



Bradley Merrill Thompson
t 202.861.1817
f 202.861.3517
bthompson@ebglaw.com

VIA EMAIL AND FIRST CLASS MAIL

April 28, 2016

Bakul Patel
Associate Director for Digital Health
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-5458
Silver Spring, MD 20993

Re: Adoption of IMDRF's SaMD QMS Guidance

Dear Mr. Patel:

The Clinical Decision Support Coalition (“CDS Coalition”) would like to commend the Food and Drug Administration (“FDA”) for its participation in the International Medical Device Regulators Forum (“IMDRF”) generally, as well as specifically in drafting the October 2015 IMDRF guidance document entitled *Software as a Medical Device (SaMD): Application of Quality Management System* (“IMDRF QMS Guidance”). In addition, the CDS Coalition asks that FDA take steps to adopt the IMDRF QMS Guidance in the U.S.

By way of background, the CDS Coalition is a diverse group of stakeholders consisting of software providers, IT infrastructure manufacturers, healthcare providers, medical device and pharmaceutical manufacturers, trade groups and members of the clinical community. Focused on clinical decision support software, the Coalition’s goal is to ensure a risk-based and clearly defined regulatory system for such software that appropriately balances the need for regulatory oversight with the need for innovation and access to new technology.

Our members appreciate the IMDRF QMS Guidance and agree with how it conceptualizes the elements of an effective QMS for SaMD. The Coalition specifically supports the risk-based approach detailed in the IMDRF QMS Guidance, including the acknowledgement that QMS elements (e.g., design, development and verification and validation) should be scalable based on the type of SaMD. Additionally, we note that the IMDRF QMS Guidance is generally in sync with FDA’s design control requirements set forth in the Quality System Regulation.

Further, on a broader level, we believe that the IMDRF QMS Guidance helps advance the ball toward international harmonization of SaMD regulatory requirements. International harmonization is important to the Coalition as many sponsors market their products across several world markets. Inconsistent regulatory requirements across such world markets create challenges for sponsors and can delay patient access to safe and effective products. Accordingly, the Coalition supports FDA's participation in the IMDRF in general, as well as in drafting this particular guidance document.

To fully realize the benefits of the IMDRF QMS Guidance, however, it must be formally adopted in the U.S. To that end, the CDS Coalition requests that FDA adopt the IMDRF QMS Guidance. Specifically, we propose that FDA issue the IMDRF QMS Guidance (utilizing the Agency's good guidance practices) in its current form with a cover letter/sheet attached that provides that FDA considers the principles within the document to be applicable in the U.S.

While adopting the IMDRF QMS Guidance in the U.S. would certainly represent a positive step forward for SaMD regulation, we believe that an additional guidance document is also needed to fill an important gap not addressed by the IMDRF QMS Guidance. The key purpose of this new guidance document would be for FDA to specify the QMS elements and associated level of documentation that it expects sponsors to maintain based on the risk level of their products. Although the IMDRF QMS Guidance notes that "[m]edical device QMS principles allow for scaling of activities depending on the type of medical device; risk of the product to patients; [and] size of the organization," among other factors, it does not detail the precise QMS elements or level of documentation required for SaMD products based on their level of risk.

In developing new guidance to fill this gap, we suggest that FDA consider its current guidance document related to premarket submissions, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. That document provides a table that describes required documentation for premarket submissions based on whether a product presents a minor, moderate or major level of concern. We recommend that FDA develop a similar table for QMS purposes, which would summarize the required QMS elements and level of documentation needed for SaMD products based on their risk.

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We very much appreciate your consideration of our requests. Please let us know if we can provide any further information or assistance in this matter.

Yours truly,

A handwritten signature in black ink, appearing to read "Bradley Merrill Thompson". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Bradley Merrill Thompson
On Behalf of the Clinical Decision Support Coalition