WG3 – Pre-market: Software as a Medical Device (SaMD)

Chair: Dr. Rama

Co-Chair: Tony Yip

Advisor: NIL

AHWP 19th TC Meeting
5 Nov 2015, Bangkok

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Updates

- No. of WG members: 8

Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
1	**Guidance document on Medical Device Software – Qualification and Classification** — *The White paper on this topic that was prepared by the earlier WG1 will be the foundation for this. The appropriate aspects from the recent IMDRF document on Software as Medical Device (SaMD)will be kneaded with the existing white paper to develop this AHWP document*	Guidance document	Q3 2015
2	**Risk Classification of Medical Device Software / SaMD** — *To draw reference from the IMDRF SaMD workgroup and also to develop a AHWP document with adequate examples to illustrate and clarify on risk classification of software MDs*	Guidance document	Q1 2016 (First Draft)

Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
3	**White paper / Position paper on Pre-market initial and change Submission format for SaMD** • To draw up a white paper or position paper for AHWP TC covering the **pre-market submission format** and also on **change management system** for SaMD — highlighting the need for considering approaches different from those in practice for traditional MDs	White paper / Position paper	Q4 2016
	Other Projects are yet to be developed.		

WG Progress Update

since last AHWP Seoul TC Meeting in 2014

No.	Work Item	Status	Achievements
1	**Guidance document on Medical Device Software – Qualification and Classification**	Published at AHWP website for public consultation	Draft for public consultation already completed. Some feedback received and pending review

Guidance document on Medical Device Software – Qualification and Classification

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- **Scope of paper:**
  To provide guidance and information to Regulatory Authorities (RAs) and the Medical Device Industry (Industry) on the Software Qualification and Classification.

- **Objective of paper:**

  The main aim of developing this document for medical device software qualification is to provide information to AHWP members economies' RAs and industry in establishing, a consistent approach to determine the qualification of a software based on its intended purpose and determine its classification as a medical device or otherwise. Appropriate classification of the medical software is the key in determining the appropriate regulatory controls for this software in the interest of public health while supporting continued innovation and development of safe medical software.

Guidance document on Medical Device Software – Qualification and Classification

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- **Summary:**

This guideline is drafted based on currently available IMDRF documents on Software as Medical Devices, AHWP white paper on medical device software Regulation – Software Qualification and Classification and published guidelines from global agencies including European Union, Health Canada and US FDA with focus on the recent developments in regulation of SaMD.

This document should be read together with the following AHWP guidance documents

- White Paper on Medical Device Software Regulation – Software Qualification and Classification (AHWP/WG1/F001:2014)

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Thank you