DITTA Contribution on Medical Device Single Audit Program

at the occasion of the IMDRF Meetings in San Francisco, 25-27 March 2014

DITTA shares IMDRF's view on MDSAP in recognizing the value of an international approach to the auditing of medical devices on a global scale. Public health in the 21st century will be further advanced by increased coordination between regulators combined with a more efficient and sustainable audit process that saves resources for regulators as well as manufacturers.

DITTA appreciates the opportunity to share the following key points with regard to MDSAP:

1. **IMDRF member countries should fully adopt and implement the IMDRF MDSAP guidance documents.**
2. **Ensure transparent, clearly-defined and timely communication with manufacturers.**
3. **Regulatory Authorities adopt a consistent approach to Auditing Organizations oversight.**
4. **Auditing Organizations requirements must follow and be evaluated against common requirements.**
5. **Witnessed Audits need to be clearly explained and kept to a minimum.**

Implementation – the success of the IMDRF MDSAP depends on the commitment of IMDRF members to implement the guidance documents they helped draft. We recognize reasons for some member country delays in pilot participation, adoption, and implementation of the final guidance (e.g., changes to medical device laws and creation of mutual agreements). We urge others member countries, especially the EU and its member states, to hasten decisions that would allow the EU to implement MDSAP.

Transparency – the MDSAP's processes must be made transparent and include regular, timely communications to manufacturers. Strict, clearly-defined requirements for AO's handling of confidential information are needed, e.g., notify manufacturers in advance of proprietary information being shared publically. Additionally, a well-defined appeals process is needed when a manufacturer disagrees with the audit findings.

RA Oversight – Consistent, well-defined, and transparent RA oversight of third-parties AOs is critical to MDSAP working as intended. RAs must adhere to guidance documents (N5 and N6) which describe the assessment methods and competency requirements for RAs to recognize and monitor third-party AOs.
A mechanism is needed for manufactures' input to be considered by RAs when AOs are evaluated for recognition and revocation purposes. An appeals/complaint process for the manufacturer should be clearly defined and include timelines. DITTA appreciates the opportunity for public comment on any additional AO guidance documents created/released during the MDSAP pilot.

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AO Requirements – AOs should have equal opportunity to succeed and further the objectives of IMDRF MDSAP. In doing so, participating AOs should be required to institute and follow a Code of Conduct as defined by IMDRF, including adherence to guidance documents (N3 and N4) that describe the recognition, competency and training requirements of participating AOs. Conflicts of interest will need to be properly addressed by IMDRF and the contractual requirements/stipulations between AOs and manufacturers that participate in the MDSAP be clearly defined and understood by all involved.

Witnessed Audits – The N5 guidance document should provide clarification as to what constitutes a witnessed audit, including the frequency and transparency of witnessed audits, as well as requirements for the manufacturer to receive advance notice. In the interest of preventing bias during the assessment of an AO, it is important that the RA assessor not unduly influence the AO regarding a manufacturer. Once an AO has begun an audit, the RA should refrain from questioning the AO until the final report is issued.

DITTA is a global association of manufacturers that represent medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers. Member companies manufacture: medical x-ray equipment; computed tomography (CT) scanners; ultrasound; nuclear imaging; radiation therapy equipment; magnetic resonance imaging (MRI); imaging information systems; medical software and health IT; and radiopharmaceuticals.

DITTA's membership currently includes ABIMED (Brazil), CAMDI (China), COCIR (Europe), IMEDA (Russia), ITAC (Canada), JIRA (Japan), KMDICA (Korea), MEDEC (Canada), MITA (United States) and THAIMED (Thailand).