DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

July 18, 2018

Melissa Torres
Associate Director for International Affairs
Center for Devices and Radiological Health
Office of the Center Director
U.S. Food and Drug Administration

RE: Medical Device Single Audit Program (MDSAP)

Dear Ms. Torres:

On behalf of DITTA, we want to commend the MDSAP Consortium for convening the May 9 Medical Device Single Audit Program (MDSAP) Stakeholder Day in Ottawa, Canada. DITTA is the united global industry voice for diagnostic imaging, radiation therapy, healthcare ICT, electromedical and radiopharmaceuticals. DITTA strongly supports the aims of the MDSAP program, and the Consortium's efforts to move towards international harmonization of medical imaging regulations. However, we continue to have concerns about the implementation of the program and offer recommendations to improve it.

Many medical imaging manufacturers continue to experience long wait times to schedule audits and receive audit results or certificates, despite MDSAP Program guidelines that require adherence to specific timelines[1]. Earlier this year, DITTA conducted a survey of its members and noted the following issues.

Timing

- "Auditing organizations (AOs) [are] taking significant time from audit completion to issue certificates for MDSAP."

- "The main issue we have experienced is the timely receipt of our MDSAP certificate. We were audited to 13485:2016, under MDSAP scope as well, back in early September and still have not received our MDSAP certificate."

[1] Medical Device Single Audit Program, Post-Audit Activities and Timeline Policy, MDSAP AU P0027.004, https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM406006.pdf.

- "It takes a while to get audit date confirmation. Sometimes this takes a couple of months."

In addition, companies continue to note variances between audits at different manufacturing plants that make it difficult for manufacturers to ensure they receive certification under MDSAP. Companies have also noticed issues with interpretation of findings, and with organization, costs, and planning.

Interpretation of Audit Findings and Results

- Misinterpretation of what is considered to be an outsourced process. Some AOs believe that all activities that are conducted by resources outside of the four walls of a site should be treated as "outsourced processes," even if conducted under the same Quality Management System. This was clarified in the ISO handbook but it is not widely known by AOs.

- Inconsistent audit time calculations and audit response criteria where multiple certification schemes are audited simultaneously. For example, MDSAP nonconformance response timeframes and evidences required do not align with ISO.

- Inconsistencies in the scoring methodologies between the various AOs as well as within the individual AOs. Scoring should be based on the applicable ISO clause associated with the MDSAP audit task found to be deficient, then escalated as needed according to MDSAP rules. This does not happen consistently. In addition, each AO seems to have a different interpretation of what is considered a "repeat" finding. These inconsistencies create a tremendous amount of angst for industry as repeats and high scores (4's and 5's) can have a significant impact on the success/failure of the audit.

Organization, Costs, and Planning

- Questions as to why audits of the European Union (EU) Medical Devices Directive (MDD) Technical File are being conducted as part of MDSAP, even though the EU is not a participating member of MDSAP.

- AO requests to review premarket applications that have already been reviewed and

approved by regulators, such as Health Canada or ANVISA.

- Audits against the requirements of all five MDSAP countries, even if the audited site is not required to be audited by a certain jurisdiction (e.g. audited site is not a legal manufacturer for Health Canada).

- Comparisons of the requirements between the five countries and the MDD and trying to draw equivalence or comparison between the actions taken for compliance across these jurisdictions, vs. evaluating each set of regulatory requirements and compliance to them independently. This type of activity would imply that a requirement in one jurisdiction should be applied across all jurisdictions, which is not the case.

Therefore, we request that the MDSAP Consortium gather to review program inconsistencies, revise the companion document, and ensure that manufacturers and AOs are aware of the MDSAP timeline requirements. We request that the group include additional guidance that would address variances in interpretations, as well as MDSAP expectations for auditing against country-specific regulatory requirements.

DITTA also encourages the US FDA to continue to support a strong MDSAP and international regulatory harmonization at the upcoming September meeting of the International Medical Device Regulators Forum in Beijing.

If you have any questions, please don't hesitate to contact Carolyn Hull, Manager of Global Regulatory Standards at MITA (703-841-3242, or chull@medicalimaging.org).

Thank you for your consideration.

Sincerely,

Patrick Hope
DITTA Chair

Cc: David Boudreau, Executive Director, Health Canada