The Role of Standards Development Organizations & Essential Standards for Medical Devices and IVDs

Workshop on Conformity Assessment, Product Imports & International Standards

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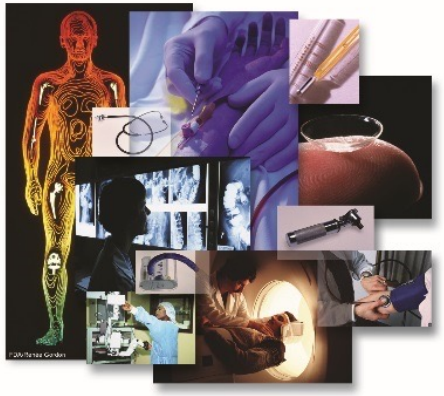
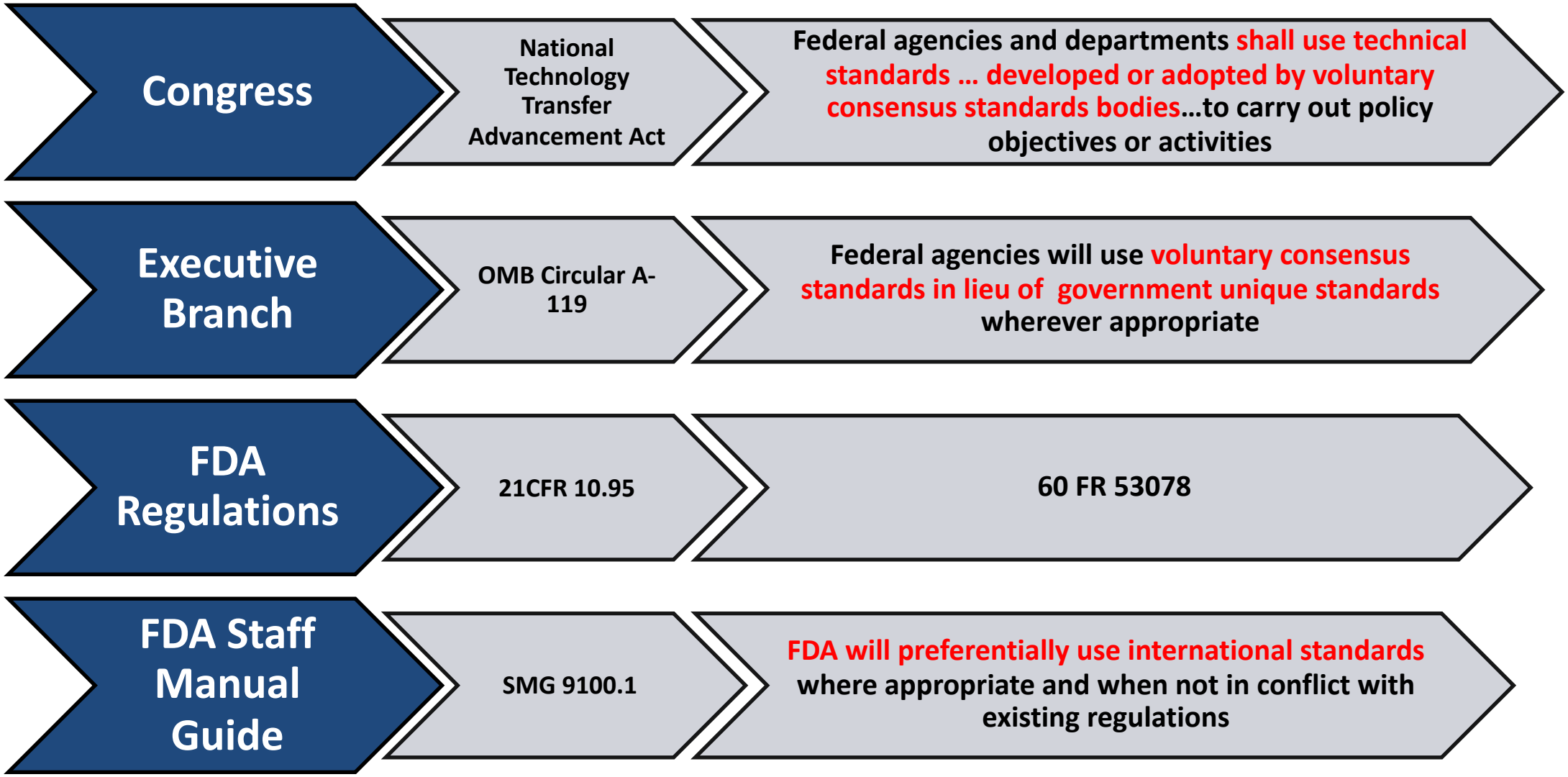
THE ROLE OF STANDARDS DEVELOPMENT ORGANIZATIONS & ESSENTIAL STANDARDS FOR MEDICAL DEVICES AND IVDS



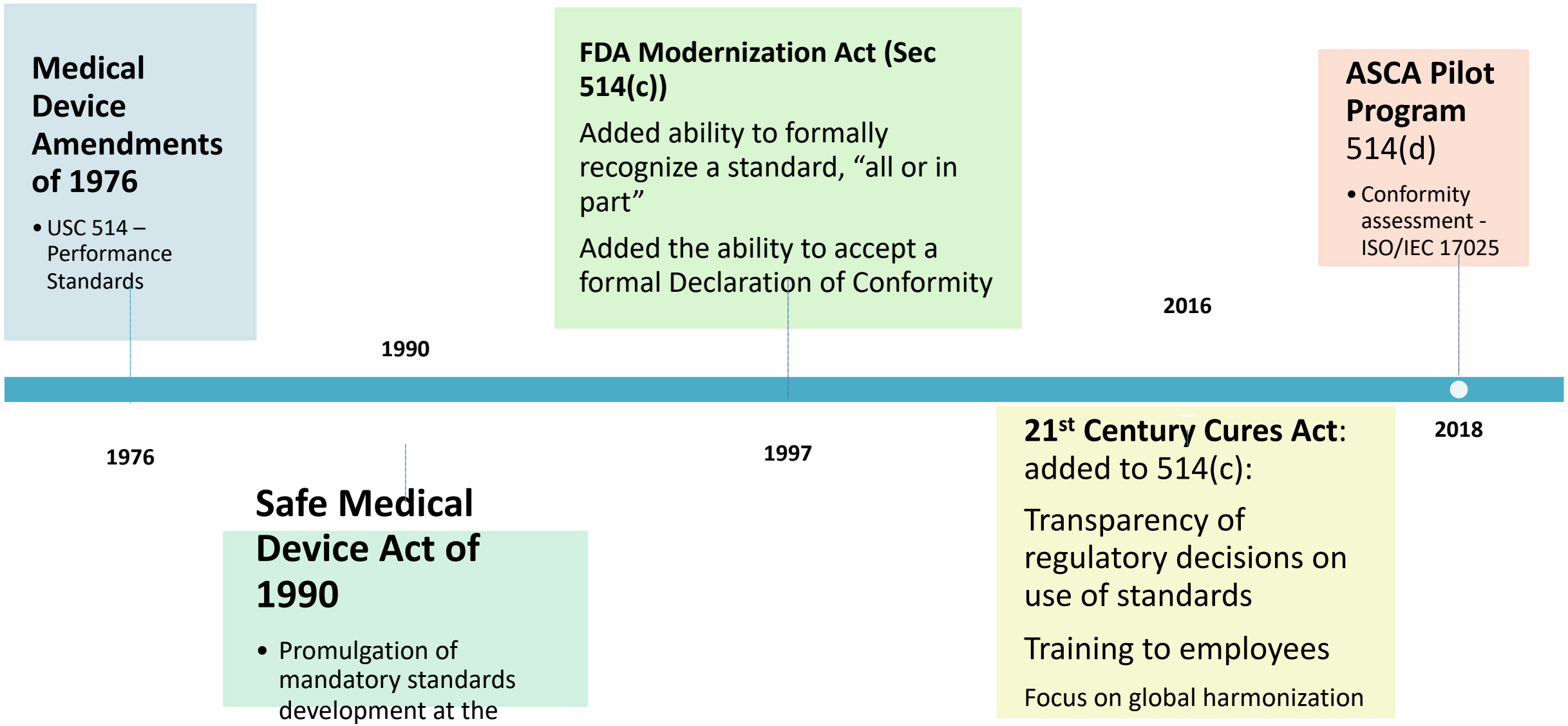
CDRH In Perspective

- CDRH oversees
  - 175,000 medical devices on US market
  - 18,000 medical device manufacturers
  - 25,000 medical device facilities worldwide
- Each year we receive
  - 22,000 premarket submissions (includes supplements and amendments)
  - 1.4 million reports on medical device adverse events and malfunctions

Legislative Authority, Executive Branch Policy and FDA Participation



Evolution of the use of standards at CDRH



Standards Recognition section 514(c)

- 514(c)(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register, **recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity** in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable.

Standards Recognition section 514(c)

- (B) **If a person elects to use a standard recognized** by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, **the person shall provide a declaration of conformity** to the Secretary that certifies that the device is in conformity with such standard. **A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.**

Standards Recognition section 514(c)

- GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and update, if necessary, previously published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), **taking into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry,** and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

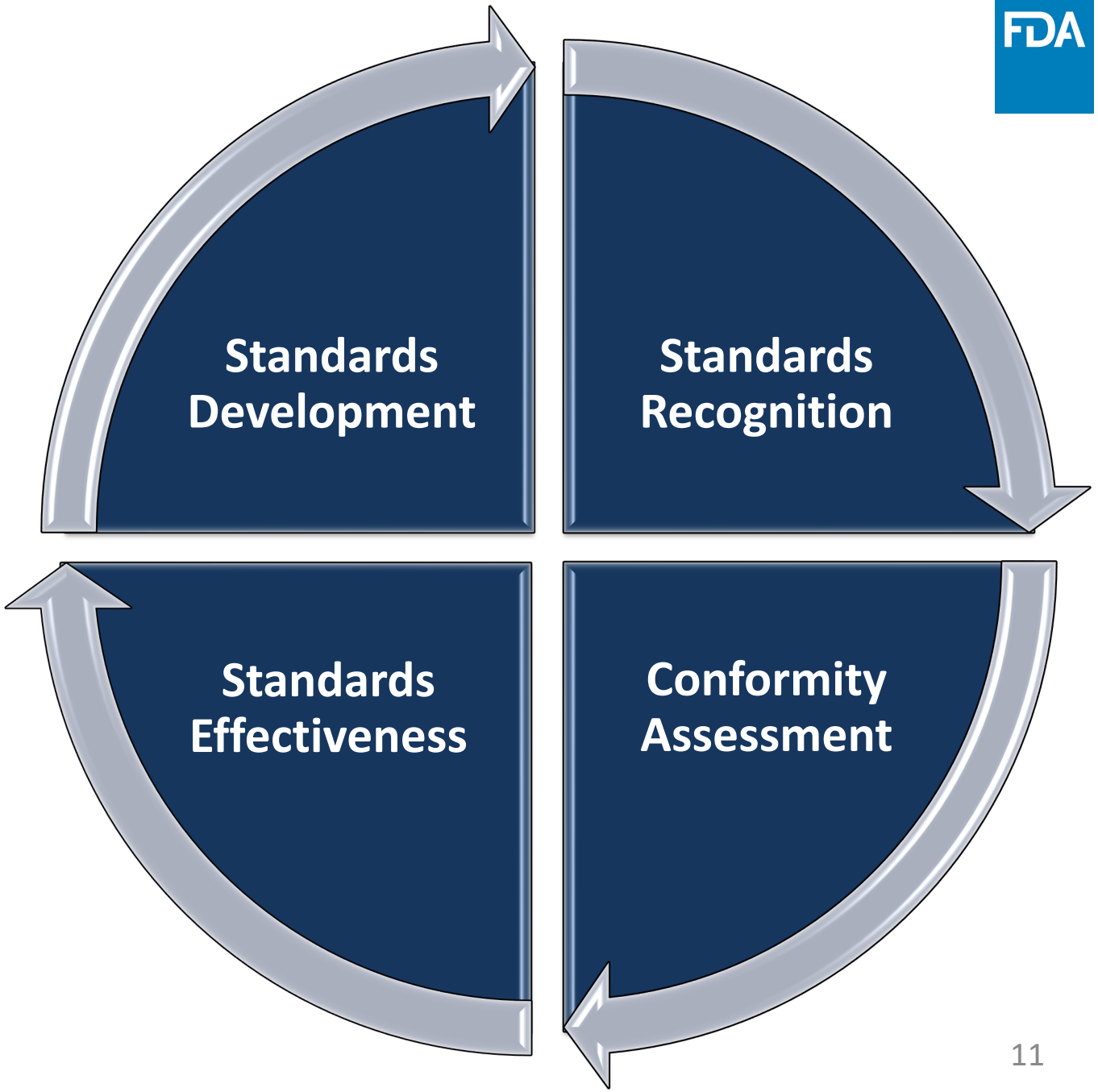
Why Consensus Standards?

- Participation by all stakeholders in standards development including - *especially* - regulators
  - Chance to influence standards during development
- Reduce burdens on manufacturers by harmonizing expectations across jurisdictions
- Streamline conformity assessment
- Promote regulatory science at national and international levels
- Speeds Patient access to safe, effective devices

Using Consensus Standards

- Voluntary
  - Only mandatory if cited in regulation ('incorporated by reference')
- In any type of premarket submission
- With a DOC (recognized standards only) or 'General Use' (any standards, recognized or not)

Standards and Conformity Assessment Program (S-CAP)



S-CAP goal: advance the development and use of regulatory-ready standards

FDA recognized standards

- International Standards:
  - Participate/vote by country: ISO IEC ...
  - Participate/vote by organization: ASTM, IEEE …
- About 30 SDO's with recognized standards
- ASTM, ISO ~ 30 % each
- 7 SDO's cover ~ 90 % of recognized standards

Using FDA-Recognized Standards

FDA strongly encourages the use of recognized standards in premarket submissions

Declarations of conformity (DOCs) are used with recognized standards, reducing documentation submitted to FDA

A DOC is a communication tool, conveying key information to review staff in a coherent and concise fashion

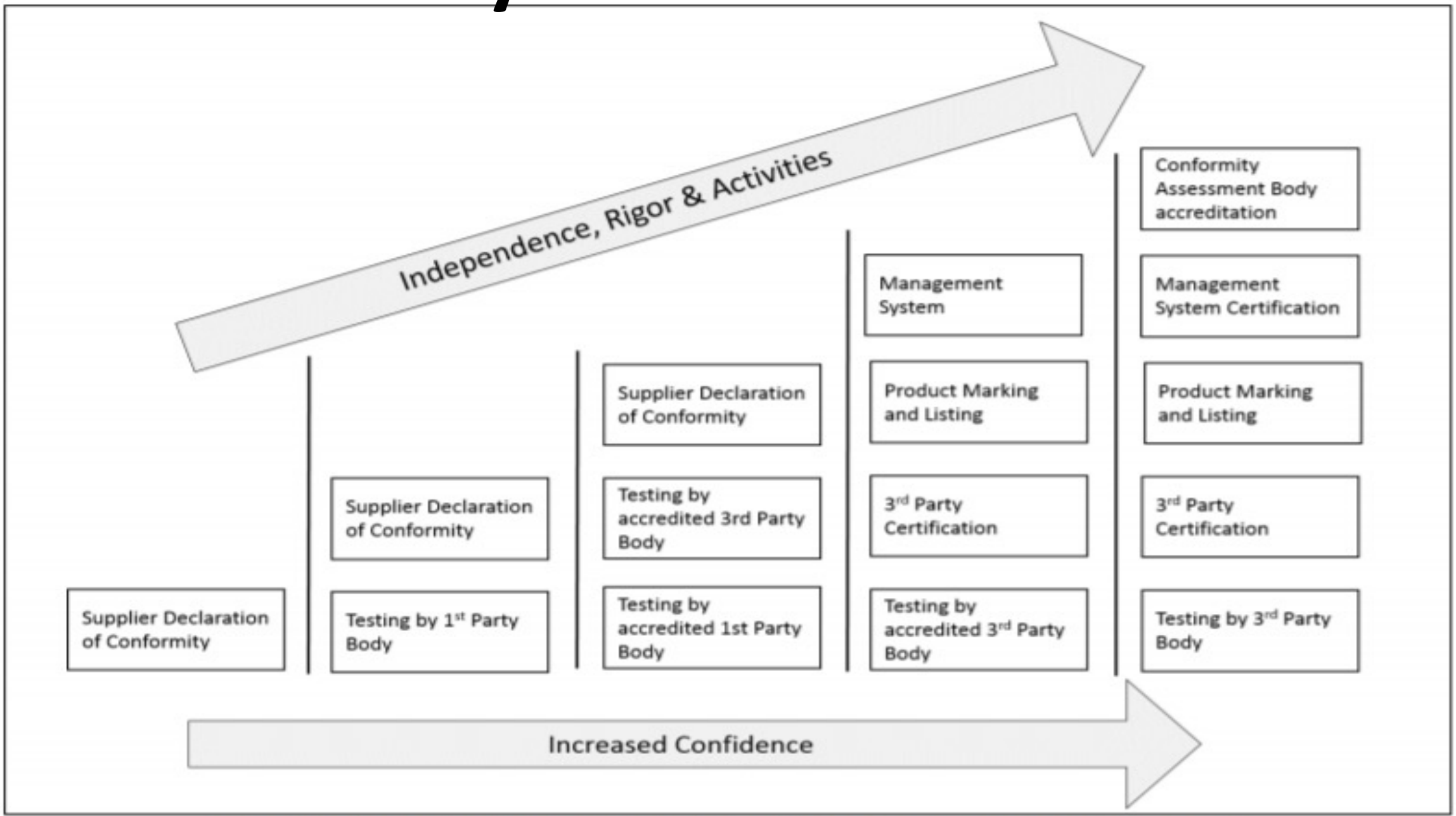
Standards Recognition Program

'Recognition' - FDA's formal identification of a standard after determining that it is appropriate for manufacturers to declare conformance (using a declaration of conformity) to meet relevant requirements.

The FDA:

- Encourages external and internal stakeholders to nominate standards for recognition
- May recognize all, part or none of the standard
- Will publish the decision rationale
- Regularly updates recognition and non-recognition decisions
  - Recognized Consensus Standards Database
  - Non-recognized Consensus Standards Database
- May withdraw recognized standards, as appropriate

Flexibility to Address Confidence



OPTIMIZING STANDARDS FOR REGULATORY PURPOSES

Affiliate Members

Official Observers

World Health Organization

Regional Harmonization Initiatives

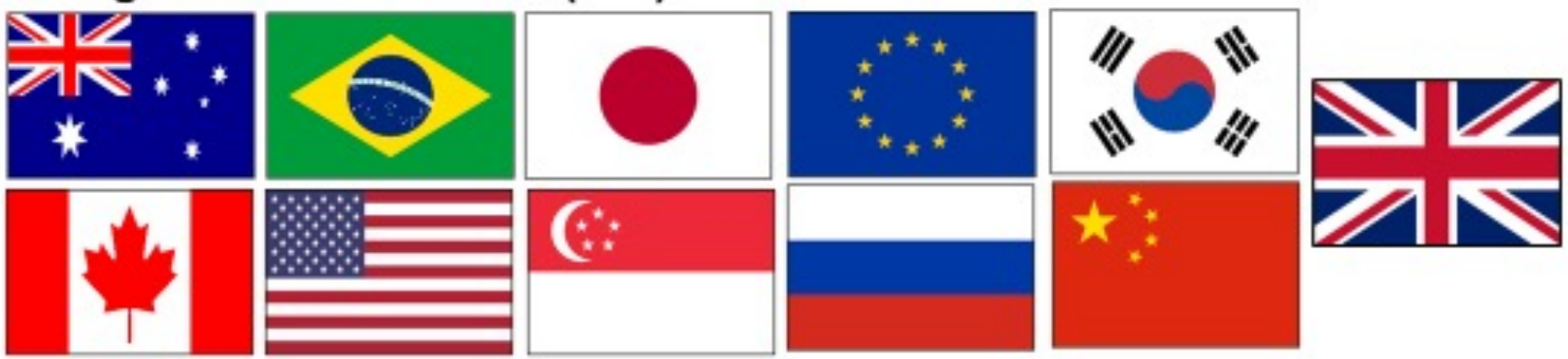
APEC
Asia-Pacific Economic Cooperation

African Medical Devices Forum

Pan American Health Organization

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Management Committee (MC) Members



FDA

IMDRF
International Medical Device Regulators Forum

www.imdrf.org

How do regulators get the standards they need?

- How do regulators know what standards exist?
- How do you decide what is an essential standard?
- How can standards help with refurbished equipment?
- **What can we do to help?**

- National Standards Body – ANSI; KEBS – ARSO
- Regional – ARSO
- Global – IMDRF
- Regulators – FDA PPB

One Possible Path Forward

- Depend on manufacturer's QS/RM and review by a regulator;
- leverage CA and approvals from other jurisdictions (FDA, CE, PMDA, TGA, etc) together with requirements for importers\distributors like Registration & Listing

CALL TO ACTION

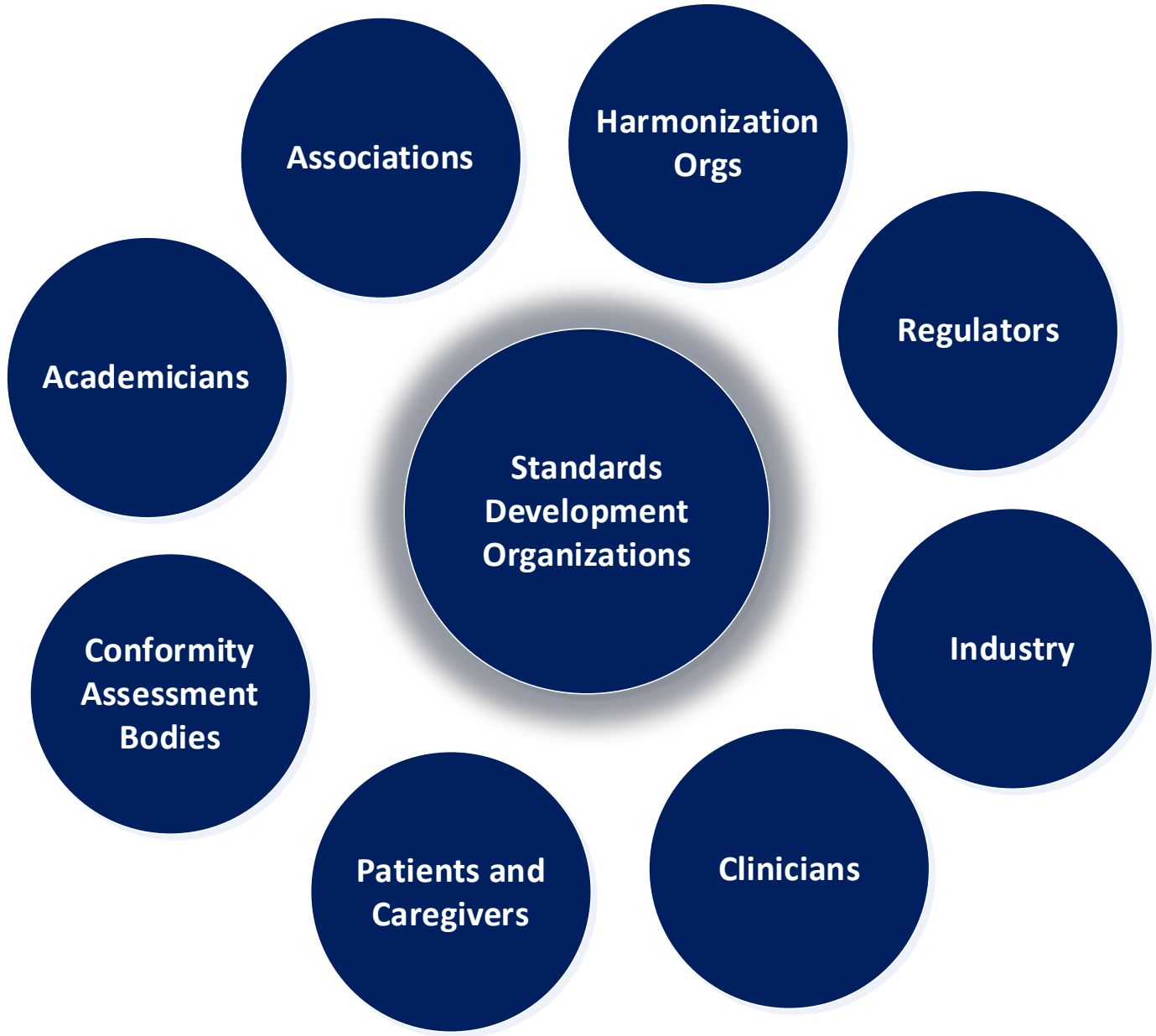
Promote the use of consensus standards

Join a committee

Contribute substantively – and do so early!

Be nominated to the SDO Technical Committees

Continue today's discussions



U.S. FOOD & DRUG ADMINISTRATION + Devices

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