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

Monday, February 11, 2024
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- Steps for global convergence/harmonization and reliance
- Cases/examples of reliance of pre-market review
  CAB/Abridge Pathway/Unilateral or Mutual recognition
- Take a home message
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

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)
Steps for international reliance of pre-market review

Conformity Assessment by Own reviewers in each jurisdictions

Abridge Pathway using reliance (IMDRF or MOU)

Unilateral or Mutual recognition using reliance

MOU: Memorandum of Understanding between country A and B

Certification of Applicant in Country A

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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.

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**Application Process**

1) Application
2) Evaluation
3) Site Inspection/Document Review
4) Certification
5) Certified product report
6) Follow-up Inspection After Certify

**The Registered Certification Body**
- Conformity to Medical Device's Essential Principles
  - STED (Summary)

**Conformance to QMS based on Quality assurance standard (ISO)**
- Appropriateness of design control
- Appropriateness of manufacturing control

**MHLW**

**Facilities (Manufactures)**

**Application Form + STED**

**QMS (Based on ISO13485)**

**Periodic Inspection QMS (Based on ISO13485)**
### Abridge Pathway using reliance as IMDRF/GHTF jurisdiction

**Shortened timeframes and simplified documentation for submission**

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<td>IMDRF/GHTF</td>
<td>Singapore</td>
<td>Applicable</td>
<td>Evaluation route (immediate, expedited, simplified) selection for application using Japanese, U.S., European, and other approvals.</td>
<td>If the GHTF country approval is in place, the review period is 160 days, which is about two months earlier than the local inquiry.</td>
</tr>
<tr>
<td>IMDRF/GHTF</td>
<td>Malaysia</td>
<td>Applicable</td>
<td>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.</td>
<td>The number of days saved is unclear, although it has been reduced.</td>
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<td>IMDRF/GHTF</td>
<td>Saudi Arabia</td>
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Abridge Pathway using reliance as MOU or MOC

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

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<td>The company registration based on QMS, called QSD, accepts the results of QMS Inspection conducted by Japanese certification bodies accredited by the TFDA.</td>
<td>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.</td>
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<td>The review process can be simplified by translating and presenting the Japanese marketing authorization and certification.</td>
<td>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.</td>
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**Abridge Pathway; 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,

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

QMS Auditing

Manufacturer

Data exchange on the database

MDSAP Auditing Report
by IMDRF N24

Outcome of assessment for QMS

MDSAP Cert.

MDSAP Auditing Report
by IMDRF N24

*Recognition for AO (IMDRF N3,11)
*Competency for Auditor (IMDRF N4)

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
• 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.

For Assessor in RA.
Competency and Training for RA Assessor (IMDRF N63)

For Recognition of CAB
- Assessment and Decision Process for the Recognition of a CAB (IMDRF N66)
- Assessment Methods for Recognition of CABs (IMDRF N61)
- Organization Recognition Requirements and Processes” (IMDRF N59)

For Reviewing of MD
Reviewing Criteria, Standards??
Essential Principle (IMDRF N47)
Labeling (IMDRF N52)
Consensus standard (IMDRF N51)
RPS ToC ? The others?

For the Acceptance of CAB Report by jurisdictions
Required Next Step For GRRP

Data exchange on the database
• 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”