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

HOST: ASTM Latin America, Lima, PERU
Calle Monterosa 233
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Surco, Lima 33 PERU
Phone: +51 (1) 205-5502
DATE: 3 Days, November 2-4, 2015

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 – TBD
8:45 a.m.	Welcoming Remarks – - Rocio Barrios, Executive President, INACAL (National Institute of Quality- Peru) - María Isabel Barrios, ASTM International
9:00 a.m.	Photo Opportunity of Welcoming Speakers and the Keynote Speakers, and of Attendees with all Speakers
9:20-- 9:40 a.m.	Peru: Quality National System, Rosario Uria, INACAL
9:40 – 9:45 a.m.	United States: ANSI/Standards Alliance perspective, Jessica Roop, ANSI, Standards Alliance Program

Day 1 Components of Good Regulatory Practice in Healthcare

9:45 – 10:30 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.

Moderator: INACAL –Augusto Mello

Speaker(s):

- Rocío Barreda, Ministry of Foreign Trade and Tourism (MINCETUR) representative,
- Nathan Frey, U.S Office of Management and Budget. (virtual connection)

10:30 – 11:00 a.m. Coffee Break

11:00 – 12:30 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 cases from Peru's Directorate General for Medicines, Supplies and Drugs (DIGEMID), and the US Food and Drug Administration, FDA.

Moderator: ANSI – Jessica Roop

Speakers:

- Pedro Sánchez, DIGEMID representative, Directorate General for Medicines, Supplies and Drugs (DIGEMID)
- "Overview of Regulatory Requirements: Medical Devices" - A US-FDA Video (Video and slides available in Spanish) (*FDA participation, by WebEx to address questions TBC*)

- A Case Study: Implementation of ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes and Peruvian regulations. Corina Canales, Tagumedica Co. SA

12:30 – 1:45 p.m. Luncheon

1:45 p.m. – 2:45 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

Speakers:

- Quality Control of Medical devices in the National Center of Quality Control, Carlos Huamaní - National Center of Quality Control (CNCC), National Institute of Health (INS)

- María Isabel Barrios - A brief review of ASTM International and an introduction to the relevance of the Food and Drug Modernization Act of 1997 (Section 204) and the National Technology Transfer and Advancement Act

2:45 – 3:15 p.m. Coffee Break

3:15 – 4: 30 p.m. **Session 4:** Developing Sustainability

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

Moderator: INACAL – Rosario Uría

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

- Opportunity of using technical standards in public purchases through reverse auction, Jan Karlo Zavalaga, Sub Directorate of Special Process - Supervisory Body of the State Peru representative (OSCE),
- 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 Ken St. John and Ken Perry who will share their views/experiences on how private sector standards support the FDA's regulatory role and objectives while enabling the private sector to incorporate innovation into regulation*].

4:30 p.m. Day One Regulation-related Conclusions
INACAL

4:45 p.m. Adjourn

Day 2 Medical Device Standards: Overview of Committee and Technical Training-Biocompatibility Test Methods

8:30 a.m. Registration

9: 00 a.m. Logistical Announcements –INACAL

9:15 – 10:15 a.m. **Session 1:** ASTM Background and Resources-

- Overview of the ASTM Technical Committee F04 on Medical and Surgical Materials and Devices and.
  Stakeholder Participation in ASTM– an Overview of the ASTM Process and Electronic Tools

Speaker: ASTM International- María Isabel Barrios, ASTM,

10:15 – 10:45 a.m.	Coffee Break
10:45 –2:00 p.m.	**Session 2:** Technical Training: Medical Devices-- ASTM Quality and Performance Standards: Biocompatibility, Test Methods ASTM F748-06(2010) Selecting Biological Test Methods **Speaker:** Kenneth St. John, Ph.D.
12:00 – 1:30 p.m.	Luncheon
1:30-2:30 p.m.	**Session 3:** Medical Device Biocompatibility: ISO TC194 Overview and 10993 Standards **Speaker:** Jon Cammack, Ph.D.
2:30- 3:30 p.m.	**Session 4:** Technical Training: Medical Devices – ASTM Quality and Performance Standards: Biocompatibility, Test Methods, ASTM F748-06(2010) Case Study, and possibly overview F2901-Guide to Evaluating Potential Neurotoxicity **Speaker:** Kenneth St. John, Ph.D.
3:30 - 3:45 p.m.	Coffee Break
3:45- 4:45 p.m.	**Session 5:** Technical Training: Medical Devices – ASTM Quality and Performance Standards; Testing Biomaterials, ASTM F719-81(2012) Testing Biomaterials in Rabbits for Skin Irritation and F720-13 Testing Guinea Pigs for Contact Allergens **Speaker:** Kenneth St. John, Ph.D.
4:45 – 5:00 p.m.	Day Two Conclusions INACAL
5:00 p.m.	Adjourn

Day 3 — Medical Device Standards: Technical Training on Cardiovascular Materials or Device Aspects

8:00 a.m.	Registration and Morning Coffee
8:45 a.m.	Logistical Announcements, INACAL
9:00 – 10:15 a.m.	**Session 1:** Technical Training—Cardiovascular, F2514 - 08(2014)

	Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading **Speaker:** Kenneth Perry, PhD., EchoBio, LLC
10:15 – 10:45 a.m.	Coffee Break
10:45 –2:00 a.m.	**Session 2:**Technical Training- Cardiovascular, Test Methods Stents, ASTM F2477-07(2013) Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents, plus some on Shelf-life Test Attributes for Endovascular Devices ASTM F2914-12 **Speaker:** Kenneth Perry, PhD., EchoBio, LLC
12:00 – 1:30 p.m.	Luncheon
1:30 - 2:30 p.m.	**Session 3:** Technical Training—Cardiovascular and Current Issues in Materials, Fatigue and Fracture and Testing of Implantable Devices and some Standard Guide for Testing Absorbable Stents, ASTM F3036-13 **Speaker:** Kenneth Perry, PhD. EchoBio, LLC
2:30 - 2:45 p.m.	Coffee Break
2:45- 3:30 p.m.	**Session 4:** Panel on Medical Device Standards: Questions and Answers **Speakers:** Dr. St. John and Dr. Perry Moderator: María Isabel Barrios
3:30 p.m.	Day Three Conclusions INACAL
3:45 p.m.	Adjourn Workshop - INACAL