QAI

*Change Adapt Improve*

Quality and Accreditation Institute

# THE VOICE

Newsletter | Volume 1 | Issue 1 | Jan-Mar 2021

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www.qai.org.in

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# 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 three years, QAI has extended its presence in India as well as in some other countries. The year 2020-2021 has been unprecedented due to COVID-19 Pandemic which has led to several challenges for all sector including healthcare. 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 Goal-3. 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 2021-2022.

# 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.

## QAI Divisions

- CET - Centre for Education and Training
- CLA - Centre for Laboratory Accreditation
- CAHSC - Centre for Accreditation of Health & Social Care

## QAI Programmes

QAI is offering programme under three different verticals:

**CET: Centre for Education and Training**

- Training Programmes on Accreditation Standards and related topics
- Capacity Building Activities

**CLA: Centre for Laboratory Accreditation**

- Medical Laboratory (ISO 15189) Accreditation Programme
- Testing Laboratory (ISO/IEC 17025) Accreditation Programme including food, forensic and veterinary testing labs
- QAI Recognition for Medical Laboratory (Basic, Medium and Advance) (Based on the requirements prescribed in Gazette Notification G.S.R.468 (E) dated 18 May 2018 and related amendment dated 14 Feb 2020 by Ministry of Health and Family Welfare, Government of India related to Clinical Establishments (Central Government) Rules, 2012)
- Biobanking (ISO 20387) Accreditation Programme

**CAHSC: Centre for Health and Social Care**

- Assisted Reproductive Technology (ART) including IVF Centres Accreditation Programme


- Home Health Care Accreditation Programme Home Healthcare accreditation standards achieved ISQua accreditation in 2020 making them International standards.


- Dialysis Centres Accreditation Programme Dialysis accreditation standards achieved a milestone by receiving International recognition from ISQua in 2019
- Green Health Care Facility Accreditation Programme
- Healthcare Facility Certification Programme
- WHO Patient Safety Friendly Hospital Standards Certification Programme
- Primary Care Clinic Accreditation Programme
- Ambulatory Care Facility Accreditation Programme (dental, imaging, eye, day care etc.)
- Telemedicine Practitioners Recognition Programme
- Telehealth Accreditation Programme

**Key Milestone**

QAI is the first and only accreditation body in India to get two standards internationally recognised.

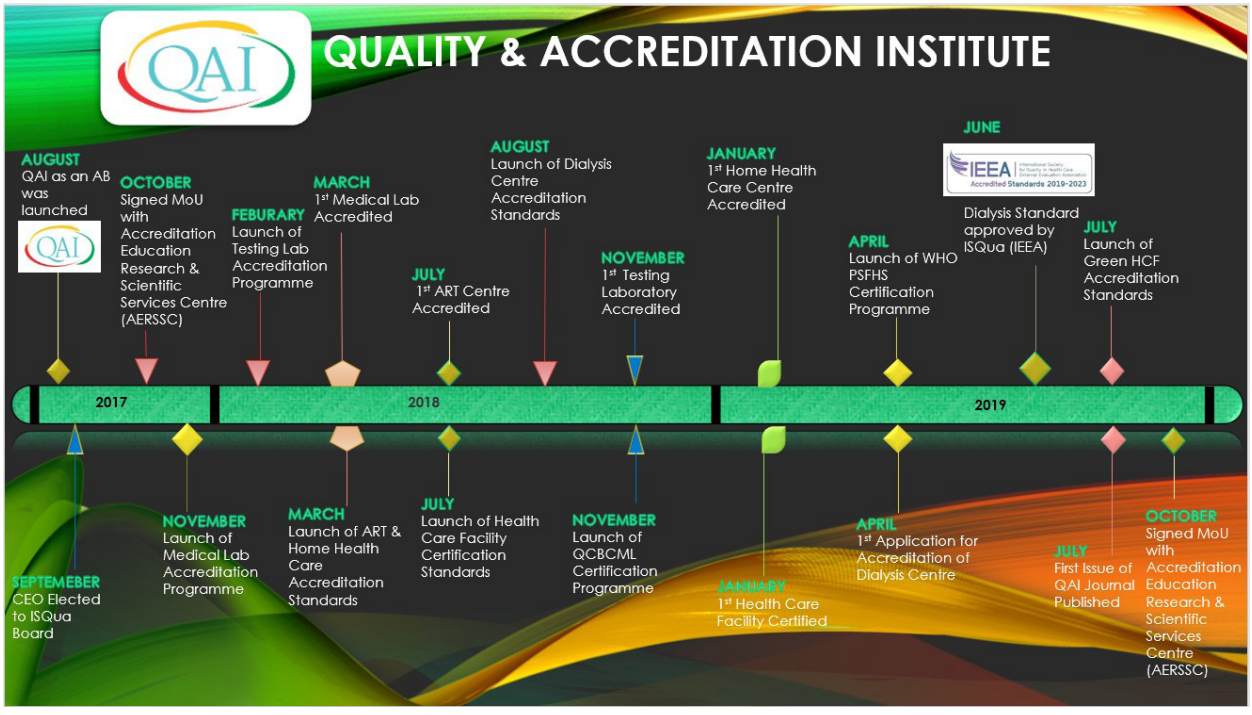
## International Recognitions and Affiliations

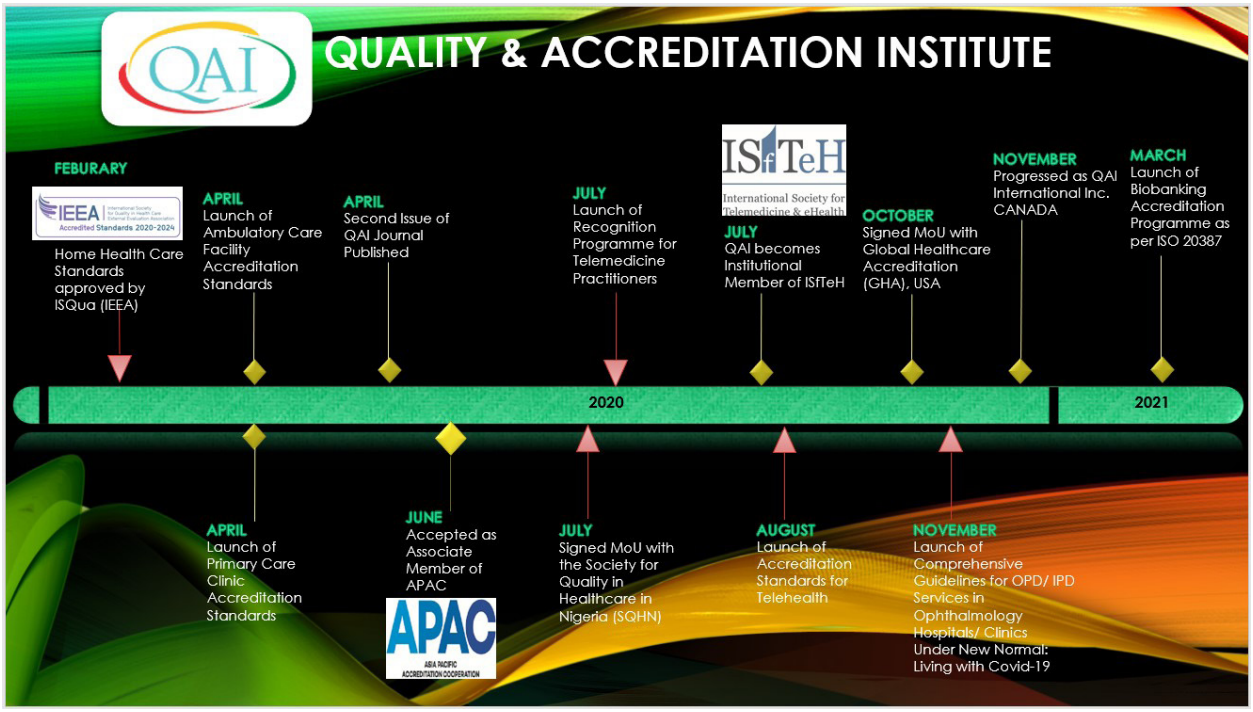
Institutional Member of the International Society for Quality in Health Care (ISQua) (www.isqua.org)

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

Associate Member of Asia Pacific Accreditation Cooperation (APAC) (www.apac-accreditation.org)

## Journey so far since Inception – 3 Years






## Key Milestones Achieved

**Number of Accreditations/ Certifications** || **30 +**

**Number of Assessors** || **150 +**

**Number of Training Programmes Organised** || **49**

**Number of trained Internal Auditors** || **200 +**

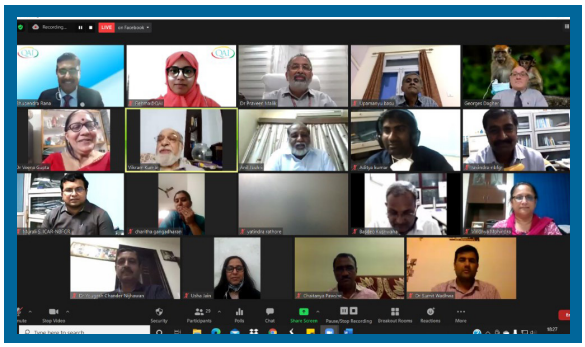
**Number of Global Partnerships** || **10**

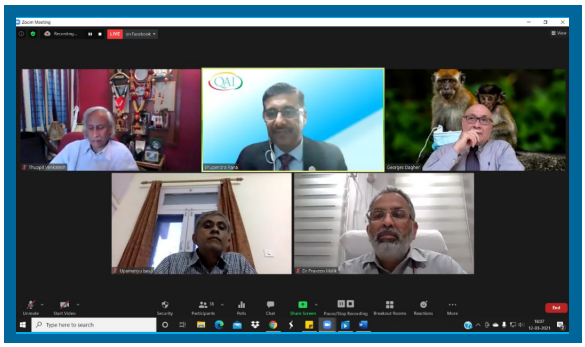
## New Programs Launch

QAI is the first Accreditation Body in India to launch Accreditation Programme for Biobanking as per ISO 20387. Programme was launched by special guest and key stakeholder Shri Upamanyu Basu, Joint Secretary, Department of Animal Husbandry & Dairying, Govt. of India. Chief Guest: Dr. Praveen Malik, Animal Husbandry Commissioner, Govt. of India. Chairman-QAI CLA: Prof. Vikram Kumar, Chairman-Board of QAI's Centre for Laboratory Accreditation & Ex-Director, CSIR National Physical Laboratory, New Delhi. Guest of Honour: Mr. Georges Dagher Convenor, ISO/TC 276/WG2 Biobanks and Bioresources Mr. Anil Jauhri Ex-CEO NABCB/QCI & International Expert on Conformity Assessment Special Invitee: Dr. Pramod Kumar Bajaj, Chairman-TC for biobanking Dr. Birendra Kumar Yadav, Manager, National Liver Disease Biobank, ILBS, Delhi & Regional Ambassador-Indo Pacific Rim of ISBER Session Moderator-Dr. Bhupendra Kumar Rana, CEO-QAI

**Launch Video of Accreditation Programme for Biobanking as per ISO 20387**

## Pics Gallery



# CONTRIBUTION TO MINISTRY OF AYUSH GOVERNMENT OF INDIA INITIATIVES

### Rashtriya Ayurveda Vidyapeeth (RAV) coming up as an Accrediting Agency

Rashtriya Ayurveda Vidyapeeth (RAV), an autonomous institution under Ministry of AYUSH that has been notified as the accrediting agency for various Ayurveda professional courses being run in various countries and for Ayurveda professionals not covered under IMCC Act, 1970 including therapists/ counsellors etc.

A technical committee was constituted by RAV, the Ministry of AYUSH comprising of experts from Ayurveda and Accreditation background to develop an accreditation scheme. A draft of the scheme has already been prepared as 'Rashtriya Ayurveda Vidyapeeth Quality Enhancement Initiative for Ayurveda Training Courses'. This document has been made available on RAV website (http://www.ravdelhi.nic.in/en/accreditation-scheme) and QAI website (RAV-AYUSH) for public consultation process.

In addition to operate an accreditation scheme, RAV will also be providing an opportunity to training course providers to get themselves listed (simple listing and listing based on self-declaration of conformity to the standards). The objective is to create an inventory of training courses available globally in Ayurveda with the ultimate aim of bringing them under the framework of formal accreditation.

QAI is very much pleased to extend its support to RAV in this initiative including dissemination of information and reach out to stakeholders to create awareness.

# NATIONAL NEWS

# VOICE OF INDUSTRY

SERVICES EXPORT PROMOTION COUNCIL

www.servicesepc.org

**Services Export Promotion Council (Setup by Ministry of Commerce) and Industry, Government of India**

## About SEPC

The Ministry of Commerce and Industry, Government of India, with a view to give proper direction, guidance and encouragement to the Services Sector, set up an exclusive Export Promotion Council for Services in the name of Services Export Promotion Council (SEPC). The Council since its inception in 2006 has been instrumental in facilitating exports of services through the following services:

1. **Trade Intelligence:** Trade Information, Market Analysis, Business Contacts, Business Opportunities and Market Access Conditions
2. **Export Development:** Export Readiness, Training and Counselling, Strategy Formulation and Development, Value Chain Optimization
3. **Export Promotion:** Exhibitions, Buyer Seller Meet, Business Delegations to overseas markets, Brand Campaign for India's Services Sector
4. **Enabling Business Environment:** Policy inputs to Ministries, Facilitating Cross Border Trade, Policy Advocacy, Facilitating implementation of various export promotional schemes.

## Vision

To make India an international services exports powerhouse by effectively promoting and representing every sector of Indian services and contributing to the overall growth of the economy.

**Dr. Abhay Sinha**
Director-General, SEPC

## Mission

- To be an effective voice of the Indian services sector globally, raising its profile through interventions and exchanges leading to increase in business.
- To serve as a bridge between government and other stakeholders and the services sector.
- To disseminate knowledge and recognize the achievements of organizations in their quest to increase services exports.

## About Services Sector

Services sector has been a mainstay of the Indian economy. India has emerged as a global hub for supply of various services, and today India exports over $200 billion of services annually, which contribute to 7% India's GDP. India's services exports base has been growing at over 8% per annum in the last few years. Services account for 54 per cent of India's Gross Value Added (GVA) and contribute more than 40 percent to India's total global exports.

According to World Trade Report 2019, India is

the fifth largest services trader in the world and a large number of jobs are supported by services exports in India. ICT sector alone employs 3.5 million workers in India. Services exports lead directly to employment of approximately 2.6 crores people in India (accounting for around 30 per cent share), while leading to indirect employment as well.

## Service Sectors Mandated to SEPC

At the time of inception, SEPC was mandated to promote export of 14 services sectors. As per the Public Notice No 26/2015-20 dated 1st August, 2018 by DGFT, others category was added where more sectors were brought under SEPC purview.

Further in 2018, the Union Cabinet chaired by Hon'ble Prime Minister Shri Narendra Modi approved the proposal of the Department of Commerce to give focused attention to 12 identified Champion Services Sectors having following major objectives:

- Enhance the competitiveness of India's service sectors through the implementation of focused and monitored Action Plans, thereby creating more jobs in India, contributing to a higher GDP and exports of services to global markets.
- As the Services sector contributes significantly to India's GDP, exports and job creation, increased productivity and competitiveness of the Champion Services Sectors will further boost exports of various services from India

SEPC covers the following services sectors including 12 Champion Services Sectors.

| Services covered under SEPC | | |
|---|---|---|
| **Champion Services Sectors** | | |
| 1 | Hotel and Tourism related Services | Tourism and Hospitality Services |
| 2 | Healthcare services including services by nurses, physiotherapist and paramedical personnel | Medical Value Travel Services |
| 3 | Maritime Transport Services | Transport and Logistics Services |
| 4 | Accounting/Auditing and book keeping services | Accounting and Finance Services |
| 5 | Entertainment services including Audio-Visual Services | Audio-Visual Services |
| 6 | Legal Services | Legal Services |
| 7 | Architectural Services and related services | Construction and Related Engineering Services |
| 8 | Environmental Services | Environmental Services |
| 9 | Others Services | Information Technology & Information Technology Enabled Services |
| 10 | | Communication Services |
| 11 | | Financial Services |

| | | |
|---|---|---|
| 12 | Educational Services | Education Services |
| 13 | Consultancy Services | |
| 14 | Distribution Services | |
| 15 | Advertising Services | |
| 16 | Marketing Research and Public Opinion Polling Services/Management Services | |
| 17 | Printing and Publishing Services | |

## Overview of Healthcare Sector in India

With the growing old age population, the demand of the hospital industry and advanced healthcare is rising and enhancing the healthcare services within India is the need of the hour. According to IBEF, India's healthcare industry is worth around US$100 billion and is estimated to reach US$280 billion by 2025. It has been regarded as one of the most popular destinations for medical value travel because of its cost-effective healthcare, skilled professionals, quality healthcare, its proximity to major countries, availability of latest medical technology and low cost of living which makes India a foremost destination for the foreign patients holding a strong position in the world in terms of advanced healthcare services as well as wellness services.The emergence of big multispecialty hospital chains being set up in the subcontinent bringing over USD 7,034 Million Foreign direct investment inflow in the sector till December 2020 has led to an major improvement in technological and infrastructural development in the sector.

India holds a strong position in advanced healthcare services such as organ transplants, cardiovascular procedures, cancer treatments, etc. with a high success rate. Countries such as Africa, South Asia, CIS countries, Gulf bring most of the patients in India capitally for an organ transplant, orthopaedic, and oncology treatment. India offers lower cost for skilled treatment compared to Europe and USA. There is a rise of super-specialty hospitals in the country, which has upgraded facilities with skilled professionals. Due to these productivity and cost-effective advantages, India is one the key MVT destinations in Asia with 6.9 lakh foreign patients seeking treatment. India's medical value travel was pegged at US $164 million in 2019-20 with a YoY growth of 56 %. Medical tourists stood at 4.2 lakh, 4.9 lakh, 6.4 lakh and 6.9 lakh in the years 2016, 2017, 2018 and 2019 respectively.

## Role of SEPC in Promoting Healthcare Services

SEPC has been active in promoting healthcare sector through its Sectoral Panel on Healthcare and membership. SEPC provides policy inputs to the Government on various issues related to Healthcare services exports from the country with a special focus on MVT. SEPC also promotes healthcare through its events especially its flagship programme "India Heals" and other B2B events.

AIMED

**AATMANIRBHAR BHARAT INITIATIVES HEALTHCARE SECTOR**

# Big Role Played by Indian IVD Manufacturers in Addressing COVID-19

**Mr. Rajiv Nath**
Managing Director,
Hindustan Syringes & Medical Devices P Ltd &
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As India geared up to fight the Covid 19 crisis, Indian IVD Manufacturers relentlessly worked to address the crisis with rapid ramp up of Testing for COVID, as Testing was considered most critical to containing COVID-19. The staggering demand for COVID-19 diagnostic tests sent shockwaves through the IVD industry.

The Government of India through its flagship "Make in India" initiative relied heavily on the Indian manufacturers to meet the rising demand of essential healthcare equipment's for the country, pushing the Indian medical devices sector to become Atmanirbhar or self-reliant.
Amid the clarion call given by the Hon'ble PM to become Atmanirbhar (self-reliant), from immediately developing all required Covid-19 test kits to producing millions & millions of tests, the Indian IVD Industry was the solution provider in the biggest healthcare crisis of our Nation.

In-Vitro Diagnostics (IVD) industry of the world and entire India has observed phenomenal changes in the ways it supported the diagnosis of Covid-19 samples. From logistics capabilities to testing capacities to reporting, all activities were observed a turn-around in the way it used to function before Covid-19. India alone has registered 400% growth in number of new labs which started molecular testing during the pandemic. By mid-March 2021, India crossed 2400 molecular laboratories performing Covid-19 PCR testing. This is a huge step toward making India Atmanirbhar (self-reliant) for complex disease testing where molecular techniques are proven to be gold standard. While the disease remains uncontained, such demand is likely to keep growing.

Demand for IVD products of all kinds—reagents, instruments and systems used to diagnose and monitor COVID-19, heart disease, diabetes and other conditions—is surging. Prominent players including 3B Blackbio Biotech, Himedia, Trivitron Healthcare, Mylab are expanding in the market very quickly. And they are meeting an increasingly supportive regulatory landscape for product development and commercialization.
Today, 3B Blackbio Biotech has developed more than 100 molecular tests which covers technologies like Real-Time PCR and Next Generation Sequencing (NGS).
Soon after ICMR approved their RT-PCR kit for Covid-19, they started receiving more than 100 calls a day as they were the only second kit to get approval in India. From the production capacity of 5,000 tests a day, they started scaling up their efforts to produce more than 1,00,000 tests per day.

3B Blackbio Biotech India became FIRST EVER Indian molecular diagnostics company to receive US-FDA EUA (Emergency Use Authorization) to make their mark on the global IVD industry. This led to more than 50 countries enquiring for their kit. They further also received EUA on our RT-PCR kit for Saliva samples.

Today, they are happy to acknowledge more than 400 private laboratories and almost equal number of government laboratories who used their kits and relied on their world class quality. By the end of January 2020, 3B Blackbio has

produced and sold over 6 million tests not just in India but in other nations too. Under a new quota system, they are now exporting their RT-PCR kits to United States of America.
With this new zeal, 3B Blackbio Biotech's team is even more committed to offering reliable and affordable molecular testing solutions to India for its Atmanirbharta and to the entire world.
Being ranked among the top 3 bio suppliers in India, HiMedia whose mission is to deliver world class quality products at affordable cost was at the forefront of the fight against Covid from the day one.

Himedia undertook the task of fighting the COVID-19 pandemic by developing a vast array of diagnostic products and tools that include VTM, a range of ELISA-based kits (viral detection kit), RNA extraction kits, RT-PCR kits, RNA extraction machine, and RT-PCR machines. HiMedia's capacity was to produce 5 Lakh (0.5 Million) VTM tests per Annum for the last 12 years. However, on the request of the DPIIT they ramped up to 35 Crore tests (350 million tests) per Annum, over the months of April and May-2020. This was a 700-fold or a 70,000% increase.

All the above steps helped India to be Atmanirbhar in this vital field of Covid Viral Sampling. They ramped upto 350 million tests at that time and helped to test almost 95% of the patients. All components & raw material of VTM are manufactured by HiMedia.

Himedia has developed both qualitative and quantitative ELISA- based antibody detection kit for COVID-19 infection. The antibody detection kit is the only way to determine whether a person have developed immunity against of SARS-CoV-2 and with the mass vaccination drives happening, it will be really important from a clinical point of view to determine the immunological status of the people before and after vaccination.

When the pandemic had only just began, India hardly had infrastructure to develop COVID-19 testing solutions and was heavily dependent on imports. Trivitron Healthcare, a leading Medical Devices organization took the beginner steps and invested heavy in manufacturing comprehensive range of COVID-19 solutions including RT-PCR Tests, RNA Extraction kits, Viral Transport Media, Total Antibody ELISA Test, ELISA IgG &Covid Antigen testing kits. This pandemic triggered an unprecedented demand for high-performance health technology products with extremely short turnaround time and unmatched precision. Keeping abreast of the contagion, existing infrastructure and logistics support, and the demand, Trivitron converged majority of their efforts in the production of new Covid-specific products.

Trivitron had established new production facilities for large scale manufacturing of Covid-19 products and is committed to manufacturer & scale up cost-effective and globally accepted high-quality kits, and other COVID-19 solutions.
With India beginning the biggest vaccination drive reaching one & all, Trivitron have begun to look beyond existing developed covid products. Trivitron research & development team is working on to develop Lyfoung RT PCR tests, RT PCR Direct which will enable to reduce the steps & turnaround time for testing, Over The counter Antibody testing Point of Care test kits for covid.

In March 2020, despite being the first and only Indian company to get approval from the Indian FDA for Covid-19 test kits, Mylab placed society first and offered covid-19 kits at one fourth the cost borne by the government. They are working with the central and state governments, ICMR and NIV to ensure kits are available at remotest parts of the country and to the friends of India. They want to develop end-to-end molecular diagnostics products for India including tests and machines.

They have developed an automated machine called Compact XL to bring Lab in a Box and Lab in a Van. The product makes possible establishing molecular diagnostics laboratories in space and resource constrained environments such as airports, national borders, country-side establishments. During Covid-19 pandemic, the world realised that RT-PCR testing is the most reliable way to find infections. The Compact XL product enables RT-PCR testing for all infections such as HIV. Hepatitis, Dengue, Malaria. Tuberculosis and hundreds more.
The Indian In-Vitro Diagnostics (IVD) industry is expected to record a year on year growth of 30 per cent in the year 2020. This will be double the rate at which the industry has been growing in the past decade. The size of IVD industry in the year 2019 was Rs 7500 crore which was slated

to grow at a CAGR of about 15 per cent before the COVID crisis. COVID related products have already added Rs 3400 crore to the market size during the first half of the year and by the end of the year, this figure is expected to touch an estimated amount of Rs 7300 crore. Even if the size of non-COVID routine diagnostics products plummet to one third its original value, a base value of Rs 2500 crore will still remain, taking the total industry size to a value of Rs 9800 crore.
The de-growth in the IVD industry may sound alarming but the sharp surge in COVID test and large production of indigenous products will more than make up for the loss this year.
The IVD market has been propelled by the COVID-19 pandemic for much of this year, and the global response to the crisis is expected to continue to drive diagnostics growth. But it is not the only driver
.
Also pushing the market for IVDs will be a number of factors. First, as diagnostics laboratories increasingly use fully automated instruments, they will decrease hands-on time, reduce batch testing, and provide doctors with quicker tests compared to non-automated instruments. Second, the integration of biomarkers and the availability of bio molecular tools are predicted to help in the development of a new set of condition-specific tests, thus creating new opportunities for the growth of IVD market size. And last, the IVD market will be driven by the use of personalized medicine products in treating cancer and other chronic diseases, along with increasing technological advances related to artificial intelligence and machine learning, which makes it possible to achieve higher levels of diagnostic precision.

Up to date, the development of COVID-19 tests has ramped up massively. The rapidness of disease spreading and the urge to carry out large-scale testing, has led to the commitment of the diagnostic industry to concentrate its production and development capacities on one common goal. Despite the pace and urgent need, it remains critical to ensure a test's reliability. Therefore, despite the high number of tests required to be readily available, Indian developers are ensuring an in-depth quality control and quality assurance infrastructure to maintain accuracy and comparability

Mr. Rajiv Nath, Forum Coordinator of the Association of Indian Medical Device Industry (AiMeD) recognized that the government interventions helped the medical devices industry scale up production during the pandemic. We enjoyed an unprecedented teamwork and rapid proactive communication from NPPA who became a facilitator instead of a Regulator & Dept. of Pharma, DPIIT, Invest India and MSME Ministry as they set up help desks to address production bottlenecks of all Medical Devices especially, those related to COVID viz COVID IVD Test Kits, Sanitizers, Masks, Ventilators & Gloves. The number of Indian firms manufacturing RNA extraction kit listed with AiMeD before the outbreak of Covid-19 was Zero but today 16 Indian firms listed with AiMeD are manufacturing 265.4 million pcs/annum.

Similarly, the number of Indian firms manufacturing Diagnostic Kit (PCR Kit) went from Zero to 8 manufacturing 1.47 billion+ pcs/annum, Covid-19 Rapid Diagnostic Test Kit from zero to 3 manufacturing 46.5 million pcs/annum and VTM from Zero to 10 manufacturing 3.77 Billion pcs/annum listed with AiMeD.

COVID-19 crisis has shown that Indian medical devices sector can rise to the challenge. When imports got disrupted, specific devices detailed with quantified production shortages and a focused Inter-Ministry Group coordinating with domestic manufacturers via AiMeD had addressed production bottlenecks and challenges so that not only capacity got utilized but also ramped up rapidly.

"Prime Minister Narendra Modi's call for self-reliance Aatmanirbhar Bharat will not only see India emerging as a manufacturing superpower but will also strengthen India to vie for being the 2nd factory in world for Medical Devices & a dependable Manufacturer of quality products in Global supply chain. We have shown the ability and capability of Indian Entrepreneurs to Make in India when we have the support of Govt." said Mr. Rajiv Nath.

PWMAI

## Covid-19, Conundrum for PPE manufacturers

**Dr. Sanjiv Relhan**
Chairman, Preventive Wear Manufacturers Association of India
www.pwmai.com
chairman.pwmai@gmail.com

Covid-19, Boon or Bane for Indian Industry of Infection Prevention Clothing, is a question which we are still not able to answer.
2nd week of February 2020, Manufacturers of Infection prevention clothing were in a dilemma, how to help the Healthcare Workers. No clear guidelines about Corona Virus. Long debates on Whatsapp groups to understand how Coroanvirus spreads, whether it is Aerosol or Surface born. None of the research papers made it clear and situation was confusing. Pressure of safety of Health Care Workers was mounting. Then on 27th February, WHO in its Guidelines for Rational Use of PPE made it clear that Coronavirus doesn't act as EBOLA and hence a coverall also known as EBOLA PPE is not required and they suggested Surgical Gowns preferably impervious to fluids as primary safety gear for body along with other PPEs viz. Head Gear, Eye Protection, Gloves & Respiratory Protection.

It was the time to act and all these manufacturers started working upon creating a stockpile of Gowns which were impervious to fluids & some of them also made coveralls as Coveralls are a practical option, when lots of movement is anticipated. But in absence of any National Standards for PPEs, the demands from various Government & Private Hospitals were of varied specifications, and was another enigma for manufacturers, which Standard to follow.

And then finally, MOHFW published Rational use of PPE guidelines which provided specifications of Coverall required. But this was not the end of the problems, in fact it was beginning of struggle for manufacturers as within 24 hours, India was under lockdown. There was only one lab in Coimbatore to test the Prototype Coverall for MOHFW specifications & no courier, no train, no flights. Production came to a standstill for few days as there were no permissions, no raw materials, no workforce and demand was surging to a new peak. But thanks to Department of Pharmaceuticals, AiMED (Association of Indian Medical Device Industry) & PWMAI (Preventive Wear Manufacturers' Association of India) who kept raising the problems with various ministries and within a few days Industry was not only manufacturing the PPE Coveralls but also helping Manufacturers from other Garment Sectors to meet the surging demands. Kudos to support of Ministry of Textiles as they were instrumental in setting up a few more labs with DRDO, Ordinance Factory Board & Heavy Vehicle Factory, which helped in ease of testing the prototype samples.

By the end of April 2020, India was producing sufficient numbers of PPE Coveralls to meet country's requirement, but these moments of rejoice were temporary as whole nation was celebrating India becoming second country in producing PPE Coveralls, manufacturers from Medial Industry were tense about safety & comfort of Healthcare Workers. This all happened because in absence of National Standards & Regulatory Framework, fly by

night operators jumped into manufacturing of PPE Coveralls. For them it was once in a lifetime opportunity to earn quick buck by using the services of tailors doing contract manufacturing for them. As MOHFW guidelines asked for Fluid Penetration Resistance as only parameter which was easily achievable with any laminated nonwoven, so without understanding the role of comfort they flooded the market with substandard PPE Coveralls at throwaway prices.

Now, India is preparing for exports of PPE products and that's the riddle which has to be solved. We are ready for exports as we have enough spare capacities now, but will we be able to meet Global Regulatory requirements? Do we have infrastructure to comply with Global Standards? Answer is a big NO as manufacturers here still believe that obtaining certificates is the key to compliance, although it is not. Compliance with norms and standards is a continuous exercise with quality and safety of the user as top priority and only way out is to upgrade the technical skills of manufacturers, publish Nationals Standards for various protection levels which are at par with Global Standards and implement a Regulatory Framework to ensure compliance with the Standards. Manufacturers need to understand that upgrading infrastructure only won't do, upgrade in mindset of manufacturing quality product is required.

Government has a major role to play for this upgradation. Manufacturers need to be handheld for infrastructure upgrade. Technical skill training centres are required to impart skills necessary to workforce. Robust laboratory infrastructure is required to test the product in accordance with standards as the quantum required in future is very high and testing capabilities are far less.

This will unearth the solution to The Conundrum and India will emerge as a Preferred Supplier to Globe for quality Infection Prevention Clothing. A beginning of New Era...

# CLIENTS CORNER

## Onwards and Upwards

SARS-CoV-2, the virus causing COVID-19, has blanketed the entire world in its throws. It has inflicted its far-reaching impact on every walk of life, infecting at least 10 crore people and claiming more than 20 lakh lives. However, these numbers do not even begin to account for ground-reality. With thousands of people not getting tested, this number might actually be two- or even three-times what has been reported.

The most direct ramifications of this have been observed by the healthcare sector, especially what the essential services. With more patients than what the healthcare infrastructure can support, COVID-19 has reinstated that expenditure made on healthcare delivery (hospitals, clinics, beds, equipment) and healthcare education (professionals) are long-term investments. The pandemic has also changed the healthcare narrative across the world by bringing us back by many years in the fight against illnesses such

**Dr. Kshitiz Murdia**
CEO and Co-Founder
Indira IVF

as non-communicable diseases such as diabetes, cancer, and more.

With multiple advisories in place by state and national governments as well as international bodies such as the World Health Organisation, people have been wary of stepping out to a healthcare setting for other needs in a bid to avoid nosocomial infections. Elective healthcare services, including assisted reproductive techniques, had to close down when a country-wide lockdown was announced in March to ensure patient and staff safety. For us and our patients at Indira IVF, it meant that we had to halt patient treatments or had to delay their counselling till a time it was safe to resume them. During this time, IVF treatments were at a complete standstill.

Human fertility is a function of time; it keeps deteriorating with age, hence, fertility treatments such as IVF are immensely time sensitive. To add on to that, childless couples in India are highly stigmatised in the society. The amalgamation of the two lead to mental distress similar to that observed in patients with cancer and hypertension. Research on the topic conducted in Canada and the United States during the pandemic on women aged 20 to 45 whose fertility treatments were stopped midway due to the pandemic found that 52% reported clinically significant symptoms for depression, and 86% observed a negative impact on their mental health in this duration.

At Indira IVF, we picked up treatments in the month of June. Gaining patient confidence since has been crucial for us. Even after re-opening, there was a dip in the number of patients who visited us for their treatment. In addition to counselling patients about IVF, it was necessary that we put in efforts to gain their trust and ensure them that all safety protocols are in place.

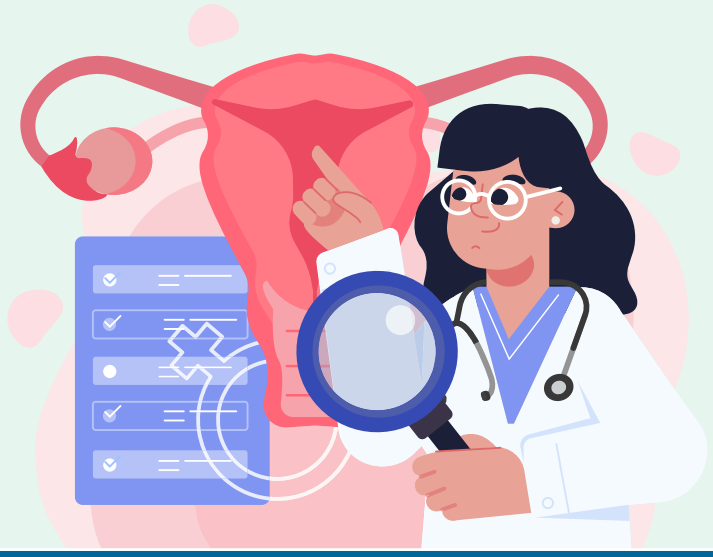
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239253

Through rigorous following of protocols as directed by authorities and the government, we have ensured the safety of our patients, doctors, and supporting staff. These include mandatory temperature checks for all who enter the clinics' premises, entry only by prior appointment, as well as self-declaration form by patients in order to identify those that are high-risk. In addition to this, practice of precautionary measures is encouraged by all and regular sanitisation and disinfection protocols are followed in the hospital facility.

Additionally, we have found a friend in digital media and telemedicine to assist our patients. COVID-19 has transformed the acceptance of digital health technologies, and has hastened the rate at which they are used in medicine. Digital media has helped us reach our patients with essential information and advisory about infertility, and telemedicine has enabled us to counsel them real-time.

Gradually, we are taking small steps towards accepting and living in the new normal. Our efforts at Indira IVF have empowered us to serve the same volume of patients as we had pre-pandemic, in just a matter of 8 months; this in turn has allowed us to empower aspiring parents see the light at the end of the tunnel.

A patient-centric care that spans counselling for treatment as well as helps ease their mental burden is essential, and patients must be provided with the same during and after treatment. We only go onwards and upwards from here.



# Role of Health Workers and Challenges for Medical Researchers Amid COVID-19 Pandemic

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The COVID-19 pandemic has been shaking the entire system including the health care system globally. This deadly novel pandemic seems to be the most unfortunate time in the world's history as it has brought the whole world to its knees.

The virus seems to be keeping no discrimination and keeps on rolling with equal ferocity across every community from smart cities to rural ones. On the other hand, there are unending efforts to mitigate the spread of this novel COVID-19 pandemic. Under such terrible and scary circumstances, health care workers are always in forefront to combat this pandemic. But unfortunately, our society has been taking their role as for granted.

These workers are always on the front lines in providing uninterrupted services adopting the standard operating procedures (SOPs) under such troublesome times. From sample collection (oropharyngeal and nasopharyngeal swabs as well as blood samples) from suspected/ COVID-19 patients to sample processing where they are at higher risk to get infected, they are silently working behind the scenes with selfless determination just to save humanity. While people across India and around the globe were confined to their homes, these warriors are facing an agonizing pain by remaining secluded from their families considering the infectious threat around all the times. They are truly the real heroes in such challenging and unprecedented times. Sometimes they are being ostracized from communities as they are working in hospitals dealing and exposed to this contagious virus.

## Challenges

The real challenge was the development of the vaccine. Everybody was perplexed why the vaccine for COVID-19 took so much time. It was a mystery to unfold. As this COVID- 19 virus mutates (changing shape) very rapidly. The genetic material is single-stranded Ribonucleic Acid (RNA) it easily gets cut up and remixed once broken so vaccines made for a specific RNA may become quickly obsolete.

## Vaccine Development

Vaccine development begins in the laboratory. If tests show that a vaccine has potential, it is tested in experimental animals like mice, rabbits, or guinea pigs. After that, the clinical trials are done with the human volunteers if a vaccine is found safe in animals.

## Clinical Trials

According to the Centre's for Disease Control and Prevention (CDC), there are three main phases of clinical trials. The Food and Drug Administration (FDA) sets guidelines for the three stages of clinical trials to ensure the safety of the volunteers.
Phase 1 clinical trials focus on safety and include healthy volunteers. In Phase 1, the size of the dose is related to the side effects of the vaccine. At this early phase, scientists learn the efficacy of the vaccine. If no severe side

effects are found in the vaccine, then it goes on Phase 2 trials, which involves several hundred volunteers. This phase includes studies that may provide additional information on common short-term side effects and how the size of the dose is allied to immune response.
In Phase 3 studies, thousands of volunteers participate. Vaccinated people are correlated with people who have received a placebo or

another vaccine so scientists can learn more about the test vaccine's safety and effectiveness and identify common.

Clinical trials are conducted to ensure the highest scientific and ethical standards. In addition to examining the results of the clinical trials, scientists also evaluate a wide range of information regarding the vaccine's physical, chemical, and biological properties carefully to ensure that it can be made consistently safe, pure, and potent. The trials and all other data must unveil that the vaccine's benefits supersede the side effects for people who will be recommended to receive the vaccine only if a vaccine's benefits are found to outweigh its potential risks then its granted license and allowing to be used for the public. After vaccines are licensed, they are monitored minutely as people begin using them. The purpose of monitoring is to watch for adverse events. Therefore, it is a lengthy and time-consuming procedure; it may not be developed overnight.

## Drawbacks

Meagre funding and resources for the research in India. Meanwhile, this pandemic taught us the lesson to reassess the value of health workers in our society.

# EXPERTS CORNER

## Medical Labs – Regulation or Accreditation?

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Medical labs are undoubtedly an important part of the health ecosystem in any country but in India, like many other sectors related to health and safety, they have remained largely unregulated and therefore lacking assurance of quality and reliability.

The Clinical Establishments Act, 2010 intended to fill this gap but unfortunately only 11 states and almost all union territories have adopted the Act till now and from all accounts none has enforced the minimum standards prescribed under it. Therefore, there is not even data on how many medical labs are operating in the country much less any measure of their quality.
The role of medical labs came into sharper focus as covid pandemic set in and India scrambled to develop covid testing facilities.

Fortunately, there existed a voluntary accreditation programme as per international standard, ISO 15189, under the aegis of NABL and it had a pool of labs accredited for the RT PCR technique which enabled ICMR to quickly approve a number of labs for covid testing based on NABL accreditation. NABL also responded magnificently to the challenge to grant more accreditations for RT PCR testing and we now have a fairly large pool of covid related testing labs available.

However, is that the approach India should stick to in the long run even as covid shows no sign of going away and given India's population, a much larger pool of labs may be necessary for promoting accessibility and bringing down cost of testing.

The question begs an answer not only in relation to covid testing but for the larger issue of assuring quality of medical labs in general in the country.

Are all the medical labs in the country capable of meeting the international standard, ISO 15189? The

answer should be no. Even if one may wish that all of them should meet ISO 15189. Hopefully one day they would and would have an international class medical lab ecosystem. Is it then necessary to impose ISO 15189 on medical labs in the country – the answer again would be no. Given the large numbers involved and their current state.

One can be sure that the experts who framed the minimum standards under CEA would have asked these questions and come to the same conclusion – and hence the minimum standards for medical labs under CEA. Therefore, the conversation in relation to medical labs should centre around the minimum standards under CEA rather than ISO 15189 as it currently tends to be which actually works to undermine the cause of quality in medical labs. Which means that even ICMR may be well advised to look at the minimum standards under CEA rather than only NABL accreditation as per ISO 15189 to augment its pool of labs for covid related testing.

One of the reasons why NABL accreditation take primacy in the conversation on medical labs is that there is a robust, institutional mechanism available under NABL to attest conformity to ISO 15189 while there is no mechanism to check or certify labs against the CEA mandated minimum standards. The next question therefore should be – who would check compliance to the minimum standards laid down under CEA if a state were to adopt these. One traditional option is that state governments who adopt these standards should have their own pool of auditors or inspectors to check compliance – the time tested but now much maligned model of regulation in various sectors. Do the states have the wherewithal to manage such a system of regulatory compliance. Both in terms of expertise and manpower. Most probably not but if they can, let them do.

## What is the option then?

Should NABL be asked to set up a system of checking compliance to minimum standards? After all it already has a pool of assessors and well-established system of assessing medical labs. Some private accreditation bodies like Quality & Accreditation Institute (QAI) and the Federation for Development of Accreditation Services (FDAS) have also come up and could supplement the resources. The answer in the interest of preserving the gold standard of accreditation and NABL's focus and image would be no. Its best as a matter of principle that regulation and accreditation are kept separated and accreditation bodies do not get into regulatory space of checking compliance to regulations. This has been articulated in the Indian National Strategy for Standardization (INSS) released by the Department of Commerce in June 2018.

However, as the worldwide experience shows, the regulators are increasingly relying on independent, third party agencies for checking regulatory compliance and some of the more progressive regulators in India have already gone that way – be it PNGRB in oil and gas sector for safety audits or FSSAI for food safety audits of food businesses or CDSCO for audit of medical device industry using notified bodies.
Therefore, we should start looking seriously at this option.

## Where are such agencies you may ask?

As of now there may be none because there is no market need. However, if the regulations provide certainty that such agencies would be used, there is no reason why the private enterprise in India would not respond as it did in case of covid testing and even production of PPEs over past year. India has also seen in the past not only in covid times that when there is regulatory certainly, suitable competent agencies or labs do come up be it oil & gas sector or electronics & IT products or toys.

As in case of labs under NABL, there is a well-established system of accreditation of inspection agencies under NABCB, the sister Board of NABL, and as many as 70 plus inspection agencies are accredited as per international standard, ISO 17020, which is most ideally suited for third party agencies checking regulatory compliance, be it food safety or environmental compliance or safety audits.

Therefore, it would be desirable that the Ministry of Health & Family Welfare looks at this option seriously and frames at least model rules for adoption by states if not implement a system of notifying such agencies centrally as FSSAI and CDSCO do which state governments can utilize. In such a system, any lab which is accredited to ISO 15189 or certified to any recognized standard which covers minimum standards specified under CEA could be accepted automatically and subject to relaxed oversight following the now globally recommended risk-based approach. Even individual states can institute such a system on their own without waiting for the central government to act. The question is who would act – or would it need courts to push executive into action.

# INTERNATIONAL NEWS

## QUALITY

## 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)

# ISO TC 304 – ANNOUNCEMENT FROM ISO TC 304

## Welcome to ISO/TC 304

ISO Technical Committee 304 Healthcare Organization Management is committed to advancing quality of healthcare, continuity of care, safety, resource management, and patient health and well-being. If you are an organization, institution or individual who is passionate about healthcare organization management and would like to make a global impact, TC 304 welcomes you to join its work.

## Importance of ISO TC 304's Work

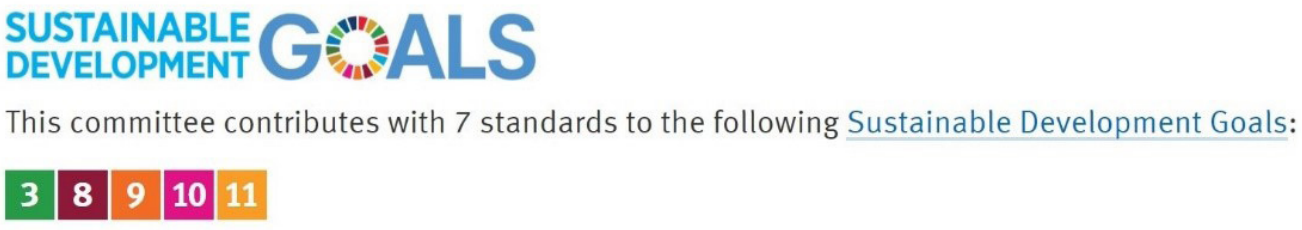
Healthcare organizations around the world have been facing a triple threat for a number of years; decreasing financial resources, workforce shortages and aging populations. Many countries have embarked on universal healthcare coverage and in 2020 alone the pandemic has highlighted the importance of digital healthcare and the skills required to adapt to deliver care in new and different ways. These health issues, coupled with increasing co-morbidities of patients requires that we take bold steps to improve healthcare around the world in a sustainable way.

Some anticipated benefits of TC 304'S work

- Improved population health
- Improved resource utilization
- Increased patient/customer satisfaction and better health outcomes
- Stronger risk management
- Sharing of evidence-based best practices around the world
- Increased confidence amongst stakeholders
- Improved continuity of care

## Scope

Standardization in the field of healthcare organization management including: classification, terminology, nomenclature, management practices and metrics that comprise the non-clinical operations in healthcare entities.
United Nations' Sustainable Development Goals
TC 304 is proud to produce work that addresses the following SDGs:




TC 304 encourages the work that will continuously support and promote the attainment of more SDGs.

**References:**

https://committee.iso.org/home/tc304

https://www.iso.org/committee/6131376.html

# LEARNING AND DEVELOPMENT CORNER

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## Good Clinical Practice (GCP) – Raising the Bar

The ensuing COVID-19 pandemic has heightened the emphasis on clinical research and training aligned with the primary objective of providing a uniform platform for executing large-scale, high-quality clinical trials. This has led to the requirement of large number of trained workforces having the skill and knowledge necessary to advance the translation of discoveries via clinical trial execution. The trainings need standard practices to ensure uniform quality approaches for the persons involved in clinical research.

The Helsinki Declaration (1964 and 2013) acknowledges: "medical research must be conducted only by individuals with the appropriate ethics and scientific education, training, and qualifications". To meet this Declaration, a need arose to train clinical research personnel to execute clinical trials following Good Clinical Practice (GCP).

The New Drugs and Clinical Trials (NDCT) Rules, 2019 released by the Indian drug regulator, Central Drugs Standard Control Organization (CDSCO), also lay emphasis on this area. CDSCO released the GCP Guidelines in 2001 and mandated them through the third chapter of NDCT Rules, 2019 by stating that the 'clinical trial shall be conducted in accordance with the provisions of the Act and the Rules and principles of Good Clinical Practice Guidelines''. This is to be followed by all the stakeholders like sponsor, investigator, ethics committee member, etc. This in turn generated the need for training for professionals in GCP.

With the growth of the clinical industry and the ever-growing demand for the trained clinical professionals, Clinical Development Services Agency (CDSA), an extramural unit of Translational Health Science & Technology Institute (THSTI), Department of Biotechnology under the Ministry of Science and Technology, Government of India has been into training of GCP professionals and has expertise in the domain. CDSA and has conducted more than 150 training programs (majority in GCP). The total number of professionals trained in GCP is more than 12000.Various other organizations have also initiated training in GCP.

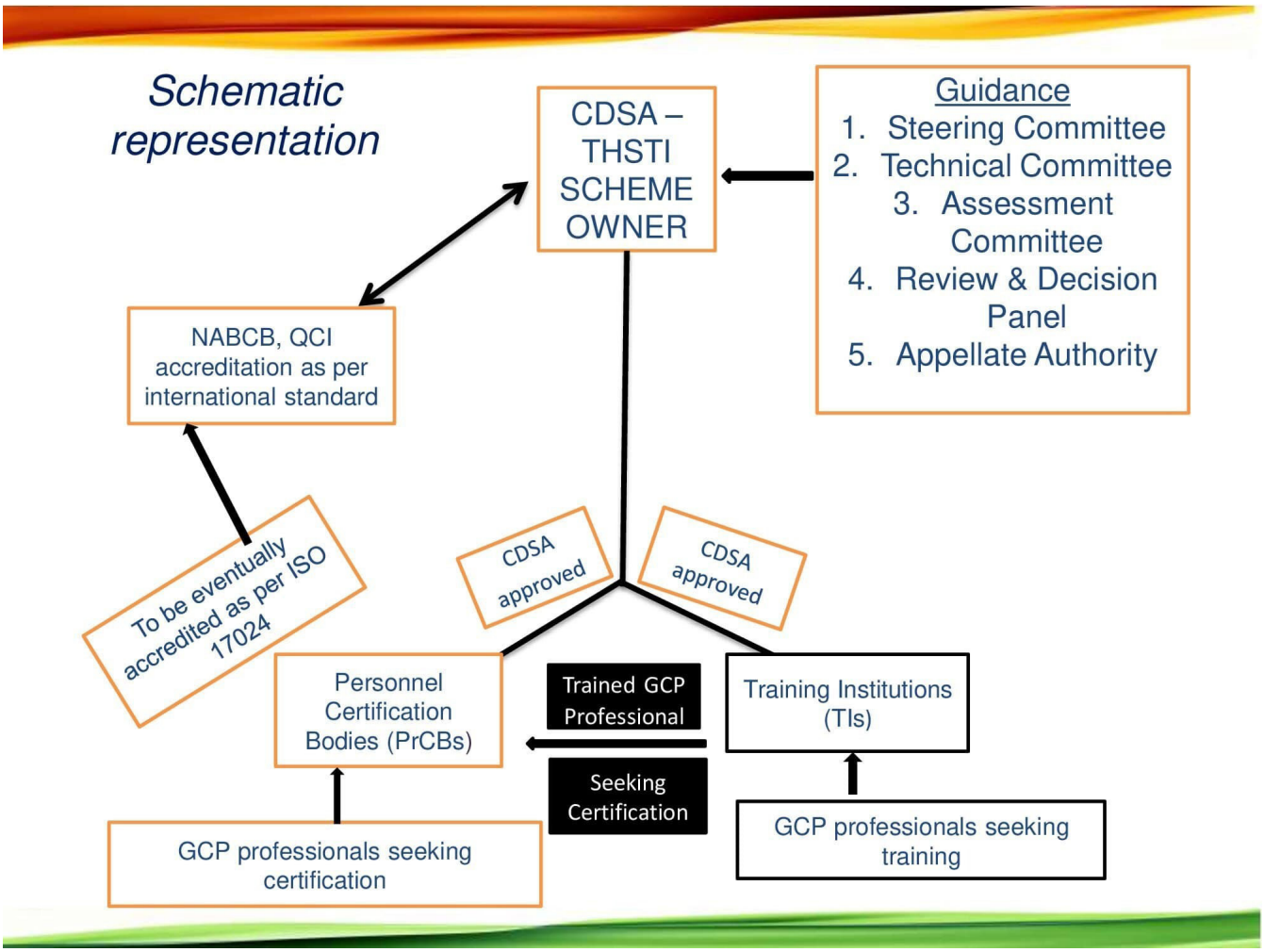
With the pandemic, CDSA felt the need to produce even greater number of competent GCP professionals with uniform standardized quality training and benchmarking of their knowledge and skill. The only way to do this was to create an ecosystem where a number of

training providers would provide GCP training and the competence of GCP professionals would be evaluated by independent Third-Party Certification Bodies following international norms to promote acceptance of certified professionals and accredited training providers within the country as well as in overseas markets.

In order to create of such an ecosystem, CDSA-THSTI decided to become the Scheme Owner of the ecosystem following the widely practiced international model which meant instead of being a training organization itself, it upgraded itself as an accreditor of training organizations to evaluate training organizations across the country, to begin with – given CDSA's expertise. In parallel, as the Scheme Owner it also decided to create a system of independent evaluation and certification of GCP professionals by competent Third-Party Certification Bodies. The GCP professionals, whether they are formally trained or not, who think they meet the competence criteria as per the Minimum Standard of Competence established by the CDSA, can go for evaluation and certification. Through this ecosystem, training becomes a support function to help produce competent professionals. By adopting this strategy, CDSA now has assumed a higher role as a 'supervisor' rather than as a 'doer' that is , as a training institution itself. The Scheme is based on the fundamentals of 'Third-Party Certification' and leverages the concept of accreditation to international standards, ISO 17024 in this case, to facilitate international acceptance. The Scheme documents have been prepared by domain experts, subjected to worldwide public comments and are available at

https://thsti.res.in/cdsa/GCPPCS/

## The schematic diagram below shows an overview of the Scheme



GCPPCS has a robust Governing structure guided by the Steering Committee and supported by a Technical Committee and an Assessment Committee to draft, review and approve the relevant documents and monitor effective implementation of the Scheme. These committees are comprised of multiple stakeholders for example subject and process experts with representatives from ministries, regulator, government agencies, industry, academia, accreditation body, certification bodies, training institutions and civil society organizations.

The Scheme will attest the technical competence of the GCP professionals boost user confidence and satisfaction and help the certified professionals in getting International recognition.

## Contact Us:

For more information, updates, please visit - https://thsti.res.in/cdsa/

Email: gcppcs.cdsa@thsti.res.in

## Learning and Development Activities

| S.No | Title | Link | Date |
|---|---|---|---|
| **QAI Trainings** | | | |
| 1 | Quality Management System and Internal Auditor Training Course as per ISO 15189:2012 | Click here to apply | 3-9 May 2021 |

| S.No | Title | Link | Date |
|---|---|---|---|
| **Startup India Workshop** | | | |
| 1 | Capacity Building Programme for Startups, Entrepreneurs, Professional & Students | Click here to apply | 16 April 2021 |
| **Association of Healthcare Providers India** | | | |
| 2 | Certified Healthcare Quality Practitioner (CHQP) | Click here to apply | 2 Months |
| 3 | Certified Infection 'Prevention & Control' Nurse | | 6 Months |

# QUALITY TOOLS

All the healthcare organisations are striving hard to intensify the business strategies and minimise the errors. Everyday, professionals are engaged in getting the desired result to meet the goal and commit to achievements. But no goal is accomplished without challenges and problems.

Kaoru Ishikawa came with a strategy to deal with such challenges in business. The cause-and-effect diagram helps in identifying different factors (or causes) leading to an effect, desiring to solve the problem. It is also called fishbone diagram for its resemblance to a fishbone. This is one of the seven quality management tools which helps in defining a quality-related problem on the right-hand side of the diagram, with various root causes and sub causes branching off to its left.

A fishbone diagram's causes and sub-causes are usually grouped into six main groups:

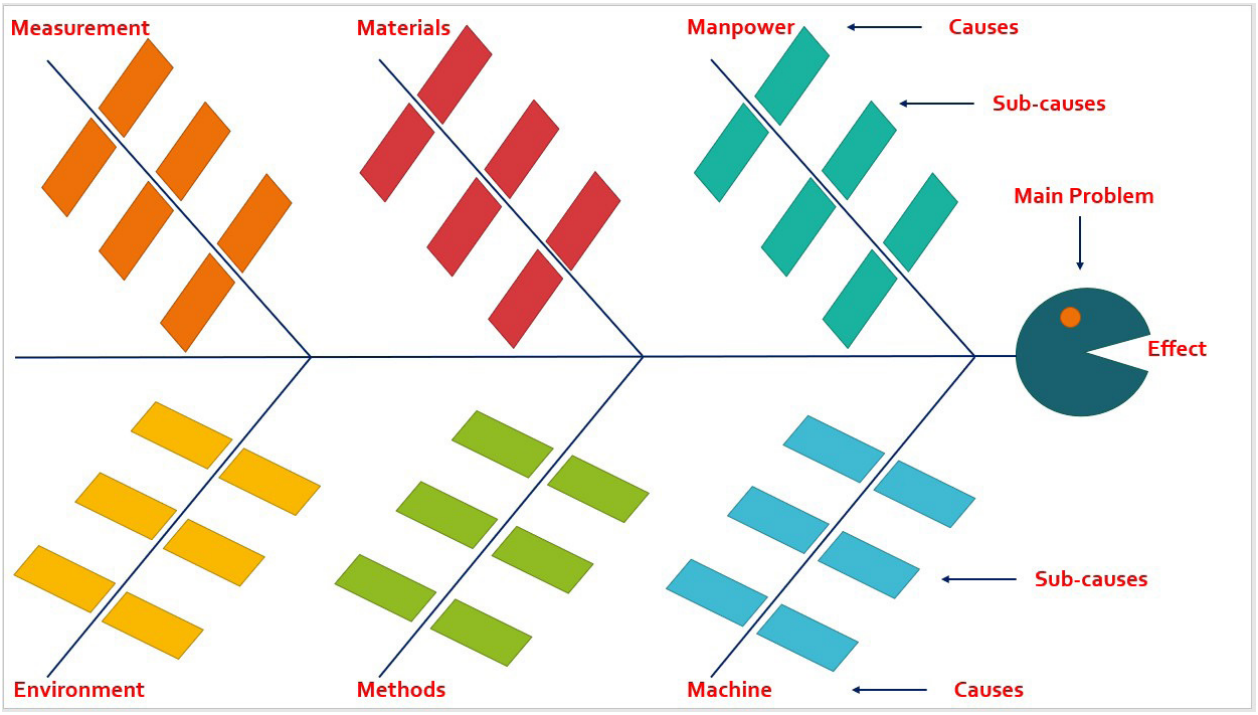
- Measurement
- Material
- Manpower
- Environment
- Method
- Machines

For a better understanding, refer to the structure below and frame one for your own actual problems and hypothetical for practice.

## Quiz Corner:

QAI is identifying effective readers. To become one, attend a quiz from the below link and become an effective reader. We are going to mention first five winners on our website. ALL THE BEST!

**Link:** https://forms.gle/Y5hE92XQRUJ2BA2x9




*Change Adapt Improve*

# Quality and Accreditation Institute

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