

Kalam Institute of Health Technology (KIHT)

Innovations, at a certain stage of clinical clearance and prototyping, often require an essential clinical application-based assessment to cross the hurdles from bench to bedside. Medtech specific innovation leads, like for example, Health Technology Assessment (HTA), creation / adoption of medical device specific industry standards, technology upgrades in manufacturing, skill development programs etc., require a focused effort by a dedicated institution. It was with this objective **the Kalam Institute of Health Technology (KIHT)** was formed in July 2017.

The Department of Bio-Technology, Government of India acts as the nodal Department for supporting KIHT in meeting its objectives. KIHT facilitates focused research on critical components pertaining to medical devices by supporting institutions involved with R&D, industry, policy makers and knowledge repositories. It also provides guidance on market access and policy interventions for the medical technology sector.

This Policy Institute aspires to create a holistic ecosystem in India for medical technology development in the country as part of the healthcare needs of the country. The mission is to bring in affordable indigenous solutions for the Indian population which can serve as a model for other domains in the future.

The Principal Scientific Advisor to the Government of India has nominated KIHT as the Programme Management Unit for all healthcare technology projects in the country, thus making KIHT as the nodal Institution for giving constant inputs for policy support and ensuring highly focused funding for medical technology research.

KIHT has since its inception made inroads, inter-alia, in the following areas:

- ***Focused Research and Development:*** through landscaping the critical components of medical devices. KIHT is endeavouring to deliver the innovation needs of the country mapping devices specific to Indian context and subsequent funding focus in relevant Research. The Biotechnology Industry Research Assistance Council (BIRAC), a Public-Sector Enterprise of the DBT, is also collaborating with KIHT for focused funding for research initiatives in medical technology.
- ***Technology Transfer to Industry:*** Developing a system for Technology transfer from the government funded research projects to manufacturers and industry partners. Unique centralised **e-Auction portal launched on February 15, 2018**, for facilitating transfer technologies available with the research entities to the Industry. This aims

towards having a sustainable and transparent model of health technology transfer and use the revenue generated for systematic up-gradation of Research, by ploughing back the revenue.

- **HTA:** Annual Fellowship program is conducted with the objective of the imparting practical knowledge to the participants on how to report decision-making on health care technologies and health system interventions with multidisciplinary and evidence-based assessment approach. Participants from various research, academic and professional healthcare domains, especially from central research laboratories, healthcare administration, pharmaceutical sciences, clinical sciences and traditional medical research are integrated into this course.
- **Product Dossiers:** Indian medical industry players/ research/ stakeholders do not have enough information on this highly technology intensive sector. To facilitate dissemination of information on various products/ components of medical technology, KIHT has started making priced dossiers on product segments from April 2018. These give information relating to technology involved, product design features, target group, trade, patent applicable etc. This is expected to increase the awareness of the needs of the product segments and facilitate easy entry of newer players into manufacturing.
- **NIPUN certification:** Manufacturers/innovators/ start-ups in the medical technology sector do not have a clear understanding of regulatory as well non-regulatory requirements for developing a product with market authorisation. To facilitate entry of new players and creating market access avenues for existing manufacturers, KIHT launched on April 30, 2018 the facilitation programme under the name “NIPUN”. NIPUN certification of KIHT creates a platform for manufacturers or innovators to have a non-regulatory certification system by covering all related aspects under one umbrella viz: mapping of suitable standards, confirmatory assessment in empanelled labs, product testing, comprehensive Health Technology Assessment (HTA), etc and based on the certification process involved, the product qualifies for competing with internationally accepted norms for market access. The certificate is given along with all outcomes of research studies, certification process done for the product and this qualifies the product for moving for regulatory filing in various markets.

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