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Department of

Pharmaceuticals

MAKE IN INDIA

QCI | NABCB

Resource Document

on

"Indian Certification for Medical Devices-ICMED"

Building Capabilities,
Enriching Quality and Patient Safety

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Building Capabilities,
Enriching Quality and Patient Safety

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Secretary

भारत सरकार
रसायन और उर्वरक मंत्रालय
औषध विभाग
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Dated: 26th February, 2020

FOREWORD

I am delighted to write this foreword for the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India supported "Industry Awareness Programme on MDR 17 – Regulation of Medical Devices & Indian Certification for Medical Devices (ICMED)" being organized by Association of Indian Medical Devices Industry (AiMeD) and Biotech Consortium India Limited (BCIL), New Delhi. These workshops are being organised for awareness creation and capacity building of medical device industry in the Country. The medical device sector in India, recognised as "Sunrise Sector" by the Government of India hasmarket size for this sector in India through retail sales is estimated to be over US $ 10.00 billion (Rs. 61,800 Crore) in 2013-14, growing steadily at a rate of over 15-17% CAGR, currently about US $ 15 billion. The sector is highly import dependent with about 75% of the requirements being met through imports.

To provide impetus to this sector, ensure quality and credibility of the Indian Medical Devices, The Ministry of Health, Government of India rolled out Medical Device Rules 2017 (MDR17), which became effective in the country since January 2018. Further, recently Government of India, Ministry of Health and Family Welfare on 11th Feb, 2020 has published notification to regulate all medical devices in phase wise manner by voluntary registration, followed by mandatory registration, followed by licensing within 42 months from 1st April, 2020. Meanwhile to fill the vacuum in quality certification space for medical devices in the country, the Association of Indian Medical Device Industry (AiMeD) jointly with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB) rolled out a voluntary quality certification scheme for Medical Devices on March 15, 2016 World Consumer Day.

The Scheme is intended to enhance patient safety, and provide enhanced consumer protection along with much needed product credentials to manufacturers for instilling confidence among buyers and for enabling capacity building for Manufacturers for Regulatory Approvals.

I congratulate AiMeD and QCI for rolling out this scheme and BCIL for joining hands with them in organising industry awareness and capacity building workshop for on MDR17 and ICMED scheme by the medical device industry.

It is envisaged that this workshop will serve as a tool for capacity building of the Indian Medical Device Industry. It will help in creating awareness, building capabilities, enriching quality and patient safety by deliberation on key issues and pathway for Indian Certification for Medical Devices for ensuring patient safety and consumer protection.

I wish this Workshop a huge success!!

(Dr. P.D. Vaghela)

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FOREWORD

To fill the regulatory vacuum in quality certification space for medical devices in the country, the Quality Council of India (QCI) jointly with the Association of Indian Medical Device Industry (AiMeD) rolled out a Voluntary Certification Scheme for Medical Devices on March 15, 2016, World Consumer Day, named as the ICMED Certification scheme. I am pleased to note that through generous support from Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India a workshop on "Indian Certification for Medical Devices (ICMED) Manufacturers" certification is being organized by Association of Indian Medical Device Industry (AiMeD), Biotech Consortium India Limited (BCIL), New Delhi and Quality Council of India (QCI).

The Scheme is intended to enhance patient safety, and provide enhanced consumer protection along with much needed manufacturer / product credentials for instilling confidence among buyers and for enabling capacity building of Manufacturers for Regulatory Approvals. This move is also intended to significantly eliminate trading of sub-standard products or devices of doubtful origins, a widespread and injurious phenomenon in the Indian market to enhance patient safety.

To ensure need to have the highest Quality Standards, the Certification Scheme is built over the base Standard ISO 13485 (Medical devices — Quality management systems — Requirements for regulatory purposes) which had 184 Compliance Requirements. The ICMED 13485 has in addition 23 Regulatory Requirements, 13 Essential Requirements for ensuring Patient Safety and with 16 Labelling Requirements for ensuring Consumer Protection.

It's a growing practice worldwide that certification to standards which may encompass regulatory requirements is accepted as demonstration of compliance. MDR17 along with ICMED certification of medical devices will facilitate regulatory compliance requirements and will certify the medical device manufacturers for bringing in credibility and acceptability to the Made in India medical devices. We are thankful to Department of Pharmaceuticals, Government of India in providing generous support for awareness creation and capacity building of medical device industry for ICMED Certification scheme. QCI is delighted to join hands with AiMeD and BCIL in organising this very important workshop. I wish this workshop a huge success!!

Rajesh Maheshwari
CEO (NABCB)

ACKNOWLEDGEMENTS

Association of Indian Medical Device Industry (AiMed) and Biotech Consortium India Limited (BCIL) would like to thank the following stakeholders for their support and contribution to the Industry Awareness Programme on Indian Certification for Medical Devices (ICMED) Manufacturers:

- Ministry of Health and Family Welfare (MoHFW)
- Department of Pharmaceuticals (DoP)
- Central Drug Standard Control Organization (CDSCO)
- Quality Council of India (QCI)
- National Accreditation Board for Certification Bodies (NABCB)

The following contributors are acknowledged:

Association of Indian Medical Device Industry (AiMed):

Mr. Rajiv Nath, Founder and Forum Coordinator
Mr. Manoj Tiwari, Secretary to the Forum Coordinator
Mr. Rajiv Chibber, Vice President, Sahajanand Medical Technologies
Mr. Gurmit Chugh, Managing Director, Translumina & Jt. Coordinator, Implants, AiMeD

Biotech Consortium India Limited (BCIL):

Dr. Suchita Markan, Asst. General Manager
Dr.Yogmaya Verma, Deputy Manager
Dr. Vasundhara Shukla, Senior Project Executive

Quality Council of India (QCI):

Mr. Rajesh Maheshvari, CEO
Dr. Manish Pande, Director and Head, PAD Division
Mr. C.S. Sharma, Deputy Director, PAD Division
Mr. Mrutunjay Jena, Joint Director, NABCB
Dr. Jaishree Kasliwal, Assessor, NABCB
Ms. Poonam Gupta, Asst. Director, NABCB

Overall Guidance:

Dr. Purnima Sharma, Managing Director, BCIL

ABBREVIATIONS

ACCCP	ASEAN Coordinating Committee on Consumer Protection
ACCSQ	ASEAN Consultative Committee on Standards and Quality
AECC	ASEAN Economic Community Council
AIMED	Association of Indian Medical Device Industry
AMDD	ASEAN Medical Device Directive
BCIL	Biotech Consortium India Limited
BIS	Bureau of Indian Standards
CAB	Conformity Assessment Body
CAGR	Compounded Annual Growth Rate
CDSCO	Central Drugs Standard Control Organization
DOP	Department of Pharmaceuticals
ENT	Ears Nose and Teeth
FSSAI	Food Safety and Standards Authority of India
GOI	Government of India
ICMED	Indian Certification of Medical Devices Scheme
ISO	International Organization of Standardization
MOHFW	Ministry of Health and Family Welfare
NABCB	National Accreditation Board for Certification Bodies
NABH	National Accreditation Board for Hospitals and Healthcare Providers
NABL	National Accreditation Board for Testing and Calibration Laboratories
NITI	National Institution for Transforming India
QCI	Quality Council of India
WHO	World Health Organization
NHSRC	National Human Rights Commission of India
CCC	Civilian Conservation Corps
IMA	Institute of Management Accountants
AHPI	Association of Healthcare Providers
CII	Confederation of Indian Industry
EEPC	Engineering Export Promotion Council

AMDD	ASEAN Medical Device Directive
AECC	ASEAN economic Community Council
ACCSQ	ASEAN Consultative Committee on Standards and Quality
ACCCP	ASEAN Coordinating Committee on Consumer Protection
IAF	International Accreditation Forum
PAC	Pacific Accreditation Cooperation

Industry Awareness Programme on
"Indian Certification for Medical Devices (ICMED)"

Workshop Agenda

Date: February 28, 2020
Venue: Jacaranda Hall, India Habitat Centre, New Delhi

Start Time	Session Topic	Speakers
0900 hrs	Registration	
0930 hrs	Welcome address	**Dr. Purnima Sharma**, MD, BCIL
0935 hrs	Opening address	**Mr. Rajesh Maheshvari**, CEO, NABCB
0945 hrs	Special address	**Shri Navdeep Rinwa**, Jt. Secretary, Policy, Dept. of Pharmaceuticals (TBC)
0950 hrs	Key Note address	**Dr. Jitendar Sharma**, Senior Fellow, NITI Aayog
0955 hrs	Vote of Thanks	**Mr. Rajiv Nath**, Forum-coordinator, AIMED
1000 – 1010 hrs	**Tea / Coffee Break**	
1010 hrs	ICMED – An Overview	**Mr. Rajiv Nath,** Forum-coordinator, AIMED
1030 hrs	Essential Principles of Safety & Performance	**Mr. Srikant Tiwari**, Lead Auditor, BSCIC
1100 hrs	ICMED Scheme - Certification Process	**Dr. Manish Pande**, Director and Head, PAD Division, QCI
1130 hrs	Elements of ICMED Scheme	**Dr. Jaishree Kasliwal**, Assessor, NABCB
1200 hrs	ICMED Scheme – Provisional approval of CBs	**Mr. C.S. Sharma**, Deputy Director, PAD Division, QCI
1230 hrs	ICMED Scheme – CB's Perspective - Representative from	**Mr. Parvinder Jeet Singh**, Head Medical Devices, Intertek
1300 hrs	ICMED Scheme – Certified Client's Perspective	**Dr. Jameel Ahmad Khan**, Trivitron
1330 – 1430 hrs	**Lunch Break**	
1430 hrs	Panel Discussion – Bringing Credibility to Indian Medical Devices|| ICMED certification- Current Status and Way Forward	**Moderator:** **Ms. Rama Venugopal, Jt. Coordinator, AiMeD (South)** **Panellists:** 1. **Dr. Ravi Kant Sharma**, DDC, CDSCO 2. **Dr. Nipun Vinayak**, Jt. Secretary, Procurement, MOH&FW (TBC) 3. **Smt. Manju Sharma,** Dy, CEO, GeM

		4. AiMeD- **Mr. Ganesh Sabat**, CEO, SMT 5. MNC representative- **Mr. Sudhakar Mairpedi**, Philips
1500 hrs	Risk Management – ISO 14971	**Mr. Ravi Singh**, Head - Certification, TUV India
1530 hrs	Design File Review & Validation	**Mr. Hemant Kumar Bhardwaj**, Lead Auditor, BSCIC
1600 hrs	Risk of Unauthentic certifications in Health Sector	**Mr. Mrutunjay Jena**, Joint Director, NABCB
1620 hrs	Question – Answer Session	
1650 hrs	**Concluding Remarks**	**Dr. Suchita Markan,** Asst. General Manager, BCIL
1655 hrs	**Vote of Thanks**	**Mr. Rajiv Chhibber,** Vice President, Sahajanand
1700 hrs	**High Tea**	

Introduction

Indian Certification for Medical Devices (ICMED) Scheme

To fill the regulatory vacuum in quality certification space for medical devices in the country, the Association of Indian Medical Device Industry (AiMeD) jointly with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB) rolled out a voluntary quality certification scheme for Medical Devices viz. ICMED Certification (http://www.qcin.org/icmed-medical.php), on March 15, 2016 World Consumer Day.

The Scheme is intended to enhance patient safety, and provide enhanced consumer protection along with much needed product credentials to manufacturers for instilling confidence among buyers and for enabling capacity building for Manufacturers for Regulatory Approvals. This move is also intended to significantly eliminate trading of sub-standard products or devices of doubtful origins, a widespread and injurious phenomenon in the Indian market.

The Certification Scheme was created by a Technical and a Certification Committee under a Steering Committee with Representation from 22 Organizations like DOC, MOH&FW, CDSCO, NHSRC, QCI, NABCB, NABH, NABL, BIS, CCC, IMA, AHPI, AiMeD, CII, EEPC etc. under the Chairmanship of Dr. M K Bhan and is available as ICMED 9000 for Low Risk Devices and ICMED 13485 for Moderate Risk and High Risk Devices.

To ensure need to have the highest Quality Standards, the Certification Scheme is built over the base Standard ISO 13485 (Quality Management System for Regulatory Purposes) which had 184 Compliance Requirements. The ICMED 13485 has in addition 23 Regulatory Requirements, 13 Essential Requirements for ensuring Patient Safety and with 16 Labelling Requirements for ensuring Consumer Protection. The Certification is available through NABCB Accredited Certification Bodies of International repute for this Scheme viz. Intertek, UL, TUV Intercert, TUV SUD & TUV Rheinland. Other Certification Bodies that have sought Approval / Accreditation from NABCB are DNV, Quality Austria, BSI, ICS, IR CLASS, Zenith & AGSI.

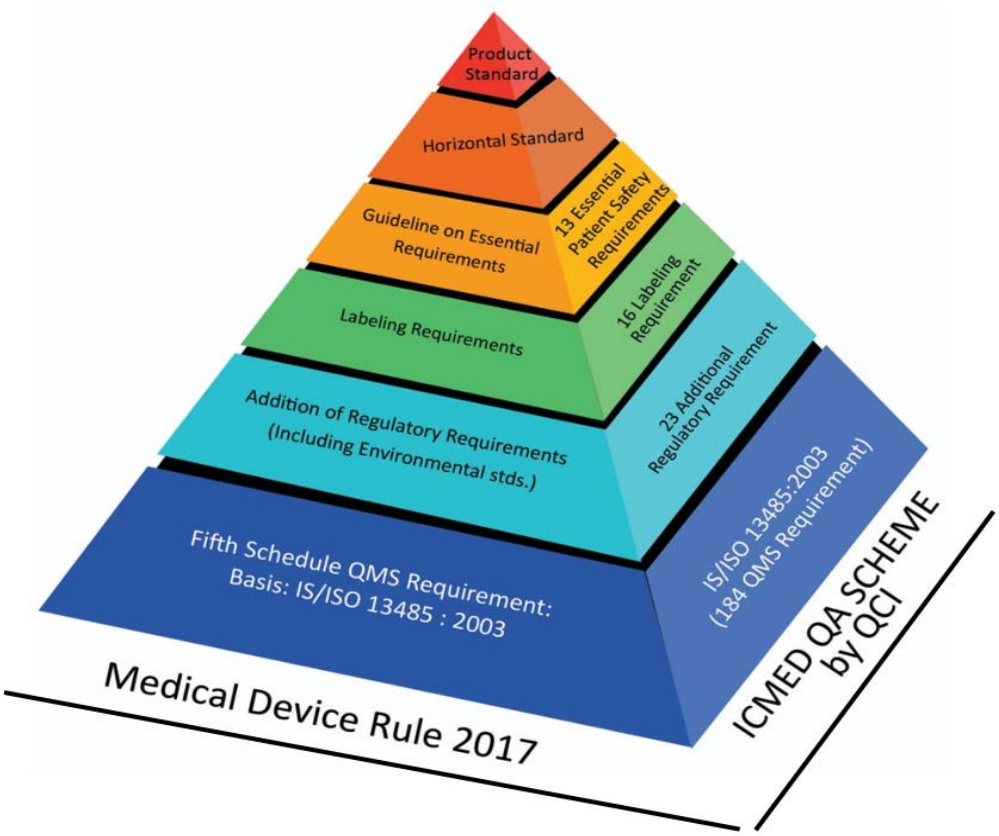


Figure 1: QA/QMS Under Mandatory MDR and Voluntary ICMED: 13485

It's a growing practice worldwide that certification to standards which may encompass regulatory requirements is accepted as demonstration of compliance. EC actually publishes a list of harmonized standards certification to which is assumed to be deemed compliance. Closer home, FSSAI has a provision in its regulations to recognize certification to national/international standards. In fact, in food sector, the international body, Codex Alimentarius Commission, is developing guidance on how regulators can take cognizance of 3rd party assurance schemes. So, if compliance to QMS as per Schedule 5 is prescribed as compulsory, cognizance can be taken of certification to any equivalent voluntary standard – be it ISO 13485 or ICMED 13485 and audit time for MDR, 2017 reduced to lessen the cost burden on the industry.

International Mutual Recognition Agreements

To gain respect and ease of access for Indian Medical Devices, India has an opportunity to work with its neighbours. In Europe, the medical devices regulations were harmonized initially as a Medical Devices Directive and more recently as European Medical Devices Regulations which permits free movement of goods within EU member nations while safeguarding its citizens from unsafe products by

permitting usage of a CE mark to distinguish regulatory approval .Realizing benefits of trade and ease of doing business, in 2015, the ASEAN Medical Device Directive (AMDD) agreement was signed by all the 10 ASEAN countries – Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam. The agreement is to be fully implemented by 2020. ASEAN Economic Community Council (AECC), a body entrusted with the responsibility for the implementation and monitoring of strategic measures and sectoral work plan through periodical review of key performance index. The primary purpose of this body is structured as to have an oversight of all sectors and to use its terms of reference to direct and ensure that the synchronization of cross-sectoral work will not only be feasible but accelerated and delivered at a pace far greater than its predecessor. Taking into account sectors that are crucial to consumer protection and product safety under the respective working group such as ASEAN Consultative Committee on Standards and Quality (ACCSQ) and ASEAN Coordinating Committee on Consumer Protection (ACCCP), it is submitted that in order to enhance consumer protection in product safety, ACCSQ and ACCCP shall develop product safety mechanism in the form of a directive or policy to overcome unsafe products in ASEAN countries.

India needs to integrate itself with these initiatives in ASEAN. Taking benefit of NABCB (National Accreditation Board of Certification Bodies) being an IAF (International Accreditation Forum) member and part of PAC – Pacific Accreditation Cooperation that includes ASEAN member countries as first step QCI-NABCB needs to seek Mutual Recognition Agreement for the Voluntary QA ICMED Certification with AMDD and later this can be progressively followed by seeking India to be a party to the AMDD as a member country with full compliance and harmonized regulations (Figure 10). This will enable the medical devices being made in India to have easy access and an accelerated regulatory approval mechanism to enable exports into these 10 countries. The voluntary certification scheme for medical devices, "Indian Certification for Medical Devices (ICMED) Scheme" was launched on 15thMarch 2016 at New Delhi on the occasion of World Consumer Rights Day jointly with Consumer Online Foundation in the collaboration of Quality Council of India (QCI) and Association of Indian Medical Device Industry (AiMeD).

ICMED – An overview

Indian Certification for Medical Devices (ICMED) Scheme

Quality Council of India (QCI), India's apex quality facilitation and national accreditation body, and the **Association of Indian Medical Device Industry (AIMED)** had signed an MoU on 30 October 2014 to develop and operate voluntary certification programmes for Medical Devices in order to enable medical device industry to demonstrate adherence to the best international standards and enhance its credibility in the world market.

While **QCI and AIMED** are the joint Scheme owners, the governing structure of the initiative is under a multi stakeholder **Steering Committee** and the initiative would be operated on a non-profit but self-sustaining basis. It would have a defined consensus based technical criteria laid down for the medical devices which would be evaluated by competent third-party certification bodies.

The manufacturing facility requiring certification under this **Indian Certification for Medical Devices (ICMED) Scheme** is required to be certified ultimately by an NABCB accredited Certification Body duly approved by the Quality Council of India, as the joint Scheme owner, and complying with the requirements as specified under the Scheme.

The **"QCI – AIMED Voluntary initiative on medical devices"** here in after known as Indian Certification for Medical Devices (ICMED) Scheme, comprises of specific additional requirements that the certification bodies need to fulfil in order to be accredited by NABCB for the ICMED Scheme operated by the Quality Council of India.

Scheme shall be able to offer the certification for the following levels:

- ICMED 9000 certification which is ISO 9001 plus additional requirements
- ICMED 13485 which is ISO 13485 plus additional requirements

Certification Criteria

The industry is expected to implement one or more of the following criteria documents for certification.

- ICMED 9000

- ICMED 13485

Technical Criteria for Certification of Medical Devices – ICMED 9000

A quality management system for medical device industry which:

a) needs to demonstrate its ability to consistently provide medical devices that meet customer and applicable statutory and regulatory requirements, and
b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

ISO 9000:2015 describes the fundamental concepts and principles of quality management which are universally applicable to the following:

- organizations seeking sustained success through the implementation of a quality management system;
- customers seeking confidence in an organization's ability to consistently provide products and services conforming to their requirements;
- organizations seeking confidence in their supply chain that their product and service requirements will be met;
- organizations and interested parties seeking to improve communication through a common understanding of the vocabulary used in quality management;
- organizations performing conformity assessments against the requirements of ISO 9001;
- providers of training, assessment or advice in quality management;
- developers of related standards.

Technical Criteria for Certification of Medical Devices–ICMED13485

Safety and quality are non-negotiables in the medical devices industry. Regulatory requirements are increasingly stringent throughout every step of a product's life cycle, including service and delivery. Increasingly, organizations in the industry are expected to demonstrate their quality management processes and ensure best practice in everything they do.

ICMED 13485 similar to ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*, is a quality management system specific to the medical devices industry.

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or

external parties that provide product, including quality management system-related services to such organizations.

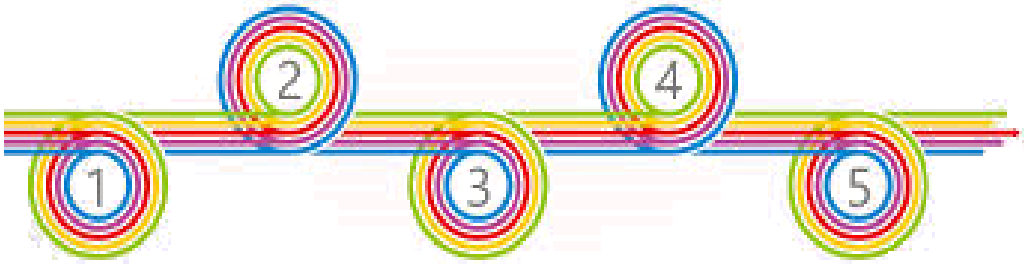
Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by ISO 13485:2016 that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to ISO 13485:2016 reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of ISO 13485:2016 is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.

ICMED Scheme – Certification Process



Certification Process

The certification process to be followed by the Certification Bodies approved under the Medical devices manufacturer facility Certification Scheme operated by the **Quality Council of India** for ICMED 9000, ICMED 13485 and **ICMED 13485 Plus (Product specification as per MoHFW's Technical specifications)** as per criteria specified for each type of scheme.

1.0 Types of Certification

The following certification schemes shall be available:

i. ICMED 9000, An ISO 9001 requirements Plus additional requirement
ii. ICMED 13485, An ISO 13485 requirements Plus additional requirements
iii. ICMED 13485 Plus (Product specification as per MoHFW's Technical specifications)

2.0 The certification shall be granted for each manufacturing facility after due verification of compliance to the prescribed criteria.

2.1 Application Form

2.1.1 The applicant shall clearly indicate the type of certification being applied for.

2.1.2 The application form shall include the information about each manufacturing facility to be certified.

2.1.3 The Application form shall clearly indicate if any of the activities covered under the criteria for certification are being carried out at any other premises other than the main location. This is to plan & facilitate covering the applicable criteria under the same audit. Example Deign or R &D, Testing and any outsource processes etc.

2.1.4 The applicant shall specify/enlist all the activities to be audited and certified. It shall mention whether all the activities are covered at single or multiple

locations/sites. For multiple sites overlap activities, if any shall also be mentioned.

2.1.5 Irrespective of the number of facilities of a manufacturer, to be covered under certification, each and every manufacturing facility shall be audited for the Medical device manufacturer certification scheme Criteria as applicable.

2.2 List of Documents

The applicant shall submit all necessary documents (as per applied criteria) to the Certification Body (CB) for document review.

2.3 Information for Applicants

2.3.1 The certification body shall maintain and make publicly available (on its web site and by other modes) accurate information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and geographical areas in which it operates. The information shall include:

a) An Application form;
b) Reference to the Certification Criteria,
c) Procedure for obtaining Medical devices manufacturing Certification, a detailed description of the initial and continuing certification activity, including the application, initial evaluation, periodic surveillance, evaluations, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and re-certification.
d) List of documents required to be submitted along with the application.
e) Information about the fees for application, initial certification and continuing certification and policy for the fee
f) Documents describing the obligation of applicants/ certified clients, and
g) Information on procedures for handling complaints, feedbacks and appeals

2.4 Registration of Application

2.4.1 The CB shall respond to all enquiries received from prospective applicant organisations for Medical device manufacture scheme Certification with

complete information for facilitating a registration of an applicant, within 7 working days of receipt of the query.

2.4.2 The applicant shall apply to any of the approved Certification Bodies on the Application format prescribed by the CB, and provide the information as mentioned in previous clauses and any other information the CB may consider relevant to the certification process.

2.4.3 The applicant shall declare (in the form of an undertaking in application) whether it has been an applicant / certified under this Scheme with or by any other certification body, and if yes then shall provide the previous evaluation reports to the new certification body. The certification body may verify the information provided by contacting the earlier certification body.

2.4.4 The applicant shall along with the application declare any judicial proceedings relating to its operations, any proceedings by any Regulatory body or suspension / cancellation / withdrawal of any certification / approvals under any Regulations or otherwise. Such declaration shall be a part of the undertaking mentioned in 1.4.3 above.

2.4.5 Certification is granted only against the current relevant certification criteria. The certification body shall review all applications for the above and ensure the same.

2.4.6 All applications for certification shall be reviewed by the certification body for adequacy and deficiencies observed, if any, shall be informed to applicant within 7 working days of receipt of application. Review of applications shall be done by a competent person. Records of review shall be maintained.

2.4.7 Complete application supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration shall be done within 7 working days of receipt of application or information in response to the deficiencies communicated as per 1.4.6 above. In case the applicant discloses any proceedings, suspensions etc as per 1.4.3 above, the

applicant shall not be entertained for a period of one year from the date of conviction, suspension, withdrawal, deregistration etc.

2.4.8 If the Medical device manufacture scheme Certification of either type has been suspended / cancelled by any approved CB, the application from such a manufacturer facility shall not be accepted till suspension is lifted by the concerned CB or for one year from the date cancellation of certification. This will be applicable only for the manufacturing facility whose certification have been suspended, However this will not be applicable to other manufacturing facilities under same legal entity.

2.4.9 The certifications (ISO 9001 and/ or ISO 13485) by CBs other than IAF MLA signatory accredited CBs shall not be accepted.

2.4.10 Where the certification activities (for ISO 9001and /or ISO 13485) is carried out by IAF MLA signatory accredited CBs other than NABCB, full audit as per scheme criteria requirements shall be carried out.

2.4.11 Where manufacturing facility is certified by Certification Bodies accredited by NABCB, audit related to scheme criteria shall be carried out.

2.4.12 If ISO 9001 and/or ISO 13485 certification of the applicant is under suspension, application for Medical device manufacture scheme Certification shall not be entertained till the suspension of ISO 9001 and/or ISO 13485 certification is revoked. In case ISO 9001 and/or ISO 13485 certification of a manufacturing facility is cancelled by any CB, the application for Medical device manufacture scheme Certification can be carried out considering manufacturing facility as new client.

2.4.13 The antecedents of the applicants shall be checked in relation to the Scheme. Applications from Medical device manufacture scheme Certification facilities who have earlier either misused the Certification, or whose earlier certificate was cancelled because of violation of terms & conditions / misuse of certification or have been implicated / convicted by

the court, shall not be entertained for a period of 1 year of conviction / strictures by the court / cancellation of the certificate by any CB.

2.4.14 Applications from manufacturing facility found to be misusing the Medical device manufacture scheme Certification while their application is being processed for grant of certificate, shall not be processed any further, and rejected after a due notice of 15 days. Fresh applications from them shall be treated as per clause 1.4.13 given above.

2.4.15 Requests for grant of certification from previous applicants as per 1.4.16 (a), (b) &(c) / expired certificates shall be processed like a fresh application and the entire procedure for grant of certification shall be adhered to subject to clauses 1.4.8 to 1.4.12 above.

2.4.16 Certification Bodies shall reject or close an application under the following conditions;

a) if Initial Evaluation is not carried out within 3 months of registration of application
b) if the entire certification process is not completed within 6 months of registration of application.
c) If the applicant shows no progress towards completion of corrective actions within 3 months of Initial Evaluation and 6 months of Registration of application.
d) Misuse of Medical device manufacture scheme Certification
e) Evidence of any malpractice
f) Voluntary withdrawal of application.

2.4.17 The application fee, if charged by CB, shall be non-refundable.

2.5 Audit Programme

Considering the type of the certification sought, the following program shall be followed:

Certification activity	ICMD 9001	ICMED 13485	ICMED 13485 Plus
Certification Audit – Stage 1	√	√	√
Certification Audit – Stage 2	√	√	√
Surveillance – "Once in a year", Second surveillance audit shall be a surprise audit and shall be carried out within period of 9 to 12 months from previous surveillance audit.	√	√	√

3.0 Essential Principles of Safety and Performances

3.1 Certification Audit Planning:

3.1.1 Preliminary information to be provided to the CB

3.1.1.1 CBs shall inform client regarding documentation to be provided by manufacturing facility for "Document review" in compliance to scheme criteria requirements as applicable

3.1.1.2 Before starting the application review, the applicant shall provide the Certification Body with the documentation in compliance to ICMED 9000, ICMED 13485 and ICMED 13485 Plus requirements, as applicable.

3.1.1.3 Apart from information regarding the equipment and facilities of manufacturing facility particularly sterilization process, the applicant shall provide information regarding the plan and frequency of controls carried out on incoming material, production facilities and testing equipment in order to allow auditor to have a preliminary overview on the manufacturing facility.

3.1.1.4 The documentation to be provided is the following:

i. Quality Manual – Addressing all the requirements as per criteria document
ii. Procedures – (Procedures related to process and general area of operation such as purchase, H.R. etc)
iii. Quality Plan – Addressing controls applied & verification frequency of inspection of Incoming material, Process controls and final Product(s) etc.
iv. Standard operation procedures/ Work instructions
v. Form and Formats.

4.0 Certification Audit

4.1 ICMED 9000, ICMED 13485 and ICMED 13485 Plus based Certification

4.1.1 The Initial certification audit is performed to:

a) Audit the client's management system documentation;
b) Evaluate the client's location and specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit;
c) Review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system including scheme requirements;
d) Collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g. quality, environmental, legal aspects of the client's operation, associated risks, etc.);
e) Review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit;
f) Provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects;

g) Evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.

h) Auditors must identify personal protective equipment which may be reasonably required during while auditing processes in stage – 2 audit and report in stage – 1 audit and ensure availability of the required personnel protective equipment during Stage – 2 audit.

4.1. 2 The Stage – I shall be carried out and judge the adequacy of the system to meet requirements of applicable ICMED 9000, ICMED 13485 and ICMED 13485 Plus criteria. It shall result in a formal report and will include justifications for auditing/ not auditing shift and time to be spent for product audit in case of ICMED 13485 Plus.

4.1.3 The stage 1 audit during the initial certification shall be carried out at the client's premises in order to achieve the objectives. The CB shall have a defined guideline for the same. (Also Ref IAF MD 2)

4.2 Audit at manufacturing facility

Objective: Verifying the effective implementation of the Criteria ICMED 9000, ICMED 13485 and ICMED 13485 Plus as applicable.

The audit plan shall be modified accordingly.
During the opening meeting, the Team leader shall collect information on the situation and on changes concerning manufacturing facility, equipment, raw materials and anything else relevant.

Guidelines as per ISO 17021: 2011 and ISO 17065: 2012 shall apply.

4.3 Safety during audits

4.3.1 The Audit involves risks linked to work environments. Responsibility for risk analysis and the identification of the most suitable means of protection is shall be of the manufacturer.

4.3.2 Auditors must have personal protective equipment which may be reasonably required to while auditing different manufacturing processes of manufacturing facility particularly sterilization.

4.4 Non conformities

Certification bodies shall have a procedure, for identification, grading of findings, corrective action acceptance and closure time of any audit findings graded as nonconformities.

4.5 Audit Report

4.5.1 The Certification Bodies shall send the Audit Report within 7 working days from the date of the completion of the audit to the client.

4.5.2 The Audit report shall have the following as minimum:

a) Scope of the Certification,
b) Name and address of manufacturing facility
c) Name of auditor and date & time of audit
d) Criteria of audit
e) Describe the structure of the audited manufacturing facility
f) Report on auditing all “Additional Requirements”
g) Report on Non-conformance, if any
h) The processes excluded by the Scope of the certification, if any,

NOTE: ISO 17022: 2012 can be referred for further guidance on Audit reporting

Criteria for granting a certificate

The purpose of this section is to minimize the variation among CBs in taking the decision of granting a certificate.

5.0 Conditions for granting a certificate:

The CB shall grant the certificate when all the following conditions are met with:

a) All NCs raised are closed
b) Payment of outstanding dues
c) Certification decision is taken

6.0 Information

The certificate shall include the following information:

(a) Certificate number
(b) Certification scheme name (or logo)
(c) Reference to certification criteria
(d) company name (should be a legal entity) with all locations in the schedule
(e) Certified Manufacturing facility address
(f) Scope of certification
(g) Scheme logo
(h) logo of the CB
(i) Accreditation number with logo
(j) Date of certification
(k) Expiry date
(l) Signature of the CB's authorized representative

In case of company certification, the CB shall annex to the certificate the list of the certified manufacturing facilities.

7.0 Validity

The certificate shall be valid for 3 years from the date of issuance.

ICMED Scheme – Certification Bodies

National Accreditation
Board for Certification Bodies

Certification Bodies

1.0 Introduction

The manufacturing facility requiring certification under this Indian Certification for Medical Devices (ICMED) Scheme is required to be certified ultimately by an NABCB accredited Certification Body duly approved by the Quality Council of India, as the joint Scheme owner, and complying with the requirements as specified under this Scheme. The requirements that the Certification bodies need to comply with for getting approved by QCI under this Scheme are detailed in this document.

Initially, certification bodies would need provisional approval under the Scheme the system for which is described in the document Provisional Approval System for Certification Bodies separately.

The Certification Bodies (CBs), desirous of operating under the Indian Certification For Medical Devices (ICMED) Scheme, herein after referred to as the Scheme, shall need to primarily comply with the requirements specified in ISO17021 and/or ISO17065, as applicable and the addition al requirements prescribed by QCI and AIMED, as the joint Scheme Owners.

In order to be formally accredited by the National Accreditation Board for Certification Bodies (NABCB) as above, the CBs, even if already accredited to ISO17021 for scope sector 19 and/or ISO17065, would need to under goal limited Office Assessment and a Witness Assessment to fan actual audit under the Scheme.

The CBs would not get a client unless they are approved under the Scheme and would not be able to offer an audit for witnessing and get the relevant scope added in their accreditation.

Further, in order to launch the Scheme, it is necessary that some certification bodies are available right at the beginning.

Therefore, it is necessary to establish a procedure for provisional approval of CBs under the Scheme, till such time they can get the scope added in their accreditation or get formally accredited from NABCB.

This document sets out the requirements to be fulfilled by the CBs desirous of operating under the Scheme pending formal accreditation.

Since initially only management systems-based certification is being launched, this document covers requirements only for such certification bodies and requirements for product certification bodies shall be added when the relevant certification is launched.

1.1 The "**QCI – AIMED Voluntary initiative on medical devices"** here in after known as **Indian Certification for Medical Devices (ICMED) Scheme**, specific additional requirements that the certification bodies need to fulfil in order to be accredited by NABCB for the ICMED Scheme operated by the Quality Council of India**.**

1.2 The certification bodies approved under the ICMED Scheme shall be able to offer the certification for the following levels;

a) ICMED 9000 - ISO 9001 requirements plus additional requirements specified under the Scheme

b) ICMED 13485 - ISO 13485 requirements plus additional requirements specified under the Scheme

c) ICMED 13485 Plus, ICMED 13485 plus product specification as per MoHFW's Technical specifications

1.3 In order to be able to offer certification the certification bodies shall need to be accredited by NABCB as per the following requirements:

1.3.1 For offering certification for ICMED 9000 and ICMED 13485, the certification body shall need to be accredited as per ISO 17021-1:2015 for ISO 9001 and ISO 13485 respectively read with additional requirements specified in this document by NABCB.

1.3.2 The certification body shall have been witnessed for ICMED 9000 and/or ICMED 13485 audit, as applicable, by NABCB.

1.3.3 For certification to ICMED Plus, the certification body shall need to be accredited against ISO 17021-1:2015 for ISO 13485 and ISO 17065: 2012 with additional requirements specified in this document and shall have undergone a witness assessment by NABCB in last one year one year in scope sector 19 (DL33.1) for ISO 9001 and ISO 13485 .

1.3.4 However if above criteria in 1.3.1 & 1.3.2 is not met then a certification body can be granted a provisional QCI approval for Medical Devices Certification as per Provisional Approval System for Certification Bodies, for a period of one year subject to condition that certification bodies gets accredited by NABCB as per 1.3.1 & 1.3.2 above.

1.3.5 For being able to offer Medical devices Certification for ICMED 13485 Plus, the certification bodies shall need to be accredited against ISO 17065:2012 for the additional requirements specified in this document and requirement as specified in 1.3.3 above.

1.4 The requirements prescribed in this document are additional requirements that the certification body shall fulfil. Irrespective of which scheme (refer clauses 1.3 and 1.4 of this document) the certification body opts for, the requirements mentioned in each clause, whether they pertain to ISO 17065: 2012 or ISO 17021-1: 2015, shall apply.

1.5 If CB applies to NABCB to include ICMED schemes as extension of scope in their existing QMS accreditation, they may opt for either NABCB office assessment for scope extension assessment in which ICMED schemes would be reviewed and recommended for QCI provisional approval they may opt for QCI assessment for ICMED Schemes and latter for NABCB scope extension. NABCB would advise the CB about the options available.

2. General Requirements

2.1 Legal and Contractual Matters

2.1.1 In addition to the requirements as specified in the respective accreditation standards (clauses 4.1 of ISO17065:2012 and clauses 5.1 of ISO 17021-1:2015) following requirements shall apply:

2.1.2 **Certification agreement**

2.1.2.1 The certification body shall ensure that its certification agreement requires that the client complies with

2.1.3 **Use of licence, certificate and marks of conformity -** In addition to the requirements as specified in the respective accreditation standards (clause 4.1.3 of ISO17065:2012 and clause 8.4 of ISO 17021-1:2015)

2.2 **Impartiality related requirements –** In addition to the requirements as specified in clauses 4.2 ISO17065:2012 and clauses 5.2 of ISO 17021-1:2015, following requirements shall apply.

2.3 Liability and financing

2.3.1 In addition to the requirements as specified in clause 4.3 of ISO17065:2012 and clause 5.3 of ISO 17021-1:2015, following requirements shall apply. The requirements as specified above are applicable to all the schemes as specified in clause 1.2 of this document.

2.3.2 The certification body shall also be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

2.3.3 The certification body shall be able to demonstrate that it has a reasonable expectation of being able to provide and to continue to provide the service in accordance with its contractual obligations. Certification bodies shall also be able to provide sufficient evidence to demonstrate its viability, e.g. management reports or minutes, annual reports, financial audit reports, financial plans, etc.

2.3.4 The means by which the certification body obtains financial support shall be such to allow the certification body to retain its impartiality.

2.3.5 In addition to the above the certification body shall also demonstrate to the Impartiality committee, that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

2.4 Non-discriminatory conditions

2.4.1 The certification body shall have means of demonstrating compliance to this requirements of ISO 17065:2012 (clause 4.4), through its policies and procedures as well as actual practice.

2.4.2 The certification body's policies and procedures shall ensure that it does not practice any form of hidden discrimination by speeding up or delaying the processing of applications.

2.4.3 **Certification Fees**

2.4.3.1 The requirements as specified in clause 7 of the document "Indian Certification for Medical Devices - Certification Process" shall apply.

2.4.3.2 The certification body's fee structure shall be publicly available on its website. The structure shall provide break up of costs.

2.4.3.3 On request from a specific applicant/client, based on the specific conditions concerning the applicant, the certification body shall inform the applicable fees, which shall essentially be derived from the fee structure made publicly available. It shall not substantially differ from the one available publicly, unless some plausible justifications are recorded.

2.5 Confidentiality - In addition to the requirements as prescribed in the respective accreditation standards (clause 4.5 of ISO17065:2012 and clause 8.5 of ISO 17021-1:2015) following requirements shall apply:

2.5.1 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. There shall be a mechanism such as obtaining signed confidentiality agreements, etc, for ensuring the same.

2.5.2 The certification body shall have available and use equipment and facilities that ensure the secure handling of confidential information (e.g. documents, records).

2.5.3 When confidential information is made available to other bodies (e.g. accreditation body, agreement group of a peer assessment scheme), the certification body shall inform its client of this action, in advance, through agreements, etc.

2.5.4 In case of transfer of certificate or application, when the client decides to move from one certification body to another certification body, the certification body to which the client is now moving may ask the previous certification body for information on the reasons for such movement or the performance of the client with respect to the certification requirements. The previous certification body shall be obliged to share this information within a reasonable time, not exceeding 10 days from the date of receipt of the request. Such information shall not be considered as confidential and the certification body shall inform its client of this requirement, in advance, through agreements, etc.

2.6 Information Requirements - In addition to the requirements as specified in the respective accreditation standards (clause 4.6 of ISO17065:2012 and clauses 8.1, 8.3, 8.6 of ISO 17021-1:2015) and the document "Medical devices manufacturer Certification Process", the following requirements shall apply:

2.6.1 Publicly available information

2.6.1.1 Making the information publicly available through the certification body's website shall be the only means of meeting this requirement.

2.6.1.2 The following information with respect to Indian Certification for Medical Devices Scheme shall be made publicly available on the certification body's website. The information provided shall be accurate, non-misleading and where relevant detailed enough for the reader to clearly understand:

a) Information related to the terms and conditions of certification and the use of certificates/certification mark for ICMED Scheme, as contained in the Certification Agreement (clause 3 of this document). A description of the rights and duties of applicants and clients, including requirements, restrictions or limitations on the use of the certification body's name and certification mark and on the ways of referring to the certification granted.
b) The CB may also provide any other guidance documents on the certification criteria for the benefit of the applicant, as long as they are not advisory/consultative in nature.
c) The certification body shall make publicly available on its website the information about applications registered and certifications granted, suspended or withdrawn.
d) On request from any party, the certification body shall provide the means to confirm the validity of a given certification and the provision for the same shall be made available on the website.
e) The certification body shall maintain and make publicly available on its website, a directory of valid certifications under "Indian certification for Medical devices" scheme that as a minimum shall show the name,

relevant certification criteria, scope and geographical location (e.g. city and country) and contact details for each applicant and certified client and validity of certification for the certified clients. Please also see additional requirements given in the document “Indian certification for Medical devices” Certification Process (clause 1.3)”, which are required to be placed on the certification bodies website.

2.6.1.3 The certification body shall also make arrangement for providing and up-dating of information with respect to status of certified clients. The certification body shall have procedure for frequent updating of the information on its website. The responsibilities for ensuring accuracy of the information made available on the website, ensuring frequent updates, etc shall be documented.

2.6.1.4 The information on complaints handling process and the certification body’s procedure shall be directly available to the public, without the public having to go through layers of cross linkages.

2.6.2 Information exchange between a certification body and its clients

2.6.2.1 **Information on the certification activity and requirements-** The certification body shall provide and update clients on the following:

a) a detailed description of the initial and continuing certification activity, including the application, initial audit/evaluation, surveillance audit/evaluation, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and recertification;
b) the certification criteria for ICMED scheme;
c) information about the fees for application, initial certification and continuing certification;
d) the certification body's requirements for prospective clients;
e) documents describing the rights and duties of certified clients as well as obligations on part of the certification body including the changes within certified manufacturing facility that need to be informed to the certification body; information on procedures for handling complaints

both by the certification body as well by the certified manufacturing facility, in respect of complaints against certified facilities and appeals;

2.6.2.2 Based on the changes affecting certification, including those initiated by the client the certification body shall decide upon the appropriate actions in accordance with its documented procedure, which shall include any of the actions as specified in clause 7.10.3 of ISO 17065: 2012, singly or in combination. Responsibility for deciding about the course of actions to be taken shall also be documented.

3. Structural requirements

3.1 In addition to the requirements as specified in the respective accreditation standards (clause 5 of ISO17065:2012 and clause 6 of ISO 17021-1:2015) following requirements shall apply:

3.2 Organizational structure and top management

3.2.1 The organization structure shall include structure of the parent body (legal entity) if separate from the department/division that offers certification. It shall also include structure of the related departments in relation to the department offering certification services.

3.2.2 The certification body shall identify and document all related bodies (separate legal entities) as well as other departments of the same legal entity and their activities and functions and their relationships with the certification body when describing its organizational structure. This shall cover all relationships and related bodies, bodies related to the certification body based on ownership; governance; management; management personnel; shared resources, finances, contracts and marketing. The activities of all related bodies shall also be documented for the purpose of identifying any potential conflict of interest. The certification body shall also have a system for disclosure and documentation of the types of activities carried out by its internal and external personnel and subcontractors in general and in particular regarding the designing of relevant product/process/service, consultation, internal

evaluation/auditing, training, etc. The above information shall also be used for identification of actual/potential risks to impartiality.

3.2.3 The identification of responsibilities, however done, shall clearly and unambiguously reflect the responsibilities for activities/functions as described vide clause 5.1.3 a) to n) of ISO/IEC 17065:2012 and clause 6.1.2 a) to i) of ISO 17021-1:2015.

3.2.4 The requirement specified vide clause 5.1.4 of ISO/IEC 17065:2012 shall cover the Impartiality committee and any other committees, if established by the certification body for certification scheme development, planning for certification evaluation (sampling and determination), certification review and decision making, appeals process, etc.

3.3 Mechanism (Impartiality Committee) for safeguarding impartiality

3.3.1 An Impartiality committee with specific responsibility for safeguarding the certification body's impartiality in its certification functions and for ensuring that the policy on safeguarding impartiality and related procedures and other systems are effectively implemented shall be the only means of fulfilling this requirement. The impartiality committee as specified in clause 6.2 of ISO 17021-1:2015 will fulfil the requirement as specified in this document.

3.3.2 The Impartiality Committee shall:

a) Assist the certification body in developing the policies relating to impartiality of its certification activities,

b) Counteract any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent objective provision of certification activities,

c) Advise on matters affecting confidence in certification, including openness and public perception,

d) Conduct a review, at least once annually, of the impartiality of the audit, certification and decision-making processes of the certification body, and

e) Approve the conflict of interest analysis and the mitigation measures described in clause 2.2.12 of this document.

Other tasks or duties may be assigned to the committee provided these additional tasks or duties do not compromise its essential role of ensuring impartiality. The composition, terms of reference, duties, authorities, competence of members and responsibilities of this committee shall be formally documented and authorized by the top management of the certification This committee shall meet regularly, at least once a year, and a complete record of the proceedings of this committee shall be maintained.

3.3.3 The certification body shall ensure that a) The committee for safeguarding impartiality shall be separated from the management of the certification body operations and established at the highest level within the organization, independent of its day-to-day operations. b) In the composition of the committee, participation of key interested parties shall be ensured, with a representation of a balance of interests such that no single interest predominates. Internal or external personnel of the certification body are considered to be a single interest, and shall not predominate. c) Its chairman shall be a person independent from and external to the certification body.

3.3.4 Impartiality Committee meetings may be observed by the Accreditation Body's Assessment Teams as part of the Certification body's accreditation process.

3.3.5 Although every interest cannot be represented in the Committee, a certification body shall identify and invite significantly interested parties. Such interests may include: clients of the certification body customers of organizations whose management systems are certified, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, or representatives of non-governmental organizations, including consumer organizations. The invited representative to impartiality committee shall be some way related to medical devices field.

4. Resource related and team competence requirements

4.1 In addition to all generic personnel related requirements as specified in clause 6 of ISO17065:2012 and clause 7 of ISO 17021-1:2015 following specific requirements shall apply:

4.2 Audit/evaluation team competence

4.2.1 The auditors/evaluators of the certification body carrying out the audit/evaluation of the manufacturing facility against the criteria as described in clause 1.2 above shall have all the following qualifications as described below:

(i) A graduate in Bio Technology or degree in Electrical Engineering or Electronics Engineering or Chemical Engineering or Bio Medical Engineering or Mechanical Engineering from a University recognized by the Central Government for such purposes, followed by 2 years' experience of manufacturing or research or quality assurance in medical device field. a Graduate in Science, from a University recognized by the Central Government for such purposes followed by a minimum of 3 years experience in the manufacturing or quality assurance in medical device field; or a Diploma in Engineering or Pharmacy from a Board or Institute recognized by the Central Government or the State Government, as the case may be, for such purposes followed with a minimum of 4 years experience in the manufacturing or quality assurance of medical device fields;

(ii) Auditor experience - For a first authorization, the auditor shall comply with the following criteria, which shall be demonstrated in audits under guidance and supervision:

a) For ICMED 9000 – The auditor shall have gained experience in the entire process of auditing medical device quality management systems, including review of documentation and risk management of medical devices, implementation audit and audit reporting. This experience shall have been gained by participation as a trainee in a minimum of

two audits for a total of at least 10 mandays under an accredited QMS programme,

b) Additionally for ICMED 13485 - This experience shall have been gained by participation as a trainee in a minimum of two audits for a total of at least 10 mandays in an accredited ISO 13485 programme,

c) In addition to criteria a) and b) above, the audit team leaders shall have performed as an audit team leader under the supervision of a qualified team leader in at least three ISO 9001 audits for ICMED 9000 and ISO 13485 audits for ICMED 13485.

d) The knowledge and skills for personnel involved with the ICMED 13485 certification as defined in Annexure B of IAF MD 9 shall be applicable.

NOTE: Kindly refer to IAF MD 9 for further guidance for ICMED 13485 auditor competence and experience requirements.

4.2.1.1 The auditor/evaluator involved in offsite documentation review of information received with the application/ document review before going for onsite assessment shall have the qualifications as described in clause 4.2.1 of this document.

4.2.1.2 The certification body may use ISO 9001 auditors who do not have the requisite qualifications as prescribed above provided they are supported by technical experts (TEs) who meet the qualifications at 4.2.1 above. The time spent by the TE on an audit shall be in addition to the audit time as prescribed under the 'Certification Process' which the CB is expected to spend.

4.2.2 One of the auditors/evaluators in the team shall be nominated as the team eader. The team leader shall be an ISO 9001 TL Auditor for ICMED 9000, ISO 13485 TL Auditor for ICMED 13485 and ICMED 13485 Plus, qualified as team leader as per the requirement given in ISO 17021-1:2015.

4.2.3 The certification body will have a system for qualifying lead auditor/evaluators for "Indian Certification For Medical devices" scheme, based on experience of having performed

a) For ICMED 9000 At least three audits/evaluations under the medical devices manufacturer certification ICMED 9000 scheme. For one time initial qualification, some other evaluation methods such as audit experience as team leader in other similar areas, may be used.

b) For ICMED 13485, At least Five audits/evaluations under the medical devices manufacturer certification ICMED 13485 scheme. For one time initial qualification, some other evaluation methods such as audit experience as team leader in other technically similar areas, may be used.

c) For ICMED 13485 Plus, Requirements as described in 4.2.3 (ii) above Scheme. For one time initial qualification, some other evaluation methods such as audit experience as team leader in other technically similar areas, may be used.

4.2.4 While carrying out audit/evaluation of a manufacturer facility for ICMED criteria requirements as specified, the audit team shall collectively have competence as specified in clauses 4.2.1 and 4.2.3 above.

4.3 Other certification body personnel as relevant to the Indian certification for Medical devices scheme - Other certification body personnel involved in the scheme certification evaluation activities shall have the competence as stated below:

4.3.1 Application Review personnel – The functions to be carried out by the personnel involved in review of application review is to confirm the adequacy of the information provided by the applicant and identification of the deficiencies observed. Further in case the application reviewer also needs to carry out mandays estimation and team nomination, the persons involved in application review process, shall have thorough knowledge of “Indian certification for Medical devices scheme” requirements as defined in this document and “certification process” documents, in addition to meeting the requirements specified in the relevant requirements for application review personnel as specified in ISO17021-1:2015. The application review personnel shall be qualified based on experience of having performed at least three

application reviews under the Indian certification for Medical devices scheme or through any other equivalent route.

4.3.2 Technical Reviewer – The certification body personnel involved in technical review function shall have the same requirement as that specified in clause 4.2.1 of this document. The technical reviewer shall also meet the qualification criteria as specified in the relevant requirements of ISO17021-1:2015 and shall preferably be qualified on the basis of demonstrated competence to carry out the review function say based on experience of having performed at least three technical reviews under the "Indian certification for medical devices scheme". The technical reviewer shall be independent from the audit/evaluation team. Only person(s) employed by the certification body or on long term (2 – 3 years) full time contract with the certification body shall be entrusted the responsibility of technical review functions.

4.3.3 Decision maker - Any authorized person(s) of the certification body, independent of the persons involved in the evaluation function.

a) The person(s) or committee, who take(s) the decision on granting certification under the the ICMED scheme, shall have a level of knowledge and experience sufficient to evaluate the information obtained from the evaluation process and the review.
b) The technical review and the decision may be completed concurrently by the same person(s), provided they fulfil the necessary requirements as specified in clause 4.3.2 above and has been specifically authorized for decision making functions.
c) Impartiality and absence of conflict of interest shall be ensured before entrusting the task of certification decision making.

5. Certification Document

5.1 The certificate to be issued to certified manufacturing facility for the options as specified in clause 1.2 of this document shall be as per the certification document template as enclosed vide Annex A.

6. Complaints and appeals handling system

6.1 All the requirement as specified in clause 7.13 of ISO 17065:2012, clauses 9.7 and 9.8 of ISO 17021-1:2015, and those specified in clause 8 of the document "ICMED Certification Criteria" are applicable. In addition, the requirements specified below are also applicable.

6.2 In case of complaints related to a certified client and the products manufactured by the certified client, the examination and evaluation of the complaints shall take in to consideration the effectiveness and implementation of the client's applicable audit criteria (i.e certification level for which client is certified). The process of establishing validity of the complaint shall generally involve processes like conduct of additional surveillance activities – visit to certified client's premises for special evaluation, testing and evaluation of the manufacturing process as per implemented system in the manufacturing facility, if necessary. The decisions on complaint shall then be based on the result of additional surveillance activities.

6.2.1 The certification body's complaint handling process shall document the actions to be taken by the certification body as well as the certified client, in case the complaint is established to be valid and manufacturer's controls are found to be non-compliant with the specified criteria. Some of these actions/conditions shall also be included in the certification body's legally enforceable contract with the client.

6.2.2 In respect of appeals, the certification body shall ensure that the individual(s)/committee entrusted with handling of appeal and its resolution/decision shall be independent of the persons involved in certification related recommendations and decision and their position in the certification body shall be such that it shall not be possible to influence their decisions with respect to the subject of the appeal.

6.2.2.1 The procedure shall also have provision for giving a written statement to the appellant, of the appeal findings including the reasons for the decisions

reached and also communicating to the appellant about the provision for giving an opportunity to formally present his case. Based on the presentation made, the individual or a committee appointed for hearing the case shall take a final decision on the appeal and a formal notice of the outcome and the end of the appeal process shall be given to the appellant.

7. Management system requirements

7.1 In addition to the requirements as specified in the respective accreditation standards (clauses 7.12, 8 of ISO17065:2012 and clauses 9.9, 10 of ISO 17021-1:2015) following requirements shall also apply:

7.2 Documentation requirements

7.2.1 The certification body shall document its “Indian Certification for Medical device” scheme specific documentation in accordance with the requirements specified in the document “Indian certification for Medical device scheme “Certification Process” and this document, in order to ensure that the certified clients comply with the requirements specified in ICMED 9000, ICMED 13485 and ICMED 13485 Plus, as applicable.

7.2.2 All applicable requirements of the above document shall be addressed either in a manual or in a combination of manual and associated operational procedures.

7.3 Requirements with respect to records

7.3.1 Records of Applicant and Clients – The certification (applicants and clients) related records shall include records for all Organizations, including all organisations that submitted applications, and all organizations evaluated, manufacturing facility certified or with certification suspended or withdrawn/cancelled. Specifically, the records shall include the following:

a) Application information and results of application review and man-days estimation and team competence records;

b) Audit/Evaluation planning including decision on site visits in case of multisite certification and preparation records, evaluation plans and other related records;
c) Justification for audit/evaluation time determination/man-day estimation
d) Records of initial/surveillance and recertification audit/evaluation reports and related records;
e) Records of verification of correction and corrective actions;
f) Records of technical review and certification decisions; committee deliberations and decisions, if applicable;
g) Certification agreement;
h) Certification Documentation including scope of certification;
i) Records of complaints and appeals, and any subsequent correction or corrective actions;

7.3.2 **Other Records** – The certification body shall also maintain the following records;

a) Related records necessary to establish the credibility of the certification of ICMED Scheme, such as evidence of the competence of auditors/evaluators, technical experts, technical review personnel and decision makers, etc, as relevant;
b) Any other records as relevant to the ICMED Scheme "Certification Process", in order to provide confidence that the scheme requirements were complied with.

7.4 Internal audit – following additional requirements shall be applicable:

7.4.1 The objectives of the internal audit shall also include verification of fulfilment of requirements of the additional ICMED scheme specific requirements as specified in ICMED scheme "Certification Process" and this document.

7.4.2 The audit program shall cover all applicable elements of ISO 17065:2012 and ISO 17021-1:2015 and those specified in ICMED scheme "Certification Process" and this document.

7.4.3 The internal audit shall be conducted by personnel knowledgeable in certification, auditing and the requirements of ISO 17065:2012 and ISO 17021-1:2015 and the scheme specific requirements as specified in “ICMED scheme “Certification Process” and this document.

7.4.4 The internal audit report shall clearly report both the compliance (to the requirements specified vide clause 7.4.1 above and the certification bodies own systems) aspects as well as the observed gaps (non-conformities), areas for improvement, along with the objective evidences to support the conclusions drawn.

Provisional Approval System for Certification Bodies

Provisional Approval System for Certification Bodies

1. Scope

This document defines the process for Certification Bodies (CBs) to obtain provisional approval to operate under the Scheme for ICMED 9000 and ICMED13485 pending formal accreditation for the Scheme by NABCB as per the prescribed international standard(s).

This approval shall be valid for a period of one year within which the approved CBs would have to obtain formal NABCB accreditation.

2. Criteria for Approval

2.1 The CB shall be a legal entity in its economy, or shall be a defined part of a legal entity, such that it can be held legally responsible for all its certification activities. A governmental certification body is deemed to be a legal entity on the basis of its governmental status.

2.2 Accreditation

2.2.1 For ICMED 9000 certification scope, the CB shall hold NABCB accreditation for QMS certification as per ISO 17021-1:2015 for IAF Scope 19 covering the scope of medical devices, NACE (Rev 1.1) DL33.1 and shall have undergone a witness for the scope in the last 3 years;

2.2.2 For ICMED 13485 scope, the CB shall be accredited for ISO 13485 certification by NABCB or be accredited for scope DL 33.1 for QMS as per ISO 17021 and in case of latter, offer the first audit for ISO 13485 for witnessing to NABCB.

2.3 Competence

2.3.1 The CBs auditors for the Scheme shall have the following qualifications and experience

(i) A graduate in Bio Technology or degree in Electrical Engineering or Electronics Engineering or Chemical Engineering or Bio Medical Engineering or Mechanical Engineering from a University recognized by the Central Government for such purposes, followed by 2 years' experience of manufacturing or research or quality assurance in medical device field.

or

a Graduate in Science, from a University recognized by the Central Government for such purposes followed by a minimum of 3 years experience in the manufacturing or quality assurance in medical device field;

or

a Diploma in Engineering or Pharmacy from a Board or Institute recognized by the Central Government or the State Government, as the case may be, for such purposes followed with a minimum of four years experience in the manufacturing

or

quality assurance of medical device fields;

(ii) Auditor experience - For a first authorization, the auditor shall comply with the Issue 3 following criteria, which shall be demonstrated in audits under guidance and supervision:

a) For ICMED 9000 – The auditor shall have gained experience in the entire process of auditing medical device quality management systems, including review of documentation and risk management of medical devices, implementation audit and audit reporting. This experience shall have been gained by participation as a trainee in a minimum of two audits for a total of at least 10 mandays under an accredited QMS programme,

b) Additionally for ICMED 13485 - This experience shall have been gained by participation as a trainee in a minimum of two audits for a total of at least 10 mandays in an accredited ISO 13485 programme,

c) In addition to criteria a) and b) above, the audit team leaders shall have performed as an audit team leader under the supervision of a qualified team leader in at least three ISO 9001 audits for ICMED 9000 and ISO 13485 audits for ICMED 13485.

d) The knowledge and skills for personnel involved with the ICMED 13485 certification as defined in Annexure B of IAF MD 9 shall be applicable.

NOTE: Kindly refer to IAF MD 9 for further guidance for ICMED 13485 auditor competence and experience requirements.

2.3.2 The CBs may use ISO 9001 auditors who do not have the requisite qualifications as prescribed above provided they are supported by technical experts (TEs) who meet the qualifications at 2.3.1 (i) . The time spent by the TE on an audit shall not be counted in determining the audit time as prescribed under the 'Certification Process' which the CB is expected to spend.

2.4 Publicly available information

2.4.1 The certification body shall maintain a website for providing information about the Scheme.

2.4.2 The certification body shall maintain and make publicly available information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and about the certification activities and geographical areas in which it operates.

2.4.3 The certification body shall make publicly available information about applications registered and certifications granted, suspended or withdrawn.

2.4.4 On request from any party, the certification body shall confirm the validity of a given certification.

3. Procedure

3.1 The CB desirous of approval shall apply to QCI in the prescribed format for approval.

3.2 It shall submit the documents related to auditor competence system and certification process for the ICMED Schemes along with its application.

3.3 QCI shall designate an assessment team (AT) comprising an assessor for ISO 17021 and a technical expert to assess the competence of the CB for undertaking certification under the Scheme. The AT shall review the application and the documents specifically related to the Scheme and undertake an onsite office assessment of 2 mandays (including time of the TE) to verify competence and review certifications done and submit a report containing both review of documents as well as onsite findings. Any non-conformities/concerns observed shall be communicated to the CB at the end of the assessment for necessary action.

3.4 Based on the report, and the action taken by the CB on the nonconformities/ concerns, if any, QCI shall take a decision on granting provisional approval to the CB.

3.5 The approval shall be for a period of one year within which the CB shall obtain NABCB accreditation as needed under the Scheme.

3.6 During the validity of approval, QCI shall undertake at least one witness assessment to confirm the CB's competence until it obtains NABCB accreditation.

3.7 The approval shall be subject to suspension/withdrawal with due notice of 15 days in the event of any non- compliance to the requirements of the Scheme or if the NABCB accreditation for ISO 17021 is suspended/withdrawn.

3.8 The approved CB shall inform QCI without delay about any significant changes relevant to its approval, in any aspect of its status or operation relating to;

a) Its legal, commercial, ownership or organizational status,
b) The organization, top management and key personnel
c) Main policies
d) Resources and premises
e) Scope of approval, and
f) Other such matters that may affect the ability of the CB to fulfil requirements for approval.

QCI shall examine such information and decide on the issue on merits with or without an on-site verification.

4. Fee

4.1 The following fee structure shall apply:

Application fee Rs. 10,000/-

Man-day charges Rs. 20,000/- per man day

Travel / stay On actuals

Corrective actions review Charges – shall be charged after one round of review based on extent of review required

4.2 QCI at its discretion may revise/levy any other fee necessary with due notice to the CBs

Format of Application form for Certification Bodies

QUALITY COUNCIL OF INDIA (QCI)
2nd Floor, Institution of Engineers Building, Bahadur Shah Zafar Marg, New Delhi – 110002
Phone: +91-11-2337 8056 / 57; Fax: +91-11-2337 8678; E-mail: nabcb@qcin.org; Web: www.qcin.org;

APPLICATION FORM FOR CERTIFICATION BODIES

Indian Certification of Medical Devices Scheme (ICMED)

To apply for QCI Approval under Indian Certification of Medical Devices (ICMED) Scheme, please complete this application form and send it to QCI at the address mentioned above accompanied by:

1. *Documents as listed in Part IV of application;*
2. *Application Fee (with applicable taxes) in favour of Quality Council of India.*

Before completing this application form and submitting, relevant ICMED scheme documents available at http://www.qcin.org/icmed-medical.ph, should be carefully studied. If any clarification is needed, please contact QCI.

If additional space is required for providing information to any item, the information may be annexed as a separate sheet.

Please provide information as per the format and in the space given.

PART – I		GENERAL INFORMATION			
1.	**Name of the Certification Body**				
2.	**Address of Main Office**				
		City			
		State		*PIN*	
3.	**Contact Details**	*Phone*			
		Fax			
		E-mail			
		Web			
4.	**Ownership Details**				
5.	**Legal Registration Details**	*Status*			
		Regn. No.			
		Date of Regn.			
		Regn. Authority			

REFERENCES

1. https://www.intertek.com/assurance/icmed/
2. https://www.qcin.org/icmed-medical.php
3. https://www.iso.org/standard/45481.html
4. https://asq.org/quality-resources/iso-9001
5. https://www.iso.org/iso-13485-medical-devices.html
6. https://www.iso.org/standard/59752.html
7. Indian Certification of Medical Devices ICMED (Scheme) Requirements for Certification Bodies
8. Indian Certification of Medical Devices ICMED (Scheme) Provisional Approval System for Certification Bodies
9. Indian Certification of Medical Devices Scheme (ICMED): APPLICATION FORM FOR CERTIFICATION BODIES

Speakers Profile

Speaker Profiles

Dr. P D Vaghela,
Secretary, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, Government of India

Dr. Vaghela is serving as Secretary, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, Government of India. Dr. P.D. Vaghela is an IAS officer from 1986-batch and holds an MBA in finance from BK School of Business Management, Gujarat University. His career started as developmental head of two district councils in the state, from 1990 to 1995. He was district magistrate for three states in the year 1996 to 2001. In 2008, he was appointed as chairman of Kandla Port, where he served for five years before being named commissioner of commercial tax. The Modi government empanelled him as secretary in July last year.

Mr. Navdeep Rinwa, IAS (UP 1999)
Joint Secretary,
Department of Pharmaceuticals
Ministry of Chemical and Fertilizers, Government of India

In the Department of Pharmaceuticals, he is looking after Pharmaceuticals Policy, Pricing and International Cooperation, Besides, he is also Chairperson of the Government Council of Bureau of Public Sector Undertaking of India (BPPI), mainly concerned with the Pradan Mantri Bhartiya Janaushadhi Priyojana (PMBJP). He is holding the charge of Chairman – Cum- Managing Director, Indian Drugs & Pharmaceuticals Limited, a Government of India Undertaking.

Shri Navdeep Rinwa holds a B.Tech. degree in Computer Science & Engineering from IIT Kanpur. He joined the Indian Administrative Service (IAS) in the year 1999 from Uttar Pradesh Cadre. In the early years of service, he has worked as Assistant Magistrate, Pilibhit and SDM, Bareilly. He has also worked as Special Secretary, Rural Development, Public Works Development, Higher Education Trade Tax &

Entertainment Tax, Lucknow and Managing Director, Western U.P. Power Distribution Company, Meerut. Prior to joining the Department of Pharmaceuticals in March, 2018, he worked as Private Secretary to Minister of Culture and Tourism, Government of India (September 2014 – November 2014) Private Secretary to Minister of AYUSH (Traditional Medicine), Government of India (November 2014 – August 2016) and Joint Secretary, Department of Health & Family Welfare, Ministry of Health & Family Welfare, Government of India (August 2016 – March 2018).

Dr Jitendar Sharma
Managing Director & CEO
Andhra Pradesh Medtech Zone Ltd., and
Industry Expert, Medical Technologies

Known in policy forums as the "Med Tech Man of India", Dr. Jitendar Sharma is former Managing Director & CEO of Andhra Pradesh MedTech Zone (AMTZ) which is Asia's first medical devices manufacturing city besides being the Adviser for Health to Govt. of Andhra Pradesh, India and Executive Director of Kalam Institute of Health Technology (KIHT)- a technology policy research body set up with the support of Govt. of India. He is adjunct faculty at University of Adelaide, Australia; and program Director for Health Technology Assessment (HTA) fellowships in India. He has been founder of 6 organizations and architect of Universal Health Coverage for the state of Andhra Pradesh- the first state in India with 50 million people to declare UHC.

He is also the National Chairperson for Indian Bio-Medical Skill Consortium which is an active congregation of over 20 national academic institutions. Awarded among the "100 most impactful healthcare leaders" in global listing by Health & Wellness Congress, Dr. Sharma served as the Founder Head of Healthcare Technology Division and Head of Health Financing Divisions at National Health Systems Resource Centre (NHSRC) under Ministry of Health & Family Welfare, Government of India. He was also the Founder Director of WHO Collaborating Centre for Medical Devices in India. His past experience includes that as Hospital Administrator at Sri Sathya Sai Medical Institutions-one of India's largest not for profit health organizations, as consultant to the World Bank for health financing, as Expert Consultant to the World Health Organization, Geneva and advisor to Health Technology Innovation Centre at Indian Institute of Technology (IIT).

Dr. Sharma has authored seven books, twenty research papers and six compendiums on technical specifications for medical technologies besides contributing to a number of WHO reports on health technologies, health financing and Non-Communicable Diseases. He has been a key designer and coordinator for several health programs in India and teaches courses on health policy & health technology in several countries.

Mr. Rajesh Maheshvari
CEO
National Accreditation Board for Certification Bodies (NABCB)

CEO of National Accreditation Board for Certification Bodies (NABCB), a constituent Board of Quality Council of India (QCI) w.e.f. 01 Aug 2019., and responsible for accreditation schemes for Certification, Inspection and Validation & Verification Bodies. Earlier to this was the Director of Project Planning & Implementation Division of QCI, and responsible for Conceptualization, Planning & Management of various projects being executed by QCI. Previously was responsible for managing Inspection Body Accreditation Program of NABCB as Joint Director. Working for QCI since Feb 2012.

Had earlier worked for National Accreditation Board for Testing & Calibration Laboratories (NABL), then under the Department of Science & Technology (DST) for more than a decade, managing the Testing and Medical Laboratory Accreditation Programs of NABL. Prior to this, had worked in Specialty Chemicals Manufacturing Industry for about a decade. Holds Masters in Chemistry (with specialization in Organic Chemistry) and MBA. Having almost 3 decades of experience in industrial manufacturing as well as in standards, technical regulations, accreditation & conformity assessment. Has multi-disciplinary experience in Quality Assurance & Management, Production & Process Control, Product Development, Project Management etc. Also has experience in International Evaluations & Mutual Recognition Arrangements, Technical Cooperation in Accreditation with international bodies like UNIDO, World Bank, PTB - Germany, ITC – Geneva etc. Internationally, an APAC Evaluator for peer evaluation of Accreditation Bodies. Also, was WADA Assessor for assessment of Dope Testing Laboratories. Evaluated Accreditation Bodies in USA, Russia, Sri Lanka etc. Also, have done projects as an Expert on Accreditation with international organizations like IAEA, UNIDO etc.

Dr. Purnima Sharma
Managing Director,
Biotech Consortium India Limited, New Delhi

Dr. Purnima Sharma is the Managing Director of Biotech Consortium India Limited (BCIL), New Delhi. BCIL is a public limited company promoted by the Department of Biotechnology, Ministry of Science and Technology, Government of India and the all India financial institutions for facilitating biotechnology

commercialization. The company has been in existence for more than two decades and has made a significant contribution to biotech sector by providing valuable services in areas such as technology evaluation and transfer, IP management, consultancy, biosafety, capacity building and manpower development to the Central and State Governments, academia, research institutions and industry.

Dr. Purnima Sharma is a doctorate in Experimental Medicine from Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, the prestigious autonomous institution and deemed Medical University of national importance of the Ministry of Health, Government of India with Post Doctoral experience from IIT, Mumbai, and has to her credit many awards for excellence in academics.

She has more than 25 years of experience in the area of technology evaluation and transfer, management of IPR, project consultancy including DPRs for setting up Incubators and Science Parks, managing start-up ecosystem, public-private partnership funding schemes, entrepreneurship development etc. She has coordinated transfer of more than 50 technologies in various sectors of life sciences. She has also conducted a number of sectoral studies and market research studies on different biotech products.

She is a member of a number of national and state level committees responsible for biotech development and commercialization and also a member of The National Academy of Sciences, India (NASI), the first science academy of the country dedicated towards cultivation and promotion of science & technology in the country.

Mr. Rajiv Nath
Managing Director
Hindustan Syringes & Medical Devices Ltd.
& Forum Coordinator, AiMeD

Mr. Rajiv Nath is Managing Director of Hindustan Syringes & Medical Devices Ltd. which is having a turnover of over 600 Crores. He is President of All India Syringes & Needles Mfg. Association. (AISNMA). He is also the Founder and Forum Coordinator – Association of Indian Medical Device Industry (AiMeD) with over 350 Members nationwide whereby Medical Device Manufacturers of all types of technologies have been attracted nationwide on one Platform. He was born in 1962 and entered his family business i.e. Hindustan Syringes & Medical Devices Ltd. (HMD) soon after he finished his college in 1984.

Mr. Nath has started from the scratch i.e started his career on the shop floor of HMD to have first-hand technical experience of all the ground realities & learning basic production techniques of Medical Devices Industry. HMD has capacity of manufacturing over 6 Billion Disposables per annum. HMD's turnover has grown from a mere Rs. 2 crores to over Rs. 600 crores in the year 2017, an impressive growth rate of over 300 times in less than 35 years. Mr. Rajiv Nath has dared to challenge the rules of the market & wrote his own script with respect to syringe design, packaging and presentation. HMD created a niche for their disposable syringe "DISPOVAN" which is today the most popular brand in Syringe market in India

with over 60% market share and thereby displaced renowned MNC's – an inspirational case study for other Indian Entrepreneurs. As Forum Coordinator of AiMeD, Mr. Nath has taken many initiatives of establishing a collaborative framework with various Dept. of the Govt. and Media to bring to their attention issues troubling the industry and attract investments into India in his quest to make India as the Preferred Manufacturing Destination and the leading supplier of Medical Device worldwide. AiMeD is an Umbrella Association of Indian Manufacturers of Medical Devices covering all types of Medical Devices including consumables, disposables, equipment's instruments, Implants, electronics and diagnostics. With a Primary Membership of over 350 Manufacturers and additionally of over 200 Associate Members representing the interest of over 700 Manufacturers of Medical Devices to address the manufacturer's problems. (www.aimedindia.com).

Mr. Shri Kant Tiwari

Mr. Shri Kant Tiwari, Postgraduate (M.Sc.) in Microbiology, and Technical Expert for Design and Testing of Non-Active Implantable Medical Devices. Eighteen Years (18) of Experience in the field of Medical Device Regulations with Certifications including European CE Marking, ISO 13485 as Lead Auditor, Regulatory Expert for Medical Device Regulations of US FDA, EU and Indian Medical Device Regulations. Promoter of MDC Testing and Certifications (A Test Laboratory with 7 Years of Experience in Medical Device Design Testing, Particularly for Non-Active Implantable Orthopaedic Implants
Presently she is Independent Empanelled Auditor for MDQMS for TUV NORD, BSCIC, Quality Austria with More than 600 Man-Days of Experience and Performing Independent Testing of Medical Devices

Dr. Manish Pande
Director and Head PAD Division at QCI

Dr. Manish Pande is Director and Head PAD Division at QCI, leading flagship governmental and intergovernmental initiatives such as the India National Platform on Private Sustainability Standards, Voluntary Certification Scheme for Medical Plant Produce (VCSMPP), National GLP Cell (with the National GLP Compliance Monitoring Authority – NGCMA),instrumental in finalizing the National

Interpretation Guidelines for GLOBALG.A.P. standard for India, design and development of SAARC GAP etc. along with a host of other voluntary schemes administered under QCI. He has also initiated the international implementation of the Yoga Professional Certification Scheme.

With a progressive experience of over 20 years in the field of conformity assessment, he is responsible for design and implementation of various private, voluntary and international standards along with providing technical support, assistance, and stakeholder management with numerous industry associations, and governmental and intergovernmental bodies. He is also a trained and empaneled technical expert for NABCB and Accreditation Services International for FSC.

Dr. Pande is an expert member of various technical committees and working groups of Schemes that are run by the Government of India and its associate bodies. He has conducted several audits for agriculture based standards such as Organic as per NPOP (India), NOP (USDA - USA), EU; Good Agriculture Practices (GAP), Round Table on Responsible Soy and forestry standards such as FSC and PEFC. In the past, he has worked with the Worldwide Fund (WWF) for Nature – India, SGS – a Swiss based MNC, and as independent consultant with the UNCTAD, FAO, and SAARC. He holds a Ph.D. in forestry from the Forest Research Institute, and has received a Gold Medal for master's in forestry.

Dr. Jaishree Kasliwal
Assessor, NABCB & Forum Coordinator, AiMeD

Doctorate degree in Microbiology, Almost 37 years working experience in the field of Pharma and Research and Development for various formulations in FMCG sector too. Audit experience of 25 years covers mainly QMS and Medical Devices. Associated with QCI - NABCB since last 6 years as an assessor. Involved in developing ICMED standards right from the beginning as a member in the technical committee."

Mr. C.S. Sharma
Deputy Director in Project Execution and Documentation Division
Quality Council of India

Mr. C. S. Sharma is serving as a Deputy Director in Project Execution and Documentation Division, Quality Council of India. He has over 18 years of varied experience in 3rd party

Certification/Accreditation, Total Quality Management, Auditing, Lean Management, Resource management, Business Excellence, International cyber laws, Best Practices & Benchmarking, Skill Training and Personnel Credentialing systems. Currently, he is managing various voluntary accreditation & certification schemes under QCI. He is an Electronics & Communications Engineer and a qualified lead assessor for various management systems like Quality, Environment, Health & Safety, Energy, Social Accountability, Global Reporting Initiative (GRI), Information Security and Skill Certification, with an experience of more than 1500 assessment man-days across India and overseas.

Dr. Ravi Kant Sharma
Deputy Drugs Controller (India),
Ministry of Health and Family Welfare, Govt. of India

Dr. Ravi Kant Sharma, Ph.D is working as Deputy Drugs Controller (India) at CDSCO (HQ), FDA Bhawan New Delhi. At present he is dealing with the work related to the manufacturing, import and registration of Medical Devices and in-vitro diagnostic kits. He was actively involved in drafting the Medical Device Rules 2017 which is already implemented from 1st January 2018. He was also leading the International Cell established at CDSCO (HQ) and is involved in collaboration with the Regulators of other countries in the areas of training, sharing of best practices, and observer during audit, harmonization of standards and other information exchange.

He has more than 25 years of experience in CDSCO and has worked in different fields like approval of IND, New Drugs, Import and Registration of Pharmaceuticals, Blood Products and was also involved in Airport and zonal office activities. He actively participated in nationwide drug survey and quality risk based inspections carried out in India. He played vital role for implementation of SUGAM- portal for on-line submission of applications pertaining to import and registration of Medical Devices and in-vitro Diagnostics. Under his supervision Medical Device Division got ISO-9001 Certification. He participated in many National and International seminars/workshops in various areas of Drugs Regulations and has undergone training from USFDA, PMDA & WHO.

Mr. Nipun Vinayak
Joint Secretary, Procurement, MOH &FW (TBC)

Born and educated in Chandigarh, joined IAS in 2001 after an MBBS with gold medals from Government Medical College. Awarded ‘Director’s Best All Round Trainee Award’ by Lal Bahadur Shastri National

Academy of Administration. Promoted community approaches in sanitation in his various roles in the rural areas (as CEO, Zilla Parishad, Jalna) and in urban areas (as Municipal Commissioner, Nanded). As Collector, Raigad, he found himself embroiled in what media termed as the 'first referendum of India'. In these battles which were fought in courts, government and streets, people emerged victorious against one of the biggest Corporates of India. As Municipal Commissioner, Nanded, he prioritised working with, and for, the slum dwellers envisioning and effecting, to a great extent, a clean city.

He believes that good governance is about the 3Ps – Passion, Participation and Partnership. Calling himself a 'participative and facilitative development learner', he cherishes engagement of people in various development projects. In his last role as Director of the national programme, Swachh Bharat (rural), he worked incessantly towards reorienting the programme from a supply-driven latrine construction programme to a community led and community driven collective behaviour change programme. He has travelled extensively across the country to more than 25 States.His professional achievements include recommendation of his work as CEO Zilla Parishad, Jalna for 'Prime Minister's Award for Excellence in Public Administration' by Government of Maharashtra and first prize in the State in 'Rajiv Gandhi Abhiyaan for administrative reforms'. He has authored books on sanitation, education, health and district administration. He is an Eisenhower Fellow and a TEDx speaker. He served as Municipal Commissioner in the historic city of Aurangabad and is recently been appointed a joint secretary, Ministry of Health and family welfare.

Mr. Ganesh P Sabat
Chief Executive Officer,
SMT Pvt. Ltd (Sahajanand Medical Technologies)

Mr. Ganesh P Sabat is the Chief Executive Officer of Sahajanand Medical Technologies Pvt. Ltd. (SMT) and has served in that position since April 01, 2013. Prior to this appointment, he held other positions within SMT since joining the group in February 2010, including Chief Financial Officer with responsibility for finance and accounts department.

Mr. Ganesh has more than two decades of experience in corporate strategy and finance. He has cross-cultural as well as global exposure in medical devices, life sciences, chemical, and financial services industry. He has served on many Industry body committees of national importance pertaining to Medical Devices and Healthcare and was till recently the Chair of the Healthcare Committee of PHD Chambers of Commerce. He is the Founding President of Indian Stent Manufacturing Association (ISMA).

Mr. Ganesh has earned his MBA from Washington University in Saint Louis, USA and a Company Secretary from Institute of Company Secretaries of India (ICSI).

Mr. Sudhakar Mairpedi,
Philips

Having expertise in Domestic regulations in Pharmaceutical,Biotechnology,Medical Devices, Medical Equipments and IVD, Mr. Mairapadi is also trained in global regulations in Medical devices and Pharmaceuticals of EU,HC,TGA. He has worked with various Ministries like Ministry of Health,(CDSCO,PC&PNDT Directorate,ICMR,CDL,CDTL,IP Commission) Department of Science and Technology, Director General of Foreign Trade, Ministry of Chemicals & Fertilisers,Department of Pharmaceuticals, NPPA, Ministry of Environment and Forest, Ministry of Commerce, Ministry of Communication and Information Technology (Department of Telecommunication, Department of Electronics and IT) , Atomic Energy Regulatory Board, Ministry of Consumer Affairs and Public Disribution (Legal Metrology), Ministry Bureauo of Indian Standards, Legal Metrology., Narcotics., Quality Council of India. He is currently head of quality, regulatory and govt. affairs- Philips Health Care and consumer life style.

Mr. Ravi Singh
Head - Certification for North and East Indian operations of TUV India, TUV Nord Group

Ravi Singh is presently Head - Certification for North and East Indian operations of TUV India, TUV Nord Group. He is responsible for operations for Certification, Training and Sustainability Business. Ravi is an Electrical Engineer with 26+ years of experience. Ravi is Lead Trainer and Auditor for various management system certification schemes. He has 20 years of experience in Management System Auditing and Providing trainings. Ravi has led team within TUV India to develop Medical Device Certification Schemes (ISO 13485 & ICMED) and successfully completed approval from NABCB. Ravi had worked for achieving accreditation according to ISO 17021 & ISO 17065 and managed certification office.

Mr. Hemant Kumar
Independent Tutor/ Lead Assessor/ Technical Expert Medical Devices
Global Head QA/ RA, Narang Medical Limited

Mr. Hemant Kumar, Postgraduate in Clinical Data Management, M.Sc. (Chemistry), Diploma in Business Management, Approved analytical chemist for Medical Devices from UPFDA and Monitoring Scientist for Pre- Clinical Studies as per ISO 10993 for Non-Active Implantable Medical Devices.
Fourteen years' experience in the field of GMP, ISO 13485, ISO 9001, Research & Development, Manufacturing Pharmaceutical (Dosage Forms, SVP, LVP) and Medical Devices in Quality Assurance, Quality Control, Compliance and Regulatory Affairs. Five years of Assessment & Training experience in Pharmaceutical and Medical Devices, IT Enabled Services and Packaging Industry. Previous Organisations: Synmedic Laboratories, Mitra Industries (P) Ltd., Mankind Pharma Ltd., J. Mitra & Co. Pvt. Ltd. Independent Empanelled Auditor for QMS, MDQMS and MDR 2017 G.S.R 78 (E) for BSI Group India, TUV Inter Cert Saar India, BSCIC, Quality Austria with More than 200 Man-Days of Experience.

Dr. Mrutunjay Jena
Director,
National Accreditation Board for Certification Bodies (NABCB)

He is currently Director, National Accreditation Board for Certification Bodies (NABCB), a constituent Board of the Quality Council of India (QCI), which is India's national accreditation body and is part of an international system of equivalence of accreditations and certifications. NABCB accredits certification bodies for ISO 9001, ISO 14001, ISO 20000-1, ISO 22001, OHSAS 18001, ISO 45001, ISO 27001, ISO 13485, ISO 16363, ISO 39001, ISO 50001, Product certification, Personnel certification and Inspection bodies as per applicable international standards and has accredited more than 100 certification bodies in India.
He holds Master's degree in Business Administration from Guru Jambheshwar University of Science and Technology, Hisar and Post-Graduation Diploma in Industrial Safety after his Engineering degree in Electrical Engineering from IGIT- a government Engineering College, Talcher. Now he is pursuing research in Management.

He has Overall 26 years of experience in the field of Quality, working in management systems product certification and inspection sector for 10 plus years in National Accreditation Body (NABCB). Developed third party evaluation mechanisms for regulators such as Petroleum and Natural Gas Regulatory Board, National Horticulture Board and Warehousing Development and Regulatory Authority. He is involved in various policy matter of NABCB accreditation including that of medical devices sector for Notified Bodies as per MD Rules - 2017.

Actively participated and contributed as a member of technical committee in development of QCI voluntary certification scheme "ICMED 9000" & "ICMED 13485" for medical device manufacturers - a unique and first such scheme in the world.

Actively involved in various ISO technical mirror committee for development of ISO standards of BIS like CHD 34, MED 39 etc in development and review of management/technical standards. Also involved in drafting of ISO 50003 standard on Energy Management Systems for auditor competency as an expert to ISO/TC 242. Successfully developed and operated various management system accreditation schemes including OHSMS as per OHSAS 18001, MDQMS as per ISO 13485, ISMS as per ISO 27001, EnMS as per ISO 50001, ITSMS as per ISO 20000-1, RTSMS as per ISO 39001, TDRMS as per ISO 16363, BCMS as per ISO 22301. He has been an empaneled assessor with United Nation Framework Convention on Climate Change (UNFCCC) for CDM assessments since, 2010.

Dr. Suchita Markan
Assistant General Manager,
Biotech Consortium India Limited, New Delhi

Dr. Markan is working as Assistant General Manager in Biotech Consortium India Limited (BCIL). She has done PhD from Department of Experimental Medicine and Biotechnology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh and Executive General Management from IIM, Lucknow. She is leading management of School of International Biodesign Programme for more than eleven years and Heading the Technology Transfer activities at BCIL.

She has extensive experience and expertise in the Biomedical Device sector. She is a thought leader in the biomedical device innovation space assisting Government and policy makers to draft appropriate policies for boosting this sector. She has been leading the techno-legal and fellowship management of Department of Biotechnology, Government of India supported flagship program for boosting biomedical device innovation-Stanford India Biodesign programme, renamed as School for International Biodesign for more than eleven years. She is providing strategic IP management, business plan development, licensing advisory and mentorship to more than 125 entrepreneurs and about 20 start-ups in the medtech domain. She has managed number of strategic collaborative programs aimed at fostering biomedical device

innovation and entrepreneurship development with AIIMS, IIT Delhi, Stanford University, USA, QUT Australia, Tottori University, Japan, Hiroshima University-Japan, J&J-COSAT USA, Siemens etc.
She is member of number of national level committees for biotech development and commercialization and has numerous international publications to her credit.

Mr. Rajiv Chhibber
Vice President External Affairs,
Sahajanand Medical Technologies

Mr. Rajiv Chhibber is a Senior Corporate Affairs, Policy, Communications and Media Strategist with experience across Pharmaceuticals/Medical Devices Industry, Development Sector (Health, Environment, Climate Change, Energy and Sustainable Development) and Education Industry.
At SMT, Mr. Chhibber is responsible for driving strategic priorities and business vision with the Central and State governments, Regulatory agencies, Industry bodies, NGOs and Associations in addition to advising on policy matters, advocacy, managing complex reputational issues, Outreach and stakeholder engagement for the adoption of portfolio products while working closely with the senior management and global leadership.
Mr Chhibber hold a master's degree in Journalism and Mass Communication and a bachelor's degree in English Literature from Delhi University. He has a post-graduate diploma in Newspaper and Feature writing (Montgomery College, University of Maryland, USA) and pursued a Public Health Leadership in-professional course in NCDs from Emory University, Atlanta USA (2014-15) and a Communications Development Programme in Public Health Engagement by Wellcome Trust, UK at the London School of Hygiene and Topical Medicine (LSHTM), UK, (March 2016).
He was awarded an Honorary Doctorate from Aztec's University (UNESCO), Mexico in the year 2019 in the field of "Global Public Health Communication and Policy". He is a member of various government committees / sub-committees in areas of public health advocacy, nutrition, tobacco control, NCDs, and climate change in addition to being on various committees of CII, FICCI, USIBC and American Chambers of Commerce (AmCham).
He is a Member of Asia-Pacific Association of Communication Directors (APACD), Hong Kong, (2014-2020), the International Society for Disease Surveillance, CDC Atlanta, USA and the on the Advisory Board of the International Human Rights Council representing India. He is a Founding Member of Public Relations Society of India and the Founding Member of Climate Action Network, South Asia (CANSA), a civil society led South Asia Chapter of a global platform that advocates on climate change, energy, power and related issues on sustainable development.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