Change Adapt Improve

Quality and Accreditation Institute

THE VOICE

Newsletter I Volume 3 I Issue 1 I Jan- Mar 2023

We Understand you Better

www.qai.org.in

info@qai.org.in

Foreword

Dr. B. K. Rana
CEO, QAI

The Mission of QAI is “To conceive and deliver education, training, accreditation and related programmes in partnership with stakeholders using an approach of co-design and co-creation.” Over the past five years, QAI has extended its presence in India as well as in some other countries. We at QAI wish to support our participating organisations, government, regulators and stakeholders in appropriate capacity in their endeavours to achieve Quality. We are also committed to support Government of India’s commitment towards Universal Health Coverage and Sustainable Developmental GoaI-3.

We aim to set international benchmarks as an Accreditation Body and I am delighted to report that our Standards for Hospital Accreditation has been internationally recognised by ISQua, making us the only Accreditation Body in India to have three sets of Standards recognised.

Bringing out this Newsletter is an attempt to spread the awareness and educate stakeholders in current affairs related to Quality, Accreditation, Certification, Conformity Assessment and other key areas of relevance. I want to thank QAI’s Board members, Committee Members, Assessors/ Experts, Stakeholders including accredited/ applicant organisations and Staff for helping to spread QAI mission.

I wish that we continue getting your support to achieve our Mission and wishing you all a productive year 2023-2024.

Change Adapt Improve

Quality and Accreditation Institute

About Quality and Accreditation Institute (QAI)

THE VOICE

About QAI

QAI was set up to create an ecosystem of education, training, quality improvement and accreditation/ certification. This organisation provides a platform to stakeholders including professionals and organisations, associated with quality in any way, to share their wisdom and knowledge in order to make its Vision realised. This further provides tremendous opportunities to all concerned to learn and contribute in improving organisations engaged with QAI. Different activities are initiated under different verticals in a manner that they remain independent of each other

VISION

Nurturing the largest global pool of organisations and people through quality improvement and accreditation framework.

VALUES

Listener: Seek continuous feedback from stakeholders to address their concerns

Competitive: Look for viable options to benefit users of our services

Transparency: Clearly defined policies made available in public domain

Innovation: Continuously evolve using co-design and co-creation

MISSION

To conceive and deliver education, training, accreditation and related programmes in partnership with stakeholders using an approach of co-design and co-creation.

QAI Structure

Centre for Education & Training (CET)

Centre for Accreditation of Health & Social Care (CAHSC)

Centre for Laboratory Accreditation (CLA)

Centre for Accreditation of Veterinary Facilities (CAVF)

About QAI

CET: Centre for Education and Training

- Trainings- specific topic and accreditation standards related
- Education Activities- Internal Auditors, Infection Prevention & Control, Medication Safety, Risk Assessment etc.
- Capacity Building (Setting up Accreditation Bodies, Developing Accreditation Standards)

CLA: Centre for Laboratory Accreditation

Accreditation of Medical Laboratories as per ISO 15189: Medical laboratories - Requirements for Quality and Competence

Certification of Medical Laboratories as per the requirements of the Central Clinical Establishments Act

Accreditation of Calibration laboratories as per ISO/ IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories

Accreditation of Testing laboratories as per ISO/ IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories

Biobanking Accreditation as per ISO 20387: General requirements for Biobanking. (For the First time in India)

About QAI

CAHSC: Centre for Accreditation of Health and Social Care

- Assisted Reproductive Technology (ART)/ IVF Centre
- Home Health Care
- Dialysis Centre
- Green Health Care Facility
- Hospital Certification (Entry Level)
- Certification based on WHO Patient Safety Friendly Hospital
- Clinics
- Ambulatory Care Facility (Dental/ Eye/ Imaging etc.)
- Telemedicine Recognition
- Telehealth Accreditation
- Emergency Department Accreditation
- Hotel and Home Stays Accreditation
- Hospital Accreditation
- Transition care/ Inpatient Rehabilitation Centre
- Small Hospitals Accreditation
- Primary and Advanced Stroke Centre Accreditation

About QAI

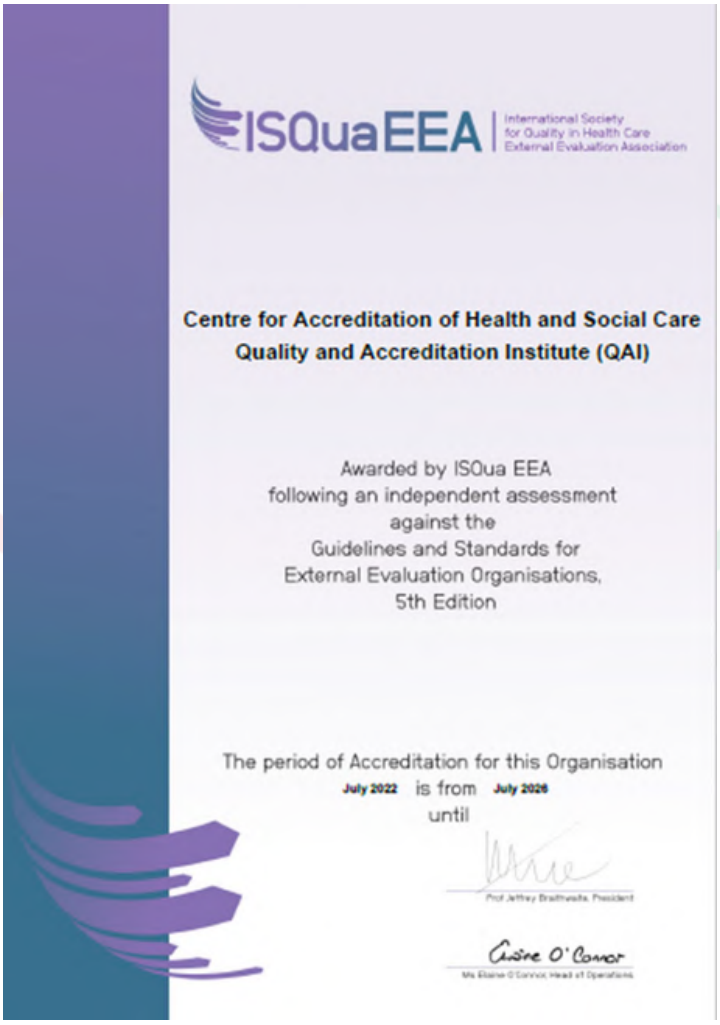
Key Milestones

QAI is the ONLY accreditation body in India having ISQua Accreditation as an Organisation and Three Sets of Standards

About QAI

Key Milestones

QAI becomes the first accreditation body in India to achieve ISQuaEEA Accreditation in less than five years of operations


ISQuaEEA International Society for Quality in Health Care External Evaluation Association

Centre for Accreditation of Health and Social Care
Quality and Accreditation Institute (QAI)

Awarded by ISQua EEA
following an independent assessment
against the
Guidelines and Standards for
External Evaluation Organisations,
5th Edition

The period of Accreditation for this Organisation
July 2022 is from July 2026
until

Prof Jeffrey Braithwaite, President

Ms Elaine O'Connor, Head of Operations

ISQuaEEA International Society for Quality in Health Care External Evaluation Association
Accredited Organisation 2022-2026

About QAI

Key Milestones

QAI CLA is a Full Member/ MRA Signatory of the Asia Pacific Accreditation Cooperation (APAC) (https://www.apac-accreditation.org/membership/full-member/) for the following scopes:

Medical Testing-ISO 15189
Testing-ISO/IEC 17025

APAC
ASIA PACIFIC
ACCREDITATION COOPERATION

APAC
ASIA PACIFIC
ACCREDITATION COOPERATION

Mutual Recognition Arrangement (MRA) Certificate

In accordance with ISO/IEC 17011:2017 and the procedures of the Asia Pacific Accreditation Cooperation Incorporated (APAC), APAC hereby confirms the following APAC Member is a signatory to the APAC MRA:

Quality & Accreditation Institute Pvt Ltd.,
Centre for Laboratory Accreditation (QAI CLA)
INDIA

for the scopes and sub-scopes of

		Date
Scope	Medical testing – ISO 15189	31 Oct 2022
Scope	Testing – ISO/IEC 17025	31 Oct 2022

Signed on behalf of APAC by:

Ms. Jennifer Evans
APAC Chair
Date: 31 October 2022

APAC Secretariat
PO Box 3154, South Turramurra, NSW 2074, Australia
Tel: +61 466 262 372, Email: secretariat@apac-accreditation.org
Web:https://www.apac-accreditation.org/
New Zealand Society Number: 1877392 Australian Business Number (ABN): 32 287 148 894

About QAI

Key Milestones

QAI CLA is a Full Member/ MRA Signatory of the International Laboratory Accreditation Cooperation (ILAC) (https://ilac.org/signatory-detail/?id=210) for the following scopes:

Medical Testing-ISO 15189
Testing-ISO/IEC 17025

ILAC MUTUAL RECOGNITION ARRANGEMENT

SIGNATORIES

We, the undersigned, endorse the terms of the ILAC Arrangement and undertake, to the best of our ability, fulfillment of its objectives.

Accreditation Body: Quality and Accreditation Institute, Centre for Laboratory Accreditation (QAI CLA)

Economy: India

Scope and date: Testing ISO/IEC 17025 – 10 December 2022
Testing ISO 15189 – 10 December 2022

Authorised Representative:

Signature: _____ Date: 20 December 2022

Dr. Bhupendra Kumar Rana

Chair, ILAC Arrangement Council:

Signature: _____ Date: 22 December 2022

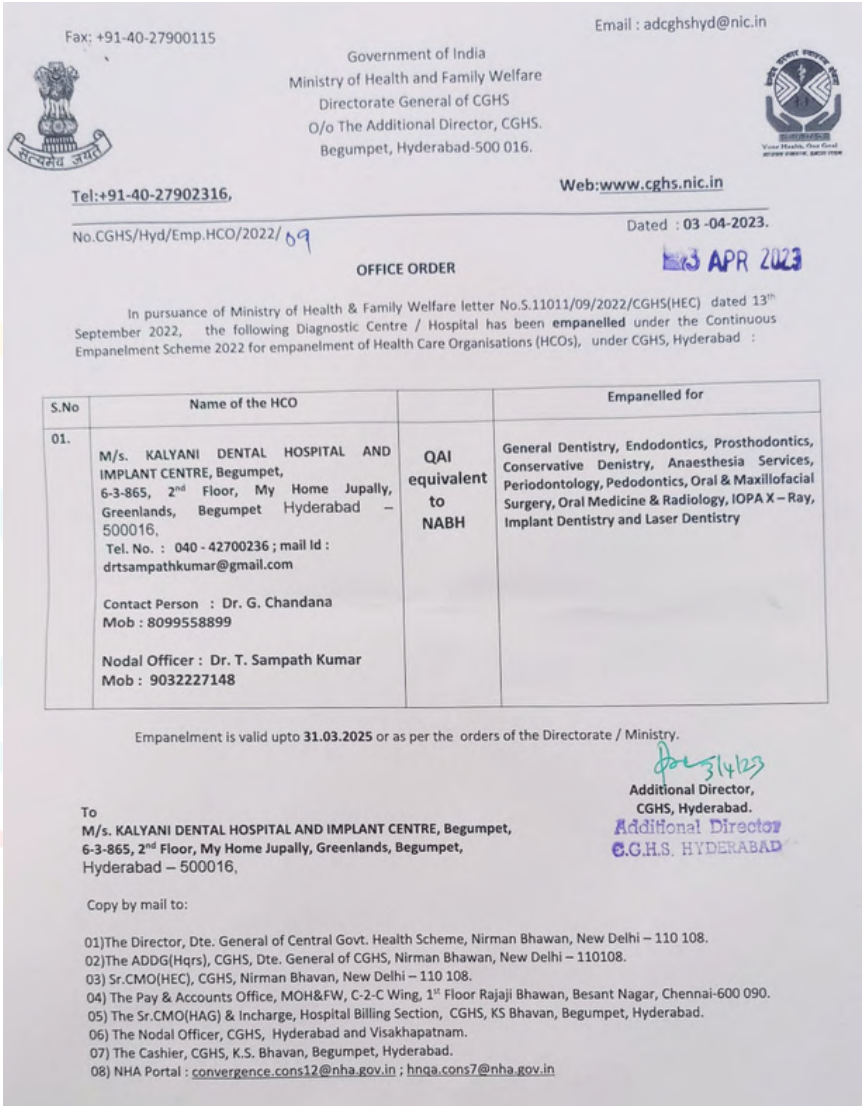
Etty Feller

Annex A: Signature Sheet, ILAC MUTUAL RECOGNITION ARRANGEMENT

About QAI

Key Milestones

QAI Accreditation is recognised by the Ministry of Health's Central Government Health Scheme (CGHS) for empanelment of Private Hospitals, Eye Centres, Dental Centres & Imaging Centres



Fax: +91-40-27900115

Email : adcghshyd@nic.in

Government of India
Ministry of Health and Family Welfare
Directorate General of CGHS
O/o The Additional Director, CGHS.
Begumpet, Hyderabad-500 016.

Tel:+91-40-27902316,

Web:www.cghs.nic.in

No.CGHS/Hyd/Emp.HCO/2022/69

Dated : 03 -04-2023.

OFFICE ORDER

03 APR 2023

In pursuance of Ministry of Health & Family Welfare letter No.S.11011/09/2022/CGHS(HEC) dated 13th September 2022, the following Diagnostic Centre / Hospital has been **empanelled** under the Continuous Empanelment Scheme 2022 for empanelment of Health Care Organisations (HCOs), under CGHS, Hyderabad :

S.No	Name of the HCO		Empanelled for
01.	M/s. KALYANI DENTAL HOSPITAL AND IMPLANT CENTRE, Begumpet, 6-3-865, 2nd Floor, My Home Jupally, Greenlands, Begumpet Hyderabad – 500016, Tel. No. : 040 - 42700236 ; mail Id : drtsampathkumar@gmail.com Contact Person : Dr. G. Chandana Mob : 8099558899 Nodal Officer : Dr. T. Sampath Kumar Mob : 9032227148	QAI equivalent to NABH	General Dentistry, Endodontics, Prosthodontics, Conservative Denistry, Anaesthesia Services, Periodontology, Pedodontics, Oral & Maxillofacial Surgery, Oral Medicine & Radiology, IOPA X – Ray, Implant Dentistry and Laser Dentistry

Empanelment is valid upto **31.03.2025** or as per the orders of the Directorate / Ministry.

Additional Director,
CGHS, Hyderabad.
Additional Director
C.G.H.S. HYDERABAD

To
M/s. KALYANI DENTAL HOSPITAL AND IMPLANT CENTRE, Begumpet,
6-3-865, 2nd Floor, My Home Jupally, Greenlands, Begumpet,
Hyderabad – 500016.

Copy by mail to:

01)The Director, Dte. General of Central Govt. Health Scheme, Nirman Bhawan, New Delhi – 110 108.
02)The ADDG(Hqrs), CGHS, Dte. General of CGHS, Nirman Bhawan, New Delhi – 110108.
03) Sr.CMO(HEC), CGHS, Nirman Bhavan, New Delhi – 110 108.
04) The Pay & Accounts Office, MOH&FW, C-2-C Wing, 1st Floor Rajaji Bhawan, Besant Nagar, Chennai-600 090.
05) The Sr.CMO(HAG) & Incharge, Hospital Billing Section, CGHS, KS Bhavan, Begumpet, Hyderabad.
06) The Nodal Officer, CGHS, Hyderabad and Visakhapatnam.
07) The Cashier, CGHS, K.S. Bhavan, Begumpet, Hyderabad.
08) NHA Portal : convergence.cons12@nha.gov.in ; hnqa.cons7@nha.gov.in

Launched 14 Accreditation Programmes within a span of 5 years

About QAI

International Recognitions and Affiliations

Institutional Member of the International Society for Quality in Health Care (ISQua)
(www.isqua.org)

ISQua | International Society for Quality in Health Care

Board Member of the International Society for Telemedicine and eHealth (ISfTeH)
(www.isfteh.org)

ISfTeH
International Society for Telemedicine & eHealth

Full Member/ MRA Signatory of Asia Pacific Accreditation Cooperation (APAC)
(www.apac-accreditation.org)

APAC
ASIA PACIFIC ACCREDITATION COOPERATION

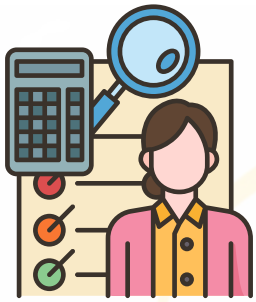
Full Member/ MRA Signatory of International Laboratory Accreditation Cooperation (ILAC)
(www.ilac.org)

ilac
Accreditation: Delivering Global Confidence

About QAI

Key Milestones Achieved

Number of Accreditations/ Certifications
||
80 +



Number of Assessors
||
200 +

Number of Training Programmes Organised
||
70+

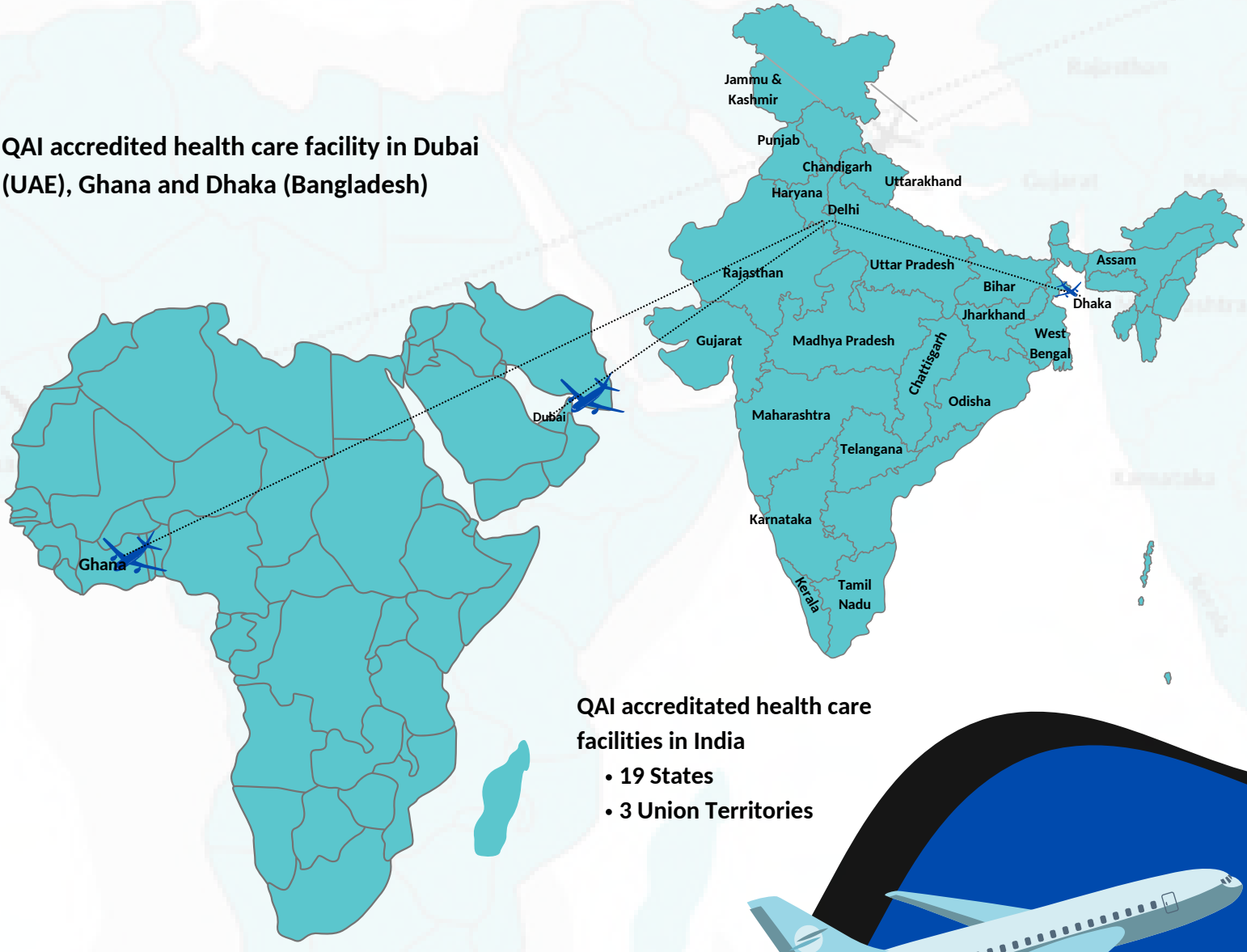
Number of trained Internal Auditors
||
320 +

Number of Global Partnerships
||
6

About QAI

Key Milestones Achieved

QAI accredited health care facility in Dubai (UAE), Ghana and Dhaka (Bangladesh)



QAI accreditated health care facilities in India

- 19 States
- 3 Union Territories

About QAI

Key Milestones Achieved

Quality And Accreditation Institute
Centre for Accreditation of Health & Social Care

ISQuaEEA Accredited Organisation 2022-2026

Certificate of Accreditation

HCAH SuVitas Transition Care Centre
(Healthcare at Home India Private Limited)

S.No. 100 (Part), Gachibowli Village, Near Jayaberi Enclave,
Serilingampally, Ranga Reddy (Dist.),
Hyderabad – 500029, Telangana, India

has been assessed and accredited in accordance with the
QAI Accreditation Standards for

Transition Care Centre

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued compliance to the above standard & any other requirements specified by QAI.

QAI

QAI/CAHSC/TCC/2023/0001

Valid from: 14 March 2023 Valid until: 13 March 2026

Dr. Bhupendra Kumar Rana
Chief Executive Officer

Prof. (Dr.) Mahesh Chandra Misra
Chair, CAHSC

www.qai.org.in

HCAH SuVitas
YOUR EXPERT RECOVERY & CARE PARTNER

HCAH Suvitas, Hyderabad is the first transition care centre to get accredited.

About QAI

Key Milestones Achieved

Quality And Accreditation Institute
Centre for Accreditation of Health & Social Care

ISQuaEEA Accredited Organisation 2022-2026

Certificate of Accreditation

Ucchvas Healthcare Private Limited

D.No.-2-50/2, Plot No. 2, SY. No. 60/63,
Jayabheri Pinevalley Colony, Gachibowli, Ranga Reddy (Dist.)
Hyderabad – 500032, Telangana, India

has been assessed and accredited in accordance with the QAI standards for

Transition Care Centre

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued compliance to the above standard & any other requirements specified by QAI.

QAI/CAHSC/TCC/2023/0002

Valid from: 29 March 2023 Valid until: 28 March 2026

Dr. Bhupendra Kumar Rana
Chief Executive Officer

Prof. (Dr.) Mahesh Chandra Misra
Chair, CAHSC

www.qai.org.in

UCCHVAS

Transitional Care | Rehabilitative Medicine | Extended Home Care

Ucchvas Healthcare Private Limited, Hyderabad is the second transition care centre to get accredited.

About QAI

Key Milestones Achieved

Quality And Accreditation Institute
Centre for Accreditation of Health & Social Care

ISQuaEEA
Accredited Organisation 2022-2026

Certificate of Accreditation

Qikwell Technologies India Private Limited
(A Practo Group Company)

We Work, 3rd Floor, Salarpuria Symbiosis, Bannerghatta Main Road, Bengaluru-560076, Karnataka, India

has been assessed and accredited in accordance with the QAI Accreditation Standards for

Telehealth

This certificate remains valid subject to continued compliance to the above standard & any other requirements specified by QAI.

QAI/CAHSC/TH/2023/0002

Valid from: 02 April 2023 Valid until: 01 April 2026

Dr. Bhupendra Kumar Rana
Chief Executive Officer

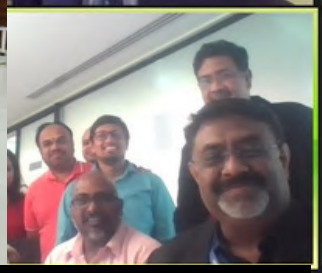
Prof. (Dr.) Mahesh Chandra Misra
Chair, CAHSC

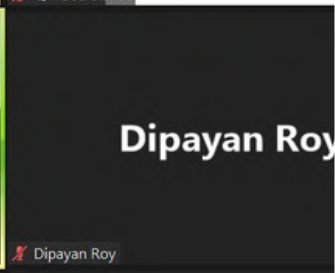
www.qai.org.in

practo

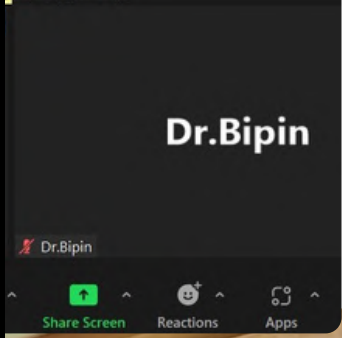
Qikwell Technologies India Private Limited (A Practo Group Company), Bengaluru became the first Telehealth provider in India to get QAI Accreditation.


QAI
Change Adapt Improv
QAI Secretariat




Dipayan Roy
Dipayan Roy

OUR GALLERY


Dr.Bipin
Dr.Bipin
Share Screen
Reactions
Apps


QAI

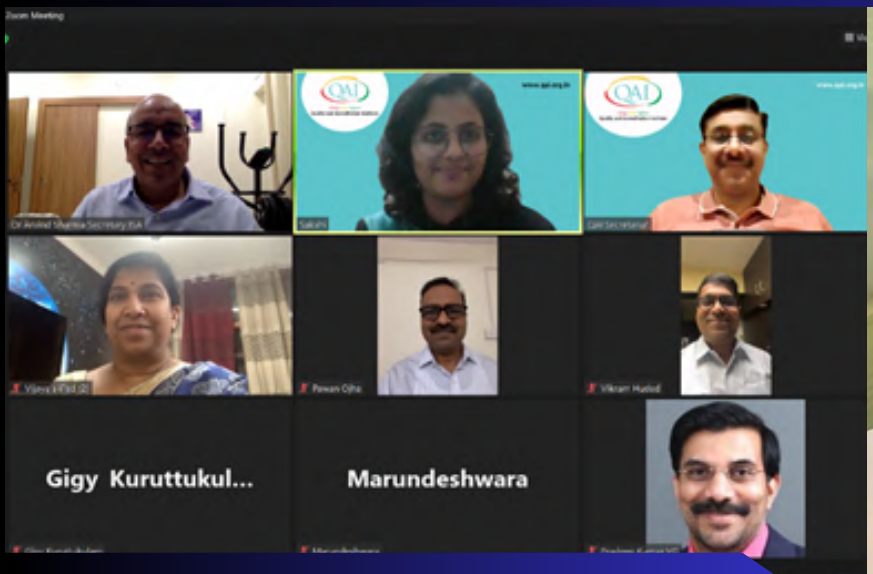

RA IVF


NSC 202

7th Edition CAHOCON

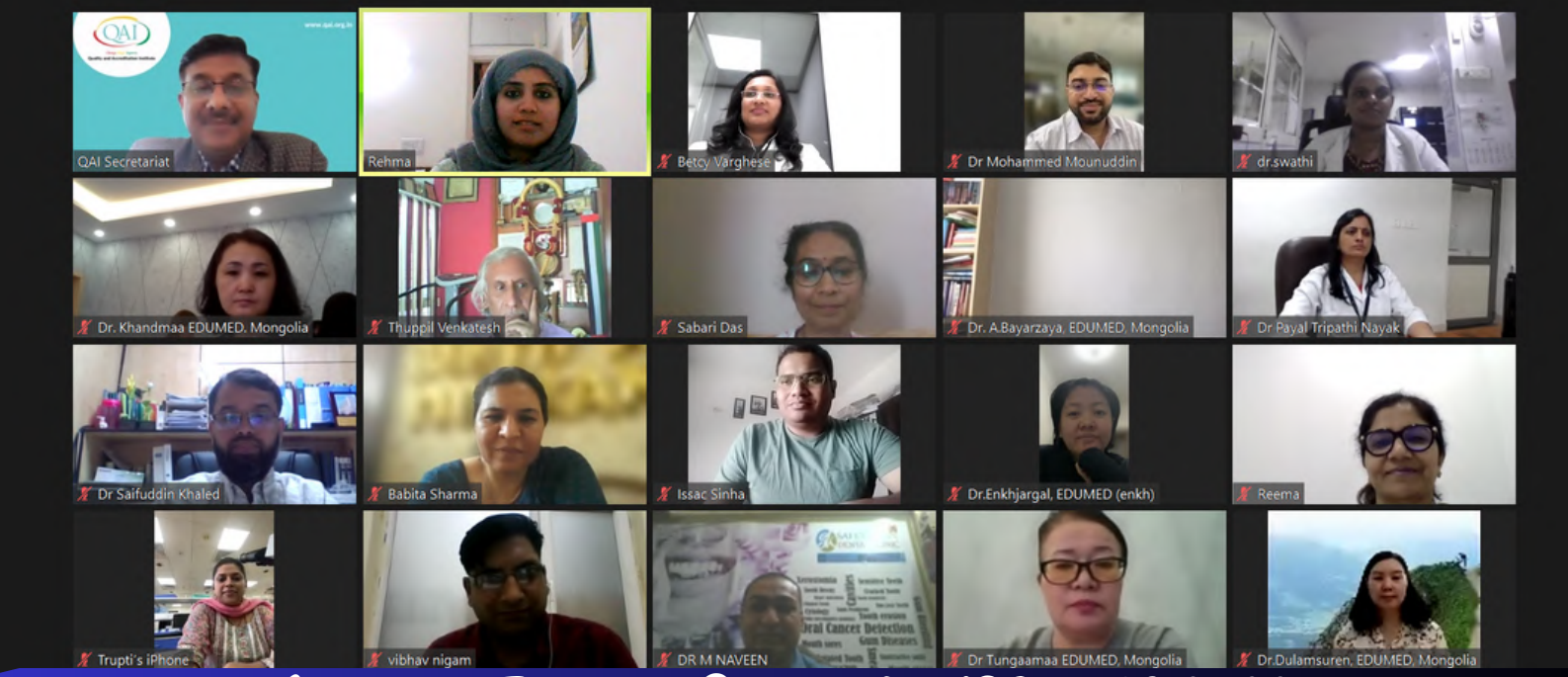
INSC 2023

First assessment of Stroke Accreditation Programme conducted in Lalitha Super Specialities Hospital, Guntur



Assessor Training Course for Stroke Accreditation Programme

MOU signed with EDUMED, Mongolia



Assessor Training Course for ISO 15189:2022

Ist Assessor Training Course for Hospital Accreditation Programme, Delhi

2nd Assessor Training Course for Hospital Accreditation Programme, Mumbai

Assessor Training Course for ISO 17025:2017

Assessor Training Course for Home Health Care Accreditation Programme

Our Assessments

Our Assessments

New Programme Launched

Accreditation Programme for Primary and Advanced Stroke Centre in association with

Dr. V.G. Pradeep Kumar
Chairperson,
Technical Committee &
President ISA

Dr. Arvind Sharma
Co-Chairman,
Technical Committee &
Secretary ISA

Mr Neeraj Lal
Member,
Technical Committee &
COO Apollo Hospitals,
Ahmedabad

Dr. Vikram Huded
Member,
Technical Committee &
Treasurer ISA

Mr. Jatin Kumar
Member,
Technical Committee &
Asst. Vice President-
Strategic Quality &
Training BVG India Ltd.

First Accreditation Assessment for Primary and Advanced Stroke Centre at Lalitha Super Specialities Hospital Pvt. Ltd., Guntur

Mr. Neeraj Lal
COO, Apollo Hospitals, Ahmedabad

“Stroke is the leading cause of long-term disability & in every 45 seconds, someone has a stroke, so advanced stroke care is essential to prevent strokes and decrease the amount of incidents.”

There's been great advancement in the treatment of stroke. The use of intravenous clot busting medication and catheter techniques to remove blood clots from brain arteries (Thrombectomy) have become the standard of care in treating patients in the emergency setting. These treatments are highly time sensitive – in the situation of a stroke, a person will lose 1.9 million brain cells, or neurons, per minute. Even a 15-minute improvement in time to treatment can allow more patients to walk and live at home without disability. It's truly a situation where every second and every minute counts.

With this in mind, in association with Indian Stroke Association (ISA), QAI has launched Accreditation Programme for Primary and Advanced Stroke Centre in 2022 with 10 chapters, 64 standards & 280 objective elements with the aim to improve outcomes for stroke patients by promoting the use of evidence-based practices and ensuring that stroke centres have the necessary resources to provide high-quality care. The standards rely on measurable criteria to ensure proper governance, competent human resources, adequate facility, appropriate information management, quality improvement opportunities and safe practices. Achieving certification means these hospitals have placed great effort into process development and optimization, as well as safety and quality to ensure they meet appropriate national standards to perform procedures appropriate to the level of their hospital. These hospitals ensure they are continuously working on processes and monitoring to ensure optimal patient outcomes.

The first accreditation assessment took place at ***Lalitha Super Specialities Hospital Pvt. Ltd., Guntur on 28th & 29th March 2023.*** This first assessment was a significant step towards improving the quality of stroke care in the country. The accreditation process involved a rigorous evaluation of the centre's infrastructure, clinical protocols, and the expertise of the healthcare professionals involved in stroke management. The center performed well in implementing these standards & setting up the process in place.

Overall, the Stroke Centre accreditation is an essential initiative that can help improve the quality of stroke care in India. It provides a framework for stroke centres to evaluate and improve their practices, and it promotes the use of evidence-based approaches to stroke management.

Client's Voice

THE VOICE

What India's first accredited Transition Care Centre has to say?

"Thank you for taking time in assessing HCAH SuVitas for Transition Care Accreditation Standards. From the time of application, QAI's entire team has been very supportive. HCAH SuVitas has always been committed to Quality, and our team was excited to showcase the good work we have been doing for past decade. QAI's assessors were very cordial and helped the team to showcase their everyday routine in the best possible way. Standards were comprehensive and deep to make it a moment of pride after successful completion. We are positive that this recognition from QAI, will continue to inspire HCAH SuVitas and beyond to deliver best of transition care.

Thank you once again to all the QAI Leadership, Technical Committee and Team for drafting the accreditation standards for Transition Care on par with global best standards."

What India's first accredited Telehealth Facility has to say?

"The Indian healthcare sector, over the years, has witnessed many historic moments, especially those that took the quality of healthcare delivery to a newer level. It started from Apollo Hospital, Indraprastha becoming the first JCI accredited hospital in India and 6th in Asia to BM Birla Heart Research Centre, Kolkata becoming the first NABH-accredited hospital in India to now– Practo becoming the first digital healthcare company to receive a QAI accreditation. We are proud of the advancements in Indian healthcare sector," **Dr. Alexander Kuruvilla, Chief Health Strategy Officer.**

What it means to become the first digital healthcare company in India to receive telehealth accreditation

In the wake of the COVID-19 pandemic, the world woke up to the potential of telehealth. The limited access to healthcare accelerated its adoption as a safe and convenient alternative to conventional in-person consultations, changing the future of healthcare as we know it. While existing digital healthcare companies experienced a much-needed boost in adoption, new players recognizing the potential of digital healthcare joined the sector pushing it to be bigger and better.

Now after almost 2 years, with a wholesome perspective on the sector, one can see the positive impact of digital healthcare. However, to help telemedicine grow and multiply its impact much like large healthcare institutions and hospitals, adequate accreditation of the quality of its services was imperative. With growing acceptance of telehealth, ensuring standardisation in delivery of quality healthcare and promotion of patient safety in digihealth was extremely critical.

Echoing this sentiment, several healthcare companies recognised the need for an independent external body to monitor and certify the quality standards adopted to ensure delivery of high-quality care. And, the Quality and Accreditation Institute (QAI) accreditation did just that and recently created a history by giving its certification to one of the leading digital healthcare companies- Practo.

As one of the fastest growing accreditation bodies, QAI has launched 14 accreditation programs in less than 5 years. QAI is a board member of ISfTeH and has ISQua certification as an organisation and 2 sets of standards

"*The Indian healthcare sector, over the years, has witnessed many historic moments, especially those that took the quality of healthcare delivery to a newer level. It started from Apollo Hospital, Indraprastha becoming the first JCI accredited hospital in India and 6th in Asia to BM Birla Heart Research Centre, Kolkata becoming the first NABH-accredited hospital in India to now– Practo becoming the first digital healthcare company to receive a QAI accreditation. We are proud of the advancements in Indian healthcare sector,*" **Dr Alexander Kuruvilla, Chief Health Strategy Officer.**

Benefits of Accreditation

From improving credibility to empowering the healthcare ecosystem, the accreditation is impactful. Here are a few ways how it will be beneficial:

- A clear demonstration of the organisation's commitment to deliver quality and safe patient care. Assurance of quality services and better health outcomes.
- Uphold transparency, accountability and ethics.
- Ensure compliance to the prescribed telemedicine practice guidelines of the applicable Council.
- Ensure patient information is secure and their privacy intact.
- Have a mechanism of risk management to safeguard provider from potential legal liability.
- Support the organisation to become a part of the National Digital Health Ecosystem

How will QAI impact Practo?

QAI is the first and only accreditation body in India that has 3 standards accredited by the International Society for Quality in Health Care (ISQua). Now an institutional member of ISQua, QAI accreditation is a significant step in upholding the gold standard of quality in healthcare.

And, recently leading integrated healthcare company, Practo earned the prestigious accreditation for its telehealth services becoming the first digital healthcare company in the country and second in Asia to receive it. A milestone for the company, it will enable Practo to set new industry benchmarks and further its commitment to delivering high quality healthcare.

Practo earned this accreditation after a rigorous evaluation of its healthcare services across 239 criteria covering 61 standards defined by the institute. For the past 15 years, Practo has focused on providing quality healthcare through its team of trained and credentialed healthcare professionals, streamlined protocols with ethical clinical process, all of which is aimed at providing enhanced patient experience. And now the QAI accreditation serves as a testament to Practo's unwavering commitment to excellence and quality in healthcare.

Set up to create an ecosystem of education, training, quality improvement and accreditation or certification, QAI began with the intention to provide a platform for cross-learning and ensuring higher standards of quality for all the healthcare stakeholders.

Aiming to operate globally, one of QAI's verticals called the Centre for Accreditation of Health and Social Care (CAHSC), operates various accreditation/ certification activities in health and social care, one that certified Practo's telemedicine services.

"At Practo, quality comes first and this certification reflects that commitment to make healthcare patient-centric and accountable. However, while this is a significant milestone for us, it is not a win that's just ours to celebrate. It's history in the making as it will impact the entire healthcare system by improving its credibility and creating the potential to heighten the standards of care furthermore. It's a new era and we are at the cusp of redefining the sector entirely and this accreditation is a big step towards this," **says Dr Alex.**

An independent body, QAI certification is earned after undergoing a rigorous process of self-assessment and peer review that works as an enabler for the organisations to improve their self-regulatory systems. This inturn ensures patients get access to a gold standard of quality healthcare- the ultimate goal that the entire sector has been motivated to achieve.

Learn with us

Learn with us

Dr. Poornima Prabhakaran
Head-Environmental Health &
Additional Professor
Director, Centre for Environmental Health
Public Health Foundation of India
Senior Research Scientist, Centre for Chronic Disease Control

Dr. Ishika Jharia
Senior Program Coordinator
Sustainable Healthcare
Centre for Chronic Disease Control

Global Healthcare Sustainable Procurement

Global Healthcare Sustainable Procurement

The health sector supply chain represents the largest proportion of a health system's greenhouse gas emissions. Global figures show that the healthcare sector's climate footprint is equivalent to around 4.4% of net global emissions (2 gigatons of carbon dioxide equivalent). This would make it the fifth highest-emitting country in the world, behind only China, the U.S., India and Russia. Greenhouse gas emissions are divided into scope 1, 2 and 3.

SCOPE 1-direct emissions from health care facilities

SCOPE 2 -indirect emissions from purchased energy

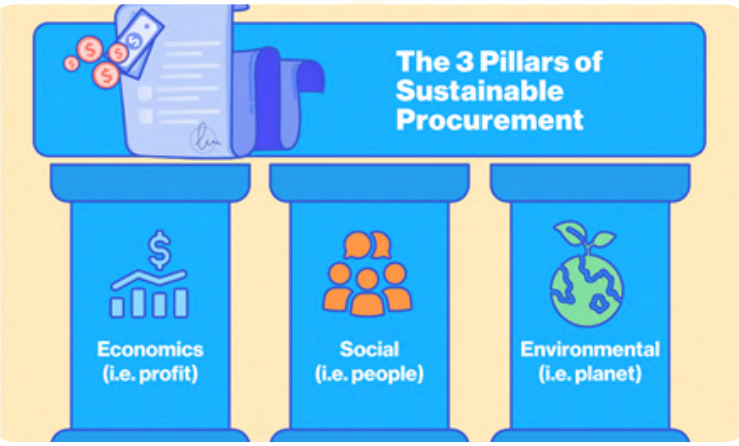
SCOPE 3- all indirect emissions, not included in scope 2, that occur in the value chain, including both upstream and downstream emissions

Supply chain emissions mostly come under scope 3 which include purchases, products and services (including transportation and the distribution of products), patient transportation and employee commuting and waste management* . Recent research shows that the supply chain is responsible for 71% of health care's carbon emissions.

Healthcare organizations can reduce harm and improve the health of their communities through sustainable procurement, the procurement of goods and services whose life cycle has a reduced impact on human and environmental health when compared to products that are usually considered based on their cost effectiveness and quality. Sustainable procurement overall can be a key strategy to push demand for sustainable manufacturing and waste management within the health sector globally.

*** World Resources Institute. Greenhouse Gas Protocol. Retrieved 26 July from www.ghgprotocol.org.**

Sustainable Procurement stands on the three principles of environmental, social and economic sustainability as described in goal 12: sustainable production and consumption of the UN Sustainable Development Goals. In sustainable procurement, organizations meet their needs for goods and services while generating benefits for the organization, society, and the economy while minimizing damage to health, with the lowest environmental impact and most positive social results.



There are many opportunities for improvising the hospital supply chain by adopting sustainable practices into the procurement processes. Organizations can begin putting their purchasing strategies in closer alignment with their care strategies.

To get started, healthcare leaders and hospital purchasing managers need to plan and adopt sustainable procurement policies/environmentally preferred purchasing policies and procedures to drive in sustainability into the sourcing process.

For example, a hospital concerned about investing in major sustainability initiatives may opt for low-cost efforts with short project payback periods. Once the healthcare leaders determine their approach, executives should consider adopting a formal statement to document the organization's commitment to sustainability. Sustainability statements typically include the motives for change, the results the organization hopes to achieve and activities planned to reach those goals. This will act as a sustainability roadmap for the organization.

Hospitals can establish sustainability committees, a group of committed hospital staff comprising of leaders and representatives from different departments in the hospital, who collectively strategizes and implement initiatives within the hospital or healthcare facility to improve the health of people, communities and the environment in which they serve. The committee can take different actions including energy efficiency measures, water conservation, efficient cooling and lighting, sustainable waste management, sustainable purchasing, etc.

There are a few significant initiatives and best practices in India under the Sustainable Health in Procurement Project and Health & Environment

Leadership Platform that has made concerted efforts to incorporate sustainability into the procurement processes of network members, to identify carbon hotspots in supply chain and to build capacities of members on sustainable procurement.

A comprehensive National Green Hospital Standard Accreditation was developed in collaboration with the Health & Leadership Platform (HELP) & Quality Accreditation Institute (QAI) that highlights the relationship of procurement to the standard as a whole.

The developed standard was open for stakeholder consultation from March 2019 to May 2019. Experts from various national and international bodies gave their comments and suggestions in the stakeholder consultation process. The standard was successfully registered under QAI in July 2019 and its first evaluator assessor training was conducted on September 7 and 8, 2019, at the Public Health Foundation of India. The document framework includes 8 chapters, 33 standards and 127 criteria.
Another example is an impact story from The National Centre for Disease Control (NCDC), which has made enormous strides in incorporating environmentally friendly practices and systems into its day-to-day workings to ensure sustainability practices are embedded in all departments and in the institute as a whole. Some of their initiatives include phasing out PVC gloves, minimizing water and energy usage where possible, avoiding environmental health hazards on campus and within the community and supporting locally produced goods and services.
Sustainable procurement is certainly the key element to support the development of a more resilient, sustainable and ethical supply chain within the health sector to create sustainable climate-smart healthcare systems.

Learn with us

Ms. Sakshi Singhal
Accreditation Officer
Quality and Accreditation Institute (QAI)

AYUSHMAN BHARAT DIGITAL MISSION

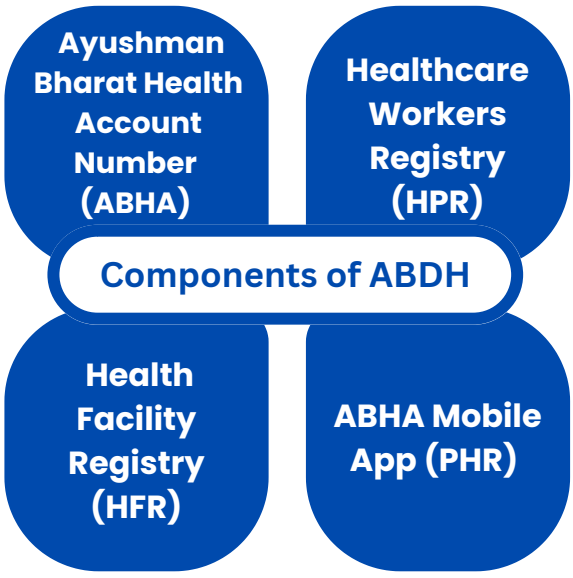
The Ayushman Bharat Digital Mission was introduced by Prime Minister Narendra Modi on February 27, 2021, via video conference, in the company of Shri Mansukh Mandaviya, the Union Minister of Health and Family Welfare, and Dr. Bharati Pravin Pawar, the Minister of State for Health and Family Welfare.

The National Health Authority (NHA) is the implementing agency for the Ayushman Bharat Digital Mission (ABDM) of the Ministry of Health and Family Welfare, Government of India, with a budget of Rs. 1,600 crores for five years, which was released on February 26, 2022.

Across the healthcare ecosystems, digital health solutions have gained immense benefits and CoWIN, Arogya Setu and various other digital platforms further demonstrate the role that technology plays in making healthcare easily accessible.

The vision of ABDM is to create a digital health ecosystem for the nation which can support universal health coverage in an efficient, accessible, inclusive, affordable, timely and safe manner.

The mission is expected to improve the efficiency, effectiveness and transparency of Health service. It will provide a choice to individuals to access both public and private health services, whereas the healthcare professionals will have better access to patient's medical history to provide a better healthcare.



The ADBM has four essential components.

- **ABHA (Ayushman Bharat Health Account) Number** will be used to uniquely identify and authenticate the person and to connect their health data across various systems and stakeholders (but only with the patient's informed consent).
- **The Healthcare Workers Registry (HPR)** is an extensive database of all healthcare workers engaged in the provision of medical services.
- **The Health Facility Registry (HFR)** is a complete database of all of the country's medical facilities, spanning a variety of medical specialties.
- **ABHA Mobile App (PHR)** is an electronic document of a person's health-related data.

In the six Union Territories of Chandigarh, Daman and Diu, Dadar and Nagar Haveli, Ladakh, Puducherry, Lakshadweep, and Andaman and Nicobar Islands, the technology platform created by NHA was effectively tested as part of ABDM. Ayushman Bharat Health Accounts have been established in total of 37,05,28,631 instances as of April 5, 2023.

Additionally, 26,04,11,104 health records have been digitally linked to Ayushman Bharat Health Accounts, and 1,62,406 healthcare providers and 2,02,280 healthcare facilities have been verified under ABDM.

The National Digital Health Mission hopes to increase the efficiency of data transfer between patients and healthcare practitioners with the help of this framework.

*** National Health Authority, www.abdm.gov.in**
***https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1813660**

Consultant's Voice

Consultant's Voice

Sathyendra MG
Founder - Qmart-Global
Management Systems Consultant & Trainer for ISO 17020,17025,13485, Training on MDR2017, Global Compliances, CE marking

Medical Device Testing in India

In India, medical devices are a category of almost 5,000 products. Different categories of medical devices require different kinds of testing infrastructure. Medical devices include products such as electronics equipment, implants, consumables and disposables, IVD reagents and surgical Instruments.

Medical device testing is a critical aspect of the medical device industry in India. Testing ensures that medical devices are safe and effective for their intended use and comply with relevant Indian regulations and National / International standards.

Medical device testing in India covers a wide range of tests, including biocompatibility testing, sterility testing, shelf-life testing, performance testing, EMC and safety testing. The testing requirements vary depending on the type of medical device and its intended use.

The Medical Device Rules, 2017, are the primary regulations governing medical devices in India. These rules define the requirements for the registration and sale of medical devices in India and specify the testing requirements that must be met for regulatory approval. Conformity to Indian standards and in their absence, International/manufacturers standards is suggested.

In addition to complying with Indian regulations, medical device testing in India may also need to comply with international standards such as ISO 10993 for biocompatibility testing, , and ISO 14971 for risk management(simulation of foreseeable misuse/ faults likely to occur).

The union health ministry has directed state governments to set up their own laboratories for testing and evaluation of medical devices amid a push for medical device manufacturing. This seeks to remove regulatory bottlenecks to make in India, facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety.

This will help create an enabling environment and fill the existing gaps in the backdrop of India importing 80% of its medical device requirements, especially from China.

In 2021, CDSCO directed all manufacturers of category A & B medical devices (low risk devices) to come under a compulsory registration scheme and manufacturers of category C & D medical devices (high risk medical devices) were directed to do so up to September 2023. After the compulsory registration period, these classes will respectively move to the licensing regime.

The testing of medical devices is being done as per Central Drug Standard Control Organisation (CDSCO) norms notified in the medical devices rules, 2017.
In India, medical device testing is typically conducted by accredited testing laboratories. Accreditation Bodies accredit testing laboratories based on their compliance with ISO/IEC 17025, the international standard for laboratory competence.

ISO/IEC 17025 is a globally recognized standard for testing and calibration laboratories, including those in the medical device industry. The standard was first published in 1999 and has since been revised twice, with the most recent version released in 2017.

ISO/IEC 17025 is applicable to all types of laboratories, including those in the medical, chemical, mechanical, and electrical industries. The standard covers a wide range of laboratory activities, including sampling, testing, calibration, and the use of laboratory-developed methods.

To comply with ISO/IEC 17025 in India, medical device testing laboratories should pay attention to the following key requirements:

1. Management requirements: This includes having a documented quality management system that is appropriate for the scope of the laboratory's activities. The quality management system should include policies and procedures for laboratory operations, document control, internal audits, corrective and preventive actions, and management review.

2. Technical requirements: This includes ensuring that the laboratory has the appropriate technical competence to perform the testing or calibration activities. This requires that the laboratory has qualified personnel, appropriate testing methods, equipment, and facilities.

3. Measurement traceability: This requires that the laboratory can demonstrate that its measurements are traceable to a recognized national or international measurement standard.

4. Sampling: This includes ensuring that the laboratory has appropriate procedures for sample collection, handling, and storage.

5. Reporting of results: This includes ensuring that the laboratory has appropriate procedures for reporting test results, including the provision of accurate and timely results, and maintaining confidentiality.

The main purpose of ISO/IEC 17025 is to ensure that laboratories are competent to perform specific tests or calibrations and that the results they generate are reliable and accurate. Compliance with the standard demonstrates to regulators, customers, and other stakeholders that the laboratory has implemented a robust quality management system and has the technical competence to perform its testing or calibration activities.

In addition to complying with ISO/IEC 17025, medical device testing laboratories in India must also comply with relevant Indian regulations and standards, including the Medical Device Rules, 2017, and the Indian Pharmacopoeia. Laboratories seeking accreditation from accreditation bodies must demonstrate compliance with these regulations and standards in addition to ISO/IEC 17025 requirements.

Overall, medical device testing is an important aspect of ensuring the safety and efficacy of medical devices in India. Accredited testing laboratories play a crucial role in providing reliable and accurate testing services to ensure compliance with Indian regulations and international standards.

The current challenges faced by the medical device industry is the lack of adequate laboratories for complete evaluation of any device. Looking at the requirements from a generic aspect, this is what we find

Bio compatibility;

There are very few accredited labs currently available for this testing.

The challenge here is biocompatibility is more of a study than a simple test and quite expensive

Electromagnetic compatibility: This is another critical requirement. As all most all electromedical devices have electronic components with in , the need to comply to these requirements is very important l . The intention is the device remains undisturbed and also not disturb other similar devices in the neighbour hood . With diagnosis, monitoring, surgery and many procedures being assisted by devices any error caused due to such disturbance can even be fatal.

There are just around 3-4 laboratories for Electromagnetic compatibility (some of them not accredited).

Safety- both the patient and the clinician the devices have to be safe and not cause electrical, mechanical, ergonomic, or thermal hazards . At the BIS website, we find there is only one laboratory qualified under IS 13450 (the Indian version of IEC 60601-1)!

Only for general safety not performance!

RoHS - A manufacturer aiming to export with CE has to meet RoHS requirements too. The chemical management of electronic components by restricting the quantity of mercury, lead, chromium 6, cadmium, certain plastic additives like PBD, PBDE etc.
Here also there are just around 5-6 labs!

Calibration of medical devices – The situation here is encouraging! There are a sufficient number of calibration labs for medical devices.
The discouraging part--Are the hospitals using them? An informal chat with some, revealed that they did not even know such facilities existed and relied on 'servicing' by the AMC provider or the manufacturer. Lot of education required by healthcare industry associations like AHPI to take up at least with mid-sized and large hospitals to begin with.

In conclusion- It is understood that no private lab would invest unless it is sure on the return of its investment. So it is up to the Government/ associations to take up this issue to provide proper and economical test facilities. A committee under IIT Kanpur has made few recommendations to the Government to fund IITs and NIPER's to create dedicated performance test facilities. Let's hope that the initiative will be accepted, and projects fast tracked.

Besides the competency of the doctor a safe and accurate diagnostic device can save many a life and at least reduce the number of times we all simply mention " Oh! What can be done, his/her time had come!!!'

Lets hope India will not be just number one in manufacturing and exporting medical devices but in ensuring that all are ' competent' devices!

Faculty's Voice

ISO 15189:2022

The new ISO 15189:2022 standard emphasizes a risk-based approach, quality indicators, customer satisfaction, and competency of personnel, and aligns with other ISO management system standards to promote consistency and integration of management systems. Laboratories are expected to review and update their quality management system to comply with the new requirements of the ISO 15189:2022 standard.

Dr. Anikode Ramaswamy
Professor and HOD
PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh

ISO/IEC 17025:2017

QAI's Centre for Laboratory Accreditation (QAI) conducted 6 days Assessor Training Course for Testing & Calibration Laboratories as per ISO/IEC 17025:2017. It's my pleasure as faculty of this training program attended by senior officers of various testing & calibration laboratories from all parts of India & abroad. The course of training framed by QAI was purposeful & effective. The level of participation by all participants in discussions & team activities during training was encouraging. Wishing more training programmes by QAI in future for assessors.

Dr Y C Nijhawan
Ex-Director, PhD
National Test House, Ghaziabad

ASSESSOR TRAINING FOR HOSPITAL

Program is intended to train new assessors who can participate to build a strong healthcare system through structured accreditation programme which will benefit patients, healthcare professionals, Hospitals and concerned stake holders and further giving a scope of constant learning, improvement and development.

Dr. Parvez Ahmed

Hospital Administrator, Consultant Physician & Accreditation Expert Dehradun

ASSESSOR TRAINING FOR HOME HEALTH CARE

QAI Assessor program was conducted with insightful, innovative and detailed best practices guidance, laws and strategies to help you accommodate more assessors and to support home care/assisted care homes for fulfill legal, statutory obligations along with best safe patient care services. It was dedicated to covering the latest developments in the rapidly evolving home care sector especially pre and during the condi pandemic.

Ms. Usha Prabhakar

Regional Director-Nursing Apollo Hospitals Jubilee Hills, Hyderabad

DIVE

Importance of quality and documentation is a well understood fact in healthcare industry. Quality and Healthcare Institute has taken a step ahead by providing a tool to the applicant ART facilities, for establishing quality driven culture through Documentation Implementation Verification Elevation (DIVE) program.

This training emphasizes on importance of documentation and outcome monitoring through well established internal audit process, essential to set path for best outcomes in healthcare practices. It was overall an interesting experience to interact and understand implementation challenges from the first hand execution staff. The most challenging fact during this training program was to install the sense of ownership and inspire key healthcare personnel on benefits of data collection and evaluation. However, it was satisfying to observe that the program provided the participants an opportunity to share a vision and rationale of quality management system along with the leaders of their organization & QAI. Understanding of data monitoring and waste reduction through quality tools has provided a different approach towards quality management system and importance of accreditation to the leaders and drivers of the organization.

I believe such programs by QAI will initiate a trend where as an accreditation Institute we are not only demanding quality but also recommending the platform by furnishing them autonomy, ability and aptitude to develop their own document and implementation process so as to increase the ownership eventually leading to staff satisfaction & motivation.

I believe QAI shall evolve as repository of knowledge and education to not only install but also sustain quality implementation and improvement process in healthcare industry.

Dr. Zainab Zaidi

Director, Propitious Healthcare Solutions Pvt. Ltd. (PHSPL)
Former Director, Health Sector Skill Council & Deputy Director, NABH
Lucknow

ACCREDITATION

Accreditation can be defined in simplest terms, meeting the requirement of the standards.

It is the most interesting and engaging activity where learning is grabbed everyday.

Few find it exhausting and tedious, but to think programmatically, accreditation makes the process streamlined and helps in executing the best practices possible.

One such example can be quoted, a small clinic, run by a Gynaecologist in remote locations of tier 1 cities, hand over the prescription without keeping any patient records. This creates a challenge at the time of next of appointment.

Why to think about spending money to get accreditation, become an advocate to deliver best care possible and apply immediately.

Ms. Rehma Javeed

Assistant Manager
Quality and Accreditation Institute (QAI)
Noida

Assessor's Voice

Assessor's Voice

Mr. Arkaprabha Bhattacharya
Sr. Manager Quality and Accreditation coordinator
TRSCH (Tirath Ram Shah Hospital), Delhi

Home care regulatory compliance: Present Scenario and way forward

A regulatory compliance encompasses the meticulous adherence to the requirements as per laws of the land. This goes without saying; healthcare is one of the most regulated sectors in any part of the world due to its own inherent risk, maintaining quality standards, to be cost effective and assessable, as well as to ensure patients' rights. This is a given fact, healthcare is dealt with life and regulators are supposed to keep no stone unturned to make sure patients are safe at every step of service delivery. Not only patients, but the health care providers and community as whole also to be safe. This is only possible when there are sets of norms, guidelines, processes etc. are mandated and the service providers are instructed to follow without deviation. Home health care is also no exception to this proven eco system though there is no specific data available pertaining to the number of home care organisations functional in India. However, the number is rising due to change of disease patterns, increasing population, especially elderly group and off course limited hospital beds.

Home health care is yet to be considered as a conventional Clinical or healthcare establishment and so their regulatory obligations are to be looked through from every nook and corners. But, given the above statement, can we consider that home health care is out of the purview of any regulatory compliance in India? The answer is for sure 'NO'. For example,

- Home health care providers have to ensure services rendered by qualified and registered healthcare practitioners only, as per the state or national regulations.
- If a home health care organization delivers or sells medicines of their patients; they shall obtain Drug license under drug and cosmetic act, 1940. Pharmacy to be managed by qualified and registered pharmacists.
- Ensure patient rights are under the ambit of regulatory compliance. For example, home care providers are also liable to obtain informed consent from patient/ Next of Kin before any invasive or high risk intervention.

- Application of information technology is the key of today's health care delivery. There are a couple of digital health technologies in the system or in pipelines. Like EHR, e-pharmacies, AI, Cloud computing etc. Keeping the 'digital health data' safe, confidential and preventing unauthorized access is the biggest challenge for any health care facility including home care. All these are regulated in accordance with DISHA, 2018, HIPAA compliance, IT Act 2000. Home care is no exception, since most of them are substantially 'Digital health data' driven.
- Management of Bio Medical Waste (BMW) in healthcare is always under the scanner of the regulator and in the past few years this has been reemphasized. Home care also to comply to the best possible extent as per the state pollution control board norms and ensure that community / environment is not at risk due to generation of BMW.

Above are only some of the examples and there are many more regulations that are applicable directly or indirectly to home care to minimize risk and ensure safety.

Present Home care organizations adhere to regulation as per their best possible understanding depending on their scope of services. However, a prescribed and well-designed regulatory requirement is a need of the hour. Because home health care is the paradigm shift in health care. This is not a substitute for hospitals. But, undoubtedly a parallel and extended form of health care model which can reduce the burden of long hospital stay and hospital beds can be utilized more effectively.

A defined regulatory compliance in home care possibly will provide medical insurance companies more confidence to have a level playing field and come out with more innovative home health insurance plans. Accreditation bodies will have more clarity to set their standards. A comprehensive and holistic approach from the health sector along with the regulators would equip home care to be an indispensable part of mainstream health care delivery.

Participant's Voice

ISO 15189:2022

The new standard introduced for medical labs in 2022 has been a quite comprehensive, concise and up to date effort in terms of implementation, quality improvement and effective utilization of captured data sets at te lab soft floor.

Post pandemic, in this new era of machine learning and AI, the new standard ISO 15189:2022 - Medical laboratories — Requirements for quality and competence is bound to play a pivotal role for existing labs and upcoming labs in terms of information management, Point of care testing, emphasis on risk management.

Moreover, the new standard's alignment to ISO 17025: 2017 has made it all the more robust, dynamic and specific in term of defining a laboratory's quality and competence needs.

It is also quite encouraging to note that the new standard has clearly outlined the clauses pertaining to structural and governance requirements (clause 5), resource requirements (clause 6) and process requirements (clause 7) in further enhancement to the previous version's management and technical requirements.

Myself, being part of the recent assessor training program, QAI secretariat's efforts and longstanding vision towards implementation and alignment of quality systems with the new requirements in wholeheartedly appreciated

Mr. Issac Sinha

Operations Head

Spandan Diagnostics

Nagpur

ISO 15189:2022

ISO 15189:2022 is an international standard that provides requirements for the competence and quality management system of medical laboratories. The standard ensures that laboratories produce accurate and reliable test results that meet the need of the users.

Some of the benefits of implementing ISO 15189:2022 are as follows:

- Improve in patient safety
- Enhanced confidence in laboratory reports
- Increase in customer confidence and satisfaction
- Continuous improvement in quality management system
- Efficient cost reduction by preventing wastage.

With more emphasis given on risk management in the revised standard, potential harm to patients, laboratory personnel and the environment can be identified by defined processes and minimized.

Point of care testing (POCT) has many challenges related to quality assurance and requires an understanding of the entire testing process. Inclusion of POCT in the revised standard will also play an important role in reliable test reports and patient safety.

Dr. Sabari Das

Head Quality

Spice health, Gurugram

ISO 15189:2022

It was a wonderful experience getting acquainted with new ISO 15189:2022 standards. I have tried to sum up some of the significant changes which have been introduced through these new standards.

"ISO 15189:2022 standard contains requirements for the medical laboratory to plan and implement actions to address risks and opportunities for improvement.

The emphasis on risk management within a laboratory's quality management is a fundamental change in the new ISO 15189 standard. It calls for Laboratory management to create, execute, and maintain procedures for recognizing patient safety risks and opportunities associated with its tests and activities, as well as developing countermeasures to both risks and possibilities. The laboratory director must also see to it that these procedures are examined for efficacy and changed if necessary.

An important modification has been inclusion of requirements for point-of-care testing (POCT) in the standard's scope. Another notable change is that ISO 15189:2022 specifies that the management system documents may be included in a quality manual but are not obliged to do so. Formerly, ISO 15189:2012 mandated that the laboratory shall establish and maintain a quality manual."

Dr. Vibhav Nigam
Ram Manohar Lohia Institute of Medical Sciences
Lucknow

ISO 15189:2022

I am very happy to participate in the laboratory training ISO 15189:2022.

Through this course, I learned how to monitor and evaluate the quality and safety of laboratory care, and the skills to identify incidents and risks.

Ability to identify and evaluate resources needed to provide standard laboratory care and to train and direct other medical professionals working in the laboratory.

Khandmaa Bayanjargal
Sun Medical Center
Ulaanbaatar, Mongolia

Important Links:

We aim to bring to you the news and updates from the global community. To begin with, we are providing some links to international trade, commerce, standards, conformity assessment and regulatory channels below:

Global Organisations Ruling Trade and Commerce between Nations

- World Trade Organisation - https://www.wto.org/
- World Economic Forum - https://www.weforum.org/
- United Nations Industrial Development Organisation - https://www.unido.org/
- Organization for Economic Cooperation and Development (OECD) (www.oecd.org)
- World Health Organisation (www.who.int)
- Food and Agriculture Organization of the United Nations (FAO) (www.fao.org)
- European Commission - https://ec.europa.eu/info/index_en
- US Food & Drug Administration - https://www.fda.gov/

International Standards & Conformity Assessment Organisations

- International Organisation for Standardisation (www.iso.org)
- International Accreditation Forum (www.iaf.nu)
- International Laboratory Accreditation Cooperation (www.ilac.org)
- International Society for Quality in Health Care (ISQua) (www.isqua.org)
- ISQua External Evaluation Association (www.ieea.ch)
- International Network of Quality Infrastructure (INetQI) (www.inetqi.net)

Regional Standards & Conformity Assessment Organisations

- Asia Pacific Accreditation Cooperation (www.apac-accreditation.org)
- Asian Society for Quality in Health Care (ASQua) (www.asquaa.org)

Change Adapt Improve

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