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 Uria Toro

**Speakers:**

- Jorge Alberto Fernández Vargas - National Center of Quality Control (CNCC) representative, National Institute of Health (INS)
- 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 and Devices, and Subcommittee on Material Test 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, Ph.D., Director, Research & Laboratories,
Science Institute, American Dental Association, ADA

10:00 – 10:30 a.m. Coffee Break

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