



IMDRF

International Medical
Device Regulators Forum

Opinions to IMDRF

**General QA session
September 2015**



List of Opinions

- General Affairs
- Specific Activities: *MDSAP, SaMD, RPS, NCAR, Standards*
- [Reference] Others



General Affairs:

1. IMDRF jurisdictions should report their implementation plans and progress in international regulatory alignment based on completed work items at future IMDRF meetings.
2. IMDRF MC should create a formal opportunity for industry to contribute to MC decision-making prior to final decision.
3. On the final day of IMDRF meeting week, IMDRF MC should brief about MC meeting result because of its importance for industry.



MDSAP WG:

1. This work item is considered as a very successful endeavor.
2. Explain the consideration of MDSAP scheme, report the status of the MDSAP pilot, and provide opportunity to understand outcomes and use of the audits under MDSAP Pilot.



SaMD WG:

1. This work item is considered as a very successful endeavor.
2. More practical items for implementation into regulatory requirements should be considered.



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NCAR WG *(will addressed in NCAR session)*:

1. Greater industry engagement should be accepted in the development of this important system.
2. Share more information on the activities that have taken place to date and future plans.



RPS WG (will addressed in RPS session):

1. The RPS standard is one possible format. The chosen harmonized format must make business sense for both regulators and industry, e.g. cost/risk benefit, ease of use, infrastructure required.
2. There should always be an effort to maximize harmonization of RPS process.
3. Business Case should be taken into account cost/benefit, and an implementation guide should be developed.



Standards:

1. The willingness to explore additional actions related to standards by IMDRF is welcomed.
2. Future IMDRF standard work with stakeholders should include such points as:
 - A) Establishing Short List of Key Standards,
 - B) Developing the mapping of Standards into ToC,
 - C) Establishing Transition Rule for Standards, and
 - D) Establishing Structure & Categorization of Standards in regulatory purpose



[Reference] Others:

1. The time is right to set longer-term goals to guide IMDRF.
2. The development of the IMDRF UDI guidance was appreciated. It is expected that each jurisdiction will introduce universal UDI system according to the guidance in the implementation.



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Thank you

for your cooperation with IMDRF activities