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

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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
1	**Guidance document on Qualification of Medical Device Software** *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 Submission format for SaMD** • To draw up a white paper or position paper for AHWP TC covering the **pre-market submission format** for SaMD — highlighting the need for considering approaches different from those in practice for traditional MDs	White paper / Position paper	Q4 2016 (First draft)

WG Progress Update

No.	Work Item	Status	Achievements
1	**Guidance document on Qualification of Medical Device Software**	Completed	Endorsed in the AHWP Annual Meeting in 2015
2	**Guidance document on Risk Categorisation of Software as a Medical Device**	Published on the AHWP website for public consultation Comments consolidated and document updated	Final version for endorsement in AHWP main meeting (Nov 2016)
3	**White paper on SaMD Pre-market Submission Requirement**	Drafting in progress: First working draft circulated in Nov 2016 but pending completion	
4	**White paper on SaMD change management – Requirements and Processes (NEW)**	First draft in Aug 2017	

Guidance document on Risk Categorisation of Software as a Medical Device

- *For endorsement Nov 2016*

- **Scope of document:**
  To provide guidance and information to Regulatory Authorities and the Medical Device Industry on the Risk Categorisation of Software as a Medical Device (SaMD).

- **Objective of document:**

  The main aim of this document for medical device software categorisation is to provide information to AHWP member economies' RAs and industry in establishing,a consistent approach to determine the risk categorisation of SaMD based on its intended purpose. The purpose of the document is to introduce a foundational approach, harmonized vocabulary and general and specific considerations for manufacturers, regulators and users alike to address the unique challenges associated with the use of SaMD.

Guidance document on Risk Categorisation of SaMD

- **Summary:**

This guideline is drafted based on currently available IMDRF documents on Software as Medical Devices, AHWP-WG3-SaMD-001:2015 guidance document, 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

- AHWP-WG3-SaMD-001 :2015: Guidance Document on qualification of medical device software
- White Paper on Medical Device Software Regulation – Software Qualification and Classification (AHWP/WG1/F001:2014)

Guidance document on Risk Categorisation of SaMD

- **Acknowledgements to the sub-group**

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Tony Yip (Elekta) – Co-chair, WG3

Rama Sethuraman (HSA) – Chair, WG3

White paper on SaMD Pre-market Submission Requirement
- First draft under review

- **Scope of document:**
  This document provides a snap shot of the pre-market submission requirements for some regulatory bodies and jurisdictions such as Australia TGA, China CFDA/CMDE, the European Union, Health Canada, Korea MFDS, MHLW Japan and the US FDA. The information collated is with reference to their published guidelines for medical software regulation and pre-market submission requirements.

White paper on SaMD Pre-market Submission Requirement

- **Objective of document:**

The main aim of this white paper is to summarize the current regulatory environment around the world, by including the harmonized view on pre-market submission requirement across jurisdictions, for next development of AHWP guidelines which can serve as member economies' key reference in establishing in a consistent way, an economic and effective approach to the control of medical software in the interest of public health and in the continued innovation of medical software development.

White paper on SaMD Pre-market Submission Requirement

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ASIAN HARMONIZATION WORKING PARTY

Thank You