AGENDA:
PERU Workshop on Medical Device Regulation and Standards: Policy and Technical Aspects

HOST: ASTM Latin America, Lima, PERU
Calle Monterosa 233
of. 402 Charcarilla
Surco, Lima 33 PERU
Phone: +51 (1) 205-5502
DATE**: 2 Days, January 24-25, 2017**

Primary Audience: Government Regulators, National Medical Device Technical Committee, Medical Device Users/Purchasers from Hospitals, Companies, and Testing Laboratories

8:00 a.m.	Registration
8:30 a.m.	Logistical Announcements- INACAL – Soraya Lastra
9:00 a.m.	Welcoming Remarks – María Isabel Barrios, ASTM International
9:10 – 9:25 a.m.	United States: ANSI/Standards Alliance perspective, Jessica Roop, ANSI, Standards Alliance Program
9:25 – 9:40 a.m.	Peru National Standards System, Rosario Uria Toro, Director, INACAL (National Institute of Quality- Peru)
9:40 – 9:45 a.m.	Photo Opportunity of Welcoming Speakers and the Keynote Speakers, and of Attendees with all Speakers
Day 1	**Components of Good Regulatory Practice in Healthcare**
9:45 – 10:15 a.m.	**Session 1:** Overview of Good Regulatory Practice Experts will discuss the Code of Good practice, WTO-TBT, the role of standards in regulation, and Regulatory Impact Assessment. **Speaker:** "TBT Agreement and Good Regulatory Practices" Rocío Barreda, Ministry of Foreign Trade and Tourism (MINCETUR) representative
10:15 – 10:45 a.m.	Coffee Break

10:45 – 12:00 p.m. **Session 2:** How to Use Medical Device Standards in Regulation

This session will examine best practices in forging regulations and the use of standards for medical technology products; including Peru's Directorate General for Medicines, Supplies, and Drugs (DIGEMID), and the US Food and Drug Administration, FDA.

Moderator: ANSI – Jessica Roop

Speakers:

"Regulation of Medical Devices in Peru" – Sonia Delgado, DIGEMID representative, Directorate General for Medicines, Supplies and Drugs (DIGEMID)

"Overview of the US Medical Device Regulatory Premarket Process" – Terry Woods, PhD Laboratory Leader, Solid Mechanics Laboratory, FDA Center for Devices & Radiological Health, Office of Science & Engineering Laboratories, Division of Applied Mechanics of US FDA.

12:00 – 1:30 p.m. Luncheon

1:30 p.m. – 3:15 p.m. **Session 3:** Public Safety and Medical Device Technology

This session will address safety and health issues and standards' effectiveness in supporting these objectives

Moderator: INACAL – Rosario Uría Toro

Speakers:

- Jorge Alberto Fernández Vargas - National Center of Quality Control (CNCC) representative, National Institute of Health (INS)
- Terry Woods, Ph.D., US FDA "Terry Woods: "Utility of standard material test methods in medical device development"
- Brian Berg, Senior Research Fellow, Boston Scientific ,"Utility of standards for a manufacture"

3:15- 3:30 p.m. Coffee Break

3:30 – 4:45 p.m. **Session 4:** Developing Sustainability

Regulating medical technology devices as an ongoing process using standards. This session will include success stories.

Moderator: Secretary of Technical Subcommittee of Medical materials – Jaime Torres

Speakers: Peru and US (brief presentations then discussion, Q & A)

- Opportunity of using technical standards in public purchases through reverse auction – Gaby Pachas Tejada - Central of Public Purchases (Perú Compras) representative
- How ASTM Standards and the ASTM/INACAL Memorandum of Understanding Support the Ongoing Process of Regulating Medical Technology Devices– María Isabel Barrios

[*The presentation will be supplemented by comments from ASTM members Spiro Megremis, Steven Spiegelberg, Brian Berg and Dawn Lissy who will share their views/experiences on how private sector standards support the FDA's regulatory role while enabling the private sector to incorporate innovation into regulation*].

4:45 p.m. Day One Regulation-related Conclusions
INACAL

5:35 p.m. Adjourn

Day 2 Medical Device Standards: Technical Training- Material Test Methods

8:30 a.m. Registration

9: 00 a.m. Logistical Announcements –INACAL

9:15 – 10:00 a.m. **Session 1:** ASTM Background and Resources-
Overview of the ASTM Technical Committee F04 on Medical and Surgical Materials Methods, F04.15.

Stakeholder Participation in ASTM– an Overview of the ASTM Process and Electronic Tools

Speakers: ASTM International- María Isabel Barrios, ASTM,
Terry Woods, Ph.D., US- FDA,
Spiro Megremis, PhD., Director, Research & Laboratories, Science Institute, American Dental Association, ADA

10:00 – 10:30 a.m. Coffee Break

10:30 – 11:15 a.m. **Session 2:** Technical Training: Medical Device Professional Society Perspective-- ASTM Material Test Methods for Assessing Corrosion
Q & A
Speaker: Spiro Megremis, Director, Research & Laboratories, Science Institute, American Dental Association, ADA

11:15-12:00 p.m.	**Session 3:** Technical Training: Medical Device Contract Test Company Perspective — ASTM Material Test Methods for Assessing the Performance of Orthopedic Devices **Speaker:** Dawn Lissy, President, Empirical Technologies
12:00 – 1:15 p.m.	Luncheon
1:15 - 2:00 p.m.	**Session 4:** Technical Training: Medical Device Manufacturer Perspective – ASTM Material Test Methods for Assessing the Performance of Cardiovascular Devices **Speaker:** Brian Berg, Senior Research Fellow, Boston Scientific
2:00 – 2:45 p.m.	**Session 5:** Technical Training: Medical Device Contract Test Company Perspective – ASTM Material Test Methods for Analytical Testing and Assessing Device Cleanliness **Speaker:** Stephen Spiegelberg, President, Cambridge Polymer Group
2:45 - 3:15 p.m.	Coffee Break
3:15- 4:15 p.m.	**Session 6:** Panel on Medical Device Standards: Questions and Answers **Speakers:** Dr. Woods, Dr. Megremis, Ms. Lissy, Dr. Berg, Dr. Spiegelberg Moderator: María Isabel Barrios
6:00 p.m.	Adjourn Workshop – Rosario Uría, INACAL