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 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.

Speakers

- **Shyam Vasudeva Rao,** Founder & Director - Forus Health, Renalyx & Rx DHP
- **Chandrashekhar Nair,** Director, Bigtec

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).

Speakers:

- **Manoj Jain,** Site Head of Quality (APAC R&D), Boston Scientific
- **Nachiket Deval,** Co-founder, Coeo Labs
- **Guruprasad HC,** Lead Auditor - Medical Devices, TÜV Rheinland

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.

Speakers:

- **Vinay Chauhan,** Co-founder, Pathshodh Healthcare
- **Jayadeep Unni,** Founder, Sensivision Health Technologies
- **Dhananjaya Dendukuri,** Founder, Achira Labs

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

04:00 PM - 05:00 PM **Session 4: 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.

Speakers:

- **Malathi Lakshmikumaran,** Director - IPR, Lakshmikumaran & Sridharan Attorneys

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, Satya P Dash, Impact Lab, PATH**

09:45 AM - 11:15 AM **Session 5: 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.

Speakers:

- **Sukanta Bhatt,** Head University/Clinical Programs, Philips
- **Vinayak Nandalike,** Founder, Yostra labs
- **Deepak Raj,** Founder & Director, Osteo3D

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.

Speakers:

- **Neena Sonavane,** Philips India
- **Yogesh Patil,** Co-founder & Director, Biosense

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.

Panelists:

- **Satya P Dash,** Director, Global Innovations, PATH (Moderator)
- **Radha Kizhanattam,** Investment Director, Unitus Ventures
- **Premnath Venugopalan,** Head - NCL Innovations & Director - Venture Center
- **Mukesh Sharma,** Co-founder & Managing Director, Menterra Venture
- **Yogesh Patil,** Co-founder & Director, Biosense

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.

Speakers:

- **Anant Bhan**
- **Vinayak Nandalike,** Founder, Yostra labs

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

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

Speakers / Panelists (in alphabetical order of first name)	
 Anant Bhan	Anant Bhan is trained as a medical doctor with a masters' degree in bioethics from the University of Toronto. He is a researcher in the fields of Global Health, Health Policy and Bioethics. He is an Adjunct Visiting Professor at the Centre for Ethics, Yenepoya University, Mangaluru, India. He also works with Sangath, a leading health research organization in the field of mental health in their Bhopal hub. In the past, he has worked for NGOs and a government public health training institution in India, as well as a consultant to a project on Ethical, Social and Cultural issues in health biotechnology based at the University of Toronto, and as Senior Manager with the International AIDS Vaccine Initiative in their India Regional Office. Anant has published extensively in various national and international medical journals in the field of global/public health and bioethics, as well as contributed to popular mass media. He is on the Editorial Board of 'Public Health Ethics' (www.phe.oxfordjournals.org), a quarterly journal of Oxford University Press and also serves on the International Advisory Board of the Asian Bioethics Review http://www.asianbioethicsreview.com). He is also a member of the Ethics Working Group of the US NIH - funded HIV Prevention Trials Network (http://www.hptn.org/hptnresearchethics.htm). He serves on the Steering Committee of the Global Forum on Bioethics in Research and is currently the President of the International Association of Bioethics.
 Chandrashekhar Nair	**Director at Bigtec Private Limited** Chandrasekhar heads Bigtec labs and is Chief Technical Officer of Molbio Diagnostics. He received his Bachelors' and Masters' in Chemical Engineering from BITS Pilani. He has worked in Senior Management positions with the Vittal Mallya Scientific Research Foundation. He has extensive experience in bioprocess modeling, scale up and commercial implementation of bio and chemical processes. Over the past decade, his focus has been on realization of rapid, portable, high quality and low-cost diagnostics that would bring the power of a modern laboratory to near-care use. He holds number of Indian and International patents.

 Deepak Raj Karunakara	**Founder & Director, Osteo3D** Osteo3d provides affordable patient specific solutions to increase efficiency & accuracy of complex pre-surgical, surgical and post-surgical procedures using propreitary software & products. Deepak came to start Osteo3D with 15+ years of extensive industry experience working on systems, software interface and product development projects through roles in GE and Bosch Engineering with application in automobiles and medical devices.
 Dhananjay Dendukuri	**CEO & Co-founder, Achira Labs** Dhananjaya Dendukuri, PhD in chemical engineering from Massachusetts Institute of Technology, has established Achira as the premier microfluidics company in India. Dhananjay has more than a decade of experience with the technical, commercial, operational and regulatory aspects of the diagnostics business in India. He has received numerous awards including being named as one of 20 individuals to receive the Massachusetts Institute of Technology's (MIT's) Technology Review's prestigious TR35 awards and a New Technology Development Award from the President of India.
 Guruprasad HC	**Lead Auditor for Medical Devices, TUV Rheinland** Presently qualified as lead auditor for Medical Devices with audit experience of +10 years. Qualified from TUV Rheinland LGA products GmbH, Germany, TUV Rheinland Intercert cert, Hungary, and TUV Theinland, Italy on EN ISO 13485:2016 and MDD 93/ 42/ EEC, Qaulified Technical Reviewer in CAB office under SFDA, Saudi Arabia. With 15+ years of experience in Medical device design and manufacturing industries, worked in the areas of Medical device production, safety test, engineering, Design and Development, Safety and Regulatory Engineering (SRE) and Management representative.
 Jayadeep Unni	**Founder & CEO, Sensivision Health Technologies** Jayadeep has been in the medical device industry for close to 19 years. He worked in Medical Device companies like St. Jude Medical and Robert Bosch Telehealth in the US before returning to India to set up Sensivision in 2015. Jayadeep has a background in Biomedical engineering. He did his Bachelors in Biomedical Engineering from Model Engineering college, Kochi and then MS in Biomedical engineering from New Jersey Institute of Technology in US. He also has a business degree in Finance and Entrepreneurship from Santa Clara University in US.
 Malathi Lakshmikumaran	**Executive Director & Practice Head of Patents, L & S** Dr Malathi Lakshmikumaran has more than 30 years of experience in the field of biochemistry and Molecular Biology with an expertise in plant genomics, DNA fingerprinting and genetic transformation. She has successfully supervised several Ph.D. students in the area of

	Plant Molecular Biology. She has more than 100 publications to her credit in various International and Indian journals. Prior to joining the firm, she served as the Head, Centre for Bioresource & Biotechnology Division in The Energy and Resource Institute (TERI) for a period of 17 years. At present, she serves as an Executive Director and heads the IP division of the firm. She is a registered patent agent and has been actively engaged in preparing, filing and prosecuting of patent applications, both in India and abroad. She mainly works on pharmaceutical, chemical and biotechnological patent applications. She advises clients on plant variety protection and registration. She is actively involved in the area of Biodiversity and Traditional knowledge. Dr Malathi also undertakes extensive work for Start-ups and Incubates, especially with incubates in C-CAMP and IIT Delhi, advising them on Patents and Freedom to operate opinions.
 Manoj Jain	**Site Head of Quality - APAC R&D, Boston Scientific Technology & Engineering Services Pvt. Ltd. Gurgaon, India** Manoj Jain is the Site Head of Quality with Boston Scientific APAC R&D Center since September 2014.In his present role, he is leading, developing and mentoring a team of Quality Professionals and responsible for BSC APAC R&D quality. Prior to Boston Scientific, Manoj worked for ZIMMER-BIOMET, USA and was responsible for leading multiple strategic NPD/NPI projects including implantable Sternalock & Facial reconstruction devices and transfer projects including transferring of the implantable devices within the USA and USA to China. He has worked with Medical and Automotive industries for over 24 years in various cross functional areas which include Design & Development, Process & Manufacturing, Quality and Project Management. In his previous experience he worked with the USA FDA and EU certification/ notified bodies. Manoj holds Master of Science in Engineering Management from USA and Bachelor of Engineering in Mechanical Engineering from India. He is a certified Manager of Quality and Organization Excellence from ASQ, USA and Lean Six Sigma Black Belt from Villanova University, USA professional. He has taken active part in various working groups for harmonization and simplification of Quality Management Systems. He led the implementation of the quality management system and established a design assurance mechanical and software test lab for the BSC APAC R&D Gurgaon center to meet the ISO13485, MDSAP (Medical Device Single Audit Program) and ISO 17025 requirements for medical devices class I, II and III.

 Mukesh Sharma	**Co-Founder & Managing Director, Menterra Venture Advisors Private Limited** Mukesh is the Co-Founder and Managing Director of Menterra. Through the Menterra Social Impact Fund, he invests in start-ups that are harnessing the power of technology impacting India, by improving the quality of farming, healthcare and education. Over the last 17 years, Mukesh has invested in and worked on deals in several emerging and frontier markets. He has raised capital from diverse set of investors. Earlier, he was the Chief Investment Officer at Villgro, India's oldest and foremost social enterprise incubator. Mukesh has played an integral role in the idea to scale journey of several companies. He believes that non-linear outcomes are more likely to be achieved through big, game-changing ideas that leverage the latest science and technology. He has advised the board of several companies to deliver market-level returns with big sectoral impact. Currently, he is a non-executive director on the board of Biosense Technologies, Omix Labs, Adiuvo Diagnostics and Concept Learning.
 Nachiket Deval	**Co-founder, Coeo Labs** Nachiket Deval is the Co-Founder of Coeo Labs, a med-tech company based out of Bangalore, developing innovative and affordable medical devices in the field of emergency and critical care. He is a Masters in Product Design from National Institute of Design (NID), Ahmedabad, and has worked with companies such as Godrej and Boyce and Seasyst Engineering before starting Coeo Labs. He has 4 patent applications, 1 granted US patent and 5 research paper to his credit. Coeo Labs solves unmet clinical needs in the emergency and critical care settings and has currently developed and commercialised two first in world technologies – VAPCare, is an intelligent secretion and oral hygiene management system to reduce the incidence of Ventilator-Associated Pneumonia (VAP), a fatal infection of the ICU, and Saans is world's first multimodal transport CPAP (Continuous Positive Airway Pressure) device to provide assisted breathing support to neonates suffering from respiratory distress.
 Neena Sonavane	**Senior Manager Regulatory Affairs at Philips India Limited** Neena is Quality and regulatory specialist with 20 years of experience in the medical device industry. Her expertise spans QMS set up, NRTL marking, medical device standards and getting global access for products. In her current role, she is responsible for providing regulatory leadership by ensuring quality and efficient submission packages, partner with global project teams to get faster access to markets, maintain licenses over the lifecycle of the products, monitor, and track and ensure compliance to regulatory changes to ensure business continuity in respective markets. She is also

	responsible for ensuring regulatory strategies that are at least burdensome yet compliant approach for regulatory market access. By qualification, she is electronics engineer and a certified RAC professional (Regulatory Affairs certified for US FDA chapter).
 Premnath Venugopalan	**Founding Director - Venture Center and Head, NCL Innovations** He holds a B. Tech from the Indian Institute of Technology - Bombay and a Ph.D. from the Massachusetts Institute of Technology, USA. He has also been a Chevening Technology Enterprise Fellow with the Centre for Scientific Enterprises, London Business School and Cambridge University, UK. He brings with him considerable experience in technology development and commercialization, working with start-up companies (in Cambridge-UK and India) and engaging with large corporations on research and consulting projects as project leader.
 Radha Kizhanattam	**Investment Director at Unitus Ventures** Radha leads new investments and portfolio management for the firm. Radha brings experience building and commercializing technology products for global markets and evaluating early-stage startup investments in India. She helped make technology investments at Mumbai Angels, drove Product Marketing at GupShup, a cloud messaging startup and led product and engineering efforts at Texas Instruments and Motorola. Radha has a Master's in Computer Science from NITK and an MBA from IIM Bangalore.
 Satya P Dash	**Director Global Innovation, PATH Impact Lab** At PATH, Satya has a mandate to propel innovations in public health emergingfrom India to the next level. He oversaw the design and launch of Tata Trusts-Social Alpha's Quest in Healthcare Innovation program. Formerly, he was the Founding Head Strategy Partnerships &Entrepreneurship Development (SPED) at BIRAC (the nodal Indian biotech innovation agency) & as the 'Co-ordinator' of Make in India Cell in BIRAC. Cumulatively he conceptualized, designed & refined more than 12 programs at BIRAC including Biotech Ignition Grant (BIG), SPARSH, BioNEST, SEED &AcE Fund, SoCH, WinER, AMR partnership with Nesta UK, regional centres BREC & BRIC to name a few which have supported more than 800 biotech startups. He is an Independent Board Member at NCL's Venture Center, Pune-India's largest S&T focused incubator and was advisor to KBITS, Government of Karnataka for drafting of Biotech Policy 3.0 & advised Government of Odisha for biotech policy. He has also been Senior Consultant at IIM Bangalore & COO of nodal biotech industry association- ABLE where in 2012 he authored the Roadmap of the Indian biotech sector at the behest of the Department of Biotechnology (DBT), GoI that gave the goal of achieving US$100billion biotech industry for India. He holds triple masters from University of Leicester (UK),

	Cambridge (UK) and Sambalpur (India) and a PhD from University of East Anglia, UK. His interests are in S&T policy design, redesign, implementation and outcomes, business of science, early stage funding, entrepreneurship, and catalysing for positive serendipity across innovation communities.
 Shyam Vasudevarao	**Founder & Director, Forus Health, Renalyx, Rx DHP** Dr. Shyam holds a doctorate in Real Time High Performance computing Systems, specializing in Parallel Computer Architecture from the prestigious Indian Institute of Science (Gold medal) and has worked with CG Smith, Ericsson, Tata Consultancy Services and Philips. During his stint at Ericsson, Dr. Shyam, as the Center Head and General Manager, was responsible for building a technical team of more than 100 engineers, who were involved in new product development activities at Bangalore. Working as a Director of technology in Philips Innovation Campus, Bangalore, he established the innovation framework for consumer electronics and medical systems division. Dr.Shyam is on the governing council for leading institutions like PES Inst of Technology, SJCE Mysore, T John Institute, Nandhi, ATMA, Aditya Institute and visiting faculty at BMS Engineering, SJCE and MIT Manipal. He serves as a Technical Director for Maastricht University Medical Center, Netherlands since 2010 and has groomed more than 50 research programs in healthcare and life sciences.
 Sukanta Bhatt	**Head of Univ/Clinical Programs, Philips Healthcare Innovation Center (HIC), Pune** Dr Sukanta Bhatt holds a Ph.D. in Mathematics from IIT, Kharagpur. He has more than 29 years of experience spread across research, academics, MCAD, Medical SW design, SW V&V, SW test automation, Req management, Risk management, Medical device System & UX design, Approbation, Usability, System V&V and product release. He has played various roles in the industry like MCAD SW developer, Software architect, test architect, test manager, Dept manager V&V, Dept manager regulatory approbation, Dept manager System & UX design etc. He has also spoken in various conferences and workshops in India. Currently he is Head of Univ/Clinical Programs, Philips Healthcare Innovation Center (HIC) Pune.
 Vinay Chauhan	**CEO, PathShodh Healthcare Pvt Ltd, Bangalore** Vinay is an Indian Institute of Science, Bangalore alumnus with Ph.D. in Nano Science and Engineering. Bio-sensing technologies invented by Vinay are at the heart of PathShodh Healthcare. It has been Vinay's motto to ease the burden of people suffering from chronic diseases and serve the society. He is currently serving as the CEO of PathShodh Healthcare Pvt. Ltd., Bengaluru. His focus has been to invent out of the box solutions based on deep scientific exploration and translating scientific innovations to products and

	serve the population at large. His research has resulted in multiple patents and novel technologies for diagnosis of various disease markers. Vinay has many research publications and patents to his credit. His current research interests include the novel biosensing technologies for point of care applications. He is the recipient of MIT Technology Review TR35 award, INAE Entrepreneur award, Anjani Mashelkar Inclusive Innovation Award, IISc best PhD thesis award. Under his leadership PathShodh has also received FICCI Healthcare award, CII Grand jury award for best Innovation, Titan Tata Trusts Design Impact award for social change.
 Vinayak Nandalike	**Founder, Yostra Labs** Vinayak is the co-founder of Yostra Labs, a med-tech startup working on foot complications of Diabetes. He comes with rich experience in product development - from ideation to commercialization across multiple industry sectors.
 Yogesh Patil	**Co-founder & Director, Biosense** Yogesh is the co-founder of Biosense -a medical engineering and design firm developing revolutionary diagnostics. At Biosense, Yogesh's responsibilities include co-ordination of clinical research and patent strategy.He holds an MBBS in internal medicine from T.N.Hospital Mumbai and has a management degree from the Shailesh J Mehta School of Management, IIT Bombay.