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2 Days Workshop on

Taking Med-Tech Startups Beyond Prototyping: Regulations, IP monetization & Funding

- Organized by Venture Center and BIRAC -

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LEARN	 Overview of medical device industry and markets Planning funding and investment after POC and prototyping; Funding landscapes and Investor perspectives; Seeking post proof-of-concept funds for scaling and sustaining ventures Planning and developing technology/IP: IP strategy, FTO analysis, Collaborative IP development. Licensing/technology transfer in medical device domain; Understanding and negotiating licensing/technology transfer agreements; Valuating IP in medical device sector Planning for medical regulations. Risks in medical device technologies: start-ups/entrepreneurs point of view; Regulations and changing regulatory environment; Recent changes in Indian regulations 			
ORAGANIZED BY	 Venture Center Biotechnology Industry Research Assistance Council (BIRAC) 			
FOR WHOM	 Entrepreneurs/Start-ups and Inventors in Medical Device sector Research/ Science Managers/ CTOs/ CSOs in Research/ Technology Organizations/ Technology Incubators/Universities focusing on Medical Electronics and Devices Technology/IP Managers/Patent Professionals/ Innovation Officers Students of IPR, Business Management, Commercial Law Other law disciplines including Pharma/ Biotech 			
WHEN	9-10 February 2018 Friday- Saturday Time: 9:00 AM- 5:30 PM			
EVENT LEAD	Dr. Roshan D. Yedery, Ex-Venture Center, Pune			
WHERE	Lecture Theater, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha (Pashan) Road, Pune-411008			
CONTACT	General queries: Ms. Lipika Biswas +91-20-25865877 eventsdesk@venturecenter.co.in Technical queries Dr. Roshan D. Yedery +91-7722015062 roshan@ipface.org			
COST	Category Medium and Large companies Micro & Small Enterprises; Non-profit Organizations; Academic Institutions; Individuals BIRAC grantees (includes all BIRAC schemes) Venture Center incubatees; Students with valid ID cards WOS-C trainees; Student members of NCL-TEC and IISER-Pune-EIC; Fellows of EIR/ PRAYAS/SIIP Register soon! Seats limited to 50. First-come-first-serve. Register here: http://bit.ly/2FL4fK0 (Registration closes on 7 Feb 2018) Note:- • Fees paid is not refundable and non transferable under any circumstances • Group discount: 10% discount for groups of 3 from a single Institution/Company • Organizers reserve the right to select participants so as to maximize learning and networking	Fees Rs 8000/- Rs 5000/- Rs 2500/- Rs 2500/- Rs 1500/-		





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Introduction

A recent report has suggested healthcare, especially MedTech, as an attractive emerging market in India. This has created a great opportunity for Indian companies to make the most in this domain. Reports also suggest that the Indian healthcare industry is to reach USD 50 billion by 2050 and specifically the medical device industry is set to reach a market of USD 25-30 billion by 2030. However currently multinational companies are dominating the scene with almost top 40 medical device companies having a presence in India and about 75% of the sold medical devices are imported. Even from IP point of view only 17% of over 4700 patents filed at Indian Patent Office between 2009-2013 were of Indian origin.

However recent initiatives by the Government of India including 'Make in India', 'Startup India' and drafting of new policies/acts including the 'Medical Devices Rules 2017' and 'Drugs and Cosmetics Amendments Bill' are enabling Indian companies to gradually develop innovative medical devices and related healthcare products. In this regard the efforts of Biotechnology Industry Research Assistance Council (BIRAC) via BIG, SBIRI and BIPP programs and the recently announced National Biopharma Mission are greatly commendable. One critical need in commercialization of these innovative products is knowing how to manage IP. Indian companies need to know to how to create and monetize IP effectively to develop and expand their business in the MedTech sector in India while competing with global majors as well as enter global markets.

This 2-day workshop will focus on some important issues facing Med Tech startups after the prototyping stage – rising money, regulations and IP strategy.

Why attend this workshop?

This workshop will help you learn about technology management and commercialization in the MedTech space with a *focus on practical insights*. Venture Center events are known for their practical insights and usefulness for entrepreneurs and practitioners of technology management.

The event is being organized by two organizations shaping the MedTech innovation ecosystem in India and known for thought leadership in the field. Venture Center (technology business incubator located on CSIR-NCL campus) is India's leading inventive enterprises incubator established by CSIR-NCL (the only Indian organization listed in the WIPO's 'Top 100 Inventive Clusters' of the world. It won the National Award for TBIs in 2015 from the President of India. Venture Center is home to one of the leading BIRAC BioNest/ BioIncubator and is also home to MSME-funded IP facilitation center (IPFACE). BIRAC is a pioneering organization that has single-handedly shaped India's biotech and biomed innovation and entrepreneurship landscape through innovative funding programs. BIRAC's BIG, BIPP and SBIRI programs have supported and nurtured a large number of healthcare and biotech related enterprises towards developing relevant innovative technologies for improving the quality of human life.

Course includes

- Access to restricted website with online compilation of resources
- Certificate of Participation issued by Venture Center and BIRAC
- Course includes tea, refreshments and lunch at the Innovation Cafe at Venture Center
- Free one-year reference membership for Venture Center Library (http://www.vcenterlibrary.org)

* Please note the participants will have to arrange for their own travel, local transport and accommodation.

For more information on hotels, transport options etc: http://www.venturecenter.co.in/puneguide/





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Speakers(in alphabetical order of last names)



Sucheta Banerjee -Kurundkar **Director, Training at CDSA**

Sucheta Banerjee -Kurundkar Sucheta is Director, Training at CDSA since 2012. She has 18 years of experience in various capacities in research & CRO Industry. She started her career from Pune where she was instrumental in setting up a pre-clinical & clinical research company to revenue generating level. In her last assignment, she was Chief Scientific Officer at a multinational Clinical Research Organization. Sucheta has worked for several years in the area of Quality Assurance in pre-clinical, clinical and medical laboratories and has an avid interest in this area. She is a GLP Trainer (WHO); Auditor for NABL (ISO 15189 & ISO 17025) & NABH. Sucheta has a Ph.D. in Biochemistry from University of Pune and her doctoral work on a novel inhibitor received recognition at the World Congress on Insulin Resistance Diabetes & Cardiovascular Research, USA (2010). She has completed Advanced Quality Management Programme from IIM, Ahmedabad and Management of Training from ISTM, New Delhi. Sucheta is the reviewer to many International Journals of repute. At CDSA, she has been involved in the conduct of 73 training programs across 40 cities covering approximately 5000 participants, 1380 institutions and 749 faculty members till May 2016.



Somnath Basu

Asst Drugs Controller (India), CDSCO, New Delhi

He is currently working at National Regulatory Authority (NRA) for Pharmaceuticals, Cosmetics and Medical Devices since April 1995 as reviewer & assessor of Technical dossier of CMC, Pre-clinical & Human Clinical studies for Market Authorization of pharma products, medical devices and biological drugs like r-DNA technology based therapeutic proteins / monoclonal antibodies, vaccines, blood products and Stem Cell Based Therapeutic products. He has worked in close collaboration with WHO in regulation of human vaccines. His basic training is in chemistry with masters in biochemistry.



Somnath Basu (TBC)

Vishy Chibrolu

Managing Director, InvAscent, Mumbai



Vishy is an experienced investment advisor with over several years of experience. He previously worked with SilverCreek Capital - a USD 5 billion fund of hedge funds, where he headed the risk management group and was also involved in structuring and conducting due diligence on direct investments. He also worked at the McKinsey Investment Office, where he led the initiative for direct investments in select sectors and focused on assisting clients improve operational efficiency. He holds an MBA from Indian Institute of Management, Lucknow and a doctorate from Case Western Reserve University where his research focused on pricing derivatives and real options.



Nitin Deshmukh

Founding member of the Private Equity practice at Kotak

Nitin Deshmukh is the founding member of the Private Equity practice at Kotak. He has played a pivotal role in building the Alternate Assets business at Kotak Investment Advisors Ltd. Nitin is also a member of the CII National Committee on Private Equity and Venture Capital as well as the CII National Council on Economic Policy. He also serves as Director of ABLE in addition to being a member of the Committee on Biotech Policy of the Department of Biotechnology, Government of India



Nitin Deshmukhh

Shruti Devasthali

Manager, Equity and Grant Portfolio, Venture Center

Shruti is a Chartered Accountant and a certified Financial Risk Manager. She is currently operating seed fund activities for Venture Center and monitoring the investments in Venture Center's portfolio companies. She is also responsible for mentoring lab2mkt companies on corporate governance; and management of financial and legal matters relating to grant programs. During her previous work engagements Shruti has worked with CRISIL Limited and Dun and Bradstreet Information Services India Private Limited in the areas of credit and financial analysis.

Shruti Devasthali

Anil Gudibande

Co Founder, 1Crowd, Mumbai

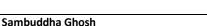


Anil Gudibande has over 24 years of experience in Banking. He spent 17 years with Citigroup and was most recently with Royal Bank of Scotland - initially as Managing Director & Co-Head of the Investment Bank, and subsequently as Managing Director. He has also spent a year with AIG Private Equity. Anil has worked on a number of marquee deals in M&A, acquisition financing, IPOs, loan and bond issuances. He was also a senior business approver with credit approval authority. Anil is an angel investor who mentors a few start-ups. He is a member of the Institute of Chartered Accountants of India and the Institute of Cost & Works Accountants of India and holds a Master's degree in Commerce from Bangalore University.

Anil Gudibande









Sambuddha Ghosh

Founder Director, ABEL Biosolutions Private Limited, Pune Sambuddha, Ghosh's startun, incubated at Venture is a

Sambuddha Ghosh's startup, incubated at Venture is a vaccine and bioprocess industry solution provider and is currently focused on development of preventive health care technology platforms for infectious diseases and is a one stop solution provider from biologics innovation to manufacturing. Currently ABEL is involved in setting up bacterial and viral vaccine projects in Western and Eastern African countries, as a part of global vaccine initiatives. He has functioned in senior management positions of various multinational organizations and vaccine operations for more than 15 years. In a variety of industry environments he spearheaded many projects through the evolving global markets. He has spearheaded International collaborative projects on validation studies pertaining to various assay systems in conjunction with the World Reference Laboratory on infectious diseases in UK. He is a doctorate in Virology, with a wide experience in the areas of vaccine production, quality control as well as developmental and translational research.



Aditya Ingalhalikar

Aditya V. Ingalhalikar

Founder & CEO Indius Medical Technologies Pvt. Ltd

Aditya holds PhD in Biomedical Engineering [Specialization: Spine Biomechanics], U-Iowa and MS in Biomedical Engineering, U-Iowa. He has work experience of 10 years experience in US spinal implants industry. Earlier he was Director of Product Development, Globus Medical, PA, USA. He has 16 US patents in spine field -7 published, 9 pending and Multiple peer reviewed research publications and conference abstracts.



Amit Katiyar

Manager – IP & Technology Management, Biotechnology Industry Research Assistance Council (BIRAC) – New Delhi

Amit works as a Manager in IP & Technology Management cell of BIRAC. He is experienced in Intellectual Property Management, Patentability analysis, Patent landscaping, & Desire is also managing Small Business Innovation Research Initiative scheme (SBIRI). He holds Master's degree in Bioinformatics from the School of Biotechnology, Devi Ahilya Vishwavidyalaya, Indore



Jayant Khandare

Jayant Khandare

MD and CSO, Actorius Innovations and Research Pvt Ltd

Jayant received his Ph.D. in Chem. Eng. from NCL, Pune and was postdoctoral research fellow at Chemical Eng. Dept., and Children's Hospital, Wayne State University, Detroit, and a Research Associate at Rutgers, State University of New Jersey, USA. His research interests are at the interface of macromolecular chemistry, targeted drug delivery, 3D cancer cell scaffolds, and 3D surfaces. His research based start-up, Actorius Innovations and Research is involved in designing multi-components for cancer diagnostics. He is also a founder of Right to Research Foundation, a non- profit researcher's entity in Pune.



Nilay Lakhkar

Nilay Lakhkar

Founder and CEO of SynThera Biomedical, Pune

Nilay's startup Synthera, incubated at Venture Center, is India's first and only bioactive glass company, focused on R&D, manufacture and commercialization of proprietary bioactive glass products for the healthcare sector. SynThera is currently gearing up to launch its flagship products SynOst® and PoroSyn®, which are synthetic bone graft substitutes used in orthopaedic and dental surgeries to combat bone loss caused by injuries or diseases. Nilay has a doctorate in Biomaterials and Tissue Engineering from University College London, UK, followed by a postdoctoral stint at the Institute of Biomaterials, Helmholtz Zentrum Geesthacht, Germany. He brings 10 years of experience in development of bone repair technologies, with 15 academic papers and patents to his name.



Anand Mahurkar

Anand Mahurkar

Partner and Head, Pune Branch, Krishna & Saurastri Associates, Pune

Adv. Anand Mahurkar is a Partner and head of the Pune branch office of Krishna & Saurastri Associates, one of the leading law firms in India. He is member of the Bar Council of Maharashtra and Goa. He is has more than 13 years of overall experience including Legal industry, academics and manufacturing. Anand has a B.E in Mechanical Engineering from B. N. College of Engg., Pusad. He later pursued his masters' degree in Manufacturing Systems from BITS, Plain (Raj) and an LLB degree from the University of Pune (M.S).









Currently working as Asst.General manager in BCIL, a Department of Biotechnology, Gol promoted company, Dr. Markan has extensive and rich experience in project management, intellectual property management, technology-transfer and strategic collaborations including inter-institutional, industry-academia, industry-academia-government partnerships in healthcare sector, primarily medical devices. She has successfully managed multi-institutional programs of global repute including the Stanford India Biodesign program, School of International Biodesign Fellow program and Wellcome Trust supported CPR device development programs to name a few. Dr.Markan holds a doctorate in Biotechnology from PGIMER and Executive General Management from IIM Lucknow.



Suchita Markan

Mavuresh Mukadam

Mayuresh Mukadam

Assistant Manager (Valuation & Advisory Services), Aranca, Mumbai

Mayuresh has diverse experience of over 9 years across business valuations, corporate finance, and transaction advisory, and assurance services. At Aranca, Mayuresh handles valuation engagements for tax compliance, litigation, and other purposes. He is also responsible for feasibility studies and other advisory engagements related to M&A and funding transactions. Prior to joining Aranca, Mayuresh worked with Price Waterhouse Coopers India at their Mumbai office, where he led several assurance engagements related to companies in the financial services sector. Mayuresh is a Chartered Financial Analyst (CFA®) Charter holder and a member of the Institute of Chartered Accountants of India. He also holds Master's degree in Commerce from the University of Mumbai.



Magesh Nandagopal

Magesh Nandagopal

Scientist, NCL Innovations, CSIR-NCL, Pune

Magesh works as a Scientist and Technology Manager in NCL Innovations — a division of CSIR's National Chemical Laboratory, Pune. He manages the large pool of technologies resulting from this lab, works with partners in taking technologies to the market, and is involved in creating technology based startups. He has advised over 100 innovators and entrepreneurs in funding, start-up creation, business planning and other issues. Magesh has a PhD (in Polymer Science) and an MBA (in Finance) - both from the University of Connecticut, USA. And recently attended the Chevening Rolls-Royce Science and Innovation Leadership Fellowship (CRISP) 2017.



Nutan

Nutan

Deputy Manager- Investment Group, Biotechnology Industry Research Assistance Council (BIRAC) – New Delhi

Dr. Nutan works as Deputy Manager, Investment Group at BIRAC. In addition to management of Social Innovation programme for Products: Affordable & Relevant to Societal Health (SPARSH) Scheme, she is providing technical inputs to projects related to Healthcare area. She has worked in Stempeutics Pvt Ltd, Bangalore in the field of Stem Cell based research. She has completed her Ph.D. from National Institute of Immunology, New Delhi and continued her research as a Post-Doctoral towards development of Microbicides; an intervention to prevention of HIV-infection. She holds a P.G. Diploma in Patent Law - Intellectual Property Rights IPR from NALSAR University of Law, Hyderabad



Abhishek Pandurangi

Abhishek Pandurangi

Partner & Attorney-at-law at Khurana & Khurana Advocates & IP Attorneys, Mumbai

Presently a partner at Khurana & Khurana Advocates, Abhishek has worked in different areas of IPR over a stretch of 7 years as an IP practitioner, entrepreneur, legal expert and a trainer. Abhishek has dealt with various types of IPR matters including Patent Searches, Patent Drafting, Patent Prosecution, Patent Commercialization, Trademark Litigation, Domain Name Dispute Resolution with UDRP, Copyright and Database Infringement Counseling. Prior to this he has worked with Evalueserve and Netscribes India. He also had started his own IP firm closer2patents which supported over 300 clients in 16 countries having completed over 1000 IPR projects, and is now a part of Khurana & Khurana after a strategic acquisition. Abhishek holds a B.Tech-Chemical from UDCT(Mumbai) and a practicing lawyer and a registered patent agent.

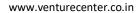


A B Ramteke

Senior Consultant for Regulatory Affairs at CDSA

Mr Ramteke is Senior Consultant for Regulatory Affairs at CDSA. He retired as a senior drug regulatory officer with 31 years of experience in drug regulatory aspects in the office of the Drugs Controller General of India (DCGI). He has in-depth knowledge of Indian Drugs & Cosmetics Act, Rules and of regulations of Global Drug Regulatory norms. He started his career at Central Research Institute Kasauli in biological-drug testing. He has extensive experience with new drugs, vaccines and biotech







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A B Ramteke	products/pharmaceuticals, medical devices approvals and development experience. He also has experience in review and evaluation of product dossier for pre-clinical, toxicological, pharmacological, CMC, and quality control, clinical trial data of new drugs, biological and medical devices (INDs, ANDAs). He has strong skills in quality assurance management, regulatory oversight of clinical trials, development of SOPs and guidelines and involvement in drug rules amendments. He has contributed to preparation and implementation of Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices. He works as an Expert to the Pharmacovigilance Program, GCP Training and Inspections of CROs in India.	
Chandrashekhar Ranga	Chandrashekhar Ranga Deputy Drugs Controller (India), CDSCO Mr. Chandrashekar has an Honors degree in Pharmacy, Masters in Pharmaceutical Technology and also Degree in law and PG Diploma in Intellectual Property Laws. He has 27 years experience in Drug Control Departments of the State and Central Governments in various capacities and is currently working as Deputy Drugs Controller (India) at CDSCO West Zone, CDSCO, Ministry of Health and Family Welfare, Govt. of India. He has earlier headed the new drugs division including the IND drugs, International Cell, Legal Cell and the E-Governance Cell at CDSCO. He played a key role in the signing of MoUs with US-FDA, UK-MHRA, Japan-PMDA, ANVISA, Brazil and the BRICS group. He has played a key role in drafting amendments to the Drugs and Cosmetics Act, Drugs and Cosmetics Rules and Medical Devices Rules. He also dealt with the litigations filed at various courts on behalf of CDSCO. He has initiated the e-Governance program at CDSCO. He was involved in the launch of SUGAM portal, the online initiative for CDSCO for filing, tracking and processing of various applications.	
Avinash Shejale	Dr. Avinash Shejale Director - Lifesciences at Ainvent Capital, Mumbai Avinash is currently heading the Lifesceinces section at Ainvent Capital. The firm currently is focusing on mergers and acquisitions, private equity, venture finanncing in pharmaceutical biotechnology, medical devices, healthcare and food/agri-biotechnology. Earlier he was heading the Lifesciences doman at Pioneer Investcorp and heading the pharma & lifesciences division at SBI Capital Markets Ltd. He holds an M.B.B.S from Grant Medical College, Mumbai and an M.B.A in Finance and Marketing from Jamanlal Bajaj Institue of Management Studies.	
Yogesh Shelke	Dr. Yogesh Shelke Assistant Manager, ARANCA, Mumbai Currently Yogesh consults a broad range of clients focusing on healthcare products for busines development, project execution and client deliverables, marketing strategy, and knowledg management. Also a registered patent agent, he has been to deliver strategic IP and business solution for companies working in broad areas of healthcare including medical devices. Prior to working wit ARANCA Yogesh worked as a patent engineer with Franks International NV and had stints wit GeneRation and OrthoCAD Networking Labs. Yogesh holds a M.B.B.S from Government Medical College, Miraj and later pursued an M.Tech in Biomedical Engineering from IIT-Mumbai.	
Tushar Shrikhande	Tushar Shrikhande Legal Advisor , LegaLogic Consulting, Pune Tushar is a graduate from Symbiosis Law (BSL LL.B) in 2007. I have worked with law firms across India, Wadia Ghandy (Pune), R. K. Dewan & Co. (Pune and Delhi), Archer & Angel Delhi, AZB Partners (Mumbai) and now LegaLogic Consulting (Pune). I have experience in IP prosecution, IP licensing and assignment agreements, commercial contracts, labour laws.	
Nitin S Tewari	Nitin S Tewari Scientist, NCL Innovation, CSIR-NCL, Pune Dr. Nitin holds a doctoral degree in Biomedical Research and is a registered patent agent. She has been awarded earlier with the Woman Scientist Scheme under DST for training in IPR. Currently as Scientist at NCL Innovations she oversees patent drafting & prosecution, IP portfolio planning, management and value addition of inventions developed at CSIR-NCL.	
	Premnath Venugopalan Head, NCL Innovations, CSIR-NCL, Pune Director, Venture Center, Pune Dr V Premnath is currently the Head, NCL Innovations – the group within National Chemical Laboratory (NCL) charged with the responsibility of championing the cause of technology innovation within NCL. Dr Premnath also provides leadership for the Intellectual Property Group at NCL and is also the Founding Director of the Venture Center – a technology business incubator on NCL campus. Dr Premnath is also a	

Director of the Venture Center – a technology business incubator on NCL campus. Dr Premnath is also a Scientist, Polymer Science & Engineering Division at NCL with an interest in technology development for





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Premnath Venugopalan

biomedical products. 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.



Roshan Yedery

Roshan D Yedery

Ex- Manager, Innovation Management Team, Venture Center, Pune

Dr. Roshan Yedery holds a Ph.D in Biochemistry from University of Mumbai. His areas of interest have been human infectious diseases, development of novel anti-microbial technologies and commercialization of innovations developed in labs. He has worked at Uniformed Services University of Health Sciences and interned at Technology Transfer Office of Henry M Jackson Foundation for Advancement of Military Medicine, both located in Bethesda, United States. He also holds a certificate in Technology Transfer Program from FAES at NIH, Bethesda, United States. Before joining IPFACE he was heading the IP team at National Innovation Foundation-India located in Gandhinagar, Gujarat.

About the Organizers				
VENTURE C E N T E R	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's 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 <u>www.venturecenter.co.in</u>			
birac ignite innovate incubate	Biotechnology Industry Research & Assistance Council is a new industry-academia interface and implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring innovation excellence to the biotech firms and make them globally competitive.			

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