US Regulatory Essentials, Medical Devices and IVDs
Monday, 1 October 2018

8:00 am	**Registration and Continental Breakfast**	
9:00 am	**Welcome and Workshop Overview** • FDA history • FDA organization • DSMICA role **David E. Chadwick, PhD, RAC, FRAPS,** director, regulatory affairs/regulatory science, Cook Inc.	
9:15 am	**Overview of Medical Devices and IVDS** • Classification • 513(g) and de novo • PMA perspectives • 510(k) perspectives • IDE and HDE perspectives • Clinical conduct perspectives	
	Medical Device Breakout **Tony Blank,** senior advisor, Infinity Biomedical	**IVD Breakout** **Lorry Weaver Huffman, MT (ASCP), CLS,** principal consultant, Qserve Group US Inc.
10:30 am	**Refreshment Break**	
11:00 am	**Medical Device Breakout (continued)** **Tony Blank,** senior advisor, Infinity Biomedical	**IVD Breakout (continued)** **Lorry Weaver Huffman, MT (ASCP), CLS,** principal consultant, Qserve Group US Inc.
12:00 pm	**QSR/QMS** **Tom Rish,** consultant, greenlight guru	
12:30 pm	**Lunch**	
1:30 pm	**Design Control** **Tom Rish,** consultant, greenlight guru	
2:15 pm	**Postmarket Compliance is No Easy Journey** • Complaint handling and management • Understanding medical device reporting and eMDR • Corrections/Removals (recalls) and statistics **Rita Hoffman, RAC,** principal consultant, Regs & Recall Strategies, LLC	

3:15 pm	**Refreshment Break**
3:30 pm	**Navigating an FDA Inspection and Aftermath** • The knock on the door • Conduction inspection • Close-out meeting • Post-inspection and enforcement **Rita Hoffman, RAC,** principal consultant, Regs & Recall Strategies, LLC
4:15 pm	**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, FRAPS, JD,** president, duval & associates
5:00 pm	**Adjourn**