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”.

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 and annual review 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.

MDSAP participants will use following five areas of focus to implement the infrastructure for the significant components of a quality management system that seeks to comply with requirements identified in ISO 9001:2008.

Quality Management Framework. Establish[1] a QM framework that is consistent with the principles of ISO 9001:2015. Whenever possible, the framework should build upon existing procedures and practices.

Quality Management Responsibilities and Resources. Identify and define key roles, responsibilities and resources needed to establish MDSAP's QM Program.

Control of Documented Information. Establish and maintain a document control procedure for Quality Management documents and forms, and a records management system for quality records.

Nonconformity and Corrective Action. Establish common corrective action and continual improvement process for each MDSAP site. This process should l include mechanisms for collecting and tracking quality issues to eliminate the cause of the nonconformity, in order that it does not recur or occur elsewhere. Additionally, the process should allow to continually improve the suitability, adequacy and effectiveness of the quality management system.

[1] *Establish* means define, document, and implement.

Internal Quality Audits. Establish an audit program that is effectively implemented and maintained by developing a procedure for which MDSAP conforms to their own requirements and that defines audit criteria and scope for each intern audit.

Management Review. Develop a management review procedure to allow MDSAP RAC to review at planned intervals the QMS, and to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of MDSAP.

Recognizing that implementation of the quality management system will take time, the following two strategies focus on applying the framework to selected key processes and services:

Key Business Processes under Quality Management. Identify and prioritize key business processes that are aligned with MDSAP priorities, to serve as the initial focus of development activity for quality procedures.

Key Business Process Evaluation. For selected business processes, assess or audit existing procedures and practices to identify quality system elements that may already exist and identify additional elements that are needed to comply with the required elements of the framework.

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Approval

Approved: Signature on file_____ Date: 2016-10-24___
CHAIR, MDSAP RAC