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.

- Conducts management review
- Assures necessary resources are provided to meet MDSAP needs
- Assigns action items and plans and approves system changes
- Designates personnel to assist in the management review activities
- Reviews and recommends final document approval, disapproval or approval with revision to the RAC Chair
- Works with the MDSAP QMS Management Representative, MDSAP QMS Site Representative and document originator (as necessary) to resolve questions and conflicts
- Provides a rationale for document disapproval or revision to the MDSAP QMS Management Representative, MDSAP QMS Site Representative and document originator as appropriate

- Ensures existence of a positive climate, which encourages continual improvement within MDSAP participants
- Reviews the preventive action reports and allocates resources needed to implement preventive action, as applicable. Additionally, reviews Internal audit reports, corrective action reports, and customer complaints/feedback for opportunities to improve processes, services, products, and the quality management system

- The RAC's role is to provide final approval or disapproval of documents and to resolve any conflicts that arise during the review process.
- The RAC is responsible for ensuring that all documents meet the requirements of the MDSAP QMS, including the development of corrective action plans when necessary.
- The RAC also reviews and approves all changes to the QMS, including new policies and procedures.

- Is informed of application packages received, and of the outcome of their review
- Makes final decision on rejecting an application;
- Is notified if it is necessary to put the application on hold and consulted during the application package review process when undefined or unclear MDSAP Program expectations are identified
- Is consulted prior to resuming the application package review process after an application package was put on hold due to potential threats to impartiality

- Makes the final recognition decision, including the imposition, removal or variation of conditions
- Designates the Chairperson and the members of the TRRC
- Makes the final Appeal Decision
- Signs the Appeal Decision Letter

- Hold reviews of Corrective Actions that Have been brought to their attention by the MDSAP QMS Management Representative
- Reviews the corrective actions database during the management review meetings convened by the RAC at least once a year

- Reviews and analyzes trends and recurrences of nonconformances, complaints and recommend appropriate remedial action
- Provides final authority of the disposition of all complaints and other issues arising from customer feedback
• Ensures that the delegation of assignments and responsibility are followed by all MDSAP members, as appropriate
• Ensures that any corrective actions determined as a result of management review activity are carried out and validated for effectiveness (can be delegated to any member of the RAC)
• Ensures that an effective quality management system program is operational, and that the management review procedure/policy is followed

• Maintains final document approval authority for all MDSAP documents (some can be delegated to the MDSAP QMS Management Representative)
• Ensures resources are available to accomplish requirements specified within the documents

• Leads and manages MDSAP

• Ensures resources are available to accomplish requirements specified within the documents

Regulatory Authority Council Chair (and CA System Manager)

QMS P0005 Management Responsibility/Review

QMS P0002 Document Control and Approval

QMS P0001 Quality Manual

AS P0017 Technical Review and Recognition Decision Making Procedure

QMS P0013 Continual Improvement

QMS P0009 Nonconformity and Corrective Action

• RAC Chairperson signs the Authorization to perform witnessed audits under the MDSAP on behalf of RAC
• RAC Chairperson signs the recognition decision letter on behalf of RAC

• Ensure the procedure is followed and enforced within all MDSAP participants

• overall responsibility for the CA system management
- Ensures that records are maintained appropriately

Regulatory Authority Secretariat (RAS)

QMS P0002 Document Control and Approval

- Preparation of official communications – including application rejection letters as applicable – to the candidate Auditing Organization
- Coordination and collection of the information for management review as needed and maintains related management review records
- Assembling summary report and documents action items and plans
- Coordination of reviews and versions of MDSAP documents, including assuring all proposed new and revised documents are available for review and comment by the RAC
- Maintaining and controlling superseded or obsolete documents as related to the RAC
- Maintaining a copy (electronic) of approved versions of documents as related to the RAC
- Coordinating the clearance of MDSAP related documents
- Serving as a Liaison between the RAC and the MDSAP QMS Management Representative, MDSAP QMS Site Representative or other regulatory authority

QMS P0005 Management Responsibility/Review at RAC level

AS P0010 Auditing Organization Application for Recognition Procedure

QMS P0007 Control of Quality Records

- Monitors the MDSAP email inbox for requests for application packages, submissions of completed application packages, or any other requests for information regarding the application process
- Reviews received application packages for completeness
- Prepares official communications – including application rejection letters as applicable – to the candidate Auditing Organizations

QMS P0014 Training

- Responsible for notifying the MDSAP Team, through the participating RA Training Representative, when new or revised procedures and policies are released

• Coordinates and collects the information for the management review
• Assembles summary report and documents action items and plans
• Maintains management review records
- Coordinates the SME’s monthly meetings
  Assigns Ad-Hoc working groups

- SME Lead Project Manager (LPM)
  (1 for all Regulatory Authorities)
  
  - Designates the Assessment Program Manager to manage the assessment process for the Auditing Organization
  - Decides when issues requiring clarification identified during the review of the application package can be addressed during Stage 1 or Stage 2 assessments
  - Liaises with the Regulatory Authority Council when the application review process is put on hold, pending clarification from the Auditing Organization
  - Consults with the Regulatory Authority Council, and seeks concurrence of the Regulatory Authority Council when the Assessment Program Manager proposes to reject the application package
  - Assists in the preparation official communication with the Auditing Organization to be issued by RAC Secretariat
  - Signs all communication to the Auditing Organization
  - Disseminates AO approval / rejection information to the participating Regulatory Authorities

- QMS P0004 Risk Management Procedure
  
  - Take responsibility for coordinating risk management across various MDSAP functions
  - Ensure that a risk management process is defined, deployed and reviewed, and that adequate resources are available, and
  - Communicate key risk issues to the RAC and Chairperson

- QMS P0005 MDSAP QMS Management Responsibility and Management Review Procedure
  
  - Chairs the management review meeting
  - Drafts Management Review Agenda and Report
  - Provides requested information as needed
  - May assist in the review activities
  - Ensures action items and plans are issued, monitored and completed
  - Communicates the results of the management review to team

- AS P0010 Auditing Organization (AO) Application For Recognition Procedure
  
  - Plans the TRRC process and convenes the committee
  - Acts as TRCC chairperson or, particularly if he/she was part of the assessment team, designates a delegate
Ad-hoc Working Group

- Meets monthly
- Develops documents supporting the program (policies, procedures, guidance documents, forms, etc.)

IT Solutions Development Team

- Develops the IT Portal specifications
- Issues Requests for Information and Requests for Quotes
- Reviews information or quotes received
- Recommends vendor
- Evaluates partnerships for hosting the portal, etc.

IT Solutions Manager
AS P0010 Auditing Organization (AO) Application For Recognition Procedure

- Initiates the witnessed audit procedure to ensure the implementation of the AO Assessment Program
- Liaises with the AO to obtain the planning of upcoming audits of medical device manufacturers, and selects the audit to witness
- Selects the assessors to form the assessment team
- Sends the assignment information to the assessors
- Liaises with the Assessment Team Leader (ATL) and the Auditing Organization (AO) to schedule the witnessed audit
- Reviews the witnessed audit report and forwards it to the Technical Review and Recognition Committee (TRRC) for review and recognition-decision, and updates the assessment Program as necessary

QMS P0015 Naming Convention of MDSAP Electronic Records

AS P0005 Assessment Program Procedure

- Assigns the record identifier for assessment documents

AS P00012 Witnessed Audit Procedure

AS P0014 Special Documentary Assessment Procedure

- Plans and schedules the Special Remote Assessment activities
- Selects the assessors involved in these activities
- Reviews the outcome of the Special Remote Assessment activities and determines their impact on the recognition decision and the Auditing Organization assessment Program
- Forwards the results of the Special Remote Assessment to the Technical Review and Recognition Committee (TRRC)

AS P0007 Appeals Procedure

- Verifies the implementation of assessment activities by the assessment team according to the Assessment Program
- Reviews assessment outcomes and proposes recognition decisions to the TRRC

AS P0013 Stage 1 Assessment of Auditing Organization Procedure

- Plans and schedules the Stage 1 assessment activities
- Selects the assessors involved in these activities
- Reviews the outcome of Stage 1 assessment activities and determines their impact on the assessment plan and Subsequent assessment activities

QMS P0015 Naming Convention of MDSAP Electronic Records

AS P0016 On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure

- Initiates the on-site assessment procedure to ensure the implementation of the AO assessment Program
- Selects the assessors to form the assessment team
- Sends the assignment information to the assessors
- Liaises with the Assessment Team Leader (ATL) and the Auditing Organization (AO) to schedule the assessment
- Reviews the assessment plan for consistency with the assignment
- Reviews the assessment report and forwards it to the Technical Review and Recognition Committee (TRRC) for review and recognition-decision, and updates the Auditing Organization’s Assessment Program as necessary

AS P0017 Technical Review and Recognition Decision Making Procedure

- Undertakes the Technical Review
- Prepares the assessment file for review and decision by the Technical Review and Recognition Committee (TRRC)
- Verifies that the assessment file is complete and contains all required documentation
- Liaises with the AO or the Assessment Team Leader (ATL) to clarify ambiguities of the assessment file
- Presents the file during the TRRC meeting and makes recommendations, taking into account the ATL’s recommendation, but shall not be one of the RA representatives of the Committee
- Determines if a candidate AO has successfully completed the requirements for a Stage 2 assessment and all identified non-conformities have been closed
- Proposes decisions regarding the authorization of an AO to perform MDSAP witnessed audits
- Prepares the authorization letter and submits for signature by the RAC Chairperson
- Prepares the recognition letter and submits for signature by the RAC Chairperson
- Ensures the implementation and follow-up of the recognition decision, including the update of the Assessment Program as applicable
- May propose the imposition, removal or variation of a condition
Assessment

Team leader (ATL)

- Issues the assessment plan
- Assigns responsibilities among the assessors and ensures the progress towards the assessment objectives
- Leads the assessment opening and closing meetings with the AO
- Finalizes and approves the assessment report
- Issues nonconformity reports and manages their closure

Assessment team (including the ATL)

- Assesses a sample of audit reports issued by the AO (off-site, prior to the on-site visit – not applicable to the initial assessment)
- Assesses the AO quality management system and practices according to the MDSAP AO Assessment Model

Assessment Team Leader (ATL)

- Leads the pre-audit and post-audit meetings with the AO audit team
- Assigns responsibilities among the assessors and ensures that the witnessed audit objectives are met
- Leads the closing meeting with the AO audit team leader and AO management representative
- Finalizes and approves the witnessed audit report

Assessment team (including the ATL)

- Observes the AO auditing practices and completes the witnessed audit checklist
- Informs the AO auditors of identified deficiencies
- Reviews the AO audit report for consistency with the audit findings
- Issues nonconformity reports if applicable
- Drafts the witnessed audit report

Assessor

- Identifies nonconformities against specified requirements in the course of any assessment activity
- Documents the nonconformity report
- Per the Assessment Team Leader, reviews the proposed action plan - including the investigation and cause analysis - and the evidence of its implementation and effectiveness

Assessment Team Leader (ATL)

- Reviews and verifies the nonconformity report prior to issuance to the AO
- Reviews the proposed action plan - including the investigation and cause analysis - and the evidence of its implementation and effectiveness, or delegates this review to the assessor who issued the nonconformity report
- Closes the nonconformity

Note: the ATL who closes the nonconformity may not be the ATL who identified the nonconformity, in particular when the nonconformity is closed during a subsequent assessment

Under the responsibility of the Assessment Team Leader (ATL), the assessment team:
- Reviews and analyses the management system documentation of the auditing organization
- Performs the Stage 1 Assessment
- Prepares the Stage 1 Assessment Report
- Reviews the information provided by the AO to satisfy any precondition necessary to progress the assessment process to a Stage 2 On-Site Assessment

AS P0005 Assessment Program Procedure

AS P0013 Stage 1 Assessment of Auditing Organization Procedure

AS P0016 On-Site Assessment (Stage 2, Surveillance, Re-recognition, Critical Location) Procedure

QMS P0004 Risk Management Procedure

Assessors and Team Leader (ATL)

- Reviews and analyses the management system documentation of the auditing organization and other requested documents
- Documents the results of the assessment in a documentary assessment report

AS P0014 Special Remote Assessment Procedure

AS P0020 Special On-Site Assessment Procedure

AS P0012 Witnessed Audit Procedure

AS P0017 Technical Review and Recognition Decision Making Procedure

AS P0015 Auditing Organization Nonconformity Procedure

The Audit Team Leader (ATL)

- Assists the APM in identifying the information that the AO needs to submit prior to the interactive phase
- Reviews and analyses the information submitted by the AO in preparation for the interactive phase
- Prepares and issues the assessment plan
- Leads the assessment team during the On-Site phase of the assessment
- Conducts on-site assessment activities
- Documents the results of the assessment in an assessment report

The Assessors (other than the ATL)

- Conducts on-site and remote assessment activities as assigned by the ATL

Take responsibility for coordinating risk management across various MDSAP functions
- Ensure that a risk management process is defined, deployed and reviewed
- Ensure adequate resources are available, and Communicate key risk issues to the RAC and Chairperson

Note: AS P0016 Site Assessment Procedure (Stage 2, Location) may not be used in particular when a subsequent audit is witnessed by the AO.
Technical Review and Recognition Decision Committee (TRRC)

- Approves the Assessment Program
- Makes recommendations for decisions, based on the completion of the outcome of the implementation of the Assessment Program

AS P0005 Assessment Program Procedure

- Reviews the application package if its rejection is recommended by the Assessment Program Manager and provides its recommendation to the Lead Project Manager

AS P0010 Auditing Organization (AO) Application For Recognition Procedure

- Determines the APM if an escalated nonconformity requires a formal recognition decision (according to the Technical Review and Recognition Decision process)

AS F0015 AO Nonconformity Flowchart

AS P0021 Appeals Procedure

- Determines whether to grant to the AO the opportunity to be heard
- As applicable, schedules and leads the AO hearing session
- Makes final recommendations and drafts the Appeal Decision

Assessment Planning Coordinator (1 per RA)

- Local correspondent for any question related to the availability of assessors
- Depending on the RA, may designate the assessor for a particular assessment activity

TRRC Chairperson:
- Leads the assessment file review and the decision-making process through consensus building or, as necessary, by vote;
- Ensures the consistency of the decision with precedence;
- Liaises with the RAC, as necessary, to explain the proposed recognition decision

AS P0017 Technical Review and Recognition Decision Making Procedure

- Reviews the assessment file and drafts the recognition decision
- May propose the imposition, removal or variation of a condition

AS P000S Assessment Program Procedure

- Approves the Assessment Program

- Reviews the application package if its rejection is recommended by the Assessment Program Manager and provides its recommendation to the Lead Project Manager
 Reviews, revises (as necessary) proposed new documents and the revision of existing documents in their area of responsibility
 Verifies the necessity and technical accuracy of the documents
 Identifies training needs resulting from new or revised documents
 Works with the document originator to resolve questions and conflicts
 Assists the MDSAP QMS Management Representative in training affected entities in new or revised documents as necessary
 Ensures biennial reviews of all documents used in his or her area of responsibility are conducted

 As a MDSAP participant: Identify opportunities for improvement in work processes, services and products

 As a team members: record complaints and/or feedback received on the MDSAP QMS F0013.1. Concern Resolution Form

 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

 As an MDSAP Team Member you are responsible for assessing your individual training needs. Team Members should document their training and coordinate with their RA Training Representative, to ensure that training records are current
Corrective Actions Administrator (1 for all Regulatory Authorities)
- Enters nonconformities into the database and periodically performs a quality review of the contents of the database.
- Responsible for the routine routing and management of Corrective Actions.
- Assigns and identifies nonconformity to the Corrective Action Assignee designated by the Regulatory Authority for the affected country/region.

QMS P0009 Nonconformity and Corrective Action (CA)

QMS P0011 Complaint and Feedback
- Populates the complaint database with information from the MDSAP QMS F0013.1 Concern and Resolution Form.
- Monitors the progress of the complaint or customer feedback.
- Ensures the implementation of the complaints and other feedback procedures and for facilitating process changes when necessary.
- Collaborates with MDSAP QMS Site Representatives and other stakeholders on the evaluation of the complaint or feedback and the determination of what (if any) process or product changes are needed.
- Reviews the completed forms to determine if the action taken is adequately completed or if further follow-up action is needed. If acceptable, the Corrective Actions Administrator signs off on the form.
- Notifies the final corrective action and disposition of the complaint to all entities involved in this process.

Regulatory Authority Corrective Action (RA/CA) Contact (1 per Regulatory Authority)
- Reviews the nonconformity to determine if the issue should be raised to a corrective action or closed with a correction and referred back to the Corrective Actions Administrator.
- If a corrective action is required, the RA/CA Contact will assign the nonconformity to a Corrective Action Assignee within his/her organization. Each Regulatory Authority must designate an RA/CA contact.

QMS P0009 Nonconformity and Corrective Action (CA)

QMS P0011 Complaint and Feedback

Corrective Action Assignee
- Develops and tracks corrections and corrective actions, and reports progress to the Corrective Action Administrator and the RA/CA Contact.

QMS P0009 Nonconformity and Corrective Action (CA)

Corrective Action System Manager
- Has overall responsibility for the CA system management.

QMS P0009 Nonconformity and Corrective Action (CA)