IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Clarification of the Term "Legal Entity" for MDSAP Recognition Purposes

Authoring Group: IMDRF MDSAP Working Group

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For purposes of MDSAP recognition in accordance with IMDRF/MDSAP WG/N11, the applicant for recognition as an Auditing Organization is deemed to be the legal entity.

The applicant must clearly delineate the perimeter of the legal entity, and establish a specific address, where the management responsible for the MDSAP recognition program is employed by that legal entity.

The management responsible for the MDSAP program must comply with IMDRF/MDSAP WG/N3 section 7.1.3. where, "The management of the Auditing Organization shall have appropriate knowledge and processes to: set up and operate a system for the selection of the auditing personnel, the verification of their competence, the assignment of their tasks, their initial and ongoing training, and, their instruction and monitoring to ensure that personnel who administer and perform the audits are competent to fulfill the tasks required of them."

The management for the MDSAP program is directly responsible for, manages, and retains authority for the following:

- Establishment of the contract with the medical device manufacturer (including the requirements of N3 – 5.1.4, 5.1.5);
- Identification of competence requirements for any internal or external auditor or technical expert to perform specific activities (N3 – 7.5.1); and,
- Final review and decision-making on conformity to regulatory requirements (N3 – 7.5.1).

These listed activities cannot be delegated outside of the applicant's legal entity, even to a related organization or a subsidiary.

Under the MDSAP recognition program, these related organizations or subsidiaries are regarded as separate legal entities.