# Report on International Workshop

## MedTech Products: Navigating Global Markets and Regulations

### - Opportunities, Regulations, Case Studies-

**25-26 March 2019 | The Park, New Delhi**

**Contents**

# Acknowledgment

The international workshop was aimed 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.

BIRAC Regional Bio-Innovation Center (BRBC) at Venture Center and Tata Trusts PATH Impact Lab are thankful to logistics organizers, speakers, and participants.

**Internal support:**

**Logistics and management, Venture Center, Pune**

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**Tata Trusts PATH Impact Lab**

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**Organizers**

**BIRAC Regional Bioinnovation Center (BRBC) at Venture Center, Pune**

**Venture Center, Pune & team**

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**Tata Trusts PATH Impact Lab & team**

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**Supported by**

Biotechnology Industry Research & Assistance Council
Entrepreneurship Development Center (Venture Center)
Regulatory Information and Facilitation Center (RIFC)
Social Alpha

# Introduction

Medical devices including in vitro diagnostics comprise one of the fastest growing industries globally. Recent developments in Indian landscape such as the introduction of the new Medical Devices Rules has played a crucial role in providing a distinct identity to the MedTech sector and laid a foundation for performance manufacturing coupled with patient safety. With a renewed effervescence in the industry, 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 knowledge of the regulatory processes & compliance with legal requirements, government communications, and market dynamics.

BIRAC Regional Bioinnovation Centre organized the joint workshop 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 large companies/multinationals.

The two-day workshop found helpful for the participants to explore the regulatory and allied requirements in India, the US, the UK & EU, Japan & South East Asia, and the African continent.

The workshop also focused on the strategies, cost, and challenges for entering international markets. The core function of the workshop was to introduce the practices and prerequisites for the Indian MedTech startups and manufacturers to open the global markets. The primary focus was on the regulatory processes and compliance, market access, government communications, and legal requirements in Asia, Africa, Europe, and North America.

This workshop was useful for innovators and startups in the following medical device categories: *Clinical grade screening, diagnostic and recording instruments* | *Medical devices for clinical intervention or treatment* |*Surgical tools and aids* | *Assistive devices or disability aids or image reconstruction or artificial body parts* |

*Molecular in vitro diagnostics | Topical, surface and open wound contact products or products in body orifices | Implants made from polymers, body tissues, metal, plastic, ceramic etc| Sensors, IOT, Big Data, Mobile, Cloud, AI/ML, Analytics, decision support, software etc used for making medical decisions | Supplies & consumables used in diagnostics, preservation, hospital equipment | Recreational and popular diagnostics, wearable.*

# Content

## *Workshop outline:*

**Session–1: Inaugural**

Setting the Scene by V Premnath, Venture Center
& Satya Prakash Dash, PATH India

**Special Talk:**

Manish Diwan, Head – Strategy Partnership & Entrepreneurship Development at BIRAC, Department of Biotechnology, Government of India

**Inaugural Address**

Shekhar Mande, Secretary, Department of Industrial Research, Government of India &Director General, CSIR – 25th March 2019

Inaugural Address: Renu Swarup, Secretary Department of Biotechnology, Government of India – 26th March 2019
(The growing Innovation Ecosystem for Medical Products in India: Opportunities and New Initiatives)

**Session-2: MedTech Products: Global Opportunities and Market Entry Strategies**

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

Chair: Satya Prakash Dash, PATH India

Speakers:
Milind Antani, Nishith Desai Associates
Krishnakumar Sankaranarayan, PwC India

**Session-3A: Understanding and Securing regulatory approvals**

The session covered regulatory perspectives of MedTech products including devices and in vitro diagnostics to understand relevant laws & acts concerning methods & procedures of manufacturing, licensing, and import 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

**Session-3B: Understanding and Securing regulatory approvals**

The session covered regulatory perspectives of MedTech products including devices and in vitro diagnostics to understand relevant laws&acts concerning methods & procedures of manufacturing, 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

**Session-4: Fire Side Chat – Regulations & Going Global**

The fireside chat was a panel discussion. The panel highlighted insights and lessons from regulators and senior leaders of global healthcare organizations on strategies to expand in regulated global markets. Leaders have shared their

perspectives and uncovered 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:
Malathi Lakshmikumaran, Lakshmikumaran & Sridharan Attorneys
Rubina Bose, CDSCO, India – West Zone
PVM Rao, IIT Delhi
Mohammad Ameel, NHSRC
Ravindra Ghooi, Scientia Clinical Services

**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

**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 the deployment and delivery of products to reduce the burden of disease. Experts in this session touched upon the learning's 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

**Session-7: Panel Discussion – Narratives of Global Navigation**

The panel covered lessons from global and Indian MedTech companies who successfully entered different regulated geographies – the dos &don's. It also shared the first-hand experiences of managing intricacies of interface with international regulatory bodies especially, in regulated markets as well as experiences with unregulated geographies. The session concluded by QnA.

Moderator: Srikant Sastri, Crayon Data

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

**Session-8: Recap &Valedictory**

Closure and Vote of Thanks
Manisha Premnath, Venture Center
Satya Prakash Dash, PATH India

## Attendees:

71 people from different cities participated in the workshop. Attendees represented a variety of organizations, with the largest to smallest numbers from the startups, technology business incubators, academic sector, not for profit hospitals and research institutes.

## *Evaluation:*

| Rating Scale | | | |
|---|---|---|---|
| 1 | Bad | 2 | Well below average |
| 3 | Below average | 4 | Average |
| 5 | Good | 6 | Very Good |
| 7 | Excellent | | |

| Category | Avg (Max-Min) Count |
|---|---|
| Quality of Pre-event (registration, queries) | 5.7(4,7)46 |
| Satisfaction with event logistics, arrangements | 6.0(5,7)45 |
| Quality of staff responsiveness | 6.2(5,7)46 |
| Satisfaction with structure, design & Pace of the event | 5.8(4,7)46 |
| Quality of food beverages | 5.8(4,7)46 |
| Venue(Was it appropriate, clean & Comfortable) | 6.0(4,7)46 |
| Overall satisfaction with event Organization | 6.2(5,7)46 |
| **Sessions** | |
| **Special talk:** Energizing Biotech Innovation Ecosystem in India | 6.1(5,7)42 |
| **Inaugural Address:** Day 1 | 5.9(5,7)43 |
| **MedTech Products:** Global opportunities & Market Entry Strategies | 5.9(5,7)241 |
| **Session-3A:** Understanding & Securing regulatory approvals | 6.0(4,7)42 |
| **Session-3B:** Understanding & securing regulatory approvals | 5.9(4,7)41 |
| **Session-4:** Fire Side Chat-Regulations & Going global | 6.1(4,7)41 |
| **Inaugural Session:** Day 2 | 6.2(4,7)44 |
| **Session 5:** Medial Product Innovations from India with global reach | 6.2(4,7)44 |
| **Session-6:** Public health & Regulations-Perspective of Global Health Agencies | 5.9(4,7)41 |
| **Session-7:** Panel Discussion-Narratives of Global Navigation | 6.2(5,7)39 |
| **Session-8:** Recap & Valedictory | 6.2(4,7)35 |

| How did you hear about the International Workshop? | |
|---|---|
| Newspaper | 8 |
| From Process | 1 |
| Email | 18 |
| Venture Center | 6 |
| LinkedIn | 4 |
| Colleague | 2 |
| Social Media | 3 |
| Peers | 1 |

| How useful was the Workshop? |
|---|
| Great in giving a holistic approach. |
| Really Useful Workshop & Good networking; Very good speakers. |
| Getting more profound & Thorough insights realized to regulations and IP. |
| Very good, made relevant connects learned or relevant, important regulatory aspects for the product. |
| Very useful learned good thongs which are relevant for our start-up journey to support newborn children. |
| Highly relevant currently when we as entrepreneurs are navigating the market, form product regulatory purpose. |
| Got a lot of networks & contacts. |

| |
|---|
| It was very informative & focused with different experts from the field. |
| I got a really good network, which will be very useful for me. |
| God experience. I came to know what is happening in India. |
| Very informative. |
| Excellent topics & Speakers: I'm now more about India & us equipment for MD: regulatory Landscape NHSRC does HTA Predicate( substantial Equivalence) |
| Really an eye-opener especially understands the essentials that go into it. |
| Thank You, I go back to lots to work progressively. |
| It was indeed holistic learning for each entrepreneur from all dimensions. |
| Very useful. |
| It was beneficial, sound learning, timely/great assembly of speakers. |
| Extremely Useful!! The insights into the domestic & Global market were excellent. |
| It is very useful. |
| Much needed startup who's who 1-1 network connect! Very Beneficial. |
| Yes, some insights were invaluable. |
| Creation terms of regulatory pathway exploration. |
| Most informative. |
| I found the workshop highly relevant. The content was well designed keeping start-ups in mind. The networking options available were excellent! |
| It's very good to meet the expectation, regarding the regulation. |
| Gave a global perspective on regulation. Was very useful in the planning of the new device. |
| Good platform for new entrepreneurs to interact with the ecological one. |
| It was very useful. As a starter in the industry, it provides ahead about for you. |
| It was useful in terms of hearing from people how to navigate & how to important are regulations. |
| Regulators challenges overview. |
| It was beneficial especially on differentiating the quality of the product in terms of cheap & affordable. |
| It was informative but lacked sufficient hands-on information. |
| Yes, it was definitely. |
| The workshop was quite useful for beginners. |
| To understand about new initiative regulatory changes & Networking. |
| The workshop was beneficial. It provided many networking opportunities. |
| This workshop cleared many of ambiguity & regarding with product, perfect. |
| Attended two sessions-found them informative. |

| **Please suggest a topic on which you wish to have Workshop On?** |
|---|
| Medical Diagnostics & health Policies of Govt. |
| Innovation |
| More cases studies of Medical Devices which may be of innovation novel for India. |
| Importance of IP Protection for startups /MSME's, Licensing Technologies in MedTech Sector. |
| Being at the ideal prototyping of stage will be needing topics on business & Market energy strategies. |
| How to integrate design in P.D with connecting to the design ecosystem(affordable) |
| Focused an approach to clinical, pilot & pivotal studies/MNCH Innovations. |
| Financial Statements from the investor perspective. |
| Industry & Partners discussion of open talks. |

| |
|---|
| Predicted devices, WS FDA regulations, more talks & case studies established experts like GE, Philips, Dr.Reddy, Design thinking. |
| Investment |
| MedTech Product development methodology-Do's & don’ts |
| On how to get funding. |
| Deep guide offer in vivo studies & funds mobilization. |
| CE mark, Regulatory Timeliness. |
| Design, Packaging technical offering with finesse, clinical research. |
| Sale cycle & Purchase Process of medical products. |
| Product testing protocols to general approval materials. |
| Healthcare services coupled with technology. |
| Funding |
| Scaling up, pricing marketing/Advertising, selling to state governments. |
| Navigating of regulatory, approval pathway for early-stage MS Medical device startups. |
| International Market. |
| Startup & Public health connect/Fundraise Innovation. |
| Low volume manufacturing & Partnership. |
| Evaluating the potential for your innovation. |
| How to avoid the foundation of the graveyard of prototypes. Just kidding! |
| Please design the course of regulation for 10-15 das/workshops only can't solve the converted need. |
| Hands-on workshop on QA & RA. |
| Material science. |
| Defining your castings cup market research. |
| Heath technology assessment(HTA) |
| Medical device Rules 2017. |
| More sessions on startup stories by experienced entrepreneurs. |
| IPR,IVD |
| Research methodology & regulatory requirements & Procedure. |
| Emergency plastic health priorities & Opportunities for startups. |
| I would like to suggest(you)that if possible arrange a workshop on "SE" ( Substantial product Equivalent) |
| Protection on design mechanisms. |

| **What changes would you like to be seen in the next international workshop?** |
|---|
| Scrutiny of the incoming Participants. |
| Interactions |
| There should be some representation from other companies like China & EU, where we may come across their novel products from them, it is feasible we may explore. Import opportunities moreover they may display their product for live show display. |
| It was perfect & Very well organized. |
| More discussion & Networking time may be 11.00am-5.00pm; the slot should be exclusively for discussion on next day/someday. |
| More scope for in-session discussion with speakers may be with just two speakers per session. |
| Question & Answer to be introduced after each event & talk. |
| The talk more about international regulation in detail. & critical thing out of the discussion was to include the regulations & CDSCO in loop while developing any med tech. Next workshop .should come up with checklist/or materials to prepare the exact SOP. |

| |
|---|
| It was perfect for me. |
| There should be an introductory session for participants & 5 mins each. This form should have a point participating in their expectation from BIRAC. |
| More interactive. |
| Extra agenda copies at the registration desk, Introductions are done by the Participants. |
| More prior Notice, I got just a week to book my tickets & it was expensive. |
| Very well done, can have a form for the question. |
| More case studies to be presented from India as well as a global scenario to learn from their failure & success stories. |
| More time to be given to the key regulations(Like CDSCO Dr. BOSE) |
| Insights & Comments from regulatory consultants would be very helpful. |
| More case study of Indian Innovation & Global Success. |
| More theme focused. |
| You could arrange for 1-1 meet up if possible in some cases. |
| Little more interaction after each talk. |
| If from the next time, we could be informed a bit earlier, it would be easier to arrange for travel. |
| A 2-way question-answer session will increase the understanding inside out. |
| More time for Q & A during keynotes & Panel Discussion. |
| A few more events which gave the audience a chance to engage with the speaker. E.g., .some workshop assignments, working on some case studies, etc. |
| Little more interactive. |
| More case studies. |
| More case studies, hands-on workshop. |
| More international speaker. |
| More IVD. |
| Engagement of more International personals & Local regulatory & Industry personals. |
| Few stalls on upcoming technologies. |
| If possible try to involve ‘WHO' & other regulatory people also. |
| Live streaming. |

# List of speakers & Mentors

| Sr | Name | Affiliation |
|---|---|---|
| 1 | Anthony Okoth | Country Director at PATH, Kenya |
| 2 | Chandrashekhar Nair | Director at bigtec Private Limited, Bangalore |
| 3 | Krishna Kumar R | Senior Manager QA & RA, Aurolab. |
| 4 | Krishna Reddy | Cardiologist - Care Hospitals, Hyderabad |
| 5 | Krishnakumar Sankaranarayan | Executive Director at PwC India, Mumbai |
| 6 | Malathi Lakshmikumaran | Director, Lakshmikumaran & Sridharan, Attorneys, Mumbai |
| 7 | Manish Diwan | Head - Strategy Partnership & Entrepreneurship Development at BIRAC, New Delhi |
| 8 | Manisha Premnath | General Manager& COO, Venture Center, Pune |
| 9 | Milind Antani | Lead, Pharma and Healthcare Practice, Nishith Desai Associates, Mumbai |
| 10 | Mohammed Ameel | Senior Consultant, Healthcare Technologies (Medical devices), NHSRC, New Delhi |
| 11 | Nandakumar Subburaman | CEO, Co – founder, Perfint Healthcare Pvt Ltd, Chennai |
| 12 | Navnath Kadam | Asst. Manager at RIFC- Venture Center, Pune |
| 13 | Neena Sonavane | Senior Manager Regulatory Affairs at Philips India Limited, Pune |
| 14 | Nikita Jhaveri | Project Associate – BRBC – BIRAC Regional Bio-Innovation Center, Pune |
| 15 | Obita Walter | Director at Kenya Healthcare Federation. Director, Sustainable Healthcare Foundation |
| 16 | P. V. Madhusudhan Rao | Lead, Pharma and Healthcare Practice, Nishith Desai Associates, Mumbai |
| 17 | Premnath V | Founding Director - Venture Center and Head, NCL Innovations, Pune |
| 18 | Priya Nagaraj | Bio incubation Manager-Venture Center, Pune |
| 19 | Priyanka Bajaj | Manager – Health& Innovation, Impact Lab, PATH India, New Delhi |
| 20 | Ravindra Ghooi | Director, Scientia Clinical Services, Pune |
| 21 | Renu Swarup | Secretary, DBT, Government of India and Chairperson, BIRAC, New Delhi. |
| 22 | Rubina Bose | Deputy Drugs Controller (I) in CDSCO (West Zone), Mumbai |
| 23 | Satya Prakash Dash | Director Global Innovations, Impact Lab, PATH India, New Delhi |
| 24 | Satyabrata Routray | Director Neglected Tropical Diseases and Malaria at PATH, New Delhi |
| 25 | Shekhar Mande | Secretary, Dept of Scientific and Industrial Research, Govt of India and Director-General, CSIR. |
| 26 | Shubham Kesharwani | Manager – Product Engineering & Innovation, Impact Lab at PATH India, New Delhi |
| 27 | Srikant Sastri | Founder, Crayon Data, New Delhi |
| 28 | Suman Rijal | Director, Drugs for Neglected Diseases initiative, New Delhi |
| 29 | Suresh Kumar | CTO – CCS Digital Incubators, GE Healthcare, Bangalore |

# Presentations

**http://www.venturecenter.co.in/restricted/**

**INTERNATIONAL WORKSHOP ON MEDTECH PRODUCTS – NAVIGATING GLOBAL MARKETS & REGULATIONS 25-26 MARCH 2019, NEW DELHI (INDIA)**

**Password – medtechworkshop@brbc2526**

# Photo Gallery





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PVM Rao


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SOCIAL alpha
26th March 2019



RIFC


More photographs are available here -- http://www.brbc.venturecenter.co.in/conference/photo-gallery/

| About the Organizers | |
|---|---|
| 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.<br><br>More on: http://www.brbc.venturecenter.co.in/ |
| PATH | About Tata Trusts PATH Impact Labs (TPIL)<br>PATH, in partnership with Social Alpha, has 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 organized under the umbrella of the Tata Trusts PATH Impact Lab (TPIL). TPIL will identify and support MedTech products with a potential to positively impact the healthcare landscape in India and beyond. It will support MedTech startups 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.<br>For more information, visit: https://www.path.org/ |

| Supported by | |
|---|---|
| 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.<br>For more information about BIRAC: www.birac.nic.in |
| VENTURE CENTER | Venture Center is India's largest inventive enterprises and scientific business incubator. Venture Center is a technology business incubator hosted by CSIR-NCL and supported by the Department of Science & Technology's National Science & Technology Entrepreneurship Development Board (DST-NSTEDB) and BIRAC.<br>For more information, visit www.venturecenter.co.in |
| 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.<br>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 catalyzing 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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