You will receive a certificate of completion at the end of the boot camp. Hours may be eligible for SoCRA and/or ACRP credit.

RSCI 521 credit available upon approval.
Contact Toni Rodriguez | tonirodr@usc.edu.

Register Here

Tentative Agenda

8:15 am	**Check-In & Breakfast**
9:00 am	**Introduction** | Eunjoo Pacifici, PharmD, PhD USC, SC-CTSI, School of Pharmacy | *Director, D.K. Kim International Center for Regulatory Science* USC, School of Pharmacy | *Associate Professor, Dept. of Reg. & Quality Sciences*
9:40 am	**History, Terms/Definitions and Regulatory Requirements** | Frances Richmond, PhD USC, School of Pharmacy | *Chair & Professor, Dept. of Reg. & Quality Sciences*
10:45 am	**Break**
11:05 am	**Institutional Review Board Views on Medical Device Trials**
11:45 pm	**Lunch (provided) & Networking**
1:00 pm	**Feasibility Trials from Industry Perspective; Case Study and Lessons Learned** Lusin Markaryan, MS | SetPoint Medical | *Vice President of Regulatory Affairs*
1:40 pm	**Advanced International Trials with Medical Devices** | Tracy Cameron, PhD T Cameron Consulting | *Clinical and Regulatory Consultant*
2:10 pm	**Break**
2:30 pm	**Auditing of Medical Device Trials** | C. Benson Kuo, PhD USC, School of Pharmacy | *Assistant Professor, Dept. of Reg. & Quality Sciences*
3:05 pm	**Gaps and Opportunities in Pediatric Device Trials** | Juan Espinoza, MD, FAAP CHLA, SC-CTSI | *Director, Consortium for Technology & Innovation in Pediatrics*
3:45 pm	**Wrap-Up** | Frances Richmond, PhD & Amelia Spinrad, MS USC, School of Pharmacy | *Chair & Professor, Dept. of Reg. & Quality Sciences* USC, SC-CTSI, D.K. Kim International Center for Regulatory Science | *RKS Project Administrator*
4:00 pm	**Adjourn**