IMDRF International Medical Device Regulators Forum

International Medical Device Regulators Forum (IMDRF) Updates

21st AHWP Annual Meeting

Fábio P. Quintino
ANVISA/Brazil
IMDRF MC Chair - 2016

IMDRF MISSION

"To strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety."

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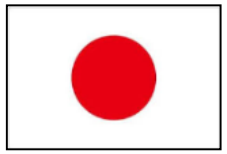

OFICIAL OBSERVERS

- World Health Organization (WHO)
- Asia Pacific Economic Cooperation / Life Sciences Innovation Forum / Regulatory Authority Steering Committee (APEC/LSIF/RHSC)

AFFILIATED ORGANIZATIONS

- **Asian Harmonization Working Party (AWHP)**
- Pan American Health Organization (PAHO)

Updates

- Last Management Committee meeting held at Florianópolis, Brazil, from Sep 13-15th 2016

- Discussions on the status of the Working Gropups (WG)

CURRENT WG

- National Competent Authority Report (NCAR)
- Software as a Medical Device (SaMD): Clinical Evaluation
- Regulated Product Submission (RPS)
- Medical Device Patient Registries
- Medical Device Adverse Event Terminology

CURRENT WG

- Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialist

- Improving the Quality of International Standards for regulatory use

NCAR

- The pilot phase expired in the end of March 2016 and the full program implementation started

- Increase of the NCAR exchange and a wider participation of IMDRF jurisdictions are the main challenge at this point

SaMD

- Clinical Evaluation document (N41) under public consultation (Due date: 13 December 2016)

- The document specifies clinical evidence recommendations according to the SaMD risk levels. Final version is expected to be approved on March 2017.

Regulated Product Submission

Remarks:

- Necessity on the development of a public strategy outlining a project plan and key milestones to implement RPS
- Need for technical expertise and Industry Support
- Long term undertaking

Regulated Product Submission

Table of Contents (ToC):

•Pilot ongoing, 12 submissions up to september 2016

•Positive feedback from applicants and reviewers. Some technical concerns

•Need more applicants to ensure implementation is successful. Full benefits cannot be realized until set up as part of eletronic format of RPS

Regulated Product Submission

Common Data Elements: F2F Meeting may31-Jun1, Canada

•Mapping common data elements to existing exchange messages

•Recommendations for data exchange guidelines of common data elements – Draft expected to be finished on november 2016

Medical Device Patient Registries

- Patient Registry - Methodological Principles in the Use of International Medical Device Registry Data (N42) under public consultation (Due date: 2 December 2016)

- Patient Registry - Principles of International System of Registries Linked to Other Data Sources and Tools (N33) final document was published

Adverse Event Terminology

- IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (N43)" under public consultation (Due date: 2 December 2016)

Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialist

- Competence, Training and Conduct Requirements for Regulatory Reviewers document public consultation closed on October 14th 2016.

- Final version is expected to be approved on March 2017.

Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers and Product Specialist

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Improving the Quality of International Standards for regulatory use

- First meeting held on September 2016 at Berlin. Mapping of technical issues and concerns, with regard to regulatory aspects of standards developed by some major international standardization committees, exploring possibilities for improvement and discussion with stakeholders and SDOs

- Possible actions to be taken by IMDRF in order to influence and support the development or amendment of standards for regulatory purposes

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

- Pilot Consortium: Australia, Brazil, Canadá, Japan and USA. EU and WHO as observers
- 150 manufacturing sites under the program
- Pilot will finish on December 31st
- Regulatory Exchange Platform – secure (REPs)
  - IT solution to facilitate the exchange of confidential/non-public information (NPI), as well as the collaboration among regulators in a secure IT environment

IN SUMMARY

- Good progress being made that will have a direct influence on advancing regulatory convergence
- 3 Work Items have finished
- 7 Work Items are at various stages of progress.

As in the words of IMDRF Terms of Reference:

•*IMDRF seeks to maintain working relationships with other international entities, regional organizations, or "Affiliate Organizations" that have a* ***mutual interest in medical device regulatory activities that are directly related to the common goals*** *of fostering global convergence, leveraging resources and making available safe and effective medical devices globally.*

- Commitment to rapid progress and concrete deliverables
- Transparency and engagement are key for building trust
- True regulatory convergence and harmonization

Thank you