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	Version Date: 2023-10-02	Effective Date: 2023-10-02
Title: MDSAP QMS Policy and Objectives	Project Manager: Hiromi Kumada, PMDA	

Quality Policy

The policy for all participating Medical Device Single Audit Program (MDSAP) Regulatory Authorities (RAs) is to promote current and best practices for the development and management of activities for a third party regulatory auditing program for medical devices.

The participating MDSAP Regulatory Authorities will strive to achieve effective, world-class development and management of the Medical Device Single Audit Program through:

- demonstrated compliance with MDSAP QMS Program policies and procedures;
- consistent adherence to high ethical standards of conduct, as individuals and organizations;
- decisions based on objective evidence generated through observation and analysis whenever possible; and,
- using intelligence gathered through program implementation to continually improve program performance.

Management is to maintain and promote this quality policy to ensure that it:

- is appropriate for the purpose of MDSAP
- demonstrates a commitment to meet requirements and to continually improve the effectiveness of the quality management system
- provides a framework for defining, establishing, documenting and reviewing quality objectives
- is a valued foundation for quality objectives, and
- is communicated and understood within the MDSAP “community”.

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Quality Objectives

MDSAP participants have set forth a number of performance goals; each being the consequence of an intentional strategy and with specific performance indicators. These goals, and their indicators, are the measurable statements of the expectations for all MDSAP participants. Taken as a whole, they are representative of the standards used to measure the achievement and accountability of each MDSAP site.

The performance goals and their indicators are the quality objectives that will affect specific functions within MDSAP. The quality objectives are to identify and drive critical areas of focus to ensure we are meeting the requirements of the participants. The MDSAP participants and the Regulatory Authority Council (RAC) will conduct an annual review of the quality objectives. They will serve as a measure of our past performance, as an assessment of the effectiveness of the quality management system, and as the basis for a needs assessment for the development of future initiatives, strategies and resources.

The quality objectives are defined in the document available on the Box.

Version 003
Approval

Approved: On File Date: 2023-09-22
 CHAIR, MDSAP RAC