RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

Title US Regulatory Essentials, Devices
Date Tuesday, 01 September 2020 (9:00 AM) - Wednesday, 02 September 2020 (2:00 PM) Eastern Time (US & Canada)

Facilitators:

- **David Chadwick Director, Regulatory Affairs / Regulatory Science, Cook Medical**
- **Christie Hughes, Consultant, Qserve Group US. Inc**
- **Wade Schroeder, Medical Device Guru, Greenlight Guru**
- **Mark DuVal, President & CEO, DuVal & Associates, P.A.**
- **Tony Blank, Senior Advisor, Barton & Blank**

Agenda:
Day 1:

8:45 AM EST	**Attendees logged into the webinar and placed in a virtual waiting room**
9:00 – 9:20 AM EST	**Welcome and Workshop Overview** • **FDA history** • **FDA organization** • **DICE role** **David Chadwick, PhD, RAC, FRAPS, director, regulatory science, Cook Medical**
9:20 - 10:45 AM EST	**Overview of Medical Devices and IVDS** • **Classification** • **513(g) and de novo** • **PMA perspectives** • **510(k) perspectives** • **IDE and HDE perspectives** • **Clinical conduct perspectives**
10:45 AM – 11:00 AM EST	**Break**
11:00 - 12:15 PM EST	**Medical Device Breakout** • **Tony Blank, senior advisor, Barton & Blank, LLC** **IVD Breakout** • **Christie Hughes, principal consultant, Qserve Group US Inc.**
12:15 - 1:00 PM EST	**Lunch**
1:00 – 2:00 PM EST	**QSR/QMS and Design Control** **Wade Schroeder, greenlight.guru**
2:00 PM EST	**Adjourn**

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Day 2:

8:45 AM EST	**Attendees logged into the webinar and placed in a virtual waiting room**
9:00 - 9:05 AM EST	**Welcome Back** **David Chadwick, PhD, RAC, FRAPS, director, regulatory science, Cook Medical**
9:05- 10:15 AM EST	**QSR/QMS and Design Control (continued)** **Wade Schroeder, greenlight.guru**
10:15- 10:45 AM EST	**Postmarket Compliance is No Easy Journey** • **Complaint handling and management** • **Understanding medical device reporting** • **Corrections/Removals (recalls)** **David Chadwick, PhD, RAC, FRAPS, director, regulatory science, Cook Medical**
10:45 AM - 11 AM EST	**Break**
11:00 - 11:30 AM EST	**Postmarket Compliance is No Easy Journey (continued)** • **Complaint handling and management** • **Understanding medical device reporting** • **Corrections/Removals (recalls)** **David Chadwick, PhD, RAC, FRAPS, director, regulatory science, Cook Medical**
11:30 - 12:15 PM EST	**Lunch**
12:15-1:00 PM EST	**Navigating an FDA Inspection and Aftermath** **The knock on the door** **Conduction inspection** **Close-out meeting** **Post-inspection and enforcement** **David Chadwick, PhD, RAC, FRAPS, director, regulatory science, Cook Medical**
1:00 Pm-2:30 PM EST	**Advertising, Promotion and Labeling** **Label and labeling** **Claims substantiation** **Lessons learned from warning letters** **Disseminating information about unapproved devices** **Intended vs. off-label use** **Direct-to-consumer advertising** **Social media** **Mark DuVal, CEO & President, DuVal & Associates, PA**
2:30 PM EST	**Wrap-up and Thank You**