Venture Base Camp on

Medical Devices Design and Risk Management

– Methods, Techniques, Tools –

- Organized by BRBC -

Potential gains	• This event is a Venture Base Camp (VBC) aimed at ***educating and enabling exchange of strategies, resources, good practices and regulatory & quality aspects of designing a safe effective and robust medical device.*** • Advice and suggestions from senior MedTech professionals on the design process for your devices.
Organized by	• BIRAC Regional BioInnovation Center @ Venture Center. • Regulatory Information and Facilitation Center (RIFC) @ Venture Center.
Supported by	• BIRAC • Venture Center
For whom	• CEOs/CTOs of innovative technology startups. • Individual Inventors. • Inventors from R&D institutes, medium/ large enterprises.
When	**Tuesday, Wednesday, Thursday | 03, 04, 05 March 2020| Time: 9 am – 6 pm**
Where	Lecture Theatre, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune – 411008.
Contact	***Technical queries***: Navnath Kadam| 020-25865877/76 navnath@venturecenter.co.in ***Logistical queries***: Lipika Biswas| 020-25865877/76 eventsdesk@venturecenter.co.in
Registration Details	**Limited seats!! Total number of seats: 20** Registration Process: • Step 1: Interested participants need to fill in registration form at the following link. **Register online at: https://forms.gle/yD1L6Vx4344GZDKD7** • Step 2: Email invites will be sent post screening of registration details. • Step 3: Attendance only on confirmation of payment of registration fee*.

Category	Fees (Rs)
A) BIRAC Grantees who are small entities ***	500/-
B) Micro/small enterprises, startups; Non-profit/R&D/academic orgs; individuals	5000/-
C) Others including medium/ large enterprises	10000/-
D) Students with valid ID card (Eligibility subject to the present nature of student-led work activities).	500/-

******Limited number of travel fellowships for up to Rs. 13000 available for Category 'A' participants. Reimbursement upon presenting receipts.***

Preference: Startup companies (LLC/PLC) vs. individuals if we receive more than 30 applications |Organizers reserve the right to select participants so as to optimize the group for better interaction and ensure benefit to as many startups as possible. NOTE: Registration closes once 30 seats are full or on 28 Feb 2020(whichever comes sooner). ***Fee paid is not refundable and non transferable under any circumstances.***

Introduction

BIRAC Regional BioInnovation Centre (BRBC) is a joint initiative of BIRAC and Venture Center. It focuses on filling up a few key innovations ecosystem gaps in India for biotech/biomed startups specifically relating to mentoring, regulations, fund raising and BioIncubation practice.

Venture Base Camps are high intensity, focused, theme based camps intended to take a startup from point A to point B in their entrepreneurial journey, prior to their execution on key goals of the company.

VENTURE BASE CAMP

The focus of this Venture Base Camp:

- Only Medical Devices (including diagnostic products)

This VBC will be 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.

Course Description
The course will cover the comprehensive design and risk management elements (as per ISO 13485, ISO 14971 and the related standards) of medical devices and in vitro diagnostics. Specific cases to be addressed by industry professionals, including subject matter experts, experienced personnel, technical assessors and auditors. Cases include Implants, In-vitro Diagnostics, Electrical, Mechanical, Software as a Medical Device (SaMD) and an example of Project Management in Medical Devices.

How will you benefit?
This course will help you:
Get versed with procedures, tools and techniques in compliance with regulatory requirements for the development of medical devices, including risk management information for submission to regulatory authorities.

Prerequisites
There are no specific requirements; however, it will be useful for delegates to have knowledge of the relevant standards before attending the course.

Workshop includes

- Workshop includes tea, snacks and lunch at the Innovation Café.
- Free membership in mailing list to follow-up on workshop and intimation of relevant events/ funding/ opportunities from Venture Center.
- Case Studies.
- One-year free reference membership to Venture Center Library (http://www.vcenterlibrary.org/)

Workshop excludes

***Please note, the participants will have to arrange for their own travel, local transport and accommodation and dinners. For more information on Pune city, travel, transport and stay options, see** http://www.venturecenter.co.in/puneguide/

Workshop Schedule

DAY 1: 03 March 2020 – Tuesday

Time	Duration	Session title	Lead
0900-0930	30 min	Registration and breakfast	
0930-1000	30 min	Setting the Scene and Tech De-risking	Priya Nagaraj
1000-1100	60min	**Session 1:** • Planning of product realization • Design & Development Procedure • D&D Planning, Inputs, Outputs • D&D Review, Verification, Validation	Ravi Sarangapani
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 2:** • D&D Transfer • Change Control • DHF • Question Answer 10 min	Ravi Sarangapani
1300-1400	60 min	Lunch break	
1400-1530	90min	**Session 3:** • Risk Management • Terms & Definitions • Risk management process for medical devices • Fundamental risk concepts	Hartesh Juneja
1530-1600	30 min	Tea break	
1600-1700	60 min	**Session 4:** • Preliminary Hazard Analysis (PHA) • Failure Mode and Effects Analysis (FMEA) • Fault tree analysis (FTA) • Hazard and Operability Analysis (HAZOP) • Risk Ranking and Filtering	Hartesh Juneja
1700-1730	30 min	**Session 5:** • Question Answer Session	Hartesh Juneja Ravi Sarangapani

DAY 2: 04 March 2020 – Wednesday

Time	Duration	Session title	Lead
0900-0930	30 min	Registration and breakfast	
0930-1100	90 min	**Session 06:** • Design development and Risk Management • **Case 1** – Implants	Ravi Sarangapani
1100-1130	30 min	Tea break	
1130-1230	60 min	**Session 07:** • Design development and Risk Management • **Case 2** – Implants(Continued)	Ravi Sarangapani
1230-1330	60 min	Lunch break	
1330-1500	90 min	**Session 08:** • Design development and Risk Management • **Case 3** – Electrical, Mechanical Devices	Aniruddha Atre
1500-1515	15 min	Tea break	
1515-1615	60 min	**Session 09:** • RISK - An Entrepreneurs Perspective • **Case 4** – IVD	Aravindan Vasudevan
1615-1715	60 min	**Session 10:** • Intro by Ravi S • Project Management in Medical Devices	Nilay Lakhkar
1715-1730	15 min	Tea break	
1730-1815	45 min	**Session 11:** • Panel Discussion	V. Premnath Ravi Sarangapani Aniruddha Atre Aravindan Vasudevan Nilay Lakhkar

DAY 3: 05 March 2020 – Thursday

Time	Duration	Session title	Lead
0900-0930	30 min	Registration and breakfast	
0930-1100	90 min	**Session 12:** • Design development Risk Management • **Case 5** – IVD	Lakshman Balajepalli
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 13:** • Design development and Risk Management • **Case 6** – Electromechanical Device	Ashish Hemade Siddarth Shetty
1300-1400	60 min	Lunch break	
1400-1530	90 min	**Session 14:** • Design development Planning, Inputs, Outputs • **Case 7** – Interventional Devices	Biten Kathrani
1530-1600	30 min	Tea break	
1600-1730	90 min	**Session 15:** • Design development and Risk Management • **Case 8** – Software, SaMD (Continued)	Siddharth Jain

Anchor Faculty and Venture Base Camp Director

Ravi Sarangapani
Consultant Medical Devices Product Development, Pune.

Mr. Ravi previously held senior positions for Sushrut / Adler in Product Development, Sales and Marketing, Regulatory affairs. He is an accomplished professional with over 25 years in the medical device industry encompassing leadership roles in New Product Development, Quality Management and Regulatory affairs, Marketing, Sales and Business Development. Mr. Ravi has proven track record of managing the new product development process from conceptualization and market analysis through development, risk management, pre-clinical evaluation, verification and validation, test marketing to commercialization. Outstanding communication talents with proven ability to build and lead highly efficient teams, train technical professionals and to convey complex concepts in understandable terms. Especially skilled at problem analysis and resolution, strategic planning and budget controls. Strong background of interactions with Key Opinion Leaders, customers and trade channels throughout Asia, Middle East, Africa and some areas of Europe.

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

Aniruddha Atre
Co-founder – Jeevtronics Private Limited, Pune.

Aniruddha Atre is an entrepreneur and the co-founder of Jeevtronics, a medical device startup based in Pune working on the world's first hand cranked defibrillator, a cardiac emergency therapy device designed for developing countries globally. He brings 21+ years of total industry experience 11 years of which is from the automotive industry in United States. His expertise spans product development, sourcing, product planning /program management and launch in high volume manufacturing plants in North America at Ford Motor Company. Aniruddha is passionate about social entrepreneurship and innovation and worked from concept to commercialization of human powered generators and solar powered devices with very long life energy storage and power electronics and now into medical devices. He also spent 1.5 years working in B2B engineering software solutions sales/marketing and technical support in India before moving to United States. He was awarded with Pune's pride and Top management consortium awards in 2014 for innovation.

Aniruddha holds Bachelors in Mechanical engineering from Pune university, Masters Degree in Mechanical engineering from Wayne State University, Detroit and MBA from Ross School of Business at the University of Michigan, Ann Arbor. During his MBA he was a student of legendary thinker Late Prof C.K. Prahalad who was his inspiration behind the journey in social entrepreneurship.

	**Lakshman Balajepalli** **Head, Quality and Regulatory, RAS Life sciences Private Limited, Hyderabad.** A Master of Sciences (Biochemistry) from a prestigious medical school in India. Over 28 years' experience in Life sciences industry (IVD and Human vaccines) which includes in over 20 years in IVD industry in R&D, manufacturing, QC, QA , Regulatory as well as of 8+ years' experience in process development, QA of human vaccines. Highly experienced in Regulatory, QMS including ISO 13485, ISO 9001, ISO 15189 systems. Faced many WHO and GMP audits. Was Consultant to overseas Biotech company for QMS. Has extensive experience in Indian MDR and QA as well as in EU IVDR, EU-MDR.
	**Ashish Hemade** **Head - Design Quality at Philips India Limited, Pune.** Head - Design Quality at Philips India Ltd. Ashish has more than20+ years of experience spanning across different domains like Medical devices, Automotive, business intelligence & Industrial Automation. He holds a degree in electronics engineering from Pune university and certified lead auditor for medical devices quality management system. He worked in multiple functions like R&D, Project management, Quality & Regulatory. Highly experience in New product development including product conceptualization, design and development, risk management, Verification / Validation and design transfer to Operations. He has rich experience in managing life cycle maintenance of medical Products and was also involved in Design/manufacturing transfers from Europe to India. He is currently looking after medical products from different modalities like interventional & Diagnostic-ray, CT etc.
	**Siddharth Jain** **Siddharth Jain is CEO and Chief Medical Device Regulatory Affair Advsior of Symbiorph Clinical Trialogy, Ahmedabad.** The company started in year 2015 and based out in Ahmedabad. He has more than 9 years of rich experience in Medical Device CE Certification, Clinical Evaluation, Post Market Clinical Follow-up (PMCF), Risk Management, Post Market Surveillance, Clinical Trial, Toxicological Analysis, and Usability Engineering. He has supported many medical device start-ups, small and mid-medical device manufacturing companies of India to accurately strategies their regulatory pathway and helps in earliest possible market entry in India, Europe and USA. Currently he is supporting the medtech start-ups in Indian Medical Device Rule, 2017 and CE Certification as per the MDR 2017/745 and IVDR 2017/746 for the Indian and European Countries respectively.
	**Hartesh Juneja** **Head Quality Operations at Peters Surgical India Private Limited. Gurgaon.** Hartesh is a QA RA professional with more than 16 years of experience in building Quality. Have hands-on experience in getting certifications like USFDA, MHRA, TGA, MCC, ANVISA, CE mark, ISO13485. Worked in companies like Axio Biosolutions, Apotex, Baxter, Torrent, Glenmark, Macleods.

	**Navnath Kadam** **Asst. Manager at RIFC - Venture Center, Pune.** Navnath provides leadership to the Regulatory Information and Facilitation Center (RIFC) at Venture Center, Pune and has been practicing regulatory science for over five years. Navnath regularly advises startups on planning their regulatory roadmap, product development, validations and facility planning. Also, he is developing a suite of services and resources of use to startups. Navnath has multifaceted working experience in managing Quality and Regulatory operations at Medical Devices startup Axio Biosolutions Pvt Ltd Bangalore and Ahmedabad for three years. He has accomplished a 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. Navnath is RAPS Credentialed Regulatory Affairs Professional 'RAC - Global' for medical devices, IVDs, pharmaceuticals, medicinal products and biologics and certified lead auditor for medical devices quality management system.
	**Biten Kathrani** **Head of R&D, Vision Care APAC at Johnson & Johnson, Singapore.** At Johnson & Johnson, Singapore, Biten is heading Medical Device R&D and Product Development Vision Care APAC. Biten worked as the GM for BSC R&D Global In-house Capability (GIC) Center, Biten lead Innovation and R&D for global & emerging markets for BSC's portfolio of Interventional Cardiology, Peripheral Interventions, Endoscopy, Urology, Neuromodulation and Rhythm Management. Biten has been instrumental in building Boston Scientific's largest R&D GIC outside of USA. The site has end to end R&D capabilities for single-use disposable devices and medical device software development with a focus on customer insights-driven innovation. In a short span of 4 years, under Biten's leadership, the site has launched 4 products, >45 patent filings and a state of the art R&D infrastructure with a team of >180 employees. Biten has been in the medical device industry for 23+ years, which includes heading medical device R&D at Johnson & Johnson in the Asia Pacific. He also specializes in New Business Development, Intellectual Property Analytics, New Ventures and Voice of Customer enabled innovation for medical devices. Biten holds an MBA from the ivy league Wharton Business School, M. Tech in Biomedical Engineering from IIT Mumbai; and he is a certified Patent Agent with the India Patent Office. He has launched more than 12 products and has several granted patents in his name. Specialties: Leadership, Customer insights-driven Innovation (Biodesign), People & Project Management, Entrepreneurship, Technology Due Diligence.

	**Neha Khaladkar** **Asst. Manager at BRBC- BIRAC Regional Bio-Innovation Center, Venture Center, Pune.** Neha is responsible for planning & co-coordinating activities of BRBC. She studied MSc. in Microbiology. During her Masters she did her project work in National Chemical Laboratory, Pune. Neha is a qualified healthcare/Lifescience expert with cross functional expertise. She is an experienced professional in Business Development and has 7+ years of experience working with a Healthcare IT company HQ in USA.
	**Nilay Lakhkar** **Founder and CEO- SynThera Biomedical Private Limited, Pune.** Nilay established SynThera Biomedical in early 2015 after returning to Pune from Germany, where he previously worked as a postdoctoral researcher at Helmholtz Zentrum Geesthacht Institute of Biomaterials Science in Teltow, close to Berlin. Before that, he completed MSc and PhD degrees in Biomaterials and Tissue Engineering from University College London (UCL Eastman Dental Institute), UK, with a research focus on bioactive glass materials for orthopedic, dental and maxillofacial applications. His undergraduate degree is in Chemical Engineering from University of Mumbai. Thus, he brings a strong background combining engineering and materials science, with special focus on healthcare materials, and he currently manages the company's overall functioning and strategic direction.
	**Priya Nagaraj** **Bio incubation Manager - Venture Center, Pune.** 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.
	**Siddarth Shetty** **Head- Post Market Surveillance (Mobile Surgery) @ Philips India Limited, Pune.** Siddarth has 17+ years of work experience, 11 of which have been in the Medical Devices industry. He has held roles in R&D, project/program management, life cycle management and more recently in the Quality & Regulatory domain. In his current role at Philips he is responsible for all the Post Market Surveillance activities @ Pune including complaint handling, vigilance reporting & product risk management. His diverse experience covers products such as Interventional & Diagnostic X-rays, Nuclear medicine (SPECT/SPECT-CT) & ICU critical care beds. Siddarth holds a Bachelors in Electronics Engineering from Mumbai university, Masters Degree in Electrical Engineering from Drexel University, Philadelphia, USA and MBA from Symbiosis Institute of Business Management.

	**Aravindan Vasudevan** **Aravindan Vasudevan is the co-founder and CEO of Actorius Innovations and Research Private Limited, Pune.** At Actorius, Aravindan was part of the team which developed the OncoDiscover - Liquid Biopsy Technology, India's first indigenously developed DCGi approved IVD technology.He has wide ranging experience in the pharmaceutical industry and is an IRCA Certified ISO 13485:2016 lead auditor. His expertise lies in creating strategies and operational capabilities for taking technologies from lab to market. Aravindan is part of multiple companies focused on developing technologies in the areas of cancer diagnostics, novel drug delivery systems and, high-performance anti-corrosion coatings.
	**Premnath Venugopalan** **Founding Director of Venture Center and Head, NCL Innovations, Pune.** Premnath 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.

About the Organizers

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/

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/

Supported by

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 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.
For more information, visit www.venturecenter.co.in