



**KALAM INSTITUTE OF
HEALTH TECHNOLOGY**



ANNUAL REPORT 2018-19



Kalam Institute of Health Technology

(Science is the sustainer of Life)

Annual Report 2018-19

**AMTZ Campus, Pragati Maidan, VM Steel Project S.O,
Visakhapatnam – 530031, Andhra Pradesh, India**

Governing Council 2018-19

Dr. Renu Swarup Secretary, Dept. of Bio-Technology & MD, BIRAC	CHAIRPERSON
Dr. Balram Bhargava Secretary, Dept. of Health Research, Govt. of India, Director General of the Indian Council of Medical Research	MEMBER
Dr. Poonam Malakondaiah Special Chief Secretary, Department Of Health, Medical & Family Welfare, Govt. of Andhra Pradesh	MEMBER
Sri Rajiv Agarwal Joint Secretary, Dept. for Industrial Policy & Promotion, Govt. Of India	MEMBER
Dr. Mohd. Aslam Senior Advisor, Dept. of Bio-technology, & MD, BIRAC	MEMBER
Dr. V. G. Somani Joint Drugs Controller India, CDSCO	MEMBER
Prof. B. Ravi Institute Chair Professor, IIT Bombay	MEMBER
Mr. Rajiv Nath Forum Coordinator, Association of Indian Medical Device Manufacturers	MEMBER
Dr. Jitendar Sharma Executive Director, KIHT	MEMBER SECRETARY

Executive Body 2018-19

Dr. Mohd. Aslam Senior Advisor, Dept. of Bio-technology & MD, BIRAC	CHAIRPERSON
Dr. Jitendar Sharma Executive Director, KIHT and MD & CEO, AMTZ	CO-CHAIRPERSON
Dr. Balram Bhargava Secretary, Dept. of Health Research, Govt. of India, Director General of the Indian Council of Medical Research	MEMBER
Dr. Rakesh Kumar Head – Strategy & Deputy Country Director, UNDP	MEMBER
Dr. Suresh Kumar K Scientist 'F', Office of PSA to Govt. of India	MEMBER
Dr. Alka Sharma Scientist 'G', Dept. of Biotechnology, Govt. of India	MEMBER
Dr. R. K. Srivastava Senior Advisor, Public Healthcare Innovations, WISH Foundation & Ex-DGHS	MEMBER
Mr. Rajiv Nath Forum Coordinator, Association of Indian Medical Device Manufacturers	MEMBER
Dr. Madhur Gupta Head, Pharmaceuticals & Technologies, WHO Country Office for India, New Delhi	MEMBER

Executive Body 2018-19

Prof. B. Ravi Institute Chair Professor, IIT Bombay	MEMBER
Dr. Meenakshi Sharma Scientist 'F', Indian Council of Medical Research	MEMBER
Mr. Nitin Bharadwaj Director & Vice President (Admin), AMTZ Assistant Director, KIHT	MEMBER SECRETARY

MISSION

Kalam Institute of Health Technology (KIHT) aims to facilitate focused research on critical components pertaining to medical devices by supporting institutions involved with R&D, industry, policy makers and knowledge repositories. This is sought to be achieved through transfer of technical knowledge and bringing together the strategic and coherent synergy of scientific facilities and institutions to complement efforts on industrial promotion. The outcome remains the single motto of bringing increased access to affordable health products to citizens and aid a thriving medical devices manufacturing sector in India.



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2018-19 Highlights

150

Technologies
for e-Auction

10

Dossiers

NIPUN
Certification



Patent
Examiner for
medical
Technology
Applications

Technical
Secretariat for
Government
e-Marketplace

Periodic
GlobExim
Reports on
Medical
Devices

Chapter 1 - The Year that went by

KIHT in its infancy stage captured the fancy of all stakeholders within the healthcare segment since there were widespread appreciation on multiple initiatives taken by this premier guidance Institute especially with its 'not for revenue approach' and willingness to extend support to key Central Government Departments, Research Institutions, Academia, Innovators and Manufacturers irrespective of the constraints of time or manpower support available.

Support to Central Government

KIHT continued its drive from it left its first year of operations in 2017-18 and carried forward its mission with more focus, passion and energy. Impact of KIHT support was observed by all its stakeholders in various ministries and departments. It was more evident in its second year of operation and strived well to achieve its objectives of:

For the first time in India, there was a focused effort to have a centralised system for addressing all the concerns and requirements of the Medtech industry and the 2nd year of its operations scaled peaks and swam through issues to synergise the efforts of the policy makers and the industrial requirements. Following were the notable achievements during the year 2018-19:

- a) Identification of key health technology gaps which could be identified for supporting Department of Bio-Technology to provide support for R&D focused development of Medical technologies; and
- b) Undertaking technology transfers of available technologies from academia and research institutes to the Health industry.



Chapter 1 - The Year that went by

In the second Governing Body meeting held on November 15, 2018 at New Delhi under the Chairmanship of Dr. Renu Swarup, Secretary, Department of Biotechnology, Govt. of India.

Some of the agenda discussed and mandate for KIHT to achieve as part of its functions by the Governing Body are as follows:

- i. KIHT to be appointed as a Patent Examiner For Medical Technology Applications by Controller General Of Patents, Designs & Trade Marks
- ii. MoU signed with Government eMarketplace on November 15, 2018, a collaboration for facilitating listing of medical devices in the procurement list of GeM and KIHT appointed as Technical Secretariat for Bureau of Indian Standards (BIS), actively involved in formulation, adoption and harmonization of standards for medical devices
- iii. It was proposed to setup a program in the name of 'Make in India leadership Institute' (MILLI), which will offer a rigorous certification program of three months duration for working professionals in the medical device sector
- iv. Affiliation of KIHT with Joanna Briggs Institute (Jbi), University Of Adelaide. KIHT would focus on medical devices, diagnostics and associate with other JBI centres in this domain of research. JBI in principle would be providing annual funding for the above as per their norms.
- v. The following recommendations were made by the Governing Body members to improve the functioning of KIHT and promote its strengths/ activities:
 - KIHT to compile a compendium of the medical technologies relevant to Aayushman Bharat.
 - KIHT to partner with Department of Biotechnology (DBT) for promoting a skilling system in all State Governments for the Biomedical professionals.
 - KIHT model to be promoted by DBT to all key Central Government departments to replicate such a model in other sectors.
 - Non-Regulatory Innovation Potential-Utility-Novelty certificate (NIPUN) programme of KIHT to be referred to Department of Health & Family Welfare for adoption, as a follow up of the reference already made by the Principal Scientific Advisor.
 - NIPUN certification programme shall converge with standards notified by the BIS notified in this sector.

Chapter 1 - The Year that went by

KIHT was notified by the office of the PSA in June 2018 as the **Project Analysis Unit** for all Health Technology Projects in the country based on a review meeting on the status of projects which received government funding in the health technology domain. The review meeting was held

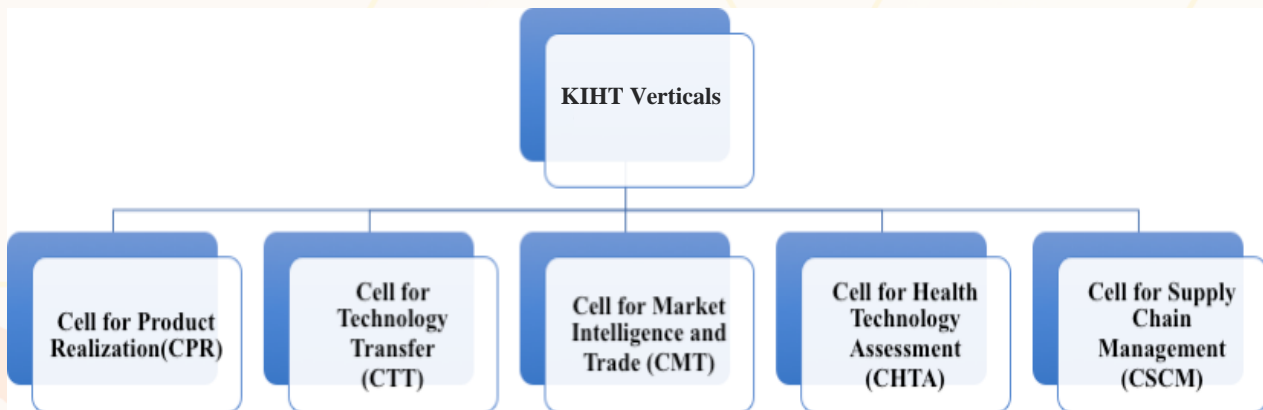
in KIHT new campus under the aegis of the Andhra Pradesh Medtech Zone Ltd, which created its own administrative office in the industrial zone near Vizag steel plant location within a record time of 113 days.



Chapter 2

KIHT Verticals

The scope of KIHT was expanded and additional cells became functional, depicted in the chart below:



I. Cell for Product Realization (CPR)

Cell for Product Realization (CPR) supports government to do focused spending of research grants on prioritized medical devices and their critical components which are highly imported. CPR also maintains a unique repository of product specific dossiers which provides end-end information to the readers with respect to the

clinical, technical, market review, operational, state-of-art, standards & regulations etc of the product. In addition, CPR also facilitates all stakeholders pertaining to developing medical devices by establishing the Core Scientific Facilities (CSFs), and through training programs. Its undertook the following activities:

A. Compendiums



Chapter 2

KIHT came out with unique type of technical compendiums, intended to disseminate information specific to devices in healthcare which are complex in technology and import dependent. These user-friendly dossiers capture key features of a product like clinical need & requirements, working principles, critical components, design &

technology upgradations, standards & regulations, market review, etc. and facilitates the readers like start-ups, students, researchers, academicians and manufacturers etc in taking decisions on R&D, investment, potential market, innovations etc. In 2018, KIHT published 12 technical compendiums.

B. LEARN - Product Specific Workshop Series

As part of its constant endeavour to cater to the needs of the medical devices industry, KIHT came out with first-of-its-kind workshop series 'LEARN' which imparts knowledge on 5 major dimensions of a specific medical device namely Live product teardown, Explore funding opportunities, Analysis of market potential, R&D strategizing, and Next level upgradation. The main objective of this unique program is to promote and accelerate

indigenous manufacturing of medical devices, which are achieved through encouraging start-ups and innovators by providing them a common platform. By attending such workshops, participants get enlightened with product specific knowledge apart from getting first hand knowledge on understanding intricacies of manufacturing and the challenges thereof.

LEARN I



(LEARN workshop on April 6-7 2018)

Chapter 2

In the first LEARN workshop was scheduled on 6-7 April 2018. A total of 31 participants were shortlisted which included biomedical professionals from hospitals, R&D engineers, and students etc. from

across India participated. In the workshop, three products, Anaesthesia workstation, Semi Auto Analyser and Infusion pumps were covered during this first workshop.

LEARN II



The second workshop in the LEARN series was organized on 31 August 2018. Ultrasound Machine and Dialysis machine were covered in this one-day

workshop. Thirty participants including students and biomedical professionals were participated.

LEARN III



Chapter 2



As part of LEARN series, KIHT conducted its third workshop to cover two products Ventilator & Defibrillator. In this two-day workshop, held on 01 & 02 March 2019, various technical sessions including clinical, theoretical, hands-on and teardown were organized and were handled by

professional experts and medical clinicians. Around 25 diverse backgrounded participants attended the workshop including Anaesthetist, Start-ups, Students and Biomedical engineers from diverse hospitals.

C. NIPUN Certification

NIPUN essentially is a system devised by KIHT to have a comprehensive certification mechanism under single umbrella and towards this objective, KIHT undertakes appropriate standards mapping, conformity assessment in empanelled labs, product testing, patenting, comprehensive Health Technology Assessment (HTA) and all other associated steps, which would make the medical product totally sanitised in non-regulatory

requirements which lead to issuing a certificate titled “ NIPUN निपुण (योग्य)”. This certification by KIHT encompasses all outcomes research studies, certifications required for the product and data etc. that can be used for regulatory filing in various countries. NIPUN thus aids/ boosts local manufacturing and also enhances the marketability of the products outside the country.

D. Standards Mapping

CPR team supports stakeholders in knowledge related to standards mapping, including various health technology-based start-ups and academic innovators. In addition, CPR also facilitated some

of the manufacturers in pre-compliance testing and Health Technology Assessment of their market ready prototypes and more than 8 requests are in pipeline as of March 2019.

Chapter 2

II. Cell for Technology Transfer (CTT)

To approach institutions and organizations engaged in core medical technology research, CTT team created database of every department and institutes under each of the Ministries. The team identified a total of 109 organizations

funded by the Government of India (GoI) for developing and innovating medical technologies. CTT team signed 28 MoUs with institutions, entities and individuals engaged in research and development in the medtech segment in this year.

One of the detrimental and intrinsic part of e-Auction is fixing the base price. However, innovators have been very subjective in fixing the base price and generally exceeded the total expenditure incurred thereby showing little interest to the bidders/manufacturers. To get a derivative and objective base price calculation CTT team constituted an expert group to determine the best possible method to analyse the base price using in-house built scoring method (Quantitative Approach) considering of the factors influencing the IP valuation. The same shall be used as a pilot method to determine the base price and put in the e-Auction portal.

A. E-Auction Portal

Since the launch of the portal on February 2018, the number of innovations listed on the portal has increased to 150. The innovations published include invitro diagnostics, early detection, implants, rehabilitation, and combinational products. Further, the healthcare innovations are

being classified into burden of disease, which shall be easy for the bidders (manufacturers) to bid the technology. Having done the preliminary exercise of collating the innovations available for auction, KIHT is now in the process of marketing the same to the industry.



Chapter 2

B. Memorandum of Understanding (MoU)

KIHT signed 28 MoUs in the year 2018 – 2019 for supporting e-auction of technologies and other KIHT services. The subsidiaries established at the AMTZ's, Medi Valley and Bio Valley Incubation

Councils utilize the CTT's consultancy by taking their innovations and placing them for bidding and also facilitating them for IP registration.

Sl No.	Organization
1	Novel Patent Services
2	Kalinga Institute of Industrial Technology
3	Entomology Research Institute, Loyola College
4	Manipal Academy of Higher Education, Mangalore
5	CDAC
6	BCIL, Delhi
7	CMET, Pune
8	Yenepoya University, Mangalore
9	Sineflex, Hydrabad
10	Biorx, New Delhi
11	IIT Delhi
12	IIT Hyderabad
13	IIT Kanpur
14	Mahendra College of Engineering, Salem
15	Mar Ephraem College of Engineering & Technology, Marthandam
16	IISC, Bangalore
17	SITRA, Coimbatore
18	Agni College of Technology, Chennai
19	Amity University, Noida
20	CSIR CLRI, Chennai
21	CSIR CGCRI, Kolkata
22	Datta Meghe Inst of Medical Sciences
23	Rajiv Gandhi Institute of Knowledge Technologies
24	MIT Pune
25	Chitkara University
26	IIT Ropar
27	VIT
28	Centurion University

Chapter 2

C. Technology Mela

CTT team conducted two Technology Mela events on the following dates to create awareness and attract innovators and manufacturers in the healthcare sector for bidding and purchase of innovations:

- i. October 1 2018, AMTZ, Visakhapatnam
- ii. February 22 2019, Pragathi Maidan, New Delhi Medical Fair India 2019

D. Patent Examination Centre

i. During the year, the cell expanded its scope of activities by providing services in Intellectual Property. This includes prior art search, patent application, patent examination request etc. CTT does prior art search for patent to be filed and filed applications, thereby giving the innovators if they are required to modify the existing innovation so no prior art exists. Further, it also helps prior art search to innovators seeking if their research idea is novel or existing one, as this search helps to avoid redundancy, cost and time saving. A report on patent was also published, "Patenting activity in medical device sector in India"

ii. The Controller General of Patents, Designs and Trade Marks acknowledged the efforts of KIHT and supported its cause for creation of a Patent Examination cell at KIHT This would help the CG Patents in identifying the right priorities for patent examination in the medtech sector, thus reducing the patent grant time period and also ensuring entry of the right technologies getting commercialized, which would address the concerns of the Indian healthcare system primarily.

III. Cell for Market Intelligence and Trade (CMIT)

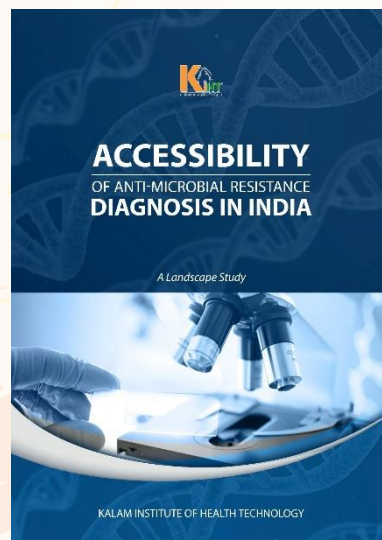
CMIT is the strategic arm of Kalam Institute of Health Technology, functioning to provide market intelligence on medical devices trade and distribution of medical devices in India. It also acts as a central repository for export import (EXIM) information, foreign direct investment (FDI), foreign institutional investment (FII) data of medical devices which includes angel, seed, venture and private equity (PE) funding players in HealthTech and MedTech greenfield and brownfield projects.

CMIT also engages in providing market analytics and assessment in various medical device projects and incubated medical devices start-ups at Andhra Pradesh Med Tech Zone (AMTZ), evaluating start-ups on their business model, market potential, commercial viability and also provide recommendation for devising a winning business strategy.

Chapter 2

A. Accessibility of Antibiotic Resistance Diagnostics in India - A Landscape Report

The report descriptively presented In-Vitro Diagnostics technologies available for diagnosing Antibiotic Resistance by companies and research groups working in development of novel technologies and key gap and challenges in pursuing research in this area. The report also describes the available technologies in India and list of companies who are marketing them.



B. Technical Compendiums

In 2018, CMIT in association with Cell for Product Realization (CPR) have published 12 techno-commercial compendiums intended to disseminate vital market analysis information to assist start-ups, techno-commercial researchers, academicians and manufacturers etc in taking

decisions on R&D, investment, potential market, innovations etc. The market information given descriptively covers the segment wise market size, the industry trends and prominent manufacturers (Indian and Foreign) of the devices

C. Med tech Regulation and Market Access in India, US and Europe

This report acts as ready reference guide for the regulatory approval process for manufacturing, sale and distribution of medical devices in India, US and Europe. The report captures the processes categorically and enlists the steps to be taken by the industry for getting registered and seek approval of for market access.

The report lists out all medical devices been approved in India from 2011 to 2018. An analysis based on the category and groups of medical devices is presented to derive an information on types of medical devices is been qualified for approvals; the trend is studied and presented quantitatively with the help of info graphics.



Chapter 2

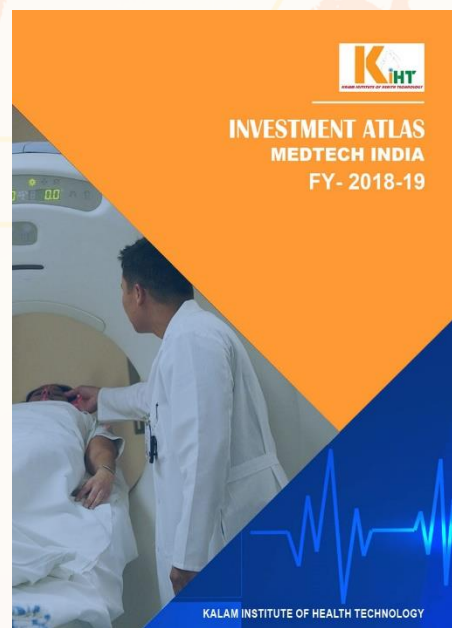
D. Glob Exim Report - Medical Devices

In 2019, the GlobExim report was prepared with a vision to map the types, value and volumes of medical device traded in India from global markets. The report analyses the types of medical devices and other related products traded in India, yearly trends and the classes of devices which are contributing in addressing the import burden of medical devices by their value, year on year growth and cumulative annual growth rate.



E. Foreign Direct Investment - Medical Devices

In November 2019, a detailed report covering FDI Investments in Medical Devices in India, Healthcare Star-ups and their funding and Mergers and Acquisitions in medical technology industry was prepared. The report captured the investment landscape in medical device and healthcare industry of India. The report would assist manufacturers, start-ups and other industry stakeholders to help them understand the investment dynamics and related avenues to raise capital via funding from venture capitalists and other associated financial houses.



Chapter 2

IV. Cell for Health Technology Assessment (CHTA)

KIHT after being recognized as a regional hub for Health Technology Assessment by Dept. of Health Research, Ministry of Health and family welfare, GoI, has got another feather in cap by getting associated with Joanna Briggs Institute, University of Adelaide as the Affiliated group. <http://joannabriggs.org/jbc.html>

The Joanna Briggs Collaboration (JBC) is a key body that contributes to the global success of the Joanna Briggs Institute (JBI), with respect to scholarly outputs and geographic footprint. The JBC has grown exponentially over the course of the 20-year history of the Institute and now incorporates more than 80 entities internationally across five regions of the world. The rationale of KIHT for pursuing JBI as Centre of Excellence is the conglomeration of JBI standards to the health technology landscape of India. Systematic Review, as defined by JBI standards would strengthen the HTA programme under KIHT and open up avenues both for government, academia

as well as private partners in more validated health access avenues.

The systematic and structured approach of the JBI system in carrying out bonafide systematic review and meta-analysis, enabled with due engagement with different international groups of JBI would act as a strong pillar in endeavours KIHT in improving market access of medical technology. The JBI process of developing transparent and evidence-based decision-making for health technologies, which would add value to the innovative product credibility by giving them comparative overview of clinical effectiveness and diagnostic accuracy. KIHT focuses on medical devices and diagnostic and associate with other JBI centres in this domain of research. All the studies done in this space would be submitted to JBI and KIHT would be involved in supporting and leading JBI in medical devices and diagnostic space globally.

A. Health Technology Assessment (HTA) Orientation workshop on January 25, 2019

Health Technology Assessment (HTA) orientation workshop was organised on 25th January 2019 to appraise innovators, clinicians, students and healthcare professionals about HTA. Approx. 30 participants from diverse health fields attended the workshop. Prof Anirban Basu from University of Washington gave a talk on economic

evaluation and the relevance of HTA. Dr Amit Dang and Dimple Dang from Marksman Healthcare communications presented on evidence synthesis and real-world evidence for HTA. The event concluded with a speech from Dr Jitendar Sharma (ED of KIHT).

Chapter 2

B. HTA as part of NIPUN (Non-Regulatory Innovation Potential-Utility-Novelty certificate)

To simplify the current process in the commercialization of product and to benefit the local manufacturers, KIHT undertakes series of processes Viz. mapping of suitable standards, confirmatory assessment in empanelled labs, product testing, comprehensive Health Technology Assessment (HTA) and all other

associated steps and thereafter issues the certificate duly with all outcomes research studies, certifications required for the product and data that could be used for regulatory filing in various countries. During the year three innovative products were taken up for HTA, systematic reviews were conducted for them as follows:

- A Systematic Review of innovative product - multi parameter monitor - ASHA device. The device does screening of blood pressure, ECG, blood sugar, temperature, pulse oximeter, and stethoscope.
- A Systematic Review of Innovative screening device based on Thermography for detecting breast cancer.
- A Systematic Review of Entonox - Delivery pain management
- Fixed dose combination of drugs versus monotherapy for treating primary hypertension in India – A Systematic Review.
- Thermography versus standard diagnostic/screening methods used in India to detect breast cancer.

C. New Automated Resuscitation Device

Protocol presented and approved by Technical appraisal committee of Department of Health Research.

D. Health policy work for Andhra Pradesh Government

As diabetes and hypertension are major non-communicable diseases, the Andhra government launched a programme on free medicines for the patients from private pharmacies also. This was an economic study which looked into the drugs which can be incorporated in the programme.

Chapter 2

V. Cell for Supply Chain Management

A. Bureau of Indian Standards (BIS)

Kalam Institute of Health Technology (KIHT) has been appointed as a technical secretariat to BIS to formulate the new standards and update the existing standards to improving the device safety performance tests that would help the

manufacturers and regulator. KIHT technical experts are nominated for 19 technical committees of BIS to contribute in the formulation of National Standards on relevant subjects.

The following are the KIHT Contribution till date to BIS

- i. No. of IEC/ISO/BIS Ballots attended - 75
- ii. No. of ASTM (American Society for Testing And Materials) Ballots attended – 45
- iii. No. of BIS sectional committees meetings attended 30
- iv. No of International Technical Committee Meetings attended- 01
- v. No of International Technical committee meetings proposed – 05

B. Government e-Marketplace (GeM)

GeM is a state-of-the-art one stop online public procurement platform that has used technology for transparent, efficient means to remove entry barriers for bona fide sellers with a wide range of goods and services. GeM helps in procurement of medical equipment in right quantity, of right quality, at right time, at right price and from right source is a very important function for any hospitals and clinics operated by Central or State Government agency. GeM is able to create a conducive environment for the domestic industry & entrepreneurs to do business with the Government. Taking into account the expertise of

KIHT, GeM, Department of Commerce, signed an MoU with KIHT on November 15, 2018 to support its functions in medical devices. KIHT has constituted a team of professionals to support exclusively for this purpose which would aid Indian manufacturing to get listed based on specifications decided by GeM and support Make in India in medical devices. KIHT and GeM are jointly promoting procurement of medical devices, surgical Instruments, medical consumables etc. on GeM portable in the country. The formulation of specifications and safety standards of various medical equipment is being validated by KIHT.

The following are the KIHT activities for jointly carrying out the work on promoting procurement of medical devices on GeM portal.

- i. Categorization of the Medical Devices into various specialties to understand the stakeholders of GeM.
- ii. Proposed new Technical Parameters forma.
- iii. Priority list of 529 Medical Devices as per the market demand.
- iv. Organized multiple GeM consultative committee meeting of buyers and sellers in association with GeM.
- v. No. of Specifications drafted for GeM – 220
- vi. No. of Specifications uploaded in GeM – 60
- vii. No. of draft Specifications in process – 80
- viii. No. of CCM Meetings conducted – 09

Chapter 2

C. Emergency Care Research Institute (ECRI)

KIHT entered into a global partnership with the world's renowned Emergency Care Research Institute (ECRI), an independent nonprofit organization that researches approaches to improving patient care globally on 13th December 2018.

ECRI Institute is an international organization with offices in the United States, United Kingdom, and Malaysia. India is the fourth office managed by

KIHT at Med Tech Capital of India, Andhra Pradesh Med Tech Zone (AMTZ), Visakhapatnam.

This association would help Indian health system, medical providers, government agencies, payers and other organizations in the private and public sectors.



Chapter 3

Independent Auditors Report

To
The Executive Director,
KALAM INSTITUTE OF HEALTH TECHNOLOGY.,

We have Audited the accompanying Financial Statements of KALAM INSTITUTE OF HEALTH TECHNOLOGY, a public charitable society registered under Societies Registration Act, 1860, ("the Society") comprising of Balance Sheet as at 31st March, 2019, Income and Expenditure Account and the Cash Flow Statement for the year then ended and a summary of significant accounting policies and other explanatory information.

Management's Responsibility for the Financial Statements

Management of Kalam Institute of Health Technology are responsible for maintenance of adequate accounting records for safeguarding the Assets and for preventing and detecting frauds and other irregularities, the selection and application of appropriate accounting policies, making judgements and estimates that are reasonable and prudent and the design, implementation and maintenance of adequate internal financial controls that are operating effectively for ensuring the accuracy and completeness of the accounting records relevant to the preparation and presentation of these financial statements that give a true and fair view and free from material misstatement, which are due to fraud or error which have been used for the purpose of preparation of the financial position, financial performance of the organization.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. While conducting audit, we have taken into account the provisions of the Act, the Accounting and Auditing Standards and matters which are required to be included in the Audit report as per provisions of the Act. We conducted our audit in accordance with Standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and the disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal financial control relevant to the Society's preparation of the financial statements that give a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on whether the Society has in place an adequate internal financial controls system over financial reporting and the operating effectiveness of such controls. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of the accounting estimates made by the Society's Office bearers, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion on the financial statements.

- C. The Balance Sheet, Income and Expenditure Account and the Cash Flow Statement dealt in this report are in agreement with the relevant books of account maintained for the preparation of the Financial Statements;
- D. In our opinion, the aforesaid financial statements comply with the Accounting Standards to the extent applicable to the organization
- E. In our opinion, the organization has utilized the proceeds of the grants only for the purposes for which it was received and is in accordance with the respective grant agreement.

With respect to other matters to be included in the Auditor's Report, in our opinion and to the best of our information and according to the explanation given to us:

- I. There are no pending litigations which would impact the financial position of the organization.
- II. The organization did not have any material foreseeable losses on long term contracts including derivative contracts.

Opinion

In our opinion and to the best of our information and according to the explanations given to us, the aforesaid financial statements give the information required by the Act in the manner so required and give a true and fair view in conformity with the accounting principles generally accepted in India:

- I. in the case of the Balance Sheet of the Financial Statements of the said organization as at 31.03.2019
- II. in the case of the Income and Expenditure Account, of there is no excess of Income over Expenditure and vice versa for the year ended on 31.03.2019 and;

For D M Rao & Co.,
Chartered Accountants,
Firm Reg 06995S

Place: Visakhapatnam
Date: 17-10-2019

Sd/-
D.Madhusudhana Rao
Partner
M.No.028434

BALANCE SHEET AS AT 31ST MARCH 2019

Liabilities	Sch	Amount As At 31.03.2019	Assets	Sch	Amount As At 31.03.2019
Corpus Fund	2	14,25,285	Fixed Assets	8	17,73,931
Unutilised Grants	3	95,8962	Receivables	9	1,70,090
Unsecured Loans	4	1,21,91,733	Deposits	10	1,80,000
Duties and taxes	5	7,35,688	Cash and cash equivalents	11	24,36,300
Provisions	6	31,500	Other current assets	12	10,46,980
Outstanding Expenses Payable	7	25,94,939	Excess of expenses over income		1,23,30,805
		17,938,106			17,938,106

See accompanying notes forming part of the financial statements In terms of our report attached

For D.M Rao & Co.,
Chartered Accountants
Firm Reg No -006995S

For and on behalf of Kalam Institute of Health Technology
(Regd. Society No. 123 of 2017)

Sd/-
D.Madhusudhana Rao
Partner
M.No. 028434

Dr. Jitendar Sharma
Executive Director

Place : Visakhapatnam
Date : 17-10-2019
UDIN : 19028434AAAAEN1160.

INCOME & EXPENDITURE ACCOUNT FOR THE YEAR ENDING 31.03.2019

Particulars	Sch	For the year ended 31.03.2019	Particulars	Sch	For the year ended 31.03.2019
HTA Recurring Expenditure			Direct Income	13	
To HTAI Staff Remuration	16	28,35,320	By Income from NIPUN		1,53,200
To Travel Expenses HTAI	17	5,09,858	By Consultancy Fees		75,00,000
To HTAI Promotion & Publicity	18	98,719	By Workshop Income		49,152
To Printing & Stationary	19	-			
To HTAI Registration & Membership	20	2,49,640	Grants from Governemnt Department	14	
To Workshop Expense	21	2,75,196	By Grant Recived from DBT		83,20,348
To Other Expenses HTAI	22	9,954	By Grants from HTA		39,74,874
			By Other Income	15	72,251
DBT Recurring Expenditure			By Excess of Expenditure Over Income		1,23,30,805
To DBT Staff Remuration	16	1,25,25,761			
To Travel Expenses DBT	17	29,68,480			
To DBT Promotion & Publicity	18	2,78,900			
To Printing & Stationary	19	1,85,701			
To DBT Registration & Membership	20	5,79,852			
To Workshop Expense	21	-			
To Other Expenses DBT	22	3,67,376			
To Sponsorship Expense		1,75,000			
To Capacity Building Program					
Recurring Expenditure-Own Funds					
To Staff Remuration	16	55,94,580			
To Travel Expenses	17	51,51,962			
To Promotion & Publicity	18	4,05,398			
To Printing & Stationary	19	-			
To Registration & Membership	20	-			
To Workshop Expense	21	1,08,813			
To Expenses HTAI	22	23,662			
To Depreciation	8	56,459			
		32,400,630			32,400,630

See accompanying notes forming part of the financial statements In terms of our report attached

For D.M Rao & Co.,
Chartered Accoun
Firm Reg No -006995S

For and on behalf of Kalam Institute of Health Technology
(Regd. Society No. 123 of 2017)

Sd/-
D.Madhusudhana Rao
Partner
M.No. 028434

Dr. Jitendar Sharma
Executive Director

Place : Visakhapatnam
Date : 17-10-2019
UDIN : 19028434AAAAEN1160.

Schedule 2: Corpus Fund	
Particulars	Amount 2019 Total
Capital Grant	
Capital Grant for Fixed assets	
i) DBT	12,61,878
ii) HTAI	1,63,407
Total	14,25,285

Schedule 3: Unutilised Grants	
Particulars	Amount 2019
Grant Received for Health Technology Assessment Programme (Specific Grant)	9,58,962
Total	9,58,962

Schedule 4: Unsecured Loan	
Particulars	Amount 2019
Loan From Related Party	
AMTZ	1,21,91,733
Total	1,21,91,733

Schedule 5: Duties and Taxes	
Particulars	Amount 2019
TDS Payable	3,43,995
GST Payable	3,91,693
Total	7,35,688

Schedule 6: Provisions	
Particulars	Amount 2019
Audit fee Payable	31,500
Total	31,500

Schedule 7: Outstanding Expenses payable	
Particulars	Amount 2019
(a) Empanel Fees Received in Advance	
M/s Diponed Biointelligence LLP	34,110
M/s. Marksman Healthcare Communications Private Limited	41,461
(a) Empanel Fees - Refundable	
Uniworld Medadvisors Pivate Limited	59,000
(a) Inhouse Consultants	
Biraj Swain	5,229
Dhruv Oberoi	4,845
Dr Devarshi Bhattacharyya	791
Ekram Hussain Basha Galeti	2,755
Gokul Krishna.V	157
Mr Agnideep Mukherjee	770
Mr Deepak Kumar	847

Mr Khasim M	235
Mr P Srinivasa Reddy	1,33,832
Mr Sandeep Patnaik	1,131
Mr Sandeep Reddy	1,200
Ms Mohini Anil Mehta	7,492
MSR Dikshit	4,764
N Naresh Kumar	373
Parminder Singh	786
P Harikanth	5,836
S Dinesh	314
Vamsi Krishna	1,865
(b) Other payables	
Ashoka Tours & Travels	8,07,670
Balmer Lawrie Travels & Vacations	2,27,426
Credit Card HDFC 7579 (CC)	3,593
DTDC Courier & Cargo Ltd	2,150
Experts Payable	5,000
Geetha Foods	15,392
Infiflex Technologies Private Limited	3,672
Inhouse Consultants	
International Travel House	1,058,199
M/s D M Rao & Co	14,000
M/s Photoden	1,50,044
Total	25,94,939

Note 8- Fixed Assets & Depreciation

Particulars	Gross Carrying Value				Depreciation						Net Carrying Value	
	As at 1st April 2018	Additions	Deletion	As at 31st March 2019	As at 1st April 2018	Deletion	Dep On OB	Dep On Addition	Depreciation for the year	As at 31st March 2019	As at 31st March 2019	As at 1st April 2018
A. Tangible Assets out of Capital Grants Received												
Computers & Laptops	4,74,841	6,98,290		1,173,131	-	-	4,03,29,321	17,22,996	-	-	1,173,131	474,841
KIHT 3D Logo	24,810		-	24,810	-	-	3,36,317	29,176	-	-	24,810	24,810
SSL Certificate		8,358		8,358							8,358	-
Basic Biomedical Engineer kit	5,392		-	5,392	-	-	16,721	-	-	-	5,392	5,392
TOTAL - A	5,05,043	7,06,648	-	1,211,691	-	-	4,06,82,359	17,52,172	-	-	1,211,691	505,043
B. Tangible Assets out of KIHT Funds												
Furniture & Fixtures	88,200	-	-	88,200	9,800	-			8,820	18,620	79,380	88,200
Software License	-	1,62,203		162,203					27,150	27,150	135,053	-
Office Equipment	1,82,090	22,800	-	204,890	9,584	-			20,489	30,073	184,401	182,090
TOTAL - B	2,70,290	1,85,003	-	455,293	19,384	-			56,459	75,843	398,834	270,290
C. Assets out of HTA Funds												
Computer and Laptops	-	80,000		80,000	-	-				-	80,000	-
Software Licenses	-	80,407		80,407	-	-				-	83,407	-
	-	1,60,407	-	160,407	-	-			-	-	163,407	-
GRAND TOTAL	7,75,333	10,52,058	-	18,27,391	19,384	-	4,06,82,359	17,52,172	56,459	75,843	1,773,931	775,333

Note :

- The society has received grant from Health Technology Assessment on 31/03/2018 amounting to 50,00,000/- vide F.NO.S.11011/08/2017-HR . Out of total Fund of Rs.50Lacs, Rs 8Lacs can be spent towards Misc. Expenditure. The society has therefore incurred Rs. 1,63,407/- towards purchase of Fixed Asset. As per the HTA order all the assets purchased out of grant shall be handed over to the department after completion of the project and if any such asset sold such sale proceeds of the same shall be the income of such department. Therefore depreciation for such assets has not been charged for the assets purchased out of such funds.
- Assets which are not approved by the Department of Bio Technology has been capitalised in the books of account and charged depreciation on the same. Further, an amount of Rs 56,459/- has been utilised from revenue grant to the extent of depreciation charged during the year.

Schedule 9: Receivables	
Particulars	Amount 2019
AMTZ Receivable	92,365
Green Ocean Research labs Ltd	60,025
Tuscano Equipments	17,700
Total	1,70,090

Schedule 10: Deposits	
Particulars	Amount 2019
Rental Deposits	1,80,000
Bank balances:	
Total	1,80,000

Schedule 11: Cash & Cash Equivalents	
Particulars	Amount 2019
Cash in hand	11,391
Bank balances:	
HFDC 50100210389242 (HDFC SB account)	24,24,909
Total	24,36,300

Schedule 12: Other Current Assets	
Particulars	Amount 2019
<i>Advances with Statutory Bodies</i>	
i) Cash ledger of GST	2,054
ii) Credit ledger of CGST	25,491
iii) Credit ledger of IGST	1,72,300
iv) Credit ledger of SGST	25,491
v) GST input	38,764
vi) TDS Receivable 18-19	7,76,320
Prepaid Expenditure	6,561
Total	10,46,980

Notes:

- Revenue grants received towards recurring expenditure is subject to reconciliation with utilisation certificate given for the purpose against the grants received
- During the year the society has received adhoc mobilisation advance from M/s AMTZ Limited amounting to Rs. 1,21,91,733. The same has been classified under Unsecured loans from related party for which the repayable terms and rate of interest is not determinable.
- During the year of 2017-18, Department of Bio-Technology has sanctioned a grant of Rs. 3,09,00,000/- to KIHT vide order no BT/MED/KIHT/01/2017. Out of the above grant in aid Rs. 1,60,50,000/- was released in month of August 2017, and has been completely utilized as on 31/07/2018 (as seen in utilisation certificate). Further, a Letter has been requested to release the balance amount of Rs. 1,48,50,000/- vide letter ref no KIHT/2018-19/ED062. In response to the request letter a corrigendum order was issued to the society vide BT/MED/KIHT/01/2017 dated 20-10-2018 where the grant amount was revised to Rs. 2,11,80,000/- from Rs. 3,09,00,00,000/-. The society thereby received the certain balance of fund of Rs. 45,75,000/- on 01.03.2019 from DBT towards recurring expenditure where the amount spent exceeded the actual amount of grant received by Rs. 93.46Lacs (noticed in UC). Project extension has been requested by KIHT vide letter dated 25.09.2018, Ref No: KIHT/2018-19/ED/069 for release of balance payments. Thereby with a view to receive the funds in near future the recurring expenses were actually incurred in excess by the society.
- The Balance of balances payable and receivable as on 31.03.2019 are good and secured and are subject to reconciliation
- The interest income earned of Rs. 1,57,042/- are respectively capitalised to grant of DBT & HTA proportionately.

Notes to Income and Expenditure account

Schedule 13: Income				
Particulars	HTA	DBT	OTHERS	Total Amount
Direct Income				
NIPUN	-	-	1,53,200	1,53,200
- Income from NIPUN 3,13,200				
- NIPUN expenses (1,60,000)				
Consultancy Fees	-	-	75,00,000	75,00,000
- AMTZ 45,00,000				
- AIC-AMTZ Medi Valley Incubation Council 15,00,000				
- Bio Valley Incubation Council 15,00,000				
LEARN Workshop Income	-	-	49,152	49,152
Total	-	-	77,02,352	77,02,352
Schedule 14: Revenue Grants received				
Particulars	HTA	DBT	OTHERS	Total Amount
Revenue Grant From Department of Biotechnology	-	83,20,348	-	83,20,348
Revenue Grant Received From Health Technology Assessment INST	39,74,874	-	-	39,74,874
Total	39,74,874	83,20,348	-	1,22,95,222
Schedule 15: Indirect Income				
Particulars	HTA	DBT	OTHERS	Total Amount
Empanelment Income	-	-	24,429	24,429
Merchandise Income	-	-	3,322	3,322
Sale of Dossiers	-	-	44,500	44,500
Total	-	-	72,251	72,251
Schedule 16: Staff remuneration & Training				
Particulars	HTA	DBT	OTHERS	Total Amount
Inhouse Consultancy	23,48,000	1,23,70,815	41,59,685	1,88,78,500
Per-Diem	1,28,364	1,08,902	2,97,356	5,34,622
Fellowship & Training	3,40,000	-	9,82,867	13,22,867
Reimbursements	18,956	46,044	1,54,672	2,19,672
Total	28,35,320	1,25,25,761	55,94,580	2,09,55,661

Schedule 17: Travel expense				
Particulars	HTA	DBT	OTHERS	Total Amount
Travel-Domestic	3,73,214	24,71,874	-	28,45,088
Travel-International			37,15,479	37,15,479
Hotel Accommodation	1,20,794	3,29,756	14,04,083	18,54,633
Service Charge	15,850	1,66,850	32,400	2,15,100
Total	5,09,858	29,68,480	51,51,962	86,30,300
Schedule 18: Promotions and publicity				
Particulars	HTA	DBT	OTHERS	Total Amount
Advertisement with HTAI	98,719	-	-	98,719
Caps/Mugs with KIHT	-	15,900	-	15,900
Corporate Gifts	-	45,650	-	45,650
Product Dossiers	-	83,050	4,05,398	4,88,448
Promotional Activities		1,34,300		1,34,300
Total	98,719	2,78,900	4,05,398	7,83,017
Schedule 19: Printing and Stationery				
Particulars	HTA	DBT	OTHERS	Total Amount
Flex Board	-	1,65,541	-	1,65,541
General Stationary	-	20,160	-	20,160
Total	-	1,85,701	-	1,85,701
Schedule 20: Registration and Membership Fees				
Particulars	HTA	DBT	OTHERS	Total Amount
HTAI Membership Fees	20,524	-	-	20,524
HTAI Registration Fees	2,29,116		-	2,29,116
Health Device Gold Membership Fees		5,01,535	-	5,01,535
International Standard Registration Fees		54,186	-	54,186
International Conference Registration Fees		20,700	-	20,700
DBA Prims Event Fees		3,431	-	3,431
Total	2,49,640	5,79,852	-	8,29,491

Schedule 21: Workshop Expenses

Particulars	HTA	DBT	OTHERS	Total Amount
LEARN Workshop Expenses	-	-	1,08,813	1,08,813
HTAI Workshop	2,75,196	-	-	2,75,196
Total	2,75,196	-	1,08,813	3,84,009

Schedule 22: Other expenses

Particulars	HTA	DBT	OTHERS	Total Amount
Audit Fee	-	35,000	-	35,000
Bank Charges	9,954	6,735	-	16,689
Commission Charges	-	1,06,200	-	1,06,200
Events/Body Meetings/Office Festivals expenses	-	1,13,448	-	1,13,448
Interest on TDS	-	2,332	-	2,332
GST Late Fees	-	300	-	300
Legal and Professional	-	14,200	-	14,200
Office Maintenance	-	-	23,662	23,662
Postage and Courier	-	7,922	-	7,922
Telephone/Internet	-	17,290	-	17,290
Hospitality Expenses	-	18,949	-	18,949
Honorarium	-	45,000	-	45,000
Total	9,954	3,67,376	23,662	4,00,992

KALAM INSTITUTE OF HEALTH TECHNOLOGY (Regd. Society No.123 of 2017)

Note 1: Significant Accounting Policies and notes on accounts

1.1. Society Information

Kalam Institute of Health Technology, a society registered under Societies Registration Act, 1860 was established on 23 February 2017 with the specific objective of to promote and facilitate development of medical technologies in India. The Society has approached the Department of Biotechnology under Ministry of Science & Technology for onetime support to facilitate research on critical components in medical devices sector through transfer of technical knowledge, policy implementation, market analysis and strategic interventions on industrial promotion in medical devices segment.

1.2. Basis of preparation of Financial Statement

Statement of Affairs have been prepared under the historical cost convention on going concern and accrual basis and generally comply with the mandatory Accounting Standards notified under the Companies (Accounting Standards) Rules 2006 (as amended).

1.3. Use of Estimates

The preparation of the Statement of affairs is in conformity with Indian GAAP which requires the Management to make estimates and assumptions considered in the reported amounts of assets and liabilities (including contingent liabilities) and the reported income and expenses during the year. The Management believes that the estimates used in preparation of the statements of affairs are prudent and reasonable. Future results could differ from these estimates and the differences between the actual results and the estimates are recognized in the periods in which the results are known / materialize.

1.4. Fixed Assets

Properties, Plant & Equipment are carried at cost less accumulated depreciation/amortisation. The cost of fixed assets comprises of purchase price, applicable duties and taxes, any directly attributable expenditure and other incidental expenses making the ready for its intended use, other incidental expenses and interest on borrowings attributable to acquisition of qualifying fixed assets, upto the date the asset is ready for its intended use.

Subsequent expenditure related to an item of tangible fixed assets are added to its book value only if they increase the future benefits from the existing asset beyond its previously assessed standard of performance.

Capital work-in-progress under which tangible fixed assets are not yet ready for their intended use are carried at cost, comprising direct cost, related incidental and attributable interest.

Depreciation has been provided on written down value method at the rates and manner provided for in the Income Tax Act, 1961.

Depreciation is not provided on Capital work-in-progress until construction and installation are complete and asset is ready for its intended use.

Depreciation is also not provided on Land as it is non-depreciable asset.

1.5. Revenue recognition

Interest earned on deposits is recognized as income net of interest attributable to unutilized grants.

1.6. Accounting of Government Revenue Grants

Generally, Government grants are recognized in books of account where there is a reasonable certainty of collecting the grant amounts. However, revenue grants are only accounted on actual receipt. Such revenue grants are recognized as revenue in the statement of Profit & Loss over the periods necessary to match them with related costs for which the grant is intended to compensate. However, any excess of grants over the actual expenditure is considered as a liability and accounted as Unutilized Grants.

1.6.1. Accounting of Grants related to Specific Fixed Assets:

Society has received the grants related to fixed assets from Department of Biotechnology. The Gross Value of the assets are treated as Fixed assets and depreciation has been not charged and the corresponding grant amount has been shown as Corpus fund in the Statement of Affairs.

Assets which are not approved by the Department of Bio Technology has been capitalized in the books of account and charged depreciation on the same. Grants related to depreciable assets are treated as deferred income which is recognized in the profit and loss statement on a systematic and rational basis over the useful life of the asset. Such allocation to income is usually made over the periods and in the proportions in which depreciation on related assets is charged.

1.6.2. Accounting of Grants related to Specific Purpose:

Generally, Specific grants are recognized in books of account where there is a reasonable certainty of collecting the grant amounts. However, specific grants are only accounted on actual receipt. Such specific grants are recognized as revenue in the statement of Profit & Loss over the periods necessary to match them with related costs for which the grant is intended to compensate. However, any excess of grants over the actual expenditure is considered as a liability and accounted as Unutilized Grants.

1.7. Provisions

Provision is recognized when the company has a present obligation as a result of past events. It is probable that the outflow of resources will be required to settle this obligation, in respect of which reliable estimate can be made. Provisions are not discounted at present value and are determined based on the best estimate required to settle the obligation as at the balance sheet date. These are reviewed at each balance sheet date and adjusted to reflect the current best estimate.

In terms of our report attached.

For D M Rao & Co
Chartered Accountants
Firm Registration No. 006995S

Sd/-
D. Madhusudhana Rao
Partner
Membership No. 028434

Place : Visakhapatnam
Date : 17-10-2019

For and on behalf of

Kalam Institute of Health Technology

Dr. Jitendar Sharma
Executive Director

Chapter 4

Media Highlights



Maharashtra Institute of Technology signed MoU with KIHT. Mr Kingshuk, CEO, Medivalley inaugurated the bioengineering facilities and also delivered an invited talk during the visit.

Cell for technology transfer, KIHT conducted the First Technology Transfer Mela at Medical Fair, Pragati Maidan, New Delhi. It was a thumping success with over 75 technologies on display.



KIHT in association with AMTZ & CII organised Start Up Day on March 25th, 2019 at Kalam Convention Center. Dr. Renu Swarup, Secretary- Department Of Biotechnology and Dr. Arabinda Mitra, Office of the principal Scientific Advisor graced the occasion. They visited the facilities in the campus and appreciated KIHT team lead by Dr. Jitendar Sharma for the huge amount of work accomplished within a short period of time.

Chapter 4

Media Highlights



Chitkara University signs MoU with KIHT which will pave way for more access points in MedTech and healthcare.

Representatives from 12 major companies along with Ms Manju Sharma, Dy CEO, GeM participated in GeM-KIHT radiology equipment specifications 2nd consultative meeting at AMTZ campus





KALAM INSTITUTE OF HEALTH TECHNOLOGY

(Department of Biotechnology, Government of India Project)

C/o AMTZ Campus, Pragathi Maidan, VM Steel Project S.O. Visakhapatnam, Andhra Pradesh, India - 530031.
Office : +91 88850 92122/33 | Website : www.kiht.in