



WG 3: Pre-market: Software as a Medical device

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26th GHWP Annual and TC Meeting
15 Feb 2023

Work Group Plan & Progress 2019 - 2023

Work Item	Deliverables	Status
<p>White paper on Pre-market initial Submission format for SaMD</p> <ul style="list-style-type: none"> •To draw up a <u>white paper or position paper</u> 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	<p>Circulated within TC for comment in late 2019. Consolidated final draft document submitted to Secretariat (Step3), pending public consultation and endorsement</p>
<p>Guidance document on Cyber Security for SaMD</p> <ul style="list-style-type: none"> •<i>To provides recommendations to consider and information to include pre-market submission for effective cybersecurity management(could be a separate work item)</i> 	Guidance	<p>Circulated within TC for comment in late 2019. Consolidated final draft document ready.</p>
<p>White paper on SaMD change management – Requirements and Processes</p> <ul style="list-style-type: none"> •Update examples in the existing guidance documents •WG1, WG2 & WG3 project for medical device change guidance 	Guidance	<p>Ready for endorsement in Annual meeting.</p>

Work Group Plan & Progress 2019 – 2023

(Cont'd)

Work Item	Deliverables	Action Plan and Timeline
<p>Guidance for Pre-Market Submission Format for SaMD</p> <ul style="list-style-type: none">•To draw up a <u>guidance document</u> for AHWP members covering the pre-market submission format for SaMD, highlighting the need for considering approaches different from those in practice for traditional MDs.	Guidance	To be reviewed the need in coming 3 year term.
<p>White Paper / Guidance on Artificial Intelligence (AI)</p> <ul style="list-style-type: none">•Joint Working Group initiative to address the regulatory concern and challenge while adopting AI in medical device.•Timelines and deliverables to be determined by project team	White Paper / Guidance	Direction to be reviewed in coming term.