MDRC Workshop with INMETRO, ANVISA, NIST, FDA

Conformity Assessment of Medical Devices in Brazil and the in U.S.

Objective: Compare regulations and procedures of medical device conformity assessment in Brazil and in the United States. Share experiences between the authorities within the context of international references and regulatory convergence and reliance.

Hybrid Meeting

Venue:
Windsor Plaza Brasília Hotel
SHS Quadra 05 Bloco H, Brasília - Brazil

Date: A half-day session to be held on the 24th of October 2023 in Brasilia during the ANVISA-hosted MDSAP week (to which ANVISA has agreed and INMETRO is available. A hybrid option will be provided for NIST which will only be in Brazil the following weeks).

All times Brazil (GMT-3 = one hour ahead of U.S. Eastern Time)

8:30	**Opening Remarks – Marina Carvalho (MDRC)**
9:00 – 10:00 9:00 – 9h15 9h15 – 9h30 9h30 – 9h45 9h45 – 10h	**Recap Session:** Authorities present briefly their procedures on Conformity Assessment procedures for Medical Devices and introduce questions regarding the procedures of the other authorities. **ANVISA (15min)** **INMETRO (15min)** **FDA (15min)** **NIST (15min)**
10:00 – 10:30	**Coffee break**
10:30 – 11:30	**Discussion session:** Authorities provide answers and comments regarding the procedures and GRP applied to CA of medical devices.
11:30 – 12:00	**Conclusion session and final remarks** Discussion of possible next steps and GRP recommendations.

The meeting will be attended in person by representatives from ANVISA and FDA. INMETRO, NIST and representatives from FDA will be connected virtually.

There will be simultaneous translation through the Zoom platform. We will provide wi-fi on site.

Anyone who is in the room in person and wants to access the information in the other language needs to join Zoom using the link below (via laptop or cell phone) and using headphones to access the translation. You need internet access to access a Zoom meeting.

Below the link for the zoom meeting:

https://us06web.zoom.us/j/81150131998?pwd=xuvJGL1IxXmflvUzl4PIbB6ba9oZsB.1

Suggested Content:

ANVISA

1. Products regulated by ANVISA that use the Conformity Assessment and mechanisms used.
2. Principles for decision making for the use of CA.
3. Advantages in the use of CA, for the achievement of the objectives of the regulation.
4. Relation ANVISA, INMETRO, Product Certification Bodies, Accredited Laboratories
5. Perceptions about the opportunities for improvement regarding the use of CA in the regulation of medical products.
6. Presentation on the use of Good Regulatory Practices, instruments used by the Agencies and what is the "benchmarking" for the definition of their instruments.

INMETRO

1. INMETRO (Brief overview of the organizational structure of the Institute).
2. INMETRO (Board of Directors of Conformity Assessment - activities and performance in Conformity Assessment).
   2.1 Briefly discuss the "regulatory" role.
   2.2 Discuss role with CA.
      2.2.1. What is CA, importance.
      2.2.2. Legal competence to act in CA.
      2.2.3. Acting over time in CA.
      2.2.4. Opportunities for improvement in the management of CA schemes.
      2.2.5. Discuss in a general way the new "services" in advisory and training in CA.
   2.3 Briefly discuss the Conformity Assessment Programs in partnership with ANVISA.
   2.2 Presentation on the use of Good Regulatory Practices, instruments used by the entity and what is the "benchmarking" for the definition of their instruments.

FDA

1. FDA-regulated products that use Conformity Assessment and mechanisms used.
2. "The Accreditation Program for Conformity Assessment (ASCA)".
3. Principles for decision making for the use of CA.
4. Advantages in the use of CA, for the achievement of the objectives of the regulation.
5. Relationship FDA, NIST, Product Certification Bodies, Accredited Laboratories.
6. Perceptions about the opportunities for improvement regarding the use of CA in the regulation of medical products.
7. Presentation on the use of Good Regulatory Practices, instruments used by the Agencies and what is the "benchmarking" for the definition of their instruments.

NIST

1. Overview of the organizational structure of the Institute, highlighting the "Standards Coordination Office" (SCO).
2. The SCO's lines of work as it relates to NIST's role as a coordinator in CA in the U.S., highlighting its interface with federal agencies.
3. Among the lines of work address "Conformity Assessment" for Federal Agencies, "Education & Training", "Federal Policy on Standards", "Standardization Coordination".
4. Opportunities for improvements in the management of CA schemes in partnership with other government agencies.
5. Seek to bring examples of work in partnership between NIST and FDA, regarding the use of CA by the FDA.

6. Presentation on the use of Good Regulatory Practices, from the point of view of the coordinator of the use of CA, and what is the "benchmarking" for the definition of its instruments.