Medical Device:

Development, Testing, Regulations and Market Access

5th & 6th September | Venue: CeNSE Auditorium, IISc, Bengaluru

organized by **Tata Trusts PATH Impact Lab, CeNSE & CPDM - IISc**

Setting the Scene:

The number of medical devices with application in health management and point-of-care screening, diagnostics and treatment will skyrocket in coming years. An accelerated development and market adoption of innovative medical device in the healthcare ecosystem will require a greater and timely dissemination of right information to the medtech innovation community and call for a systematic discussion on the associated topics. We started planning this workshop by asking the question - what are the informational asymmetries in engineering, design and product development, regulations, quality assurance and market access strategies in the startup community of medical device and diagnostic technologies? Another important consideration in the planning of the overall workshop theme is the possible reduction of time taken for newly funded medtech startups to reach from proof-of-concept (POC) to production and market ready versions of their products.

The medtech sector is increasingly multidisciplinary and several new technologies in hardware and software systems, electromechanical sensors as well as digital technologies integrate to deliver the final product. In this fast changing and evolving medtech innovations space, the role of doing good biomedical design and quality engineering with fast paced prototyping, vendor engagement and market introduction will be the defining factor in the success of many of the new startups getting funded in the ecosystem. With increasing use of smart devices for population health management and hospital to home telehealth services, the requirements for device design, usability, human factor engineering and ergonomics become more critical to the success of products.

Another critical area that impinges on the medtech product development is the overall regulatory requirement. Understanding and navigating the regulatory landscape is extremely important for successful commercialization. As regulatory compliance requirements over healthcare safety, performance and security grow in medtech sector, the innovations ecosystem has to rise to the standards of safety and quality desired and required for a world class product. For examples, devices with electronics components and power supply need to comply to electromagnetic compatibility (EMC) testing and certification in pre-

clinical phase. Early compliance to these standards can help companies achieve global marketplace adoption in later phases.

Through this workshop, we are hoping to push the boundary of knowledge for medtech startups in their product development in supporting their quest to bring their products to market as desirable, functionally packed and high quality medtech products with low lead time. The workshop covers a breadth of topics which are relevant to both early stage and mature medtech startups planning their design and development, regulatory management, quality compliance, manufacturing and vendor engagement, clinical study and market access and adoption.

Agenda

DAY 1: Thursday, 5th September

09:30 AM - 10:00 AM Registration and Tea

10:00 AM - 10:10 AM Welcome & Setting the Scene, Satya P Dash, Impact Lab, PATH

10:10 AM - 10:20 AM Medical Device Development and Translation of Medical Research, Prof. Navakant Bhat, CeNSE, IISc

10:20 AM - 11:30 AM Plenary Lecture(s): Medical Device Design, Testing and Development Processes

The plenary lecture will focus on the needs of medtech companies during productization especially on the user need assessment, design and testing of medical devices, process and outcomes of device verification, testing laboratories, communication of results, and its regulatory connection. Also covered will be the aspects of incorporating usability, desirability, safety and functionality in a medtech product. The session will detail the overall development and verification process for medtech startups from the lens of large companies and successful startups.

11:30 AM - 12:00 PM Tea & Networking

12:00 PM - 01:30 PM Session 2: Risk Management, Compliance to Quality and Safety Standards in Medical Device Design & Manufacturing

Establishing essential performance and safety, meeting regulatory compliance, filing for product registration and implementing quality management system are keys to timely introduction and success of any medical device products in markets. Also covered in the session will be compliance requirements for application of Risk Management to Medical Devices (ISO 14971), Standard for Medical Electrical Equipment Safety (ISO 60601-1) and Application of Quality Management System for Medical Device Manufacturers (ISO 13485).

01:30 PM - 02:15 PM Lunch & Networking

02:15 PM - 03:30 PM Session 3: Sensors and (Bio)MEMS Technology in Medical Device, Calibration, Measurement Technique and Communication Standards

The complexities and issues in sensors and wireless technologies and their miniaturization have become important with more medical device startups in design for devices and diagnostics kits. Through this session, the startups can gain insights on current use of sensor technologies in medtech, the integration challenges, examples of successful application and their implication on medical device product development and specific compliance requirements in hardware, communication and software development.

03:30 PM - 04:00 PM Tea & Networking

04:00 PM - 05:00 PM Session 5: Medical Device Regulations, Pathways and Securing Regulatory Approvals

The session will cover regulatory guidelines and perspectives for MedTech products including devices and in vitro diagnostics. It will help companies to understand relevant laws & acts with respect to methods & procedures of manufacturing, clinical evidence generation, licensing, and import of devices in India.

05:00 PM - 05:30 PM Open Forum

05:30 PM - 06:00 PM Day 1 Close & Networking Tea

06:00 PM - 07:00 PM Guided IISc Campus Tour

DAY 2: Friday, 6th September

09:00 AM - 09:30 AM Day 2 Registrations

09:30 AM - 09:45 AM Welcome & Recap of Day 1, Dr Satya Dash, PATH

09:45 AM - 11:15 AM Session 4: Challenges in Vendor Engagement, Material Selection, Design for Manufacturing & Assembly (DFM, DFA)

Acceleration of engineering and manufacturing for MedTech products is possible only if there is a mature network of component vendors and OEMs. The session will discuss about current ecosystem challenges in vendor engagement in design and manufacturing. Also covered will be specific topics on medical grade materials (polymers, silicone, material handling processes, integrity in clinical environment, etc.), biomaterials and manufacturing clusters in India.

11:15 AM - 11:30 AM Tea & Networking

11:30 AM - 12:30 PM Session 6: Channels for National Market Access

The panel will cover lessons from global and Indian MedTech companies who successfully entered different regulated geographies - the dos & don'ts. It will share first-hand experiences of managing intricacies of interface with international regulatory bodies especially in regulated markets as well as experiences with unregulated geographies.

12:30 PM - 01:30 PM Session 7: Funding for Scaleup

The panel will discuss strategies for securing funding, both dilutive and non-dilutive, for scale of medtech innovation enterprises.

01:30 PM - 02:30 PM Lunch & Networking

02:30 PM - 03:30 PM Session 8: Study Design, Planning, Ethics Committee Approval and Management of Device Clinical Validation

The acceptance and confidence of medical community on any device depends upon clinical data and evidence generated in support of its safety, efficacy and performance. The

systematic planning, approvals, execution and communication of data for robust clinical studies as per standard guidelines will be discussed in this session.

03:30 PM - 04:15 PM Open Session (All Speakers)

04:15 PM - 05:00 PM Close & Networking Tea