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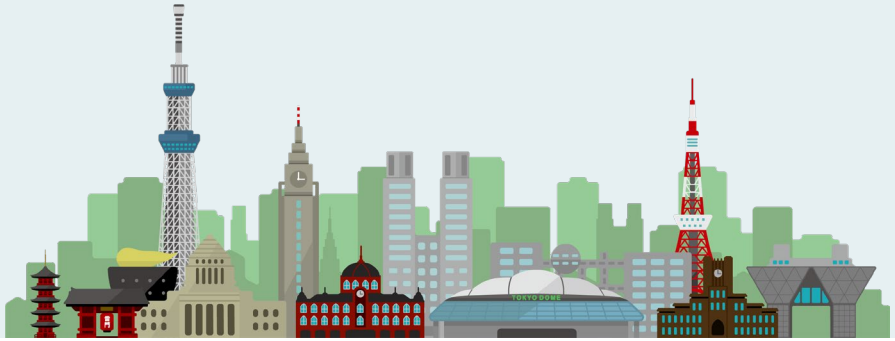

Sharing jurisdictional case studies and challenges in expanding Reliance

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Overview

- Reliance in conformity assessment for premarket review
- Abridge Pathway
- Capacity Building for Abridge Pathway or Recognition

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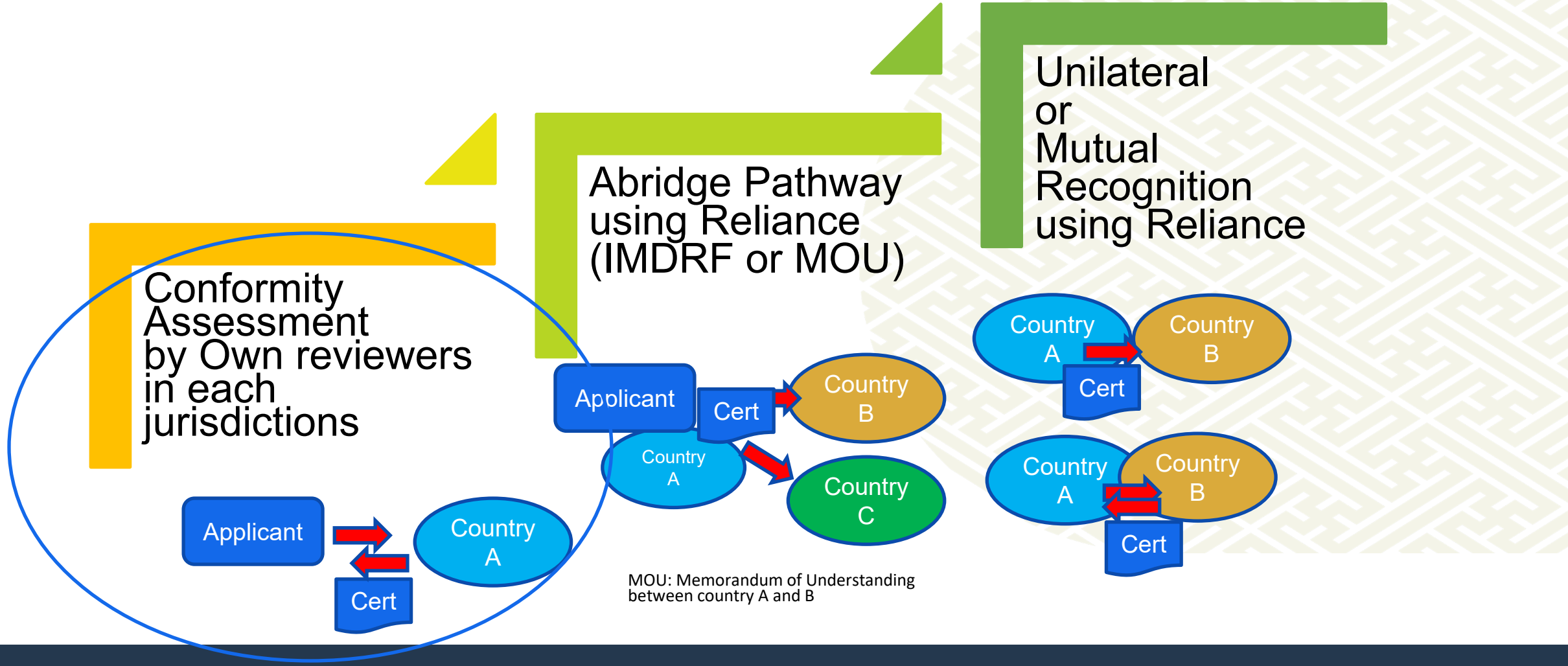
Conformity Assessment based on Reliance



MOU: Memorandum of Understanding between country A and B

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Conformity Assessment based on Reliance

- In premarket conformity assessment, conformity is verified against EP using standard.
  - ✓ As a Reliance, it is an issue that the interpretation of each provision of EP and the application of standard are different.

How to demonstrate to comply with EP using Standards
→ Reconsider the needs of mapping guidance for EP?

Withdrawn the following mapping guidance standards based on GHTF EP

ISO 16142-1 Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1 General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards

I request to reconsider the needs for the mapping guidance for EP, then ISO/TC210WG2 conduct the survey to confirm the needs,
The survey results were shared within ISO/TC210.
More analysis is still needed, but more than 80% of respondents indicated the need for mapping.
We would like to suggest to develop the mapping and the criteria to IMDRF MC and ISO/TC210WG2

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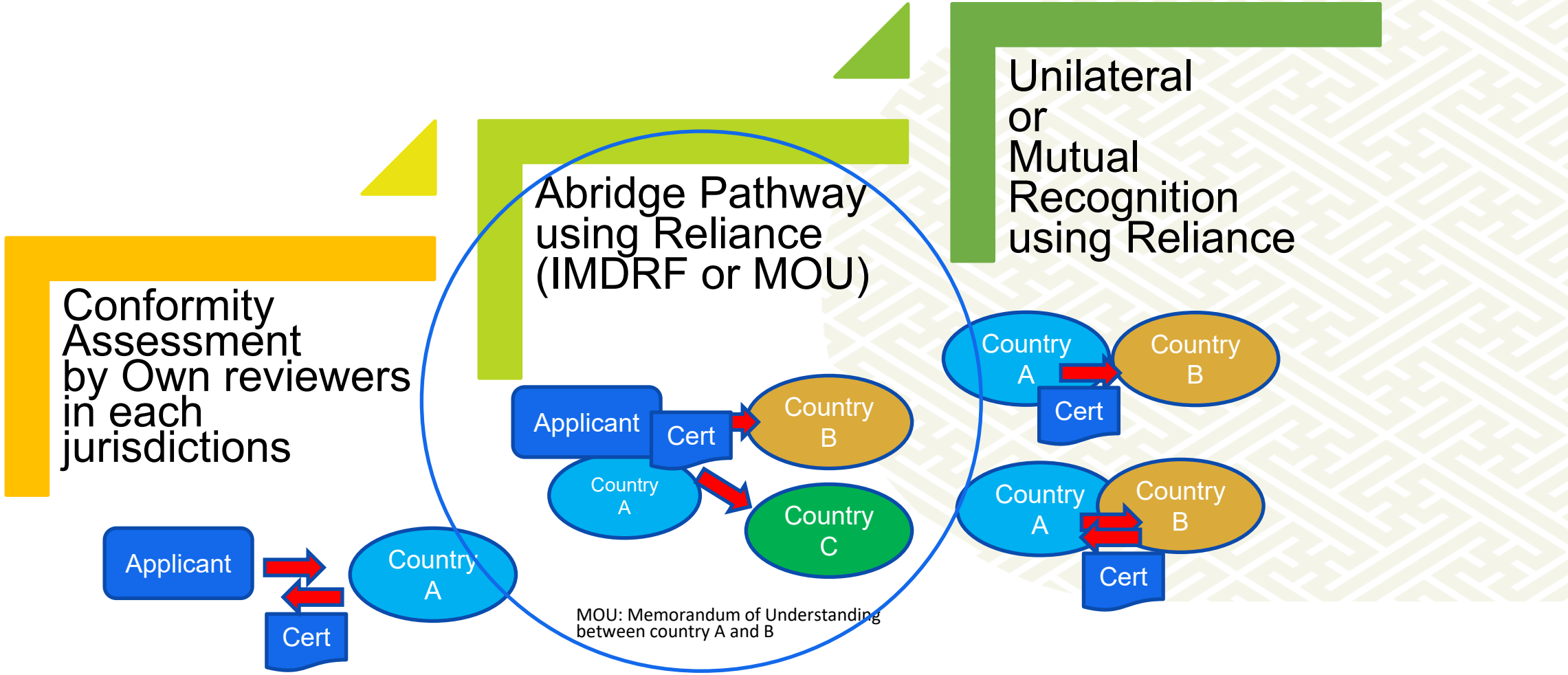
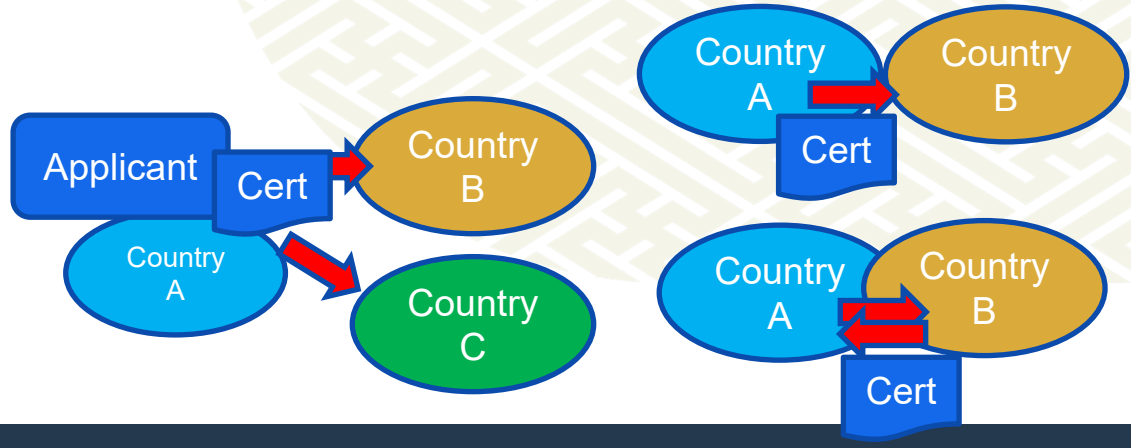
International Reliance of Pre-market Review



Difficulties in negotiation for Bilateral

- Bilateral negotiations to establish the Bridge Pathway using Reliance and Unilateral or Mutual Recognition using Reliance require time for each regulator to understand the content of each other's regulations.

  - The industry is familiar with the content of each other's regulations because it has submitted products to both regulators, which can help each regulator to understand the content of each other's regulations and reduce the time required to establish the Bridge Pathway and Recognition.



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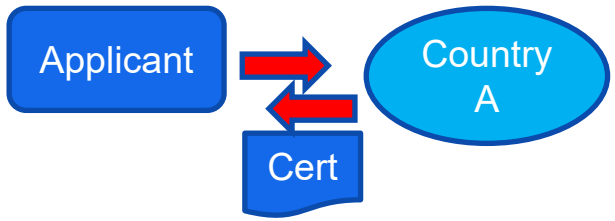
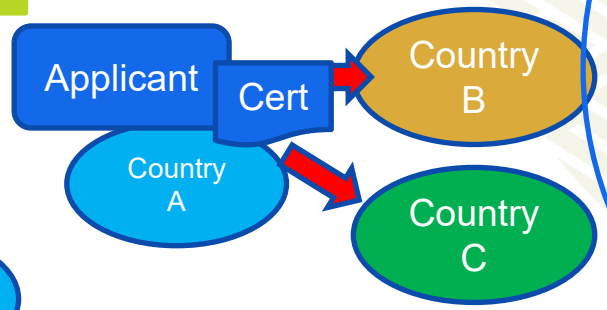
International Reliance of Pre-market Review

Conformity Assessment by Own reviewers in each jurisdictions



Abridge Pathway using Reliance (IMDRF or MOU)



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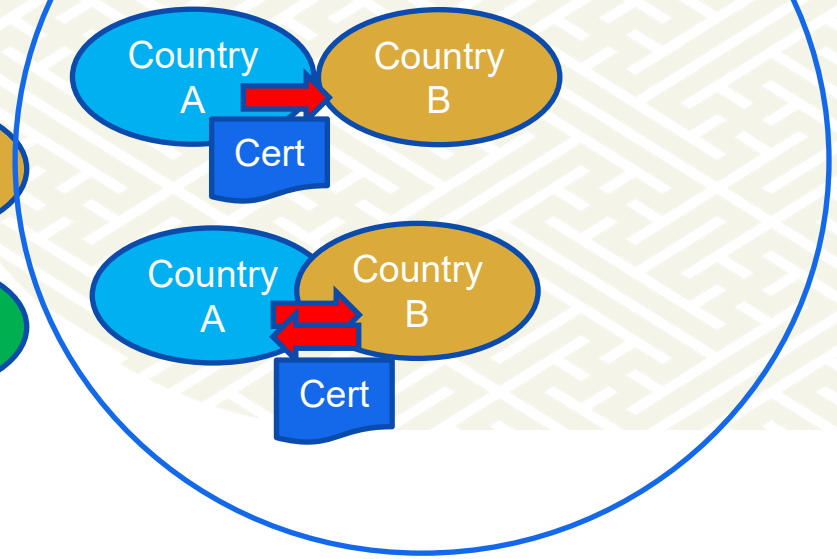
Unilateral or Mutual Recognition using Reliance



MDSAP in Japan

2012/Nov.	US,AU,CAN,BR sign off the agreement of MDSAP.
2013/Autum	JAPAN entry into MDSAP scheme as the observer.
2013/Oct.	Release the abstract of MDSAP scheme.
2014/Jan.	Starting evaluation AO, pilot study by the end of 2016.
2015/Jun.	JAPAN became officially MDSAP RAC member.
2016/Jun.	The pilot for accepting MDSAP report in Japan
2017/Jan.	Starting MDSAP officially.
2021/Sep.	The official statement for accepting MDSAP report in Japan

Japanese Industries request MHLW/PMDA to become a member of MDSAP.

- Request for the creation of differential mapping information to improve the efficiency of EU MDR/IVDR combined audit
- Request for the expansion of MDSAP Affiliate members

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Capacity Building and Training Model for Reliance e.g APEC CoE program for Medical Device PWA

Steering Committee

CO-CHAMPIONS
- Japan (MHLW / PMDA)
- Korea (MFDS)
- United States (US FDA)

SUB-CHAMPIONS
- Japan (JIRA)
- United States (AdvaMed)

CENTERS OF EXCELLENCE (CoE)
- Sichuan University (SCU), China
- Pharmaceuticals and Medical Devices Agency (PMDA), Japan
- Soonchunhyang University (SCH), Korea
- Taiwan Food and Drug Administration (TFDA), Chinese Taipei
- University of Southern California (USC), United States

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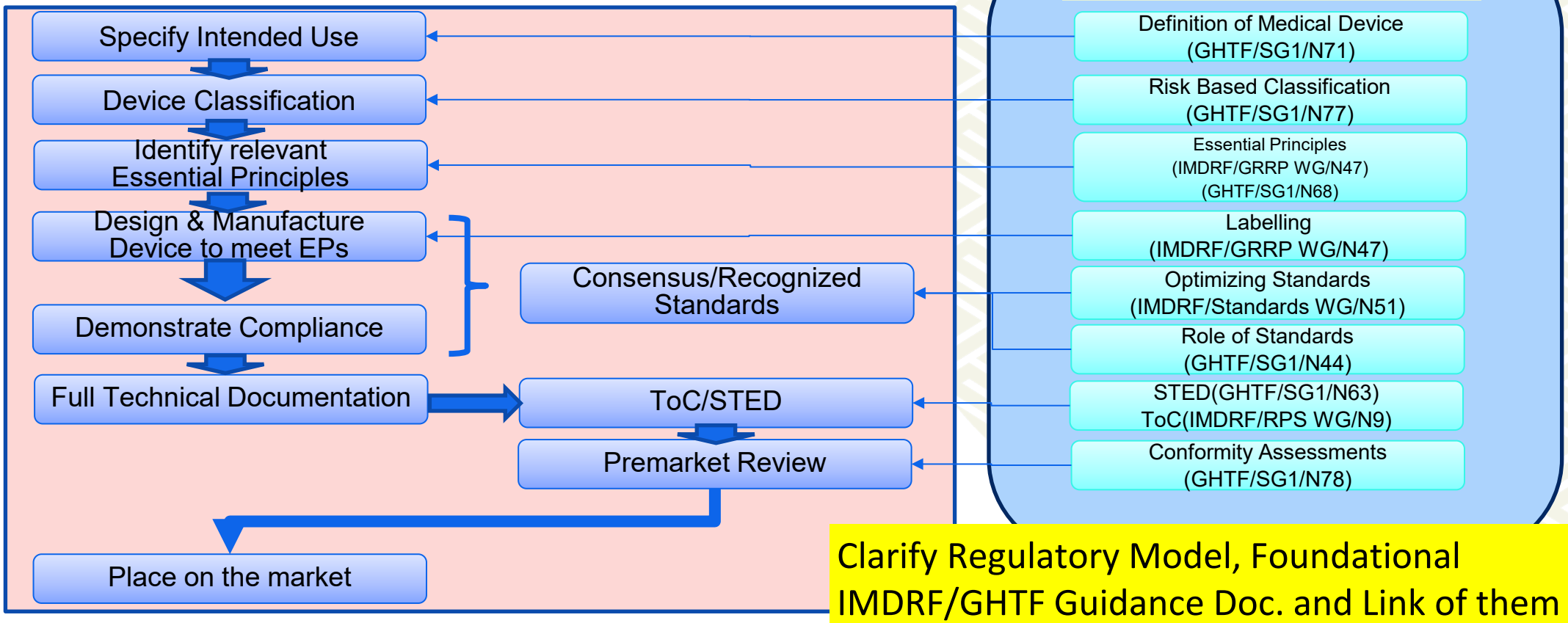
Regulatory Model and Foundational IMDRF/GHTF Guidance Doc.

IMDRF Regulatory Model for Pre-market Review modified from GHTF/AHWG-GRM/N1R13-2011 “The GHTF Regulatory Model”



Clarify Regulatory Model, Foundational IMDRF/GHTF Guidance Doc. and Link of them

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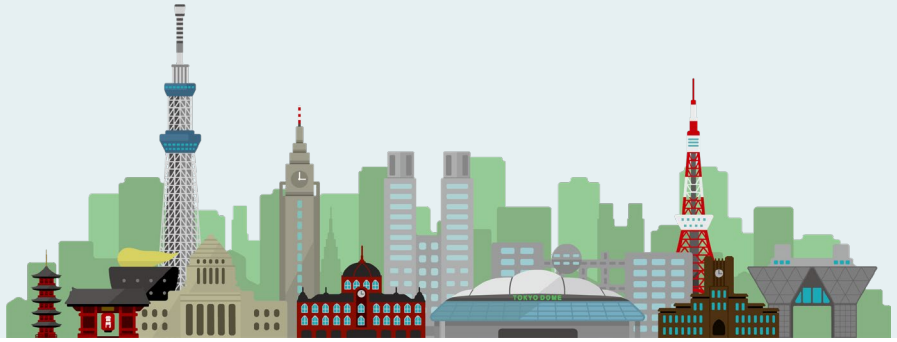

Thank you/Questions