Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Western Hemisphere Leadership in Good Regulatory Practices

Using Technology to Improve Public Consultations

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June 22,2021

Outline

- Medical Technology Sector
- Regulatory Convergence
- Our role in supporting GRPs
- Technology & Processes to Improve Public Consultations

Medical Devices: Definitions

- *'**Medical device'** means **any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article,** intended by the manufacturer to be used, alone or in combination, **for human beings, for one or more of the specific medical purpose**(s) of:*

  - ***diagnosis, prevention, monitoring, treatment or alleviation of disease,***
  - ***diagnosis, monitoring, treatment, alleviation of or compensation for an injury,***
  - ***investigation, replacement, modification, or support of the anatomy or of a physiological process,***
  - ***supporting or sustaining life,***
  - ***control of conception,***
  - ***disinfection of medical devices,***
  - ***providing information by means of in vitro examination of specimens derived from***
  - ***the human body;***
  - ***and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.****

* *GHTF/SG1/N071:2012, REFERRED BY IMDRF AT IMDRF/SAMD WG/N10final:2013*

Medical Devices – Wide Variety

3D Printers

Sutures

Catheters

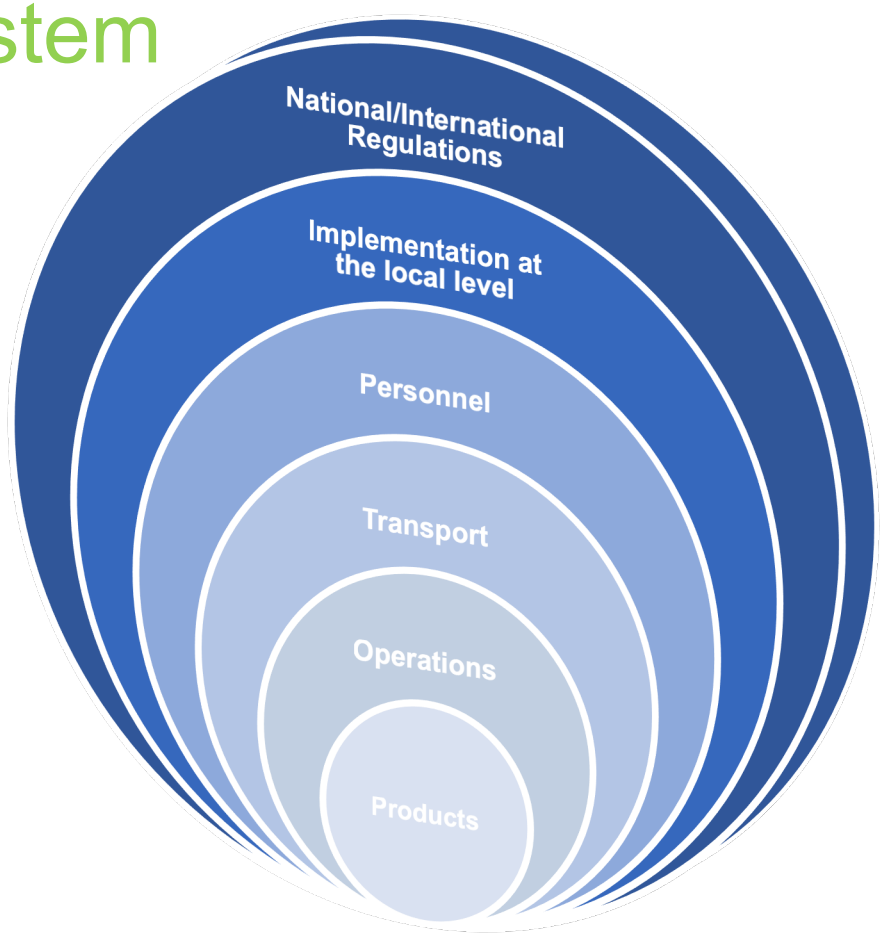
Knee Replacement Implants

Surgical Robots

Computerized Scan Tomography

… and thousands more

The Ecosystem



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The Stakeholders

Global Health Regulatory Frameworks

Global Health Technical References

International Technical Standards

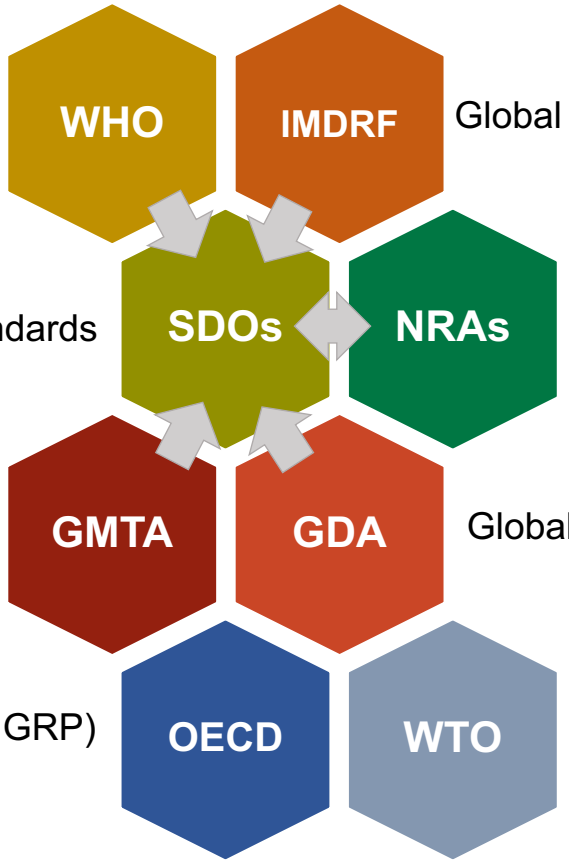
National Regulatory Authorities

Global MedTech Industry

Global Diagnostics Industry

Legal Environment (Transparency & GRP)

Legal Environment (Trade & GRP)



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Regulatory Convergence – MedTech Sector

A concerted public-private effort to systematically pursue and maximize alignment of medical technology sector-specific technical regulations, standards and conformity assessment criteria to globally harmonized international standards for medical technology.

Global Medical Technology Industry

- Eliminate every type of unnecessary barrier between the life-saving and life-improving medical technologies of our manufacturers and the patients in need.

Regulatory Environment

- Highly regulated: low, mid, high risk products
  - Agenda not deregulatory
- Regulatory Convergence:
  - Align cross-border requirements
- Regulation quality
  - Least burdensome
  - Least trade-restrictive

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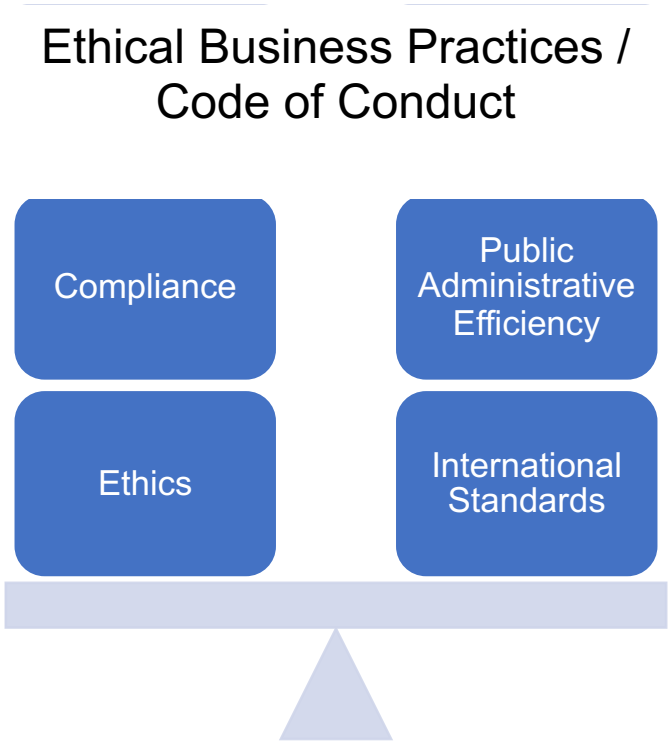
What is the Coalition about?

Vision:
One Standard, One Test accepted everywhere

- Countries: 10
- Principal Members: 17 regional associations
- Member Companies: over 3,000
- Continuous dialog with National Regulatory Authorities for Medical Devices
- Advocating for the use of International Standards: ISO, IEC, CLSI, et al.

Beyond technical regulations



Our role in supporting GRPs

- Foundational – whole of government
  - Development, implementation, enforcement
  - Techological Resources
    - Availability
    - Functionality
- MedTech Specific
  - Development of capacities
    - Tools
    - Processes
    - Local
    - International
    - Trade Obligations – multilateral, bilateral

Our role in supporting GRPs

- Med Tech Specific (cont.)
  - Promoting active participation in technical discussions:
    - SDO's
    - Regulators/Industry
    - Public consultations: local / international
  - Promoting solid science as a base for discussions and decision making
  - Development of consensus positions:
    - International standards and benchmarks

Our role in supporting GRPs

- MedTech Specific – cont.
  - Active tracking of notifications on public consultations
    - National and international
    - Individual companies and trade associations
      - ePing System: Active monitoring and utilization
      - Information sharing with international counterparts
  - Development of consensus positions:
    - International standards and benchmarks
  - Private – public sector actions
    - Enquiry Points
    - Bilateral and international dialog

Good Regulatory Practices (GRP)

- A formalized, mandatory, whole-of-government policy, that defines the common and transparent rules by which regulatory agencies develop technical regulations for all regulated sectors (i.e., cross-sector, transverse, horizontal, foundational) following international standards for GRP.

- GRP is the quality control mechanism for the development of regulations, ensuring on a continuous and systematic basis that government rules are relevant, of the highest quality, cost-effective, internationally aligned and least economically restrictive amongst alternatives of the same purpose.

Technological aids - local

- One established, permanent website where draft regulations are posted
  - User account
  - Push notifications – specific criteria
  - Online commenting
  - Updated regulations drafts – track changes

Technological aids - international

- Standardized web technology
  - Simultaneous commenting: local / international
  - Visibility to non-proprietary comments
  - Authorities response to comments

Q & A

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Thank you!

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