MANAGEMENT SYSTEM MANUAL of DI QUALITY CERTIFICATION SERVICES PRIVATE LIMITED *(Herein after referred as DI QCS)*

Process Description	Designation	Name	Signature
Prepared by	Executive Operations	Smita Patil	
Reviewed & Approved by	Operations Head	Jaya Yadav	
Issued & Controlled by	Document Controller	Jaya Yadav	

UNCONTROLLED COPY

Revision History

Sr. No.	REVISION NO.	CRN NO.	EFFECTIVE DATE	REASON FOR CHANGE	AUTHORIZED BY
1	00	Not Applicable	15-02-2022	Initial Release	Document Controller
2	01	CRN/22/02	17-08-2022	-Addition of new ISO scheme i.e. ISO 9001, references added in below sections 1. Section 2 updated 2. Section 4.2 b updated 3. Section 9.4.2 reference updated for new Audit format - Section 1 updated for head office address	Document Controller
3	02	CRN/22/03	05-09-2022	1. Reference of D-MMS-S-0024 Virtual Audits revised. 2. Sections 8.2 and 9.1.2.3. updated as per updated forms references	Document Controller
4	03	CRN/22/04	01-11-2022	1.Section 6.1.4 updated for chairman	Document Controller
5	04	CRN/23/03	01-06-2023	Head office address updated in section 1.1	Document Controller
6	05	CRN/24/01	10-05-2024	Pune Office address updated in section 1.1	Document Controller
7	06	CRN/24/02	02-07-2024	1.1 Section 1.1: Reference to agreement between DIQC BV and DI QCS updated. 1.2 Section 5.2.10 included against comment raised in	Document Controller

				NABCB DRR 1.3 Section 7.5.7 Included 1.4 Section 7.1.4 revised for better understanding 1.5 Sec 7.2.6 revised for better understanding 1.6 Sec 9.5.4 included	
8	07	CRN/24/04	26/08/2024	The document is updated for revised Roles & Responsibility of Director, Technical & Operations head	Document Controller
9	08	CRN/24/05	05-09-2024	DI QCS new logo updated	Document Controller

1. Introduction

1.1. Legal entity information

DI QCS is incorporated in India on 17-06-2021.
The Corporate Identity Number of the company is U73100TN2021PTC144132.
GST Registration Number is 33AAICD5557A1ZY
The Permanent Account Number (PAN) of the company is AAICD5557A
The Tax Deduction and Collection Account Number (TAN) of the company is CHED12952C.

The registered address is 'M71 A, RAINBOW GARDEN, PHASE 6, HOSUR, Krishnagiri, Tamil Nadu, 635109'.
Head Office address Second Floor of the premises Plot no A-28, New Door No : 18, 86th Street, 18th Avenue, Ashok Nagar, Chennai – 600083, Tamil Nadu, India.
DI QCS has operational office at 2nd Floor,Shop number 232,VTP Trade Park, Katraj-Hadapsar Road, Undri, Pune 411060.
DI QCS undertakes responsibilities for functions such as Application/contract review, scheduling, accounts and invoicing, audit operations, auditor qualifications, certificate decisions and certificate issuance.

DI QCS complies with the relevant national and international standards through a quality system established in the lines of applicable standards and guides. The policies and procedures for accreditation by DI QCS are non-discriminatory and are implemented uniformly to all the applicants. A uniform reasonable fee is charged from all clients in lieu of the services of certification offered.

DI QCS is sister concern of DIQC BV Netherlands. DIQC B.V. was incorporated on 10-12-2020 under the 'Netherlands Chamber of Commerce'.
CCI number: 81195230.
VAT Number: NL861981108B01

We have established operation conditions in agreement between DI QCs and DIQC BV.

1.2. Purpose of this manual

This manual sets forth the criteria to which DI QCS performs independent management system assessments and registrations, against the accreditation.
DI QCS shall work to improve safety, confidence and performance, thus safeguarding innovation.

DI QCS shall ensure to service supporting the clients' reputation with our independent technical competence summarized in neutral findings and to have confidence that our work services facilitate to improve the quality of life for society.

This Management System Manual has been established considering ISO/IEC 17021-1:2015 and General management system requirements and applicable International Accreditation Forum (IAF) guidance documents. (Refer: Document: D-MMS-G-0003)

2. Scope of accreditation

The design and provision of audit and certification of management system as per ISO 9001 & ISO 13485 Quality Management System standard to support industries globally.

3. Terms and definitions

Refer: D-MMS-G-0001 Definitions

4. Principles

4.1. We have documented and implemented the Management principles and guiding principles as defined in the Policy Manual: D-MMS-P-0002 and ensured awareness to all the personnel.

4.2. While implementing the above principles, it is ensured the following, in addition:

a. Taking responsibility to verify the evaluation and implementation of statutory and regulatory compliance, as per relevant legislation and regulations.
b. Establishing appropriate agreements with the clients to provide audit report information to regulators, who recognise ISO 9001 and ISO 13485, as needed.

Refer: D-MMS-P-0002 Policy Manual

5. Legal entity requirements

5.1. Legal and contractual matters

5.1.1. DI QCS is legally responsible for all its certification activities.
5.1.2. We will ensure legally enforceable agreement with each client while providing certification activities.
5.1.3. We will undertake the responsibility and authority for all certification decisions

Refer:

D-MMS-G-0004 Responsibility and authority
D-MMS-G-0005 Responsibility and authority matrix
D-MMS-G-0006 Organization Chart
D-MMS-S-0006 Certificate decision
F-0006-01 Review Report for Certificate Decision
F-0009-05 Client certification agreement

5.2. Management of impartiality

5.2.1.The top management has committed to management of impartiality against established "Impartiality Policy" which is available in the website www.diqcindia.com , and managed against the following:

a. Consultancy is defined as the participation in developing and/or maintaining customers management systems subject to eventual certification, including, but not limited to:

- Preparing or producing manuals or procedures for clients.
- Giving client specific advice or client specific training towards the development and implementation of a management system.
- Giving client specific advice or client specific training for the development and implementation of the operational procedures of the organization.
- The management safeguards, evaluates, and offers advice on the impartiality of MMS assessments activities, processes, organization, and personnel.

NOTE: Arranging and participating as a trainer in training courses is acceptable, provided that where these courses relate to management systems or auditing they confine themselves to the provision of generic information and advice which is freely available in the public domain, and such training shall not provide any company specific advice.

5.2.2.DI QCS will not certify a management system for a client that has received management system consultancy on the same management system, where the relationship between the consultancy body and the certification body poses an unacceptable threat to the impartiality of its registrations.

a. We shall manage its impartiality to ensure that activities of other bodies do not affect the confidentiality, objectivity and impartiality of DI QCS's certification. Any situation that would create a conflict of interest arising from the activity of any other body will be avoided.
b. A relationship that threatens impartiality between the certification body and management system consultancy body may be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing, and payment of a sales commission or other inducement for the referral of new clients, etc.
c. Management systems consultancy includes the development, implementation, and operation of procedures and processes specifically to meet the requirements of the subject management system standard.
d. We shall not offer internal quality audits to any certified customer.

5.2.3.External training programs that DI QCS offers in conjunction with outside organizations will not give or imply an association with the registrations we grant. Such programs will

protect and maintain DI QCS's position as an impartial, independent, third-party certifier so that participation in the external program does not cross the line of consultancy, as described above.

5.2.4. During the course of providing certification services, it is our policy that none of our staff, office or field based, provide consultancy to any organization. Any staff, including managers, that have provided consultancy to a subscriber shall not be involved in the processing of the registration as far as it has to do with conduct of assessment, resolution of subscriber nonconformities, or review and concurrence to register. This policy applies to any staff involved in consultancy activities for the subscriber in question within 2 years of the subscriber's registration process. If such case exists, it is the responsibility of the staff member to disclose any relationships they may have with the subscriber in question before undertaking any registration activity so that applicable responsibilities can be re-assigned, and our impartiality can be maintained.

5.2.5. Personnel may not suggest or indicate that registration would be simpler, easier, or less expensive if any specific consultancy or training services were used.

5.2.6. We, being the certification body shall not provide management system consultancy services.

5.2.7. DI QCS shall take action to respond to any threats from the actions of other persons, bodies, or organizations.

5.2.8. DI QCS shall request empanelled auditors and employees to reveal situations that may present them or DI QCS with a conflict of interest. Management shall evaluate any such situation to ensure potential threats to impartiality are avoided and there is no conflict of interest.

5.2.9. No client specific training will be provided and only public training against information available in public domain will be conducted.

5.2.10. DI QCS shall not certify another certification body for its management system certification activities.

Refer:
D-MMS-S-0001 Management of Impartiality
D-MMS-S-0026 Operation of Committee For Safeguarding Impartiality
F-0026-01 CFSI Meeting Agenda
F-0026-02 List of CFSI Members
F-0026-03 CFSI Minutes of Meeting
F-0026-04 Declaration of Independence and Confidentiality Agreement

5.3. Liability and financing

5.3.1. We have evaluated risks arising from certification activities and has made adequate arrangements to have insurance or reserves to cover liabilities arising from the operations.

5.3.2. We will ensure that commercial, financial or other pressures do not compromise our impartiality management by evaluating the financial condition and sources of income initially and ongoing basis.

Refer:
Risk assessment and mitigation (D-MMS-S-0002)
Risk assessment Report (D-MMS-G-0009)

6. Structural requirements

6.1. Organisational structure and top management

6.1.1. We have documented the organisational structure against the Organisation chart (D-MMS-G-0006), indicating line of authority.

6.1.2. The duties, responsibilities and authorities of management and other personnel involved in certification are documented against the document - Responsibility and authority of personnel (D-MMS-G-0004)

6.1.3. It is ensured that certification activities are structured and managed to safeguard impartiality, by following procedure for certificate decision (D-MMS-S-0006)

6.1.4. The management of DI QCS consist of Board of Directors headed by Chairman and the functional heads having overall responsibilities and authorities defined in the document (D-MMS-G-0004)

6.1.5. The sales and marketing operations shall be carried out as per 'Sales and Marketing Process' (D-MMS-S-0025)

6.2. Operational control

6.2.1. We have established process for the effective control of certification activities, considering the risk associated against competence and impartiality management.

6.2.2. The level and method of control of activities undertaken includes against the processes, technical areas operated, competence of personnel, management controls and remote access to operations and records.

Refer:
D-MMS-S-0003 – Competence requirements
F-0003-01 ISO-13485 Auditor In Training Qualification Form
F-0003-02 Evaluation Report Certification Personnel
F-0003-03 Confidentiality and Non-Conflict of Interest Statement
F-0003-04 Service Agreement for audit personnel
F-0003-05 Service Agreement certification personnel
F-0004-01 Technical Area Code Approval
D-MMS-S-0007 – MMS registration requirements
F-0028-01 Recruitment Request Form
F-0028-02 CV Format
F-0028-02 Annex

7. Resource requirements

7.1. Competence of personal

7.1.1. We have established the documented process to ensure that personnel have appropriate knowledge and skills relevant to the quality management for medical devices.

7.1.2. We have a process for determining the competence criteria for personnel involved in the management and performance of audits and other certification activities.

7.1.3. The personnel are subjected to initial competence evaluation and on ongoing monitoring of competence and performance of all personnel involved in the management, performance of audits and other certification activities, against the established process.

7.1.4. DI QCS has access to technical expertise for technical areas of ISO 9001 and ISO 13485 in operational geographic areas. DI QCS seeks such advices from certification body personnel (Director Technical, Operations Head, Technical Reviewer etc.) and external entities who are involved in impartiality committee, empanelled auditors and technical experts.

Refer:

D-MMS-S-0003 – Competence requirements
F-0003-01 ISO-13485 Auditor In Training Qualification Form
F-0003-02 Evaluation Report Certification Personnel
F-0003-03 Confidentiality and Non-Conflict of Interest Statement
F-0003-04 Service Agreement for audit personnel
F-0003-05 Service Agreement certification personnel
F-0004-01 Technical Area Code Approval
D-MMS-S-0028 Human Resource
F-0028-01 Recruitment Request Form
F-0028-02 CV Format
F-0028-02 Annex
F-0028-03 Training Attendance Sheet
F-0028-04 Training Effectiveness Verification
F-0028-05 Annual Training Schedule
F-0028-06 Training Need Identification
F-0028-07 Exam Questionnaire Template
F-0028-08 Client Feedback Form

7.2. Personnel involved in the certification activities

7.2.1. We will have sufficient competent personnel for managing and supporting the audit programme and other certification work performed.

7.2.2. We will employ or have access to sufficient number of auditors and team leaders and technical experts as needed, to cover all the activities and to handle the volume of audits and related works performed.

7.2.3. It is ensured to provide clear duties, responsibilities and authorities of each of the personnel employed.

7.2.4. We have documented process towards selection, authorization of auditors and for selection and familiarisation of technical experts used, if any, in the certification activities (Refer D-MMS-S-0003 section 6.8.2)

7.2.5. While performing the initial competence evaluation of an auditor, it is ensured to verify the ability towards application of knowledge and skills during audits, in addition to the desired personal behaviour.

7.2.6. DI QCS ensures that auditors (and, where needed, technical experts) are knowledgeable of its audit processes, certification requirements and other relevant requirements. DI QCS provides auditors and technical experts access to an up-to-date set of documented procedures giving audit instructions and all relevant information on the certification activities whenever required. All employees will be introduced to DI QCS documents during induction training.
Auditors and concerned personnel can access applicable documents on our website www.diqcindia.com. In case of revision of any audit related document/procedure/forms concerned personnel will be sent a mail wherein details of changes along with revised documents will be provided. Training on revised documents will be provided to concerned personnel as required.

7.2.7. It is ensured that the auditors and technical experts, as and when needed, are knowledgeable of audit process, certification requirements and other relevant requirements, through training and providing access to up-to-date documented procedures towards audit instructions and all relevant information on the certification activities.

7.2.8. It is ensured to identify training needs to all the personnel and to provide training towards the competency required for the activities, they perform.

7.2.9. During the decision on granting, refusing, maintaining, renewing, suspending, restoring, or withdrawing certification, or on expanding or reducing the scope of certification to be taken up, it is ensured that the applicable personnel to understand the applicable standard and certification requirements, and have competence to evaluate the outcomes of the audit processes and recommendations of the audit team.

7.2.10. It is ensured to monitor the competence and satisfactory performance of all personnel through a documented process considering the level of risk linked to their activities.

7.2.11. We shall periodically evaluate the performance of each auditor on-site.

7.3. Use of individual external auditors and external technical experts

7.3.1. It will be ensured to have written agreement executed by external auditors and external technical experts committing to comply with applicable policies and implement processes defined, maintain the aspects relating to confidentiality and impartiality and to notify us any existing or prior relationship they had with the organisation assigned to audit.

7.4. Personnel records

7.4.1. It is ensured to maintain up-to-date personnel records of personnel performing certification activities, management and administrative personnel, containing qualifications, training, experience, affiliations, professional status and competence
Refer: D-MMS-S-0019 Control of Records

7.5. Outsourcing

7.5.1. DI QCS currently does not outsource any certification activity.

7.5.2. In case DI QCS decides to outsource an activity, we have established process describing the conditions under which outsourcing may take place.

7.5.3. While outsourcing, it is ensured to have legally enforceable agreement covering the arrangements, including confidentiality and conflicts of interests, with each body that provides outsourced services.

7.5.4. We will not outsource the activities wherein decisions for granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification, are to be made.

7.5.5. While outsourcing the activities, we will ensure

a. to take the responsibility for all the activities outsourced to another body / person.
b. that outsourced service provider conforms to the applicable competence, impartiality and confidentiality.
c. that the outsourced service provider are not involved either directly or indirectly with the organisation to be audited, in such a way that impartiality could be compromised.

7.5.6. We have established a process for the approval and monitoring of all bodies that provide outsourced services used for certification activities, and shall maintain the records of the competence of all personnel involved in certification activities.

7.5.7. DI QCS as a policy will not outsource auditing activities to a consultancy organization.

Refer: D-MMS-S-0005 Procedure for outsourcing and control

8. Information requirements

8.1. Public information

8.1.1. We will ensure to maintain through publications, electronic media or other means and make the information publicly available without request regarding:

a) Audit processes
b) processes for granting, refusing, maintaining, renewing, suspending, restoring, or withdrawing certification or expanding or reducing the scope of certification.
c) types of management systems and certification schemes in which it operates.
d) the use of the certification body's name and certification mark or logo.
e) processes for handling requests for information, complaints and appeals.
f) policy on impartiality.

8.1.2. We will ensure providing following information against the request and in our internet:

a) Geographical areas of operations
b) Status of certificates issued
c) The certified client details such as name, related normative document, scope and geographical location (City and country)

8.1.3. It is ensured that the information provided to the client or for marketing and advertisement shall be accurate without any misleading contents.

8.2. Certification documents

8.2.1. The certification document to the certified client shall be provided upon completing all the activities of certification, electronically and/or with printed certificate.

8.2.2. The contents of certificates issued based on the scope of the assessment carried are defined in the Certificate templates.

Refer:
D-MMS-S-0008 Certificate Issuance and Control
F-0008-01 Certificate Template
F-0008-02 Certificate Preparation Form

8.3. Reference to certification and use of marks

8.3.1. We have established the rules towards the use of Management System certification mark, communicated to the certified clients and monitored for effective implementation. These rules shall ensure traceability back to DI QCS

- no ambiguity in the mark or accompanying text, as to what has been certified and which body has granted the certification.
- that this mark shall not be used on a product nor product packaging nor in any other way that may be interpreted as denoting product conformity.

8.3.2. We will not permit such marks to be applied by the certified clients to laboratory test, calibration or inspection reports or certificates.

8.3.3. The rules established includes towards use of any statement on product packaging or in accompanying information, without implying the product, process or service, which is certified against management system. The statement include reference to:

- Identification (Ex; Brand or name) of the certified client
- The type of management system (Quality Management, Environments, etc.,) and applicable standard.
- The organisation issuing the certificate

8.3.4. We will ensure through the legally enforceable arrangements that the certified client:

a) Conforms to our requirements when making reference to its certification status in communication media such as the internet, brochures or advertising, or other documents.
b) Does not make or permit any misleading statement regarding its certification.
c) Does not use or permit the use of a certification document or any part thereof in a misleading manner.
d) Upon withdrawal of its certification, discontinues its use of all advertising matter that contains a reference to certification, as directed by the certification body.
e) Amends all advertising matter when the scope of certification has been reduced.
f) Does not allow reference to its management system certification to be used in such a way as to imply that the certification body certifies a product (including service) or process.
g) Does not imply that the certification applies to activities and sites that are outside the scope of certification.
h) Does not use its certification in such a manner that would bring the certification body and/or certification system into disrepute and lose public trust.

8.3.5. We will exercise proper control of ownership & shall take action to deal with incorrect references to certification status or misleading use of certification.

- Such action could include requests for correction & CA, suspension, withdrawal of certification, publication of the transgression, if necessary, legal action.

Refer:
D-MMS-S-0007 MMS registration requirements
D-MMS-G-0010 Reference to certification and certification mark

8.4. Confidentiality

8.4.1. We take the responsibility, for the management of all information obtained or created during the performance of certification activities at all levels of its structure, including committees and external bodies or individuals acting on its behalf, though legally enforceable agreements.

8.4.2. We will inform the certified client about the information that will be placed in public domain. We will treat all other information, except the information that is made publicly accessible by the certified client as confidential.

8.4.3. We will not disclose to a third party about the information of a particular certified client or individual, without the written consent of the certified client or individual concerned.

8.4.4. When we are required to release confidential information as required by law or authorized by contractual arrangements (such as with the accreditation body) to release confidential information, the client or individual concerned shall be notified about the information provided, unless prohibited by law.

8.4.5. Information about the client from sources other than the client (e.g. complainant, regulators) shall be treated as confidential, consistent with our policy.

8.4.6. Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification body's activities except as required by law.

8.4.7. We will have processes and applicable equipment and facilities to secure handling of confidential information.

Refer:
D-MMS-S-0007 MMS registration requirements
F-0003-07 Confidentiality and Non-Conflict of Interest Statement
F-0009-05 Certification Agreement
F-0026-04 Declaration of Independence and Confidentiality Agreement

8.5. Information exchange between certification body and its clients

8.5.1. Information on the certification activity and requirements

8.5.1.1. We will provide following information and updates to the certified clients:

a) detailed description of the initial and continuing certification activity, including the application, initial audits, surveillance audits, and the process for granting, refusing,

maintaining of certification, expanding, or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification.

b) the normative requirements for certification.
c) information about the fees for application, initial certification, and continuing certification.
d) our requirements for clients to:

- comply with certification requirements.
- make all necessary arrangements for the conduct of the audits, including provision for examining documentation and the access to all processes and areas, records, and personnel for the purposes of initial certification, surveillance, recertification, and resolution of complaints.
- make provisions, where applicable, to accommodate the presence of observers (e.g., accreditation assessors or trainee auditor)

e) documents describing the rights and duties of certified clients, including requirements, when making reference to its certification in communication of any kind.
f) information on processes for handling complaints and appeals.

8.5.2. **Notice of changes**

8.5.2.1. We will provide due notice of any changes to its requirements for certification to the certified clients and will ensure verification with each certified client towards complying with the new requirements.

8.5.3. **Notice of changes by certified clients**

8.5.3.1. We will have legally enforceable arrangements to ensure that the certified clients inform us the matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification without delay.

8.5.3.2. The expected change communication shall be related to, but limited to the following:

a) the legal, commercial, organizational status or ownership.
b) organization and management (e.g., key managerial, decision-making, or technical staff).
c) contact address and sites.
d) scope of operations under the certified management system.
e) major changes to the management system and processes.

8.5.3.3. We will ensure appropriate action against the changes notified by certified clients.

Refer: D-MMS-S-0007 MMS registration requirements

9. Process requirements

9.1. Pre-certification activities

9.1.1. Application

9.1.1.1. Against the enquiries received for certification, an application shall be provided to the prospective clients, to gather the information about the organisation, scope and standard against which the certification and other applicable requirements. Refer the form: F-0009-01

9.1.2. Application review

9.1.2.1. The application shall be reviewed for completeness and for applicable details to process further to provide quote. When the information is incomplete and inadequate, supplementary information shall be collected and reviewed. Refer form F-0009-02.

9.1.2.2. Upon completion of application review, considering accreditation scope and competency requirements of audit team, the decision will be made whether to accept or decline the application.

9.1.2.3. If accepted the quotation will be provided to the applicant. If declined, the reasons for declining the application shall be documented and communicated to the client as needed.

Refer:
D-MMS-S-0009 Pre-certification Activities
F-0009-01 Application form
F-0009-02 Application review form
F-0009-03 Cycle Audit Planning Matrix
F-0009-04 Auditor Nomination
F-0009-05 Certification Agreement
F-0009-06 Quotation
WI-0009-01 Scheduling
D-MMS-S-0010 Man day calculation guideline

9.1.3. Audit programme

9.1.3.1. We have established the audit programme covering all the activities required for certification cycle of the Medical Management System.

Refer:

D-MMS-S-0009 Pre-certification Activities
F-0009-03 Cycle Audit Planning Matrix
D-MMS-S-0007 Procedure for Medical Management System Certification

9.1.4. Determining audit time

9.1.4.1. The audit time required for each of the audits shall be determined following the procedure: D-MMS-S-0010 Man Day calculation guideline considering IAF MD 9 or equivalent.

9.1.5. Multi-site sampling

9.1.5.1. Whenever the client has multi-sites, the assessment shall be carried out following the procedure D-MMS-S-0007 Procedure for Medical Management System Certification and D-MMS-S-0010 Man Day calculation guideline.

9.2. Planning audits

9.2.1. While planning the audits, following will be considered

a. Determining audit objectives, scope and audit criteria
b. Selection of audit team, taking into account the competence and impartiality.
c. Participation of observers and technical experts.
d. Preparation of audit plan and communicating to the audit team and audit client.

9.2.2. All the above activities are carried out by following the procedure D-MMS-S-0009 Pre-certification Activities.

9.3. Initial certification

9.3.1. Initial certification audit

9.3.1.1. Initial certification audit of respective Quality Management System shall be carried out against stage 1 and Stage 2, by following the procedure D-MMS-S-0012 Initial certification.

9.3.1.2. The transfer of certification from one certification body to DI QCS, shall be carried out by following procedure D-MMS-S-0017 Certificate Transfer.

9.4. Conducting audits

9.4.1. We have established the process for conducting on-site audits with following activities:

a. Conducting the opening meeting
b. Communication during the meeting
c. Obtaining and verifying the information
d. Identifying and recording audit findings
e. Preparing audit conclusions
f. Conducting closing meeting
g. Proving the audit report

9.4.2. The above activities in respect of conducting audits shall be carried out following procedure: D-MMS-S-0011 Preparing and Conducting Audits.
In case an audit is to be conducted remotely, procedure for the use of D-MMS-S-0024 Virtual Audits shall be followed.
Refer:
F-0011-01 Audit Plan
F-0011-02 Attendance Sheet
F-0011-03 Audit Report _ISO 13485
F-0011-04 Non-conformity Report
F-0011-05 Audit Report_ ISO 9001

WI-0011-01 Opening Meeting
WI-0011-02 Closing Meeting
WI-0011-03 Scope Writing
F-0017-01 Transfer Application
F-0017-02 Pre-transfer review

9.5. Certification decision

9.5.1. The certificate decision shall be related to granting or refusing certification, expanding, or reducing the scope of certification, suspending, or restoring certification, withdrawing certification, or renewing certification,

9.5.2. It is ensured that the persons that makes certificate decision are independent from those who carried out the audits and the personnel shall have appropriate competence.

9.5.3. The activities related to certificate decision shall be carried out by following the procedure D-MMS-S-0006 Certificate decision.

9.5.4. DI QCS ensures that the personnel making certification decision are not part of audit team. The certificate decision maker shall be independent from auditing process.

Refer:

F-0006-01 Review Report for certificate Decision

9.6. Maintaining certification

9.6.1. It is ensured to monitor the certified client whether they continue to satisfy the requirements of management system for which certification is granted.

9.6.2. Surveillance activities are carried out as per Cycle Audit Planning Matrix (CAPM) requirements following the procedure: D-MMS-S-0013.- Procedure for surveillance activities

9.6.3. Recertification audit shall be carried out before completion of the cycle of registration / certification, to confirm the continued conformity and effectiveness of management system and relevance and applicability for the scope of certification. Refer: D-MMS-S-0014 Procedure for re-certification.

9.6.4. Special audits shall be carried out towards the scope expansion with exclusive visit of the audit team for the, against the request of the client, following the procedure: D-MMS-S-0015 – procedure for special audits.

9.6.5. In case of suspending, withdrawing, or reducing the scope of certification, procedure D-MMS-S-0016 shall be followed.

Refer:

F-0013-01 Change information form

F-0013-02 Client Change review

F-0016-01 Suspension letter

F-0016-02 Withdrawal letter

9.7. Appeals

9.7.1. We have documented process to receive, evaluate and make decisions on appeals, against the procedure D-MMS-S-0018 Appeal and Complaint Handling.

9.7.2. It shall be ensured that the persons engaged in appeals handling process are independent from those carried out audits and made certificate decisions.

9.8. Complaints handling

9.8.1. We have established the process for receipt and handling of all levels of complaints against procedure D-MMS-S-0018 Appeal and Complaint Handling and records maintained.

Refer:

F-0018-01 Appeal / Complaint Log

F-0018-02 Appeal / Complaint Report

9.9. Client records

9.9.1. It is ensured to maintain records of the audit and certification activities for all clients, applied, audits carried out, certified or certification suspended or withdrawn by following the procedure D-MMS-S-0019 Control of records.

10. General management system requirements

10.1. General

10.1.1. We have established, documented, implemented and maintained management system to demonstrate the general management system requirements defined in ISO/IEC 17021 clause 10.2.

10.2. Management system manual

10.2.1. This quality manual and associated documents referred in this manual, address all the applicable requirements.

10.2.2. It is ensured to provide access of this manual and applicable documents to all relevant personnel.

10.3. Control of documents

10.3.1. All the applicable Management System documents, including external documents are controlled according to the Procedure for control of documents, established.

10.3.2. It is ensured to review and update against changes and re-approval made.

10.3.3. It is ensured to provide identification of current revision status of documents, always.

Refer:
D-MMS-S-0020 Control of documents
F-0020-01 Obsolete Document Log
F-0020-02 Document and Records Disposal Log
F-0020-03 Document Change Request Note
F-0020-04 Document Change Request Log
D-MMS-G-0002 Master list of documents

10.4. Control of records

10.4.1. Records including records related to the certified clients are maintained to provide evidence of conformity to requirements and of the effective operation of the Management System, as per the procedure for control of records established.

10.4.2. This procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

10.4.3. The records shall be retained for a period consistent with contractual and legal obligations.

Refer:

D-MMS-S-0019 Control of records

10.5. Management review

10.5.1. Top management reviews the Quality Management System at-least once a year, as per the documented procedure with the functional representatives, against various input, to ensure its continuing suitability, adequacy, effectiveness, along with to assess the opportunities for improvement, need for changes to the quality management system, the quality policy and quality objectives.

10.5.2. The output from management review, including the input reviewed and decisions and actions agreed to be taken are recorded and complete records of management reviews are maintained.

Refer:
D-MMS-S-0021 Procedure for Management Review
F-0021-01 MR Agenda
F-0021-02 Management review record

10.6. Internal audits

10.6.1. DI QCS ensures conducting the internal audits at planned and defined intervals (at-least once a year) by assigned auditors selected with objectivity and impartiality of the audit process, to determine whether the quality management system conforms to planned and documented arrangements, quality management system and regulatory requirements established by the organization and effective implementation and maintenance, as per the document procedure.

10.6.2. It is ensured to schedule the audits considering the status and importance of the processes and area to be audited, as well as the results of previous audits.

10.6.3. It is ensured that the management responsible for the area being audited to take necessary corrections and corrective actions without undue delay to eliminate detected nonconformities and their causes and to perform follow-up activities towards the verification of the actions taken and the reporting of verification results.

10.6.4. Records of the audits and their results, including identification of the processes and areas audited and the conclusions are maintained.

Refer:
D-MMS-S-0022 Procedure for Internal audits
F-0022-01 Internal audit program
F-0022-02 Internal audit plan
F-0022-03 Internal audit report

10.7. Corrective actions

10.7.1. DI QCS ensures corrective actions to eliminate the cause of nonconformities in order to prevent recurrence, without undue delay, proportionate to the effects of the nonconformities encountered, as per documented procedure.

10.7.2. Records of the results of investigation and of action taken are maintained.

Refer:
D-MMS-S-0023 Procedure for Corrective Action
F-0023-01 Corrective Action Log
F-0023-02 Corrective Action Report