WORKSHOP ON MEDICAL DEVICE GOOD REGULATORY PRACTICES
(GRP/REGULATORY CONVERGENCE)
AND INTERNATIONAL STANDARDIZATION

ADVAMED
701 Pennsylvania Ave NW – Suite 800

AGENDA

Friday January 19, 2018		
7:30-8:15 am	1	**Opening Items**
7:30-8:00	1.0	Networking Breakfast and Registration
8:00-8:05	1.1	**Welcome** *Ralph Ives, Executive Vice President* *Global Strategy & Analysis, AdvaMed*
8:05-8:10	1.2	**Introductions and Administrative Items** *Steven Bipes, AVP, Global Strategy & Analysis, AdvaMed*
8:10-8:15	1.3	**Review of Agenda** *Marisol Sánchez González* *Executive Director, Colombian Medical Device Chamber (ANDI-CDMIS);* *Chair, Latin American Medical Device Alliance (ALDIMED)*
8:15-8:20	1.4	**Brief Overview of Topics in Medical Device Regulation that Can Benefit from Increased Regulatory Convergence and Use of International Standards:** *Natalia Valbuena, Sr. Manager, Regulatory Affairs Latin America, Medtronic;* *AdvaMed Colombia Working Group Regulatory Affairs Coordinator*
8:20-8:25	1.5	**Opening Remarks** *Dr. Elkin Hernán Otálvaro Cifuentes* *Director of Medical Devices and Other Technologies, INVIMA*
8:25-10:10 am	2	**Standards Alliance Initiative**
8:25-8:30	2.1	**Overview - Standards Alliance Project – GRP/Regulatory Coherence & Medical Device Regulatory Convergence (Tiers 1 & 2)** *Jessica Roop - Manager, International Policy* *Sharon Okello - Program Administrator* *American National Standards Institute (ANSI)*
8:30-8:40	3.1	**Standards Alliance Tier 2 International Benchmark Documents:** • **WHO GRP Guidelines for National Authorities of MD Products**

		• **WHO Global Model Regulatory Framework for Medical Devices** • **AHWP Playbook for Implementation of Medical Device Regulatory Frameworks** • **ISO 16142-1 and -2 Standards and referenced Standards** *Ms. Nicole Taylor Smith* *Sr. Director, Global Regulatory Affairs Policy and Intelligence Medical Devices* *Johnson & Johnson*
8:40-9:00		**AdvaMed Presentation**
8:40-9:00	3.2	**United States Context – Overview of Key US Policies Pertaining to Medical Device Regulation** • **21st Century Cures** • **MDUFA** *Ms. Janet Trunzo* *Senior Executive Vice President – Technology and Regulatory Affairs* *AdvaMed*
9:00-11:00 am	4	**USFDA Presentations**
9:00-9:30	4.1	**FDA CDRH Overview** ***Scott Colburn, CAPT, USPHS*** *Director, CDRH Standards Program* *Office of the Center Director* *Center for Devices and Radiological Health* *U.S. Food and Drug Administration* ***Melissa Torres*** *Associate Director for International Affairs* *Office of the Center Director* *Center for Devices and Radiological Health* *U.S. Food and Drug Administration*
9:30-10:00	4.2	**FDA Standards Overview, Resources, CDRH Recognition**
10:00-10:30	4.3	**IMDRF Update including Standardization Working Group**
10:30-11:00	4.4	**MDSAP Program**
11:00-11:10 am		**Break**
11:10-11:40	5	**Overview of International Standardization & Conformity Assessment**
11:10-11:25	5.1	**Overview of International & U.S. Standardization & Conformity Assessment** *Jessica Roop - Manager, International Policy* *Sharon Okello - Program Administrator* *American National Standards Institute (ANSI)*

11:25-11:40	5.2	**Overview of Colombian Health Standardization** *Yohany Andres Hernandez Velandia* *Standardization Professional for Healthcare Services* *Colombian National Standards Body (ICONTEC)*
11:40-1:00 pm	6	**Overview of Standards for Medical Devices** (ISO, IEC, AAMI, ASTM, MITA, et al)
11:40-12:00	6.1	**American Association of Medical Instrumentation (AAMI)** *Joe Lewelling* *Vice President, Emerging Technologies and Health IT* *AAMI*
12:00-12:20	6.2	**ASTM International** *Pat A. Picariello, J.D., CStd, FSES* *Director, Developmental Operations* *ASTM International*
12:20-1:00	6.3	**Q&A**
1:00-2:00 pm		Lunch
2:00-4:30 pm	7	**Colombian Medical Device Regulation**
2:00-2:30	7.1	**Overview of Colombian Health Regulation Development Process** *Dr. Elkin Hernán Otálvaro Cifuentes* *Director of Medical Devices and Other Technologies, INVIMA*
2:30-2:45	7.2	**Overview of Colombian MOH & INVIMA Standardization Policy & Practices** *Dr. Elkin Hernán Otálvaro Cifuentes* *Director of Medical Devices and Other Technologies, INVIMA*
2:45-4:30	7.3	**INVIMA – Shared Experiences** ***Question for joint review: What international GRP and Standardization tools are available for, and being used by, Medical Device regulators to address the topics below?*** **Topics for Discussion:** ▪ Overall Context of Medical Devices in Colombia ▪ Premarket Surveillance: Benchmarked Efficacy Evaluation, Stent Guidelines, Catheter Guidelines, Osteosynthesis Material Guidelines, Sterilization Station Guidelines. ▪ Draft of Good Manufacturing Practices

		▪ Post-market Surveillance: National Technosurveillance Program, National Reagent Surveillance Program, Quality Demonstration Program – Quality Control Program. ▪ Reprocessing and Reuse of Medical Devices ▪ Anatomic Components ▪ Donor Traceability
4:30-5:00	7.4	**Q&A**
5:00-5:30	7.5	**Overview of Pacific Alliance GRP/Regulatory Coherence and MD Regulatory Convergence Initiatives** *Marisol Sánchez González* *Executive Director, Colombian Medical Device Chamber (ANDI-CDMIS);* *Chair, Latin American Medical Device Alliance (ALDIMED)*
5:30-5:45	8	**Next Steps** **Standards Alliance Project - Medical Device Regulatory Convergence (Tier 2)** *Leticia Seixas Fonseca, Executive Director, Latin American IVD Alliance;* *Standards Alliance Tier 2 Project Manager*
5:45-6:00 pm	9	**Other Items / Closing Remarks**