Session 1: Reliance in a premarket setting
Case studies in premarket reliance implementation
(Case; Diagnostic Imaging Devices)

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IMDRF International Medical Device Regulators Forum

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Steps for global convergence/harmonization pre-market review based on reliance

Regulatory Convergence or Harmonization is the ultimate goal.
But we know well that it is a long way off.

We hope that
the expansion of Reliance will shorten the pre-market review process.

Implementation of Harmonized Regulatory Model

Establish "Reviewing Criteria and Standards"

Conformity Assessment by Own reviewers in each jurisdiction

Abridge Pathway using reliance

Unilateral or Mutual recognition using reliance

Global convergence or harmonization

Upgrading Reliance based on Capacity Building

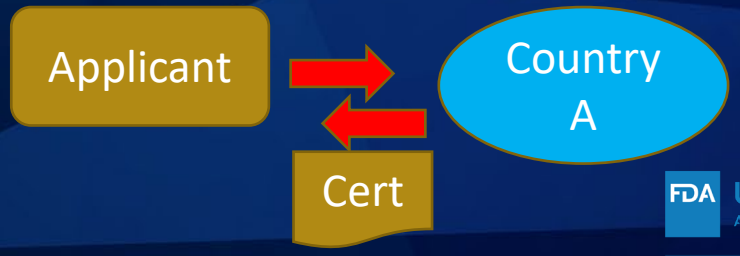
GHTF regulatory model
GHTF/AHWG-GRM/N1R13:2011

Definition(SG1 N071:2012)
Classification(GHTF/SG1/N77:2012
Conformity Assessment (GHTF/SG1/N78:2012)
Essential Principle (IMDRF/GRRP WG/N47)

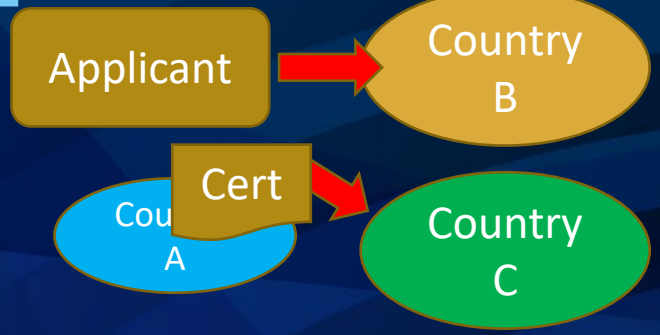
https://www.imdrf.org/sites/default/files/docs/ghtf/final/steering-committee/technical-docs/ghtf-sc-n1r13-2011-ad-hoc-regulatory-model-110413.pdf

Steps for international reliance of pre-market review

Conformity Assessment by Own reviewers in each jurisdictions

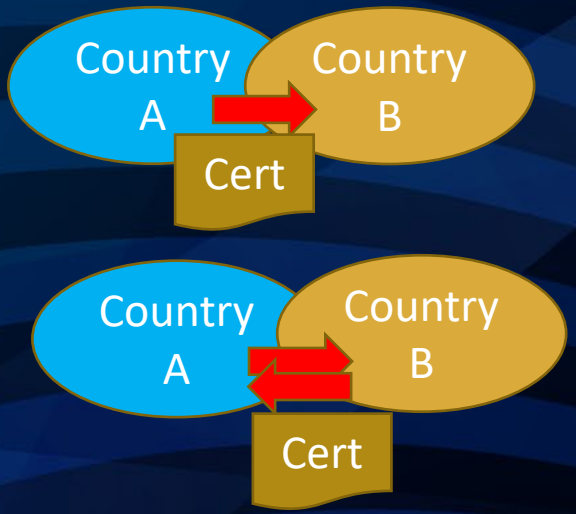


Abridge Pathway using reliance (IMDRF or MOU)



MOU: Memorandum of Understanding between country A and B

Unilateral or Mutual recognition using reliance



Conformity Assessment of pre-market by Own reviewers in each jurisdiction

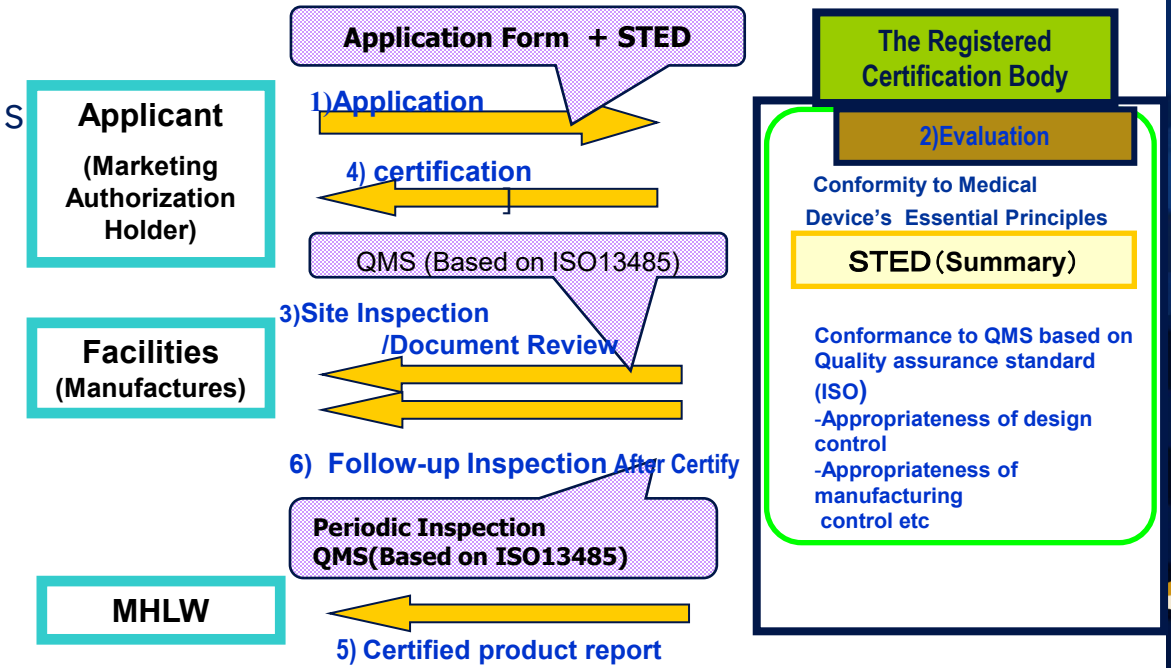
- **Case of Japanese 3rd party review system**

  Document Review based on Technical Requirement and QMS requirement (based on ISO13485)

  For Class II
  Certification Standard such as JIS Standards
  (Almost JIS standards equivalent
  with IEC/ISO standards)

  Benefit for Industry and Patient

  e.g. Timeline for Certification
  Typically within 3 month.
  Better case within 1 month.



Abridge Pathway using reliance as IMDRF/GHTF jurisdiction

- **Abridge Pathway ; IMDRF/GHTF jurisdiction**
  Shortened timeframes and simplified documentation for submission

Category	Jurisdiction	Status	Detail of pathway	Detail of Status
IMDRF/GHTF	Singapore	Applicable	Evaluation route (immediate, expedited, simplified) selection for application using Japanese, U.S., European, and other approvals.	If the GHTF country approval is in place, the review period is 160 days, which is about two months earlier than the local inquiry.
IMDRF/GHTF	Malaysia	Applicable	If the medical device to be registered is already registered in the former GHTF (USA, EU, Canada, Japan, or Australia), CAB review can choose the simplified application route.	The number of days saved is unclear, although it has been reduced.
IMDRF/GHTF	Saudi Arabia	Applicable	IMDRF participating countries are designated for simplification.	The number of days saved is unclear, although it has been reduced.
IMDRF/GHTF	South Africa	Applicable	IMDRF participating countries are designated for simplification.	The number of days saved is unclear, although it has been reduced.

Abridge Pathway using reliance as MOU or MOC

- **Abridge Pathway ; MOU or MOC**
  Shortened timeframes and simplified documentation for submission

Category	Jurisdiction	Status	Detail of pathway	Detail of Status
MOC	Chinese Taipei	Applicable or not used.	The company registration based on QMS, called QSD, accepts the results of QMS Inspection conducted by Japanese certification bodies accredited by the TFDA.	The use of this Pathway is not expanding due to issues such as the different scope of application of QMS audits. The Japanese industry associations continue to work with the governments of both countries to make improvements.
MOU	Mexico	Not used (for class II)	The review process can be simplified by translating and presenting the Japanese marketing authorization and certification.	Some have reported that the timeframe has been shortened for high-risk products and that they are being used effectively, but some have said that for Class II certified products, the resulting increase in paperwork and translation problems have slowed things down.
MOU	India	Applicable	Acceptance for QMS Certification by Japanese registration	This Pathway has allowed us to omit the QMS survey.

MOU: Memorandum of Understanding between country A and B

MOC: Memorandum of Cooperation between country A and B

Abridge Pathway using reliance as MOU or MOC

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Unilateral or Mutual recognition using reliance

- **For Japan based Unilateral or Mutual recognition on for MD/IVD. not yet.....**
- **MDSAP for US, CAN, BRA,AUS, and JPN + affiliate member**
- **EU-MDR/IVDR, MDD/IVDD for EU-Area**
- **ASEAN medical device directive for ASEAN-Area**
- **EU-AUS TGA**

Unilateral or Mutual recognition using reliance

AO(CAB) for QMS (MDSAP)

Recognized according to IMDRF Guidance Doc.
*Competency for RA Assessor (IMDRF N6)

Recognized according to IMDRF Guidance Doc.
*Recognition for AO (IMDRF N3,11)
*Competency for Auditor (IMDRF N4)

Regulatory Authority

Recognition

Auditing Organization
e.g. BSI, DEKRA, Intertek, LNE, SGS, TUV-R NA,
TUV-SUD America, UL
DQS MED, Lloyd's, NSAI, NSF Health Science,
SAI Global, TUV USA,

QMS Auditing

Manufacturer

MDSAP Auditing Report by IMDRF N24

Outcome of assessment for QMS

MDSAP Cert.

MDSAP Auditing Report by IMDRF N24

Auditing Criteria
MDSAP AU P0002.007 Audit Approach (ISO13485+Regional Requirement)
by MDSAP RAC countries
https://www.fda.gov/media/157947/download

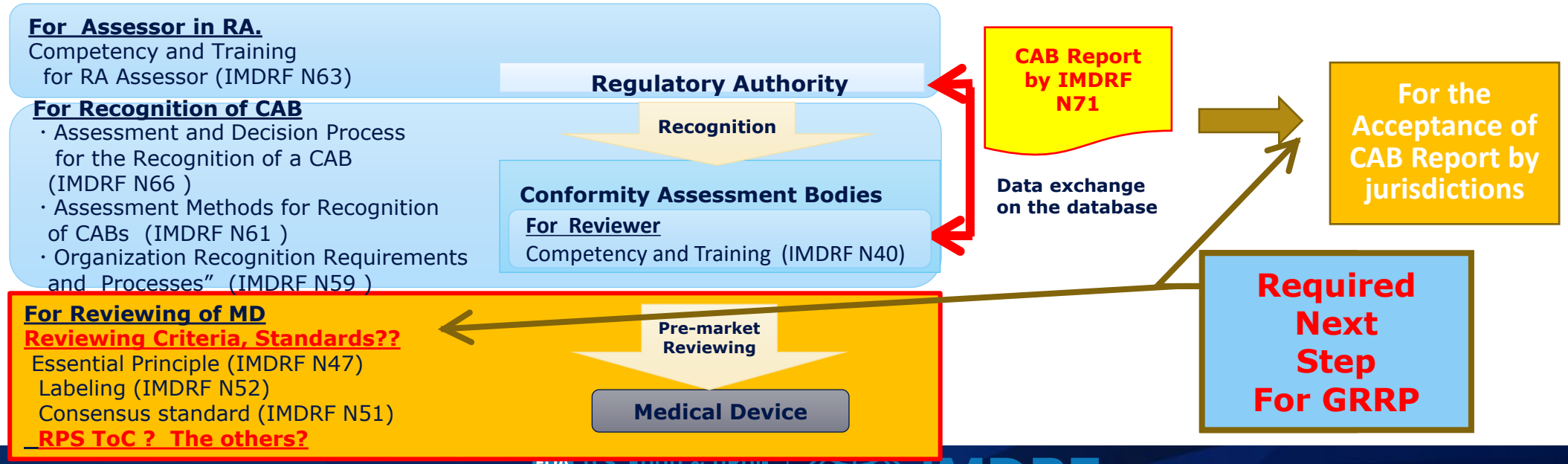
Unilateral or Mutual recognition using reliance

- **MDSAP**
  - ➢US, CAN, BRA,AUS, and JPN are accepting MDSAP report or certification.
  - ➢MDSAP RAC member can access to MDSAP database to confirm the status for Manufactures.
  - ➢Industry expect to expand to implementation of MDSAP report or certificate in Affiliate Member countries and the others.

Benefit for Industry
- Reduce duplicate audits and corresponding time
- Constancy of quality requirements

Take home message

- **Expansion of Reliance in the pre-market phase**
  - ✓**Implementation CAB system into the pre-market phase**
    - ☐ We face the difficulties of Abridge Pathway, Unilateral or Mutual recognition
    - ☐ MDSAP is good example for Unilateral or Mutual recognition by reliance
    - ☐ CAB systems for premarket review already developed by IMDRF GRRP.



Take home message

- **What is needed to expand the CAB system**
  - **Harmonized Reviewing Criteria/Consensus Standards** are not also defined yet.
  - **Training scheme for Capacity Building** is not defined yet as IMDRF level.
  - **Quality of Application for premarket review**
    Industries should have a certain level of application documentation that ensures reliability.
    Encourage “Good Submission Practice”

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International Medical Device Regulators Forum

United States of America

2024

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