MedTech Products: Navigating Global Markets and Regulations - Opportunities, Regulations, Case Studies

25-26 March 2019 | The Park, Connaught Place, New Delhi

An International Workshop Organized by
BIRAC Regional Bio-Innovation Center at Venture Center and
Tata Trusts PATH Impact Lab

Brief Description: The international workshop aims to provide MedTech Product companies (including devices and diagnostics and allied products) with information, access to experts, networks, role models to take their products through regulatory approvals in India and other geographies to help them enter global markets.

Organizers: BIRAC Regional Bio-Innovation Center (BRBC) at Venture Center and Tata Trusts PATH Impact Lab

Supported by:BIRAC, Venture Center, PATH, BRBC, RIFC, Social Alpha

For whom: Medical devices &diagnostics startups, Micro, Small and Medium Enterprises (MSMEs) and large companies/multinationals

When: 9:00 am – 8:00 pm; Monday, 25 March 2019
9:00 am – 5:00 pm; Tuesday, 26 March 2019

Where: The Park, 15 Parliament Street Opposite - Jantar Mantar, Connaught Place,New Delhi – 110001, India

ContactQueries:
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Navnath Kadam, Asst Manager, RIFC, Venture Center | 020-25865877/76 navnath@venturecenter.co.in

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Registration information: Pre-registration is mandatory. There is no registration fee.However, a **fully refundable deposit** of Rs 2000 per person shall apply.The organizers shall be providing a limited number of travel assistantship to deserving BIRAC grantees that are also registered startup companies.
Follow workshop website:http://www.brbc.venturecenter.co.in/conference/ for registration, applying for travel assistantship, and more information.

Introduction:

Medical devices including *in vitro* diagnostics comprise one of the fastest growing industries globally. Recent developments in Indian landscape such as introduction of the new Medical Devices Rules has played a crucial role in providing a distinct identity to the MedTechsector, and laid a foundation for performance manufacturing coupled with patient safety. With a renewed effervescence in the sector,medtech startups and manufacturers are seeking not only an in-depth understanding of regulations and compliance in India but also varied international geographies for potential growth and expansion. Their requirements may range from understanding of the regulatory processes & compliance to legal requirements, government communications, and market dynamics.

The joint workshop organized by **BIRAC Regional Bioinnovation Centre at Venture Center**and **Tata Trusts PATH Impact Lab**aims to demystify the national &international regulations regarding MDs and IVDs for Startups, Micro, Small and Medium Enterprises (MSMEs), and largecompanies/multinationals. The two-day workshop will help participants explore the regulatory and allied requirements in India, the US, the UK & EU, Japan & South East Asia, and the African continent. The workshop also endeavors to provide participants a clear understanding ofthe strategies including cost and challenges for entering international markets. This Workshop functions on introducing practices and prerequisites for the Indian MedTech startups and manufacturers to enter the international markets. Primarily the focus is on the regulatory processes and compliance, market access, government communications, and legal requirements in Asia, Africa, Europe, and North America.

Day – 1: Global Markets and Regulatory Pathways

09:00 – 10:00am **Registration**

10:00 – 11:15am **Session–1:Inaugural**

Setting the Scene by V Premnath (10min), Venture Center & **Satya Prakash Dash (10min),** PATH India

Special Talk (10 min):
Manish Diwan, Head - Strategy Partnership & Entrepreneurship Development at BIRAC, Department of Biotechnology, Government of India

Inaugural Address (45 min):
Shekhar Mande, Secretary, Department of Industrial Research, Government of India &Director General, CSIR

11:15 – 11:45am **Tea & Networking**

11:45 – 12:30pm **Session-2:MedTech Products: Global Opportunities and Market Entry Strategies**

The session will provide insights on Global trends and opportunities in MedTech product market including the investors' outlook. The session will also focus on regulations to enter markets in different geographies such as identification of authorized representatives, export partners, fees/ chargesand more.

Chair: Satya Prakash Dash, PATH India
Speakers:
Milind Antani, Nishith Desai Associates
Krishnakumar Sankaranarayan, PwC India

12:30 – 1:30pm **Session-3A:Understanding and Securing regulatory approvals**

The session will cover regulatory perspectives of MedTech products including devices and *in vitro* diagnostics to understand relevant laws&acts with respect to methods & procedures ofmanufacturing, licensing, and import in in India and other geographies (such as the USA, EU & Africa).

Chair: Ravindra Ghooi, Scientia Clinical Services
Speakers:
Malathi Lakshmikumaran,Lakshmikumaran & Sridharan Attorneys
Rubina Bose, CDSCO, India – West Zone

01:30 – 02:30pm **Lunch**

02:30 – 03:30pm Session-3B: Understanding and Securing regulatory approvals

The session will cover regulatory perspectives of MedTech products including devices and *in vitro* diagnostics to understand relevant laws&acts with respect to methods & procedures ofmanufacturing, licensing, and import in India and other geographies (such as the USA, EU& Africa).

Chair: Ravindra Ghooi, Scientia Clinical Services
Speakers:
Mohammad Ameel, NHSRC, Government of India
Walter Obita, Kenya Healthcare Federation

03:30 - 04:00pm Tea

04:00-05:30pm Session-4: Fire Side Chat – Regulations & Going Global

The fire side chat will be a panel discussion. The panel will highlight insights and lessons from regulators and senior leaders of global healthcare organizations on strategies to expand in regulated global markets. The aim is toprovide perspectives and uncover commonalities with the Indian system along with identifying significant unique features of the different international markets.
To be followed by QnA.
Moderators: **V Premnath, Venture Center& Satya Dash, PATH India**
Panelists:
MalathiLakshmikumaran,Lakshmikumaran & Sridharan Attorneys
Rubina Bose,CDSCO, India – West Zone
PVM Rao, IIT Delhi
Mohammad Ameel, NHSRC
Ravindra Ghooi, Scientia Clinical Services

06:00 - 08:00pm Networking Dinner

Day – 2: Global Medical Products from India

09:00 – 09:30am **Registrations & Tea**

09:30 – 10:00am **Recap & Setting the Scene for Day 2**
V Premnath& Satya Dash

10:00 – 10:30am **2nd Day Inaugural Session**

Inaugural Address: Renu Swarup, Secretary Department of Biotechnology, Government of India

(***The growing Innovation Ecosystem for Medical Products in India: Opportunities and New Initiatives***)

10:30 – 11:45am **Session-5: Medical Product Innovations from India with Global Reach**
The story of Indian MedTech products with global reach: Lessons from the art of the possible

Chair: Satya Dash, PATH India
Keynote Address: **Chandrasekhar Nair**, Bigtec
Keynote Address: **Nandakumar S**, Perfint
Invited Talk: **Krishna Kumar R**, Aurolabs

11:45 – 12:15pm **Tea & Networking**

12:15 – 02:00pm **Session-6: Public Health & Regulations – Perspective of Global Health Agencies**

Global health agencies play a critical role in the value chain of healthcare especially in working with governments and other multilateral partners in deployment and delivery of products to reduce the burden of disease. Experts in this session will touch upon the learnings from deployment of products in different geographies.

Chair: Satya Dash, PATH India
Speakers
Suman Rijal, DNDi India
Anthony Okoth, PATH Kenya
Krishna Reddy, Access Health &Relisys
Satyabrata Routray, PATH India

02:00 – 02:30pm **Lunch**

02:30-03:45pm **Session-7: Panel Discussion - Narratives of Global Navigation**

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. To be followed by QnA

Moderator: Srikant Sastri, Crayon Data

Speakers:
Neena Sonavane, Philips India
Suresh Kumar, GE Healthcare India

03:45- 04:15pm **Session-8: Recap &Valedictory**
Closure and Vote of Thanks
Manisha Premnath, Venture Center
Satya Prakash Dash, PATH India

04:15 – 04:45pm **High Tea & Close**

Dignitaries Inaugurating the Workshop Days

 **Renu Swarup**	**Secretary, Department of Biotechnology Ministry of Science & Technology, Government of India and Chairperson, Biotechnology Industry Research Assistance Council ,A Govt. of India Enterprise.** Dr Renu Swarup has taken over charge as Secretary, Department of Biotechnology (DBT). She has served in Department of Biotechnology for nearly 29 years and was holding the position of Senior Advisor/Scientist 'H' till she was appointed a Secretary to Government of India on 10th April, 2018. She also holds position of Chairperson, Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Company incorporated by the Government to nurture and promote innovation research in the Biotech Enterprise with special focus on Start-ups and SMEs.
 **Shekhar Mande**	**Secretary, Dept of Scientific and Industrial Research, Govt of India and Director-General, CSIR.** Dr Shekhar C. Mande is a Structural and Computational Biologist. He did his M.Sc. in Physics from University of Nagpur. He holds Doctor of philosophy in Molecular Biophysics, from the Indian Institute of Science. Following his PhD, he joined Prof. Wim G. J. Hol as Post Doctoral Fellow at Rijksuniversiteit Groningen in the Netherlands. Since 2001, he was senior staff scientist at Centre for DNA Fingerprinting and Diagnostics. Between September 2011 and September 2018 He served as director at National Centre for Cell Science in Pune, India. Currently he serves as the Director General of the Council of Scientific and Industrial Research (CSIR)-cum- Secretary, Department of Scientific and Industrial Research (DSIR), Govt of India. He was awarded in 2005 the Shanti Swarup Bhatnagar Prize for Science and Technology, the highest science award in India, in the Biological sciences category.

Faculty/ Mentors (in order of last names; alphabetical order)

 **Mohammed Ameel**	**Senior Consultant, Healthcare Technologies (Medical devices)National Health Systems Resource Centre a WHO collaborating center for priority medical devices & amp; health technology policy.** He spearheads the work of establishing technical specifications of medical devices for procurement under the National Health Mission (NHM).He also leads the work of identification and uptake of innovations that are of value in public health programs. He was recently invited by Harvard University under Harvard Project for Asian and International relations (HPAIR) to talk on uptake of health technology innovations under public health programs. The division of Healthcare technology also leads the work on Biomedical Equipment Maintenance Program, National Free Diagnostics Program (which includes free pathology service and radiology services), National Dialysis Program and other technology intensive healthcare Programs under National Health Mission (NHM). He has developed expertise of both product and service procurement through Public Private Partnerships (PPP) under Ministry of Health & Family Welfare. He is a member, Electromedical Equipment Sectional Committee, Bureau of Indian Standards. Member, Oxygen Therapy Review Group, UNICEF/WHO Headquarters. Collaborator, International Federation of Medical and Biological Engineering (IFMBE). Member of Technical committee of National Cold Chain equipment Specifications. Member in technical committee in QCI – AIMED Voluntary Initiative on Medical Devices. Assessor (Technical Expert), National Accreditation Board for Certifying bodies (NABCB). Trainer, Materiovigilance Program of India. He has co-authored: National Policy on National Biomedical Equipment Maintenance Program. Guidelines to setup medical device Testing Laboratories for EMI, EMC and Biomaterials. National Free Diagnostics Service Policy. Indian Certification for Medical Devices (ICMED) Scheme. WHO Technical specifications for oxygen concentrators. WHO Technical Specifications for Neonatal Resuscitator. National Dialysis Service Initiative (under Public Private Partnership).
 **Milind Antani**	**Lead, Pharma and Healthcare Practice, Nishith Desai Associates, Mumbai** Leads Pharma and Healthcare Practice at the multi-skilled, research-based international law firm, Nishith Desai Associates with offices in Mumbai- Nariman Point, Silicon Valley, Bangalore, Singapore, New Delhi and Mumbai - BKC, Munich and New York. He is also partner in charge of Social

	Sector Practice. Represents clients in matters including mergers and acquisitions, investments, regulatory and transactional matters, intellectual property prosecution and litigation, joint ventures and new companies. Practiced as an ENT surgeon in Gujarat for 14 years prior to joining Nishith Desai Associates. His practice areas include Pharmaceutical, Life Sciences, Healthcare, Social Sector, Intellectual Property and Medical Devices. He is involved in advising various corporate and not for profits in CSR and Social Business activities. Has been nominated as one of the world's leading practitioners in 'Who's Who Legal' for Life Sciences 2014 in the 'Regulatory' section as only lawyer from India. He has been conferred with the same distinction in 2015, 2016 and 2017. Has authored and co-authored many articles, publications related to the Pharma industry including a book on CRAMS. Have been invited by national and international forums to speak at conferences, seminars and webinars on the subjects of Pharma, biotech, IP, clinical trials,healthcare. Is a visiting faculty at NMIMS, IIPS, Bombay College of Pharmacy, SIES College, PG dept of Biotechnology. Attended Executive Education program "Managing and Transforming Professional Service Firms-India " by HARVARD BUSINESS SCHOOL. Member of the Committee of Tele-medicine Society of India. Had been very active Rotarian in RI District 3060 from 1995 to 2004, Jaycee member. Have been conducting soft skills workshops on various topics and have developed dedicated modules and has been GK Quiz Master. Loved playing badminton and read books.
 **Priyanka Bajaj**	**Manager – Health& Innovation, Impact Lab, PATH India** Priyanka holds a PhD in Microbiology from University of Delhi. Before PATH she was a Principal Investigator under the Science & Engineering Research Board (SERB-NPDF) scheme of Department of Science and Technology (Govt. of India). She has also worked with the University of Delhi South Campus-AMR team to develop a point-of-care diagnostic for detection of antimicrobial resistance in UTI pathogens. The project received "Discovery Award 2016" as part of wider Longitude Prize from NESTA UK and DBT- BIRAC India. At PATH she supports and advises on technical, clinical& regulatory aspects of products development of MedTech startups. She brings with her expertise in molecular biology, microbial pathogenicity, rapid point-of-care diagnostics, and public health.
 **Rubina Bose**	**Deputy Drugs Controller (I) in CDSCO (West Zone), Mumbai.** Dr. Rubina has Regulatory experience of more than 19 years, working in the Central Drugs Standard Control Organisation (CDSCO) in various capacities as Head of The Division (HOD), Zonal Head, Assistant Drugs Controller, and Drugs Inspectors.

	She is Doctor of Philosophy in Pharmacy, M Pharm, B Pharm from Jadavpur University, Kolkata. She has five years experience of working in the production of Injectable drugs before joining CDSCO. Currently, she is actively contributing as a WHO facilitator, WHO expert, WHO focal in various national and international affairs concerned about the regulations, assessments, practices, investigation, and guidelines of health tech products worldwide. Also, she is working as WHO facilitator in various national and international Advanced Good Manufacturing Practices (GMP) Training of inspectors in countries like China, Thailand, Indonesia, Vietnam, and Iran. She Worked as Deputy Drugs Controller (India) in CDSCO (HQ), MoHFW, DGHS, Govt. of India in the Divisions of a new drug, import registration, quality assurance of vaccines. Also, she was nominated by Govt of India in the four months rotational fellowship programme and worked in WHO Prequalification vaccine assessment team as Technical officer for four months at WHO (HQ), Geneva and participated in vaccine dossier assessment and inspection of vaccine manufacturer as a prequalification team member and also participated in other WHO meetings, guidance preparation activities.
 **Satya Prakash Dash**	**Director Global Innovations, Impact Lab, PATH India** 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 was advisor to KBITS, Government of Karnataka for drafting of Biotech Policy 3.0& currently advises 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.
 **Manish Diwan**	**Head - Strategy Partnership & Entrepreneurship Development at BIRAC, Department of Biotechnology, Government of India.** At BIRAC Dr. Diwan is responsible for all the Partnerships and Entrepreneurship Development activities including Bio-Incubators, BIG Scheme and Equity Investment Fund, in addition to all other activities of the Group.
 **Ravindra Ghooi**	**Director, Scientia Clinical Services.** He is also a Chairman, Institutional Ethics Committee, Jahangir Hospital, Pune. Chairman, Institutional Ethics Committee, Sahyadri Hospitals, Pune. Member, Symbiosis International University, Ethics Committee, Pune. Member, Cipla Palliative Care Centre, Ethics Committee. Member, Editorial Board, Perspectives in Clinical Research. Ph. D Guide, Symbiosis International University, Pune. Education: Graduation (B.Sc): Seksaria Science College, Belgaum. Chemistry and Zoology, Karnataka University. Post Graduation (M.Sc. Pharmacology): Karnataka Medical College, Hubli, Karnataka University Doctorate: HaffkineInstitute, (Ph.D. Medicine), University of Bombay. Specialties: Clinical Research Consultation Setting up of CR academies Consultation in setting up IECs Upgrading clinics to trial sites
 **Nikita Jhaveri**	**Project Associate – BRBC – BIRAC Regional Bio-Innovation Center.** P.S.M. (Professional Science Masters) in Biotechnology from University of South Carolina; M.Tech in Biotechnology from D.Y.Patil University, India B.Sc in Biotechnology from Mumbai University (Ruia College), India 9+ years of experience spread across Research Labs, teaching and assessments.
 **Navnath Kadam**	**Asst. Manager at RIFC- Venture Center.** He provides leadership to the RIFC at Venture Center, Pune. He regularly advises start-ups on planning their regulatory roadmap and facility planning. He is developing a suite of services and resources of use to start-ups. He has multifaceted working experience in managing Quality and Regulatory operations at Medical Device start-up Axio Biosolutions Pvt Ltd. He has completed PG Diploma in Entrepreneurship and Business Management from EDI, Ahmedabad and Master of Pharmacy with specialization in Quality Assurance Techniques from Poona College of Pharmacy, Pune.

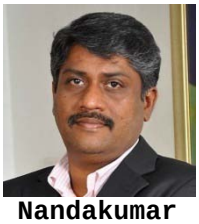
 **Shubham Kesharwani**	**Manager – Product Engineering & Innovation, Impact Lab at PATH India** Shubham graduated with a dual degree from Indian Institute of Technology, Kharagpurin mechanical engineering and brings with him deep expertise in product design, simulations, hardware control, programming, virtual instrumentation, testing and building integrative systems. He has gained experience on interdisciplinary project implementation with the Center for Railway Research where he conceptualized a wind tunnel facility to test high speed trains, an industrial fan of 1 Megawatt and worked on rail model testing in wind tunnels. At PATH he supports and advises on the engineering and manufacturing needs of the MedTech startups during product development and various healthcare projects.
 **Suresh Kumar**	**CTO – CCS Digital Incubators, GE Healthcare** Over the last 18 plus years at GE, Suresh and his team have been passionate in finding & solving their customer’s toughest problems in healthcare diagnostics and delivery. At Clinical Care Solutions, Suresh and his team are working on the next generation digital solutions across Primary care ultrasound, Patient Monitoring, Diagnostic Cardiology, Anesthesia & Maternal Infantile Care areas. His teams in last three years have delivered around 10 products for India and World. Prior to this role Suresh & his team led the Definition, Design & Development of Discovery IQ PET/CT, a breakthrough product for the Oncology Care area which was conceptualized, designed and developed In India for India and the world. Suresh is a certified Master Black Belt. Suresh holds a Doctoral Degree from IIT-Delhi.
 **Malathi Lakshmikumaran**	**Director, Lakshmikumaran & Sridharan, Attorneys** 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 a Director and heads the life science group at 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. Qualifications: PhD in Biochemistry Masters (Biochemistry) from Pune University Fellow of the National Academy of Sciences Awards: Recipient of National science talent scholarship Recipient of the prestigious Fogarty Visiting Research Associate ship from National Institute of Health, Bethesda, USA Recipient of the National Young Women Scientist Award by Department of Biotechnology in March 2000 Practice Areas: Biotechnology Biochemistry Genetic engineering and Molecular Biology Chemistry and Pharmaceuticals Biodiversity
 **Priya Nagaraj**	**Bio incubation Manager-Venture Center.** Priya holds a Ph.D. in Cell Biology from University of Virginia, USA. She worked with Advinus Therapeutics Ltd, a pharmaceutical drug discovery company for over 5 years. She has research experience in biochemistry, cell biology, developmental biology, molecular biology and drug discovery
 **Chandrashekhar Nair**	**Director at bigtec Private Limited** Dr. Chandrasekhar Nair is a co-founder of bigtec, an idea to product company in sensing technologies. His interests are in the development of rapid, low cost, high quality MEMS based diagnostic products. He holds a number of Indian and International patents
 **Anthony Okoth**	**PATH Kenya Country Director.** He is a former Chief Executive Officer for PS Kenya and also served as the Chief of Party on the USAID-funded Health Communications and Marketing Program. I have over 24 years of experience in public health programming and medical sales for HIV and AIDS, tuberculosis, reproductive health, malaria and nutrition from commercial and non-profit sectors across the continent with direct engagement with Key donors such as the Gates Foundation, DIFD and USAID. I hold a Master in Business Administration in Marketing from Daystar University in Nairobi – Kenya; a Post Graduate Course in Project Planning and Management from the University of Nairobi; a Diploma in Pharmacy, a degree in BSc Biological Sciences and a certificate in Strategic Perspectives in Non-Profit management from the Harvard Business School. I have the privilege of sitting on several governance boards and am a co-founding member of the Kenya Health Leader's Forum which brings together 10 leading organizations that contribute over $150 million annually to the health sector in Kenya through several bilateral agreements. I play a lead role in driving the Public Private Partnership (PPP) agenda in Kenya through the Kenya Health Federation (KHF) where I chair the PPP

	Committee which holds regular engagements with the private sector, civil society and government to address equity and common market failures.
 **Manisha Premnath**	**General Manager& COO, Venture Center** Manisha Premnath holds a PhD in Biotechnology from University of Pune and Post-doctoral training from University of Cambridge, UK. She has been a Chevening Rolls Royce Science, Innovation, Policy and Leadership Programme (CRISP) Fellow at the Said Business School, University of Oxford, UK during 2015 where she had the opportunity to study technology innovation ecosystems. She has research experience in biotechnology, microbiology, fungal biotechnology, molecular biology and molecular virology. She has experience in planning and setting up of advanced scientific facilities and program management.
 **Krishna Kumar R**	**Senior Manager QA & RA, Aurolab.** He is a Post graduate in Quality Management. He has over 20 years of experience in Quality Management and Regulatory Affairs. Krishna Kumar has started his carrier in pharmaceutical production. After a short span of 18 months he moved to Aurolab as Quality Control executive for its Medical device division. He spent his initial years to understand the already implemented QMS in line with ISO 9001. Alongside he started working on regulatory approvals including the European CE mark for the medical devices manufactured at Aurolab. Once the CE mark is secured for most of the products, he was promoted as Management Representative for QMS. Since then he spent all his time on effective maintenance of QMS and initiated various quality improvement activities like 5S, Quality Circles, TQM and so on. He initiated Statistical Process Control in all possible areas. During the course of his work, he has been exposed to various aspects of cleanrooms, associated Air Handling Systems, Pharmaceutical water systems, and related utilities. He has been involved in construction of integrated pharmaceutical and medical device facilities of Aurolab. Also he has taken part in designing and construction of OTs in hospitals. He coordinates several functions apart from QA and cleanroom construction like IPR, Strategy Planning and Calibration. In the span of last 20 years he has faced more than 30 external audits including customer and regulatory Audits. He has faced 4 USFDA audits and concluded successfully. He was managing the regulatory submission for our medical devices in various countries like Philippines, China, and Argentina etc… Having exposure on filing patents and other IPRs, he was instrumental in securing 4 patents for Aurolab on IOLs. Recently he is assigned with a task of strengthening

	companywide process capability by implementing Quality Improvement Projects through six sigma, lean& tries to win the IMC RK Bajaj National Quality Award within next 3-5 years.
 **Krishna Reddy**	Dr.Krishna Reddy Nallamalla began his career as a Cardiologist. He co-founded many enterprises with a mission to evolve models of high quality healthcare that is affordable and accessible. He led 50-member Cardiology Professional group as Managing Director. Co-founded Care Hospitals in 1997, a chain of tertiary care hospitals located in 5 states across India. Care Hospitals cater to ~1 million out patients and 100,000 in patients every year. Advanced procedures are done at 1/10th of cost prevalent in Developed nations with comparable outcomes. He has grown the chain across the country as CEO from 2006-13. He is currently directing various Preventive and Disease Management programs, including NCD Prevention Program, Heart Failure Program, and DiaCare program for Diabetes, STEMI Care for Acute MI etc. Founded Relisys Medical Devices in 1998 in order to create indigenous technology platform for medical devices to make them affordable. Relisys is the first company in India to have end-to-end technology capability for Stents, Catheters, and Drug-delivery systems. On account of self-sufficiency, the cost of cardiac devices has been rapidly decreasing over last few years. He is currently acting as its Chairman & MD. Piloted a unique Rural Healthcare delivery model in 200 villages having ~ 1 million populations. The model was based upon specifically trained Village Health-worker enabled with hand-held point-of-care technology solutions. It also is evaluating the role of Micro-insurance for Primary Care. He is also involved in developing Models of Primary care and Integrated care. Joined ACCESS Health International as Country Director, India to lead Health Systems Research and Transformative initiatives with an overarching objective to see Healthy & Happy India.
 **Suman Rijal**	**Director, Drugs for Neglected Diseases initiative** A non-profit Research and Development organisation. He undertook his medical training from Calcutta Medical College Kolkata, and Internal Medicine in United Kingdom. He was awarded a PhD in 2006 from University of Gent, Belgium. He has been actively working in the field of neglected tropical diseases particularly kala-azar since last 2 decades. He has lead and coordinated several collaborative clinical and operational research projects in epidemiology, validation of diagnostic tests, clinical trials etc. Prior to this he worked as Professor of Internal Medicine and Tropical Diseases at a University Hospital in Eastern Nepal for 20 years. He is a member of several national and international committees including the

	WHO Expert Panel on Parasitic Diseases (Leishmaniasis), Geneva, Regional Technical Advisory Group on VL Elimination at SEARO/WHO and National Advisory Committee of Kala Azar Elimination, Government of India.
 **Krishnakumar Sankaranarayan**	**Executive Director at PwC India, Mumbai.** His core focus is on Medical Devices sector and his role involves assisting clients with their growth strategy, technology enablement and business transformation. With over 20 years of experience in the medical technology industry in India, Krishnakumar has worked across various roles including medical device research and development, technology transfer, sales and marketing, business strategy and consulting. During this time he has successfully launched several state-of-the-art medical technologies in the Indian market. He has also spent time studying healthcare systems in other developed and developing countries like India, UK, Bangladesh, and Bhutan from close quarters. A keen writer, Krishnakumar has authored numerous papers on healthcare issues, which have been very well accepted by leading National and International Conferences. EDUCATIONAL QUALIFICATIONS Masters Degree in Technology with Specialization in Biomedical Engineering MBA from Indian Institute of Management (IIM) Calcutta. PROFESSIONAL QUALIFICATIONS PricewaterhouseCoopers, Managing Consultant 2008 to 2012 Marketing Manager, Hospimedica International Ltd : 1994-2006 Senior Scientific Officer, IIT Delhi : 1991-1994
 **Srikant Sastri**	**S**rikant Sastri is a seasoned entrepreneur and bridge-builder. He provides strategic leadership as the co-founder of Crayon Data, the ambitious Singapore headquartered start-up, which aims to build global business around Big Data platform and products. This is his third start-up. As a successful entrepreneur, Srikant had founded India and Southeast Asia's largest CRM & Digital agency, Solutions – Digitas, in 1995. In his most-recent role as VivaKi India Chairperson, Srikant led an ambitious M&A strategy to help the Publicis Groupe establish digital leadership in India, through three cutting-edge acquisitions. Respected as a leading marketing & CRM practitioner, Srikant started his career at Unilever and McCann – Erickson, and was recently inducted into the DMAi 'Hall of Fame'. He has been on the jury at Cannes Advertising Festival. At Crayon Data, Srikant loves being in the midst of crazy ideas, energetic people, and ambiguity. Srikant works closely with, and nurtures several tech start-ups, and is an active angel investor. He earned an Engineering degree from IIT, Kanpur

	and a Post-Graduate qualification in Management from IIM, Calcutta.
 **Neena Sonavane**	**Senior Manager Regulatory Affairs at Philips India Limited, Pune.** 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 an electronics engineer and a certified RAC professional (Regulatory Affairs certified for US FDA chapter).
 **Nandakumar Subburaman**	**Chief Executive Officer (CEO, Co – founder, Perfint Healthcare Pvt Ltd.** Nandu started his career in GE Healthcare and held various responsibilities in Supply Chain, Operations, Six Sigma, Sales and lastly as Vice President, Finance. He was a part of the team that helped build a strong technology, manufacturing and component sourcing base while also establishing a robust sales and service set-up for GE Healthcare in India and is a Certified Master Black Belt in Six Sigma. After GE, Nandu had a brief career outside healthcare as Director – Process Excellence at Cognizant Technology Solutions and COO at Ambit Corporate Finance before co-founding Perfint Healthcare. As CEO Perfint Healthcare, Nandu has been awarded the Indira Innovation Award and Udyog Rattan Award by Institute of Economic studies and has been a regular speaker on Healthcare, Entrepreneurship and Innovation at various forums. He is an alumnus of the Indian Institute of Management, Lucknow and

	Government College of Engineering, Tirunelveli.
 **Premnath V**	**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.
 **Obita Walter**	**Director at Kenya Healthcare Federation. Director, Sustainable Healthcare Foundation** Walter is a medical doctor and healthcare management specialist based in Kenya. His areas of expertise are management of healthcare institutions, health systems management, investments in healthcare, healthcare franchising, public-private partnerships, healthcare financing, health policy and regulatory reforms.

About the Organizers	
PATH	**Tata Trusts PATH Impact Lab (TPIL)**, established in 2018, is set out on the mission to accelerate new medical technology adoption in public healthcare and to propel affordable healthcare solutions through a range of activities and programs. TPIL identifies and supports MedTech products which show potential to positively impact the healthcare landscape in India and beyond. The selected MedTech startups are supported in product development, clinical trial design and implementation, standards and regulatory compliance, risk management and quality control, global certifications, needs analysis, usability study, business model, market dynamics and funding support. For more information, visit: https://www.path.org/For more information, visit: https://www.path.org/
BRBC A BIRAC - Venture Center Initiative	**BIRAC Regional Bioinnovation Centre (BRBC)** is the third regional centre of BIRAC and is located in Venture Center. BRBC aims to fill up key innovation ecosystem gaps for bio-based industry sectors and thus significantly impact the translation of high quality innovative ideas into viable and sustainable business enterprises. Some key BRBC initiatives are Venture Mentoring Service; Venture Base Camps; Regulatory Information and Facilitation Centre; Bio Incubation Practice School More on: http://www.brbc.venturecenter.co.in/

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birac Ignite Innovate Incubate	**Biotechnology Industry Research & Assistance Council** is a non-profit company created by the Department of Biotechnology (Government of India) with a mandate to develop the national ecosystem for biotechnology innovation and entrepreneurship and provide targeted support to innovators and entrepreneurs. For more information about BIRAC: www.birac.nic.in
VENTURE CENTER	**Entrepreneurship Development Center (Venture Center)** – a CSIR initiative – is a Section 25 company hosted by the National Chemical Laboratory, Pune. Venture Center strives to nucleate and nurture technology and knowledge-based enterprises by leveraging the scientific and engineering competencies of the institutions in the Pune region in India. The Venture Center is a technology business incubator supported by the Department of Science & Technology's National Science & Technology Entrepreneurship Development Board (DST-NSTEDB). Venture Center focuses on technology enterprises offering products and services exploiting scientific expertise in the areas of materials, chemicals and biological sciences & engineering. For more information, visit www.venturecenter.co.in

PATH	**PATH** is a global organization that works to acceleratehealth equity by bringing together public institutions,businesses, social enterprises, and investors to solve theworld's most pressing health challenges. With expertise inscience, health, economics, technology, advocacy, anddozens of other specialties, PATH develops and scalessolutions—including vaccines, drugs, devices, diagnostics,and innovative approaches to strengthening healthsystems worldwide. For more information, visit: https://www.path.org/
RIFC	**The Regulatory Information and Facilitation Center (RIFC)** is a joint initiative of the Venture Center and BIRAC under the BIRAC Regional Bio-Innovation Center (BRBC) program. The RIFC aims to assist bio-entrepreneurs in planning, seeking and securing regulatory approvals. The RIFC plans to achieve this by providing information in an entrepreneur-friendly manner, providing access to experts and regulators, providing access to practical insights from other entrepreneurs, providing services and organizing relevant and useful events. More on: http://rifc.venturecenter.co.in/
SOCIAL alpha	**Social Alpha** promotes innovations and entrepreneurship with a mission to create large scale sustainable social, economic and environmental impact. Social Alpha nurtures start-ups through their lab to market journey, helping them create high quality, commercially viable, accessible and affordable solutions. Social Alpha is focused on catalysing entrepreneurship for impact and provides critical technology and business incubation support to the mission driven start-ups. More on:www.socialalpha.org

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