MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

QUALITY MANAGEMENT SYSTEM MANUAL

Australia - Therapeutics Goods Administration (TGA)
Brazil - Agência Nacional de Vigilância Sanitária (ANVISA)
Canada - Health Canada/Santé Canada
Japan - Ministry of Health, Labour and Welfare (MHLW) and
Pharmaceuticals and Medical Devices Agency (PMDA)
United States of America - Food and Drug Administration (FDA)

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NOTE: The MDSAP Quality Management System Manual contains basic quality requirements. The Quality Management System is in the process of being implemented. As implementation takes place, more supporting documents may be added.

Foreword

The use of a quality management system approach is increasing within government and industry. To enhance consistency, efficiency and effectiveness of day-to-day work, MDSAP has adopted a quality management system model derived from IWA 4 Quality Management Systems – Guidelines for the application of ISO 9001:2015 in local government.

The MDSAP Quality Management System (QMS) provides guidance to:
(1) Design and develop processes, products/outcomes, and services related to the MDSAP's mission, and to critical management and administrative support services, and
(2) Continually improve and strengthen product/outcome and service quality.

This MDSAP Quality Management System Manual contains the required information to implement quality principles and practices throughout MDSAPs sites. The anticipated audience for this manual includes those in the public, regulated industry, counterpart agencies, and other MDSAP participants and members who wish to understand MDSAP QMS.

Training is an essential element of QMS implementation.For all MDSAP participants, training is necessary prior to achieving accountability for the policies and procedures described in this manual. For others, general information about quality systems may be found on the Internet at:

- American Society for Quality, "Learn About Quality" www.asq.org
- International Organization for Standardization - ISO 9001:2015 www.iso.org

Distribution: MDSAP participants/members and the general public may access the current ('controlled') version of the MDSAP Quality Management System Manual through FDA's website: https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-qms-procedures-and-forms.

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Introduction

The intent of the Medical Device Single Audit Program (MDSAP) is the development, management and oversight of a single audit program that will allow a single regulatory audit conducted by a recognized auditing organization to satisfy the needs of multiple regulatory jurisdictions.

MDSAP RA's have established the processes and procedures for participating regulatory authorities to recognize and monitor auditing organizations and their auditors.   MDSAP QMS will allow for the leveraging of regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers' quality management systems.

The single audit of a medical device manufacturer's quality management system will include the assessment of design and development (where appropriate), Good Manufacturing Practices (GMPs), adverse event reporting, and other applicable requirements of the participating regulatory authorities.

1. Scope

The MDSAP Quality Management System Manual specifies the requirements by which MDSAP:

- Demonstrates its ability to consistently provide services that meet customer and applicable regulatory requirements, and
- Enhances customer satisfaction through the effective application of the Quality Management System (QMS), including processes for continual improvement of the MDSAP system and the assurance of conformity to customer and applicable regulatory requirements.

The use of a quality management system within MDSAP helps MDSAP achieve its main goals and objectives in key focus areas such as:

- Processes
- Communication
- Organizational Effectiveness, and Efficiency

MDSAP participants believe that the development, implementation, and maintenance of a quality management system will improve the involvement of all MDSAP participants, staff, customers, (internal and external) and stakeholders in the decision-making process and will maximize the effectiveness of processes utilized in providing quality products and services to all MDSAP participants.

Through the implementation of the Quality Management System (QMS) policies and procedures, the Medical Device Single Audit Program provides for 1) designing and developing processes, products, and services related to the MDSAP's mission (including critical management and administrative support services), and 2) continually improving and strengthening MDSAP product and service quality. The MDSAP Quality Management System Manual is a key component for understanding the MDSAP's quality management system and is meant to provide clear organizational guidance. It is incumbent upon MDSAP participants to have an effective working knowledge of, and participate in the MDSAP Quality Management System (QMS).

In designing and implementing a quality management system, MDSAP QMS determines the following: 1) the customers' stated and implied needs; 2) applicable regulatory requirements for work processes and products; 3) other requirements identified by all MDSAP participants.

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The <u>goal</u> of the MDSAP Quality Management System is to improve the quality of MDSAP product and services. To accomplish our goal, a process-based quality management system based on ISO 18091:2014 Quality Management Systems – Guidelines for the Application of ISO 9001:2008 in Local Government, will be used to manage identified MDSAP processes. This manual describes what will be done within the quality management system to manage the identified processes utilized in providing products and services to customers and stakeholders and meet the requirement of the ISO 9001:2015 Standard. The role of the MDSAP participant in carrying out the basic business plan is illustrated below:
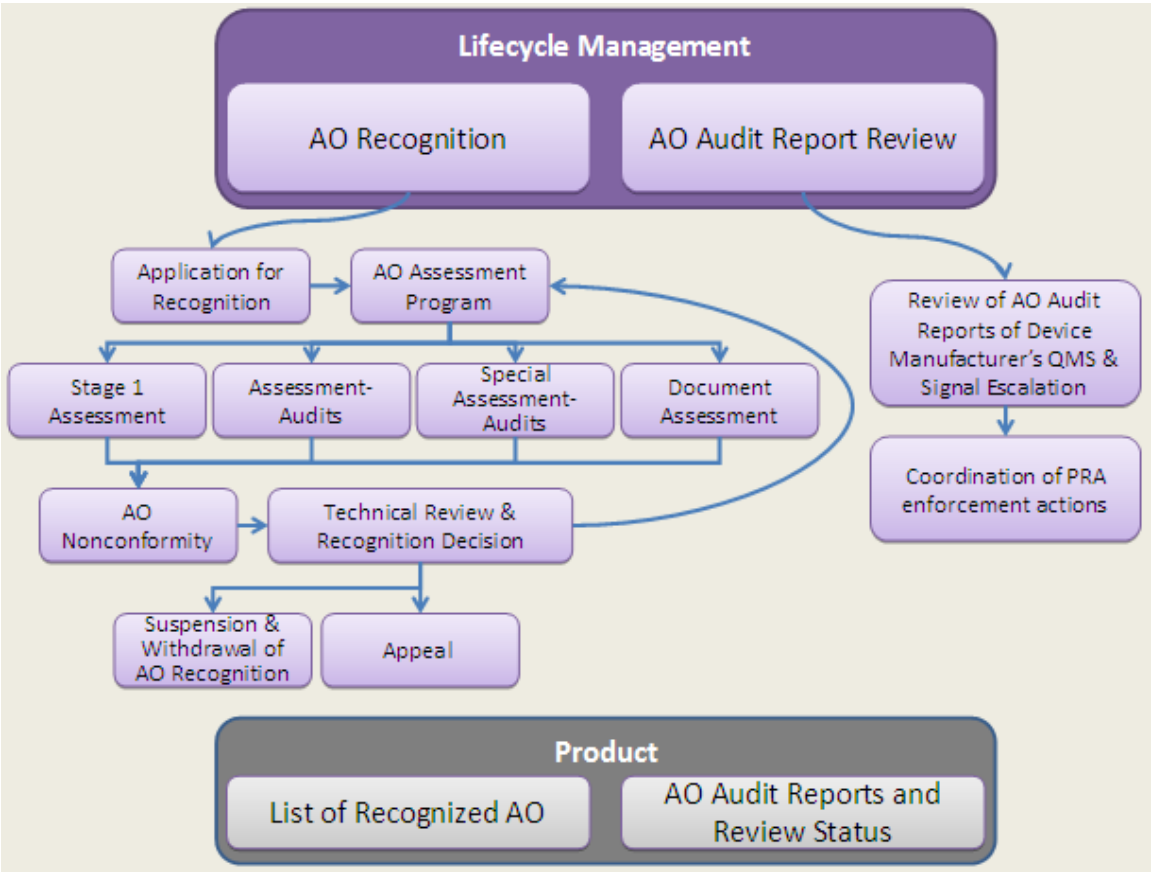
Figure 1: Basic Business Plan Graph

* * End of Section 1 * *

2. Normative References

The definitions and fundamentals upon which MDSAP Quality Management System is established are defined within the following documents:

- ISO 18091:2014 Quality Management Systems – Guidelines for the Application of ISO 9001:2008 in Local Government

- ISO 9001:2015 Quality Management Systems – Requirements

- ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary

- ASQ Quality Glossary

* * End of Section 2 * *

3. Terms and Definitions

Audit – Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled (ISO 9000:2015).

Competence – Ability to apply knowledge and skills to achieve intended results (ISO 9000:2015).

Conformity – Fulfillment of a requirement (ISO 9000:2015).

Continual Improvement – Recurring activity to enhance performance (ISO 9000:2015).

Corrective Action – Action to eliminate the cause of a nonconformity and to prevent recurrence (ISO 9000:2015).

Customer – person or organization that could or does receive a product or a service that is intended for or required by this person or organization (ISO 9000:2015).

Customer Satisfaction – Customer's perception of the degree to which the customer's expectations have been fulfilled (ISO 9000:2015).

Document – Information and the medium on which it is contained (ISO 9000:2015).

Infrastructure – System of facilities, equipment and services needed for the operation of an organization (ISO 9000:2015).

Management Review – A periodic management meeting to review the status and effectiveness of the organization's quality management system (ASQ Glossary)

Nonconformity – Non-fulfillment of a requirement (ISO 9000:2015).

Organization – person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives (ISO 9000:2015).

Procedure – Specified way to carry out an activity or a process (ISO 9000:2015).

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Process – Set of interrelated or interacting activities that use inputs to deliver an intended result (ISO 9000:2015).

Process Owner – The person who coordinates the various functions and work activities at all levels of a process, has the authority or ability to make changes in the process as required and manages the entire process cycle to ensure performance effectiveness. (ASQ Glossary)

Product – output of an organization that can be produced without any transaction taking place between the organization and the customer (ISO 9000:2015).

Provider – Organization that provides a product or a service (ISO 9000:2015).

Quality – Degree to which a set of inherent characteristics of an object fulfills requirements (ISO 9000:2015).

Quality Improvement – Part of quality management focused on increasing the ability to fulfill quality requirements (ISO 9000:2015).

Quality Management System (QMS) – Part of a management system with regard to quality (ISO 9000:2015).

Quality Manual – Specification for the quality management system of an organization (ISO 9000:2015).

Quality Objective – Objective related to quality ((ISO 9000:2015).

Quality Planning – Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to achieve the quality objectives (ISO 9000:2015).

Quality Policy – Overall intentions and direction of an organization related to quality as formally expressed by top management (ISO 9000:2015).

Requirement – Need or expectation that is stated, generally implied or obligatory (ISO 9000:2015).

Resources – People, time, money, equipment, and support activities, as necessary, that may apply to a specific project, product, process, and/or contract in order to fulfill requirements.

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Risk – Effect of uncertainty (ISO 9000:2015).

Service – Output of an organization with at least one activity necessarily performed between the organization and the customer (ISO 9000:2015).

Stakeholder – Person or organization that can affect, be affected by, or perceive itself, to be affected by a decision or activity (ISO 9000:2015).

Training – A structured process for communicating knowledge and developing skills.

* * End of Section 3 * *

4. Context of MDSAP

4.1 Understanding MDSAP and its context

MDSAP was officially created on November 27th 2012 through the signature of a Statement of Cooperation between the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Surveillance Agency (ANVISA), Canadian Health Products and Food Branch (HPFB) and the United States Food and Drug Administration (FDA). On July 24th 2015, Japan's Ministry of Health, Labour and Welfare and the Japanese Pharmaceuticals and Medical Devices Agency signed the MDSAP Functional Statement (MDSAP P0001.002) joining the Program.

The goal of the MDSAP is to provide for more effective, efficient and less burdensome regulatory oversight of the quality management systems of medical device manufacturers. The implementation of the MDSAP is intended to allow for a single audit to satisfy the regulatory requirements of the participants.

The participants developed a joint work plan for the MDSAP. This work plan was intended to enable the pooling of technology, resources and services to improve the safety and oversight of medical devices in a more efficient manner that is also less burdensome for industry.

Each participanting Regulatory Authority is responsible to fund its participation in MDSAP activities and to maintain the confidentiality of the information shared under MDSAP.

4.2 Needs and expectations of interested parties

The interested parties on MDSAP are the participanting Regulatory Authorities (RAs), Auditing Organizations (AOs), Medical Device Manufacturers (MDMs) and medical devices consumers.

The RAs expect that MDSAP will enable the appropriate regulatory oversight of MDMs quality management systems, with the use of resources in a more efficient and flexible manner through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority. The RAs also expect to promote, long term, greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices.

The AOs main expectation is to be able to perform regulatory audits that corresponds to RAs needs, based on standardized procedures and practices.

The MDMs main expectation is the minimization of the regulatory burden by reducing the number of audits/inspections and by having access to a more consistent, predictable and transparent regulatory process.

The medical device consumers will benefit from the program because of the improved safety and more efficient oversight of medical devices by the RAs.

4.3 Scope of the quality management system

All requirements from ISO 9001:2015 are applicable to MDSAP.

4.4 Quality management system and its processes

MDSAP RA's have defined, documented and deployed a quality management system that is designed to enhance customer satisfaction through the fulfillment of customer requirements. The system is comprised of a series of process-based methodologies that are designed to ensure that the system is deployed, maintained and continually improved in accordance with the requirements of ISO 18091:2014 Quality Management Systems – Guidelines for the Application of ISO 9001:2008 in Local Government. MDSAP QMS is mantained by:

- Identifying the processes necessary for the operation of its QMS within the stated scope;
- Determining the sequence and interaction of these processes;
- Determining the criteria and methods needed to ensure that both the operation and control of processes are effective. The criteria and methods have been identified within each process described or referenced in this manual (Section 8.5 – Production and Service Provision);
- Ensuring the availability of resources and information necessary to support the operation and management of these processes. (Section 7 - Support);
- Monitoring, measuring and analyzing these processes (Section 9 – Performance Evaluation);
- Implementing actions necessary to achieve planned results and continual improvement of these processes. (Section 10 – Improvement).

<div align="center">* * End of Section 4 * *</div>

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5. Leadership

5.1 Leadership and Commitment

5.1.1 General

The commitment to implement a quality management system under the ISO 9001:2015 International Quality Standard sends a strong message to MDSAP participants, staff and stakeholders that the program is committed to developing and maintaining an effective QMS. MDSAP RA's strive to maintain and continually improve the effectiveness of the QMS by:

- Communicating to MDSAP participants, staff and stakeholders the importance of meeting customer, as well as, statutory and regulatory requirements;
- Establishing a quality policy (section 5.2 – Policy), that embodies management's commitment to quality;
- Ensuring that organizational quality objectives (section 6.2 – Quality Objectives and Planning to Achieve Them), consistent with the policy, are established;
- Conducting management reviews (section 9.3 – Management Review) to ensure the continuing suitability, adequacy and effectiveness of the quality management system; and
- Ensuring the availability of resources (section 7.1 – Resources) needed to maintain and continually improve the quality management system.

Regulatory Authority Council (RAC) and RAC Chair lead and manage MDSAP in a systematic and visible manner that aligns with the following quality management principles:

- Customer Focus – Management strives to understand current and future customer needs to meet customer requirements and to continually exceed customer expectations;
- Leadership – Management develops an annual strategic action plan to meet the performance indicators for each performance goal (quality objective);
- Involvement of People – MDSAP RA's value people and maintain an environment in which people can become fully involved in achieving goals and objectives set on MDSAP;

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- Process Approach – Management defines critical processes designed to achieve desired results, measures inputs and outputs of the processes, and evaluates the impact of those processes on customers and other stakeholders;
- System Approach to Management – Management defines the system by identifying processes that affect objectives, structuring the system to achieve the objectives in the most efficient way, understanding the interdependencies among the processes, and continually improving the system through measurement and evaluation;
- Continual Improvement – Continual improvement of services, processes, and systems in an ongoing commitment of MDSAP RA's;
- Factual Approach to Decision Making- Effective decisions are based on the analysis of data and information;
- Mutually Beneficial Stakeholder Relationships – Because MDSAP and its stakeholders are interdependent, MDSAP participants seek to maintain a mutually beneficial relationship and open communication.

Management's successful use of the above principles will result in benefits to all MDSAP participants, staff, stakeholders and the MDSAP "community".

5.1.2 Customer Focus

To ensure value for all customers, MDSAP RA's determine customer needs and expectations through ongoing communication with the MDSAP "community" in a variety of venues that include: board meetings; focus groups; and customer/stakeholder surveys. Upon determining customer needs and expectations, management translates these needs and expectations into requirements as a set of standards or performance goals to which each MDSAP site will be held accountable. A "Customer Feedback Survey" was developed to establish a baseline regarding the degree of satisfaction with identified services and to identify other possible service areas for future inclusion in the QMS.

5.2 Policy

The MDSAP Policy establishes clear standards and expectations for the delivery of quality work and services, individual commitment and accountability, and continuous improvement for participating RA's sites.

Management ensures that the policy:

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- Is appropriate to the purpose of MDSAP;
- Includes a commitment to meet requirements and continually improve the effectiveness of the quality management system;
- Provides a framework for defining, establishing, documenting and reviewing quality objectives. Quality objectives have been established for each key element of the policy (section 6.2 – Quality Objectives and Planning to Achieve them);
- Is communicated and understood within the MDSAP "community"; and
- Is reviewed for continuing suitability. The review of the quality policy is a standing agenda item for the Management Review meetings as described in the MDSAP QMS P0005 – Management Responsibility and Management Review Procedure. (Section 9.3 – Management Review).

5.3 Organizational roles, responsibilities and authorities

The Top Management in MDSAP is composed of the Regulatory Authority Council (RAC), including the RAC Chair and the Vice RAC Chair.   (For additional information, refer to List of RA representative and MDSAP P0003 – MDSAP Roles and Responsibilities.)   Top Management should identify functions and their interrelations within MDSAP through organization charts, procedures and flowcharts, and meet "as needed" to conduct and discuss the business of MDSAP system and to make system-level decisions for approval. The Chairperson has defined and communicated the responsibility and authority to implement and maintain an effective and efficient QMS within MDSAP. The RAC function's as Top Management; therefore, it will also serve as the Management Review Team which will monitor the operation of the QMS according to the documented MDSAP QMS P0005 – Management Responsibility and Management Review Procedure. Responsibility for QMS core business processes, support and improvement processes have been defined within each documented process. Job descriptions are maintained at each MDSAP site within the Department of Human Resources for all employees having responsibility for and engaging in process execution.

RAC has appointed an MDSAP Quality Management System Management Representative who, irrespective of other responsibilities, has the responsibility and authority for:

- Ensuring that processes needed for the quality management system are established, implemented and maintained;

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- Reporting to RAC on the performance of the quality management system and any need for improvement;
- Ensuring the promotion of awareness of customer requirements throughout the organization;
- Serving as liaison with external parties on matters relating to the quality management system; and
- Organizational freedom to resolve quality matters.

For each Regulatory Authority there is an MDSAP Quality Management System Site Representative who is responsible for assisting the MDSAP Quality Management System Management Representative on the implementation of the quality management system at his/her respective site.

In order to fulfill the above responsibilities, the MDSAP QMS Management Representative and MDSAP QMS Site Representatives should possess the following competencies:
- Experience performing audits and/or inspections of quality management systems to regulatory requirements and applicable standards
- Experience performing MDSAP assessments of Auditing Organizations seeking to obtain or maintain recognition
- Knowledge of ISO 9001, ISO 17021, and ISO 13485
- Knowledge of the MDSAP quality management system, policies, and procedures
- Familiarity with the use of IMDRF MDSAP documents

* * End of Section 5 * *

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6. Planning

6.1 Actions to address risks and opportunities

MDSAP RA's have developed a Quality Management System that allows for the evaluation of risks and opportunities and taking actions to address them. The risks are evaluated and treated through the MDSAP QMS P0004 – Risk Management Procedure and can be identified from many QMS processes, such as, Nonconformity and Corrective Action (MDSAP QMS P0009), Internal Audits (MDSAP QMS P0008), Complaint and Customer Feedback (MDSAP QMS P0011) and Management Review (MDSAP QMS P0005). Opportunities for improvement are handled under MDSAP QMS P0013 – Continual Improvement Procedure.

6.2 Quality Objectives and planning to achieve them

MDSAP RA's set forth a number of performance goals with specific performance indicators and strategies for each goal. These goals and indicators are the concrete, measurable statements of the expectations for all MDSAP participants. Taken as a whole, these goals are an overview of the standards that will be used to measure each MDSAP site's achievements and accountability. The performance goals and indicators are the quality objectives that impact specific functions and levels within MDSAP. The quality objectives are used to identify critical areas of the Program's quality focus to ensure customer requirements are met. These quality objectives are reviewed annually (by MDSAP participants and RAC) as a measure of MDSAP performance and to assess the effectiveness of the quality management system. The results also serve as a needs assessment for the development of future initiatives, strategies and resources. The current quality objectives are defined on the document available in Box.

6.3 Planning of changes

The RAC ensures that:

- The planning of the QMS is carried out in order to meet the requirements delineated in Section 4.4 and for achieving performance goals (quality objectives); and
- The integrity of the QMS is maintained when changes are planned and implemented.

Planning of changes focuses on identifying, defining, documenting, monitoring, evaluating and improving processes that are needed to meet quality objectives and customer requirements. The RAC identifies needs and requirements for MDSAP through the continual improvement process. QMS internal audits are used to maintain system integrity.

<p align="center">End of Section 6 * *</p>

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7. Support

7.1 Resources

7.1.1 General

The MDSAP budget planning process is aligned with performance goals of the MDSAP system and identifies the human and fiscal resources needed to attain those goals. The MDSAP budget is subject to review and approval by the participating governments.

Through the budget planning process, MDSAP RA's determine and provide the resources needed to:

- Implement and maintain the QMS and continually improve its effectiveness; and
- Enhance customer satisfaction by meeting customer requirements. (Section 9.1.2 – Customer Satisfaction).

The MDSAP quality objectives include the need for identification and definition of the necessary resources to establish and maintain the quality management system.

7.1.2 People

MDSAP RA's ensure that all participants/staff performing work affecting conformity to product and service requirements are competent with respect to appropriate education, training, skills and experience. It is the responsibility of each MDSAP RA to insure that all personnel, whose job requires knowledge of product and service specifications, are made aware of any changes to product and service specifications.

The necessary training for assessment activities are defined on IMDRF/MDSAP WG/N6FINAL:2021(Edition 2) – Regulatory Authority Assessor Competence and Training Requirements.

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7.1.3 Infrastructure

MDSAP RA's determine, provide and maintain the infrastructure needed to achieve conformity to product and service requirements. This can be done through the annual MDSAP budget planning process. The infrastructure includes, <u>as applicable</u>:

   a) Buildings, workspace and associated utilities;
   b) Process equipment (both hardware and software); and
   c) Supporting services to ensure the effective functioning of the MDSAP Quality System.

7.1.4 Environment for the operation of processes

MDSAP RA's determine and manage the work environment needed for the operation of its processes and to achieve conformity to service requirements. This is accomplished through QMS planning, management review, maintenance and operations. Management also ensures the work environment has a positive influence on motivation, satisfaction and performance of each individual working for the MDSAP "community" to enhance the overall MDSAP performance.

7.1.5 Monitoring and measuring resources

MDSAP RA's provide the necessary resources to monitor and measure its results. The monitoring of MDSAP activities is described below in Section 9, Performance Evaluation.

7.1.6 Organizational knowledge

Organizational knowledge was established thorough the development of MDSAP processes and documents and is continually maintained and developed by evaluation of changing needs, group discussions, complaint handling process, management reviews, continual improvement process, etc.

7.2 Competence

Training and the methodologies used to meet the below requirements are described in the MDSAP QMS P0014 – Training Procedure.

MDSAP management:

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- Determines the necessary competence for participant/staff performing work affecting conformity to product and service requirements;
- Where applicable, provides training or takes other actions to achieve necessary competence;
- Evaluates the effectiveness of the actions taken; and
- Maintains appropriate records of education, training, skills and experience.

7.3 Awareness

Top management is responsible to ensure that its participants/staff are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

7.4 Communication

MDSAP has created appropriate processes to ensure communication among its various levels and functions regarding the processes of the Quality Management System and their effectiveness. Additionally, the RAC actively encourages feedback and communication from all MDSAP participants as a means of engaging all stakeholders.

7.5 Documented information

7.5.1 General

The Quality Management System documentation includes:

- Documented statements of a quality policy (see 5.2.1) and quality objectives, (see 6.2) or reference to them;
- Quality Management System Manual;
- Documented procedures required by the ISO Standards and MDSAP; and
- Documents, including records, determined by MDSAP as necessary to ensure the effective planning, operation and control of its processes.

The following graphic illustrates the overall structure of the QMS, and identifies the levels of documentation that make up the system.

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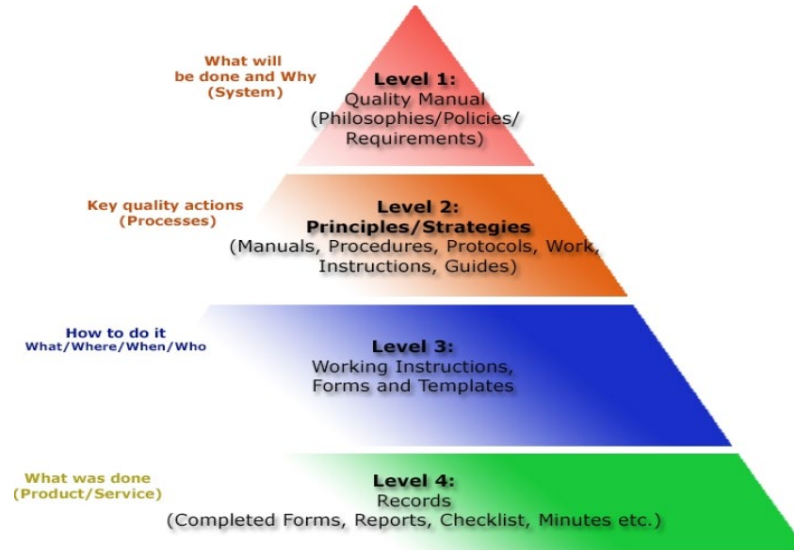
Figure 2: Documentation Hierarchy and structure of the Quality Manual.
Level 1: Defines Approach and Responsibility
Level 2: Defines Who, What, When
Level 3: Answers How
Level 4 Results: shows that the system is operating

MDSAP RA's have established and maintain the Quality Management System Manual (Level 1 document) to define ISO 9001:2015 and MDSAP requirements. The quality manual includes:

- Scope of the QMS (Section 1);
- Reference to the documented procedures (Level 2) required for the QMS and for providing products and/or services to our customers;
- A description of the interaction between processes, and
- A graph (Figure 3) that illustrates the QMS linkages of requirements presented in Section 4 to 10. The illustration shows that customer requirements play a significant role in defining requirements requires the evaluation of information relating to the perception of customers and interested stakeholders as to whether MDSAP has met its requirements.

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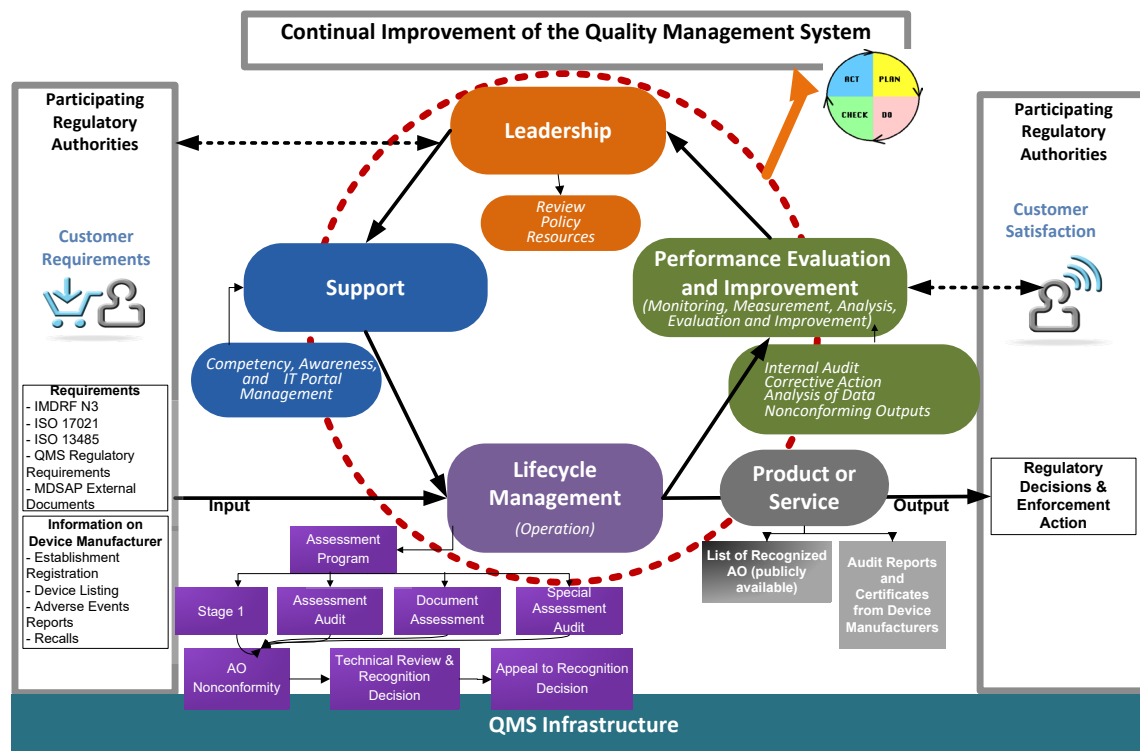
Figure 3: MDSAP Quality Management System Linkages.

7.5.2 Creating and updating

The Quality Management Manual and Level 2 and 3 documents are updated and revised as needed to reflect the current management system or changes in process methodologies. Online versions of these documents are controlled; therefore all printed versions of these documents are unofficial copies.

7.5.3 Control of documented information

Documents that are required by the MDSAP Quality Management System are identified and controlled according to the documented procedure "MDSAP QMS P0002 - Document Control and Approval Procedure", which establishes the controls needed to:

- Approve documents for adequacy prior to issue;
- Review and update as necessary and re-approve documents;
- Ensure that changes and the current revision status of documents are identified;

- Ensure that relevant versions of applicable documents are available at points of use;
- Ensure that documents remain legible and readily identifiable;
- Ensure that documents of external origin determined to be necessary for the planning and operation of the quality management system are identified and their distribution controlled; and
- Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Quality records are collected throughout the QMS as a means of demonstrating that required quality activities were performed. MDSAP QMS P0002 – Document Control and Approval Procedure, has been established to address quality record requirements. In addition, each core business process, support and improvement process document identifies the methodology for the identification, storage, protection, retrieval, retention time, and disposition of quality records.

It is the responsibility of each "process owner" to ensure that the required quality records are created and maintained in accordance with stated requirements.

* * End of Section 7 * *

8. Operation

8.1 Operational planning and control

MDSAP RA's plan and develop the processes needed to provide services to all participants within the scope of the QMS. Planning of operation is consistent with the other processes of the QMS. In operational planning, MDSAP RA's determine the following, as appropriate:

- The quality objectives and requirements for the product and/or service;
- The need to establish processes and documents, and to provide resources specific to the product and/or service;
- The required verification, validation, monitoring, auditing and activities specific to the service and the criteria for service acceptance; and
- The records needed to provide evidence that the operation processes and the resulting service fulfills the requirements.

The output of this planning has resulted in a quality management system that consists of a series of product and/or service delivery processes (Section 4.4) that includes the core methodologies used to ensure that product and/or services produced and delivered meet customer requirements.

The methodologies, also referred to as a quality plan, are used to address the above requirements are detailed below:

Elements	Planning Methodology
Quality Objectives and requirements for the product/service	Each process document includes reference to specific goals and performance indicators for the services which the processes support. Stakeholders and customers provide input regarding requirements for products/services.
Quality plans and methodologies to control the development of the product/service	Processes used to provide services are documented. That documentation specifies responsibilities related to the process, process objectives, the sequence of activities in process execution including required controls, monitoring and measurement methodologies, and provisions for document and record control.
Resources specific to the product/service	Provisions for resources to provide the service are made through the annual budget process.

Verification, validation and audit activities	Services requiring design such as technology development have these activities built into the process.
Establishment of quality records	Each documented process identifies the records that will be kept to provide evidence of process execution.

8.2 Requirements for products and services

8.2.1 Customer communication

MDSAP RA's, as necessary, determine and implement effective arrangements for communicating with customers (internal/external) in relation to requirements, changes, and customer feedback including customer complaints (See MDSAP QMS P0011 Complaint and Customer Feedback Procedure). MDSAP regularly communicates with internal and external customers through the following mechanisms:

- Communication and team meetings;
- Electronic media such as MDSAP website, Webex;
- Stakeholder input meetings; and
- RAC meetings.

8.2.2 Determining the requirements for products and services

MDSAP RA's determine:

- Requirements specified by MDSAP participants, stakeholders, internal and external customers;
- Requirements not stated by the customer, but necessary for specified or intended use;
- Other requirements (state/federal/international) related to the product and/or service; and
- Any additional requirements determined by MDSAP process.

8.2.3 Review of the requirements for products and services

Each documented core business process has built-in provisions for reviewing the requirements related to the product and/or service resulting from the execution of each process.

8.2.4 Changes to requirements for products and services

MDSAP QMS Management Representative/Site representatives ensure that the Regulatory Authorities and Auditing Organizations are aware of any change to the MDSAP requirements through the use of transmittals that are distributed to the relevant persons. Also, other stakeholders can subscribe to the MDSAP website to receive e-mail updates on documents.

8.3   Design and Development of products and services

8.3.1 General

MDSAP RA's provide planning, control and design input for the development/maintenance of the MDSAP IT Portal. MDSAP IT Portal is multi-program web-based IT portal that will assist MDSAP and other participating RAs in the secure exchange of regulatory information. MDSAP participants will also utilize MDSAP IT Portal to assist with the management of its operations and as the official MDSAP document repository.

8.3.2 Design and development planning

Design and development planning requirements are addressed in the MDSAP IT Portal Requirements document and other documents related to the project. During design and development planning the MDSAP IT Portal Working Group assists in determining:

- The design and development stages;
- The appropriate general, security and implementation requirements;
- The review, verification and validation that are appropriate to each design and development stage; and
- The responsibilities and authorities for design and development.

The MDSAP IT Portal Working Group manages the interface between different participating RA's sites and MDSAP IT Portal to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

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8.3.3 Design and development inputs

Inputs related to technology solution development requirements are determined and records are maintained. Inputs include:

- Functional and performance requirements;
- Applicable statutory and regulatory requirements;
- Where applicable, results derived from results of previous similar technology solutions; and
- Other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.

8.3.4 Design and development controls

At suitable stages within the "Technology Development Process", systemic reviews of design and development are performed in accordance with planned arrangements to:

- Evaluate the ability of the results of design and development to meet requirements; and
- Identify any problem and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained as specified in MDSAP QMS P0007 – Control of Quality Record Procedure.

Verification is performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained as specified in MDSAP QMS P0007 – Control of Quality Record Procedure.

Design and development validation is performed in accordance with planned arrangements to ensure that the resulting technology solution is capable of fulfilling the requirements for the specified or known intended use or application. When practical, validation is completed prior to the delivery or implementation of the technology solution. Records of the results of validation and any necessary actions are maintained as specified in MDSAP QMS P0007 – Control of Quality Records Procedure.

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8.3.5 Design and development outputs

The outputs of design and development of technology are provided in a form that enables verification against the design and development input and are approved prior to release. Design and development outputs:

- Meet the input requirements for design and development;
- Provide appropriate information for purchasing, production and service provision;
- Contain or reference acceptance criteria; and
- Specify the characteristics of the technology solution that are essential for its effective implementation.

8.3.6 Design and development changes

Design and development changes are identified and records are maintained. Changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on the technology solution being used. Records of the results of the review of changes and any necessary actions are maintained.
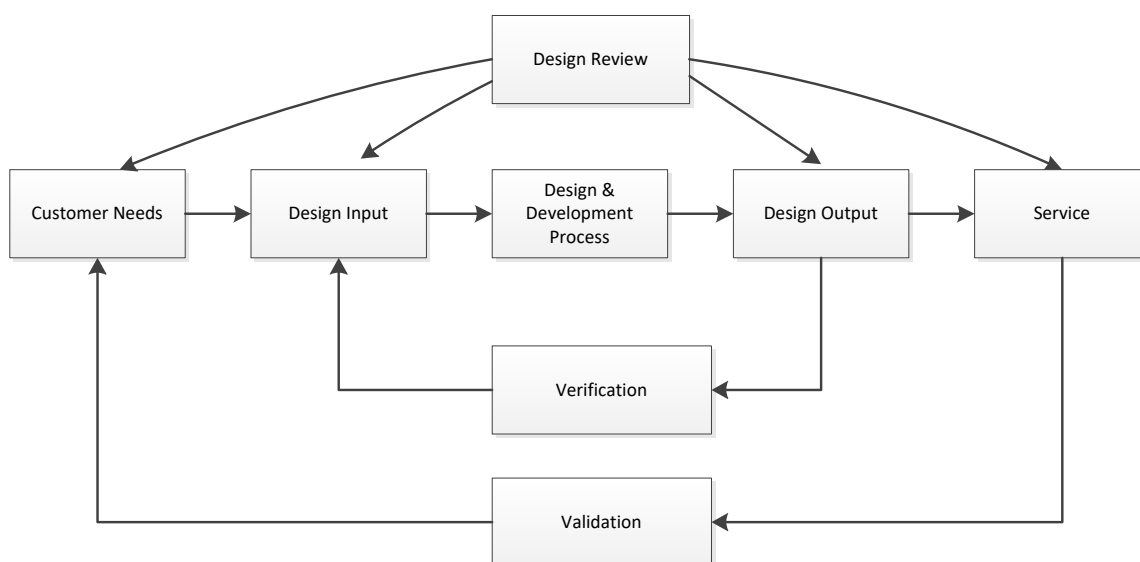
Figure 4: Design and Development Process for the IT Portal Development Project

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8.4 Control of externally provided processes, products and services

8.4.1 General

MDSAP RA's ensure that externally provided processes, products and services conform to specified requirements to assure the desired outcome. MDSAP input will be provided to the IT team to help evaluate and select vendors based on the ability to supply products/services in accordance with MDSAP and all other participating program(s) requirements. The IT team will maintain the results of evaluation and necessary actions arising from the evaluation.

8.4.2 Type and extent of control

Externally provided products or services are verified upon receipt for condition, completeness, identification, and general compliance with procurement document requirements, including availability of required documentation.

8.4.3 Information for external providers

MDSAP participants communicate with external providers its requirements for:

- Approval of product, services and processes;
- Qualification of personnel; and
- Quality Management System.

MDSAP RA's ensure the adequacy of specific purchase requirements prior to their communication to the supplier.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

To provide acceptable services to our stakeholders and/or customers, MDSAP QMS Management Representative/Site representatives have developed documented procedures to control operations. These procedures are referenced in this Quality Management System Manual.

MDSAP RA's plan and carry out those processes under controlled conditions that include, as applicable, the:

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- Availability of work instructions, as necessary;
- Use of suitable equipment, where applicable;
- Implementation of monitoring and measurement, and implementation of product release, delivery and post-delivery activities.

MDSAP RA's validate processes through monitoring, measurement and QMS internal auditing and/or assessment to ensure compliance. Validation demonstrates the ability of these processes to achieve the planned results. The execution of each process results in products and/or services which can be verified by subsequent measuring or monitoring. This includes any processes where deficiencies may become apparent only after the product is in use or has been delivered. In the case of processes that include design and development, such as technology, steps are also embedded in the processes to ensure suitability prior to release.

MDSAP arrangements for these processes include the following, as applicable:

- Defined criteria for review and approval of the processes;
- Approval of "equipment" where applicable and qualification of personnel;
- Use of specific methods and procedures;
- Requirements for quality records according to procedures and instruction; and
- Revalidation, where necessary.

8.5.2 Identification and Traceability

Where appropriate, MDSAP QMS identifies any product resulting from the execution of a process by suitable means to ensure recognition for delivery, use and the fulfillment of monitoring and measurement requirements.

8.5.3 Property belonging to customers or external providers

Customer property may include, but is not limited to, personal information received such as names, addresses, phone numbers, or other data. The MDSAP IT Portal Working Group, along with the IT team, identifies, verifies, protects, and safeguards this information and adheres to Privacy Act laws and requirements. MDSAP IT Portal is developed to provide a secure network to assist in safeguarding this information.

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8.5.4 Preservation

The outputs of MDSAP such as assessment documentation, training records, audit reports and manufacturer certificates will be securely stored on MDSAP IT Portal and in MDSAP/RAs IT systems.

8.5.5 Post-delivery activities

MDSAP post-delivery activities related to its products or services are handled under Complaints and/or Customer Feedback Procedure (MDSAP QMS P0011) and also may be an output of the Management Responsibility and Review Procedure (MDSAP QMS P0005).

8.5.6 Control of changes

MDSAP changes are controlled by MDSAP QMS P0002 – Document Control and Approval Procedure and any change on the program is properly documented and communicated to the stakeholders as stated in Section 8.2.4.

8.6   Release of products and services

The release of MDSAP products and services can be translated to the authorization/recognition of Auditing Organizations and issuance of Audit Reports and Certificates by the Auditing Organizations. Those activities are properly established, documented and controlled according to the MDSAP procedures.

8.7   Control of nonconforming outputs

MDSAP participants ensure that outputs which do not conform to requirements are identified and controlled to prevent its unintended use or delivery. The Level 2 MDSAP QMS P0009 – Nonconformity and Corrective Action Procedure define the controls and related responsibilities and authorities for dealing with nonconforming outputs.

Where applicable, MDSAP participants manage nonconformities by:

- Taking action to eliminate the detected nonconformity;
- Authorizing its use, release or acceptance under concession by a relevant authority, if needed;

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- Taking action to preclude its original intended use or application; and
- Taking action appropriate to the effects, or potential effects, of the nonconformity when a nonconforming output is detected after delivery or use has started.

* * End of Section 8 * *

9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

MDSAP RA's monitor and measure products/services to verify that products/ services requirements have been met. This is carried out at appropriate stages of the products/services operation in accordance with documented procedures. Monitoring of products/services is identified in applicable procedures and records maintained at each MDSAP RA site.

Annually, and after internal audit and/or assessment, each MDSAP site within the scope of the QMS reports to the RAC regarding its products/services and provides recommendations for improvement, as appropriate.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the project manager(s) authorizing release of the product/service. Product release and service delivery does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

MDSAP RA's apply suitable methods for monitoring and, where applicable, measuring quality management system processes. These methods demonstrate the ability of the processes to achieve planned results and also confirm the continuing ability of each process to satisfy its intended purpose. When planned results are not achieved, appropriate action is taken to ensure conformity of the process. When planned results are not achieved, appropriate corrective action is taken.

9.1.1 General

MDSAP RA's plan and implement the monitoring, measurement, analysis and improvement processes needed to:

- Demonstrate conformity to product and service requirements;
- Ensure conformity of the QMS; and
- Continually improve the effectiveness of the QMS.

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9.1.2 Customer satisfaction

MDSAP QMS Management Representative/Site representatives monitor information relating to customers' perception as to whether we have met customer requirements. Satisfaction within the MDSAP community is monitored through administration of an annual customer Feedback Survey in the execution of their processes. MDSAP also administers an annual Stakeholder Satisfaction Survey and obtains input through other sources such as RAC and team meetings.

9.1.3 Analysis and evaluation

MDSAP QMS Management Representative/Site representatives determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made.

The analysis of data provides information relating to, but not limited to:

- Customer satisfaction;
- Conformity to product requirements;
- Characteristics and trends of processes and products, including continual improvement.

The results of analysis are reported per the MDSAP QMS P0005 – Management Responsibility and Management Review Procedure to determine:

- Trends;
- Customer satisfaction;
- Effectiveness and efficiency of the processes;
- Benchmarking;
- Progress in meeting MDSAP quality objectives; and
- Areas needing improvement.

9.2 Internal Audit

MDSAP QMS Management Representative/Site representatives ensure that QMS audits and/or assessments are conducted at planned intervals to determine whether the quality management system:

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- Conforms to the planned arrangements, to the requirements of ISO 9001 Standard, and to the QMS requirements established by MDSAP; and
- Is effectively implemented and maintained.

The audit/assessment activity is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits/assessments. The internal audit criteria, scope and methods are defined. Selection of auditors and conducting these audits ensure objectivity and impartiality of the audit process. Auditors will not audit their own work.

The responsibilities and requirements for planning and conducting audits/assessments, and for reporting and maintaining records, are defined in the Level 2 and 3 MDSAP QMS P0008 – Internal Assessment Procedure and related templates. This procedure defines:

- The responsibilities and requirements for planning and conducting audits;
- That audits are conducted by personnel other than those who perform the activity being audited to ensure objectivity and impartiality of the audit process;
- That audit records and results to be maintained; and
- Reporting of results to management.

Each MDSAP RA site is responsible for the area being audited and takes timely corrective action on deficiencies found during the audit. Results of audits are recorded and maintained and follow-up actions include the verification of the implementation of corrective action and the reporting of verification results.

9.3 Management review

9.3.1 General

The RAC reviews the Quality Management System at least once a year (refer to MDSAP QMS P0005 – Management Responsibility and Management Review Procedure) and as needed to assess the system's effectiveness and its ongoing adequacy and suitability. This review evaluates any need for changes to the MDSAP Quality Management System, including its quality policy and quality objectives.

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9.3.2 Management review inputs

The input to management review is specified within the corresponding documented procedure and includes current performance and improvement opportunities related to the following:

- Internal quality audit results;
- Feedback from internal and external customers;
- Process performance and product conformance;
- Status of corrective actions;
- Follow-up action from previous management reviews;
- Changes that could affect the quality management system; and
- Recommendations for improvement.

9.3.3 Management review outputs

The output of management review is specified within the corresponding documented procedure and includes decisions and actions related to:

- Improvement of the effectiveness of the quality management system and its processes;
- Improvement of products and or services related to customer requirements; and
- Resource needs.

Results of management reviews are recorded and maintained according to MDSAP QMS P0005 – Management Responsibility and Management Review Procedure.

* * End of Section 9 * *

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10. Improvement

10.1 General

MDSAP participants continually improve the efficiency and effectiveness of the Quality Management System through the use of the quality policy, MDSAP objectives, internal audit results, analysis of data, corrective actions and management review.

10.2 Nonconformity and corrective action

MDSAP participants take action to eliminate the cause of existing nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. The Level 2 MDSAP QMS P0009 – Nonconformity and Corrective Action Procedure provides methodologies to address the requirements for:

- Reviewing quality data relating to nonconformities including customer complaints;
- Determining the causes of nonconformities;
- Evaluating the need for action to ensure that nonconformities do not recur;
- Determining and implementing action needed;
- Maintaining records of results of actions taken; and
- Reviewing the effectiveness of corrective actions taken.

Examples of information used by MDSAP to identify the need for possible corrective action are: stakeholder concerns and or complaints; internal and external audit reports; outputs from management review; outputs from data analysis; relevant QMS records; process measurements; and internal and external customer feedback surveys, including stakeholders' feedback surveys.

10.3 Continual Improvement

The effectiveness of the QMS is continually improved through specific processes and activities built into the system. The role of these quality improvement

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vehicles is described in the MDSAP QMS P0013 – Continual Improvement Procedure including the PDCA cycle (Plan-Do-Check-Act).

Continual improvement of the MDSAP processes is essential in the program's quality management system. Additional roles of quality improvement vehicles are described below.

Quality Policy – The quality policy was established to reflect the priorities of MDSAP internal/external customers and stakeholders. Additionally, it includes a commitment to strive for continuous improvement in both the quality of services provided and in the processes utilized to provide them.

Quality Objectives – Specific, measurable objectives have been established for each documented process within the quality management system. These objectives align with the key performance goals that are established to assess our overall performance. The objectives also provide a framework for measuring the effectiveness of our processes, as well as establishing a baseline for implementing and measuring improvement actions.

Internal Audit Results – The status of the internal audit results will be reported to the RAC, as described in MDSAP QMS P0008 – Internal Assessment Procedure. Summary audit reports contain recommendations for process or system improvements, including any corrective actions resulting from reported audit nonconformities.

Analysis of Data – Process owners review relevant data that is collected and analyzed to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate whether continual improvement of the effectiveness of the quality management system can be made.

Corrective Actions – This process identifies corrective actions needed to correct the cause of any existing nonconformity that occurs within the quality management system. Such actions are always viewed as an opportunity to improve the quality system.

Management Responsibility and Management Review – MDSAP QMS P0005 – Management Responsibility and Management Review Procedure describes the frequency of how often Management Reviews are scheduled/held. Those meetings provide an opportunity to review the results of all the above activities, assess the overall effectiveness of the system, and identify additional improvement initiatives that may be needed.

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The interactions of the processes and activities are depicted in the following flowchart.
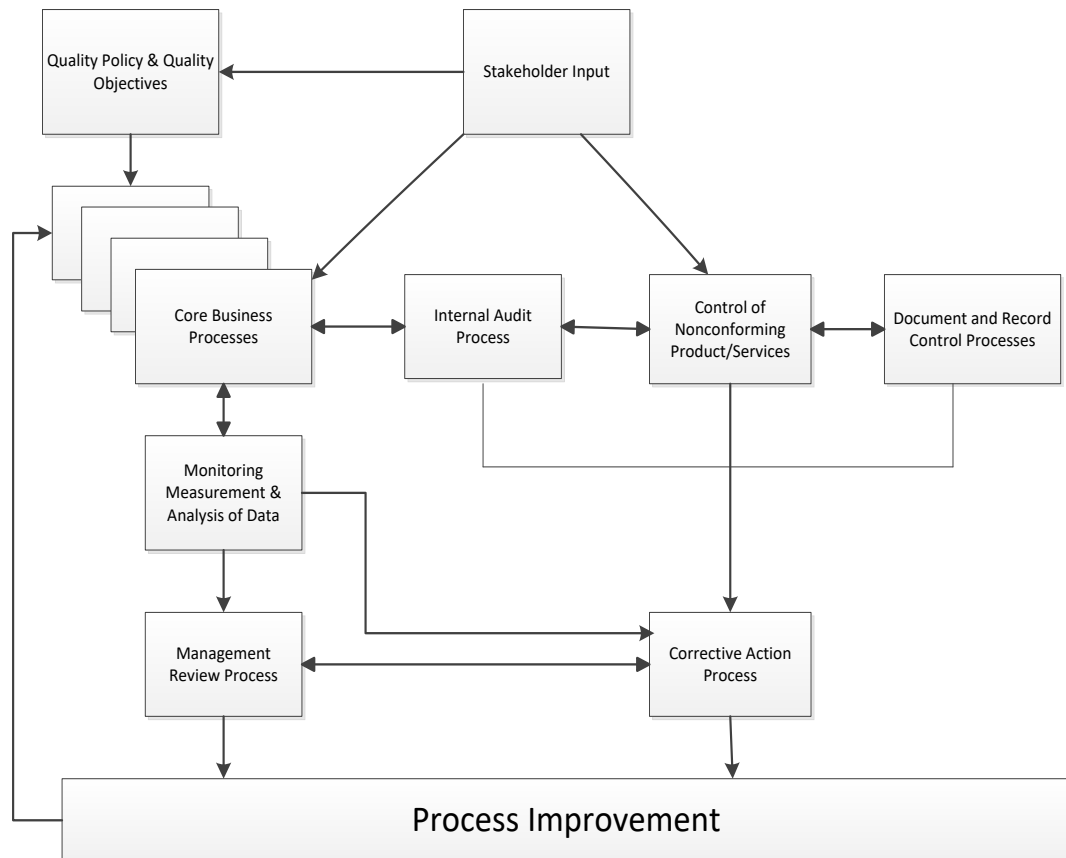

Figure 5: Interaction of the Processes

* * End of Section 10 * *

11. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-09-09	Initial Release	Liliane Brown
002	2015-09-22	The names of Japanese regulatory authorities were added on the top page due to Japan's participation to MDSAP Pilot. Minor revision was made throughout the document.	Liliane Brown
003	2017-01-09	Document revised to adequate the structure and terminology with the new version of ISO 9001:2015. Additionally, grammatical updates throughout the document including revision of the MDSAP RAs responsibilities.	Liliane Brown and Patricia Serpa
004	2019-01-11	Corrected color of font in section 8.1. "QMS Manager/replasentative" was replaced with "QMS Management Representative/Site Representatives" in section 8.2.4, 8.5.1, 9.1.2, 9.1.3 and 9.2. Deleted the word preventive action in section 10.3. Minor typo was corrected thoroughout the document.	Hiromi Kumada/Kimberly Lewandowski-Walker
005	2023-01-05	Updated the language align to MDSAP P0003 Renamed "REPS" to generic IT platform	Hiromi Kumada
006	2023-10-02	Corrected that quality objectives are defined in the document available in Box	Hiromi Kumada

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Version 006
Approval

Approved: On File_____   Date: 2023-09-21
          CHAIR, MDSAP RAC