IMDRF, MDSAP and REPS

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ANVISA

International Medical Devices Regulators Forum – IMDRF

IMDRF

- Stablished on October 2011
- Voluntary group of jurisdictions

→ - Accelerate regulatory convergency
- Promote efficient and effective model

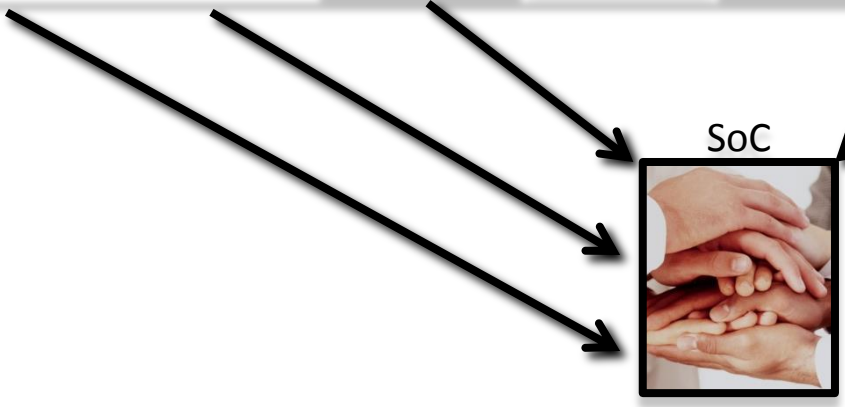
Members

- Australia
- Brazil
- Canada
- China
- EU
- Japan
- USA
- Russia

Official observers

- OMS
- APEC/LSIF/RHSC (Asia Pacific Economic Cooperation / Life Sciences Innovation Forum / Regulatory Authority Steering Committee)

International Medical Device Regulators Forum (IMDRF)



Medical Device Single Audit Program (MDSAP)

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

PANDRH
Pan American Network for Drug Regulatory Harmonization

Pan American Health Organization

World Health Organization
Americas

MDSAP GOALS

- To enable the appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry.

- To leverage, where appropriate, existing conformity assessment structures, allowing a more efficient and flexible use of regulatory resources.

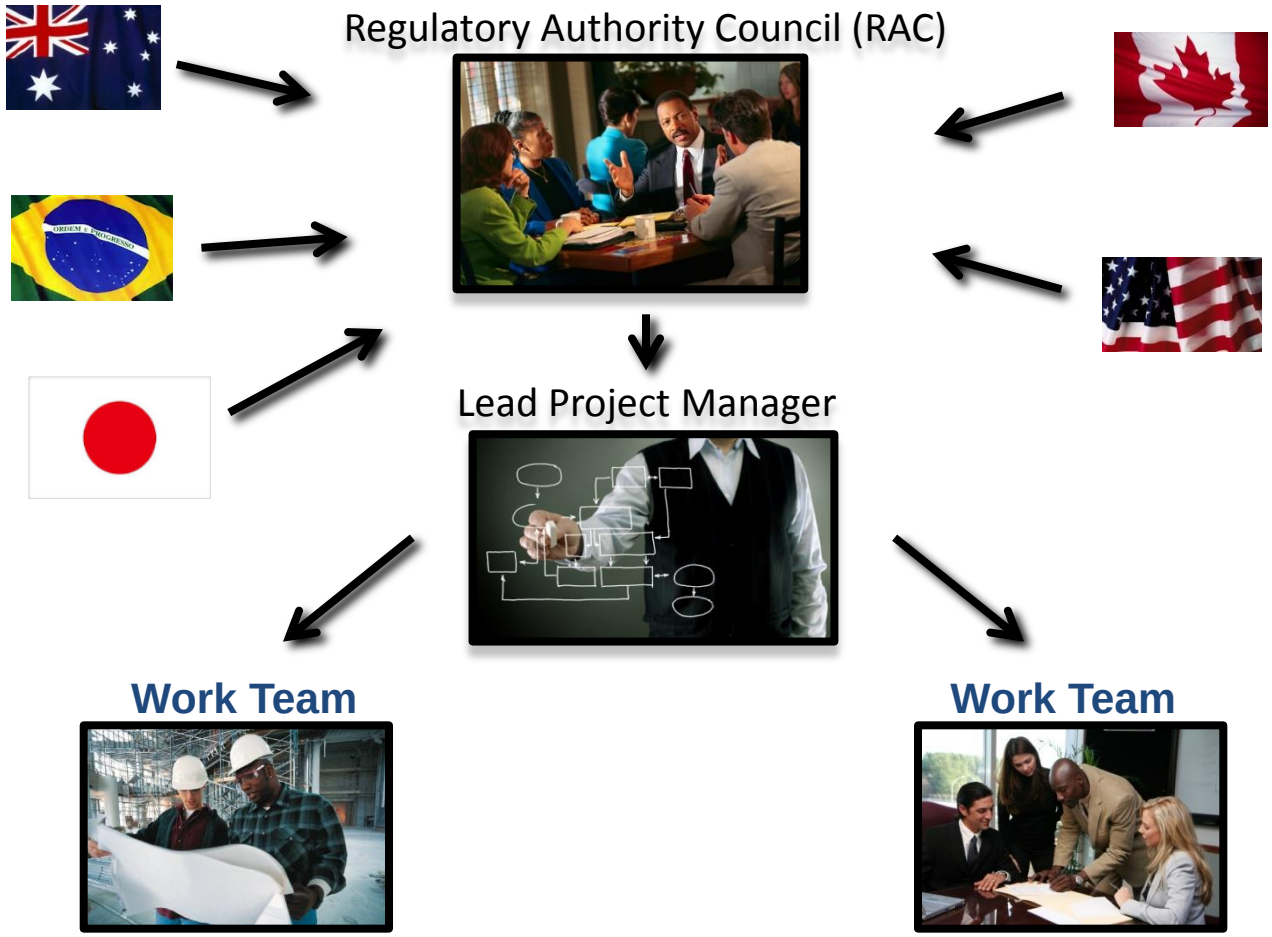
- To promote, in the longer term, greater alignment of regulatory approaches and technical requirements, based on international standards and best practices.

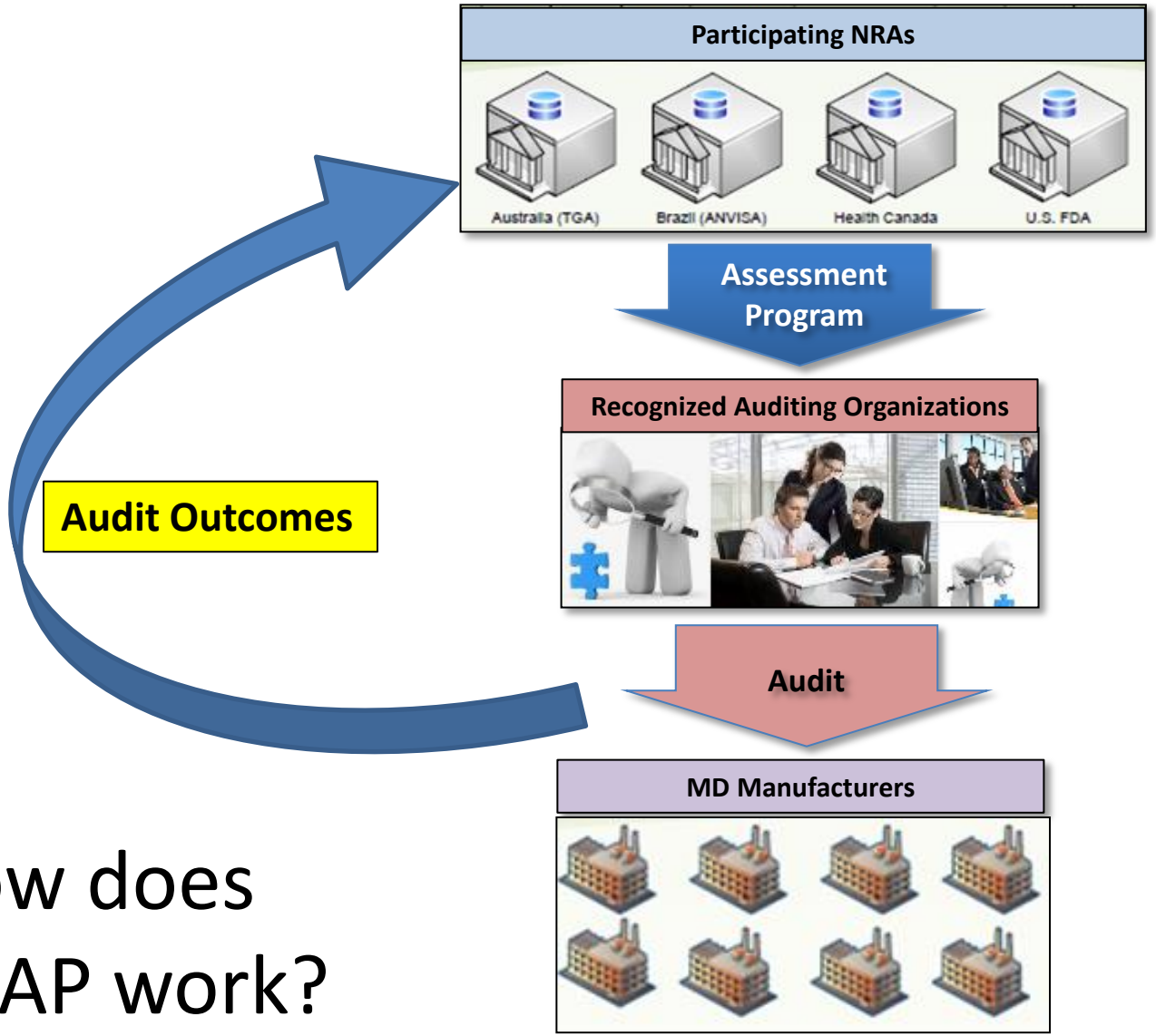
MDSAP PILOT

- 03/2013: Fouding jusrisdictions set an accelerated plan to develop the basic structure for the 3 year pilot program started on 01/01/2014

- Starting point: 13 eligible Auditing Organizations acredited under the CMDCAS – Canadian Medical Device Conformity Assesment System

MDSAP Governance





How does MDSAP work?

Regulatory Exchange Platform – secure (REPs)

- IT solution to facilitate the exchange of confidential/non-public information (NPI), as well as the collaboration of global regulators in a secure IT environment

- Partners: Australia, Brazil, Canada, Japan, USA and PAHO

- Goal: Initial Modules Supported:
  - Regional Platform on Access Innovation for Health Technologies (PRAIS)
  - Medical Device Single Audit Program (MDSAP)

MDSAP Module

- Accept Auditing Organization applications
- Accept audit/assessment documents
- Repository for finalized documents/procedures
- Manage Assessment and Audit Cycles
- Schedule/view audits and assessments
- Metrics and Reporting

THANK YOU