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

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AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Updates

- No. of WG members: 12 (Exclude Chair & Co-chair)

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 Achievement and Progress Update

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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**	Completed	Endorsed in the AHWP Annual Meeting in 2016
3	**White paper on SaMD Pre-market Submission Requirement**	Working Draft ready for public consultation	Consolidation of regulatory requirement completed. Working draft ready for public consultation.
4	**Proposed new item: White paper on Cyber Security for SaMD**	First draft in Q2 2018 (Review of the new standards in progress)	
5	**White paper on SaMD change management – Requirements and Processes**	First draft in Q2 2018	

White paper on SaMD Pre-market Submission Requirement

- Working draft ready for public consultation

- **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

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- **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.

- Highly evolving area with new guidelines and standards constantly being developed or revised

Summaries of SaMD specific Pre-Market Submission Requirements (Subject to consultation and approval)

Doc \ Economy	US FDA	EU	Health Canada	Japan	Australia TGA	China CFDA	KR MFDS
Level of Concern	Yes	No SaMD specific Guidance issued	N	N	No SaMD Specific Guidance issued	Yes	Yes
Software Description including Platform and Operation Environment	Yes		Yes	Yes		Yes	Yes
Device Hazard Analysis / Risk Assessment	Yes		Yes	Yes		Yes	Yes
Software Requirement Specifications (SRS)	Yes		N	N		Yes	Yes
Architecture Design Chart	Yes (Not required for Minor Concern)		N	N		Yes	Yes
Software Design Specification (SDS)	Yes (Not required for Minor Concern)		N	N		Yes	Yes
Traceability Analysis	Yes		N	N		Yes	Yes
Software Development Environment Description	Yes (Not required for Minor Concern)		N	N		Yes	Yes
Verification & Validation Documentation	Yes		Yes	Yes		Yes	Yes
Revision level History	Yes		N	N		Yes	Yes
Unresolved Anomalies (Bugs or Defects)	Yes (Not required for Minor Concern)		N	N		Yes	N
Software Configuration Management	N		N	N		N	Yes
Medical Device - Software Development Life Cycle (SDLC) standards	N		N	Yes. IEC62304 / JIS T 2304		Yes. IEC62304 / YY/T 0664	Yes. IEC62304
Other Non-SaMD specific requirements							
Instruction for use	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Intended Use & Indication for Use	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Contradictions	Yes	Yes	Yes	N	Yes	Yes	Yes
Market History	Not mentioned	Yes	Yes	N	Yes	Yes	N
Clinical Evaluations / Trial / Studies	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Labeling	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Essential Principal / Essential Requirements	N	Yes	Yes	Yes	Yes	N	N

White paper on SaMD Pre-market Submission Requirement

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Tony Yip (Grifols) – Co-chair, WG3

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Thank You