Venture Base Camp on

Regulatory Processes and Certifications

- Make your own regulatory roadmap in 3 intense days! -

- Organized by BRBC -

Potential gains	• This event is a Venture Base Camp (VBC). ***This VBC aims to de-mystify regulations and help startups chart out their regulatory pathway in 3 intense days.*** The primary goal is to reduce uncertainties and bring confidence amongst startups on regulatory matters. • This camp will focus only on ***Medical Devices (including Diagnostics)***. (Other products will be taken up in future VBCs). • Regulatory Booklet for reference. • Best regulatory strategy presentation award worth ≈50, 000 INR.
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 | 5, 6, 7 Feb 2019 | 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://tinyurl.com/VBC-Regulatory** • Step 2: Email invite will be sent post screening of registration details. • Step 3: Attendance only on confirmation of payment of registration fee*. • Category **'A' participants are** eligible to get travel fellowship up to 13000 INR. Reimbursement upon presenting receipts.

Category	Fees (Rs)
A) VC Incubatees, BIRAC Grantees who are small entities	1000/-
B) Micro/small enterprises, startups; Non-profit/R&D/academic orgs; individuals	2000/-
C) Others including medium/ large enterprises	10000/-

Preference: Startup companies (LLC/PLC) vs. individuals if we receive more than 20 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 20 seats are full or on 31 Jan 2019 (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)
- Only **regulatory pathway**

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.

End point of this workshop: Go home with a **Regulatory Roadmap** for your innovation or startup. You should be able to answer questions posed to you by reviewers, regulatory bodies and investors on the regulatory pathway. You will have a fundamental understanding of the processes, essential tasks ahead, expected timelines and costs.

Workshop Outline

Workshop shall consist of:

- Get **pre-workshop basic regulatory pathway** for your device from RIFC team. (Telecom and discussions).
- **Talks, classroom sessions and Q&A sessions.**
- **Workshop mode sessions** to help participants in finalizing the roadmap.
- **One on one mentor meetings** to work on your device.
- **Roadmap preparation by participant and presentation to mentors.**
- **Post workshop roadmap review** by RIFC team.
- Best regulatory strategy presentation awards worth ≈50, 000 INR ISO standards for two participants.

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.
- Free access to a restricted website and/or a workbook.
- One-year free reference membership to Venture Center Library (http://www.vcenterlibrary.org/)
- Certificate of Participation.

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/

PRE-BASE CAMP

Sr. No.	Action point for participants	Mode	Timelines
001	Pre-workshop basic regulatory pathway from RIFC	Telecom and discussions	Within 2 days of registration
003	Templates for Roadmap presentation	Electronic document	Upon registration

Workshop Schedule

DAY 1: 5 Feb 2019 – Tuesday
CONCEPTS, OVERVIEW& MENTORING

Time	Duration	Session title	Lead
0900-0930	30 min	Registration	
0930-1100	90 min	**Session 1: Acts, Laws, Standards (Industry Perspective) (45 min each)** • Overview of relevant laws, applicable acts, methods and procedures set in the rules. • Internationally agreed, device-specific standards. Introduction to BIS, ISO, IEC, ANSI, ASTM, standards for testing.	**Slot 1** Neena Sonavane **Slot 2** Neena Sonavane
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 2: Guidelines & Principles (45 min each)** • Grouping Guidelines for Medical Device Applications. • Essential Principles for Safety and Performance.	**Slot 3** Arvind Savargaonkar
1300-1400	60 min	Lunch break	

One-on-One Mentoring

Time	Duration	Room 1	Room 2	Room 3	Room 4
		TBD **Diagnostics**	**Neena Sonawane** **Electrical Devices**	**Arvind Savargaonkar** **Radiology & Imaging**	**Anil Chaudhari** **QMS& Facility**
1400-1440	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.
1440-1520	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.
1520-1540	20 min	Tea break			
1540-1620	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.
1620-1700	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.
1700-1740	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.

Workshop Schedule cont..

DAY 2: 6 Feb 2019 – Wednesday
CONCEPTS, OVERVIEW& MENTORING

Time	Duration	Session title	Lead
0930-1100	90 min	**Session 3: Pre-clinical, Characterization & Predicate device (45 min each)** • Planning for regulations in pre-clinical studies. • Planning for design, materials, and substantial equivalence (predicate device route).	**Slot 4** Mukul Pore **Slot 5** Kiran Sonaje
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 4: Clinical Investigation& Performance Evaluation (90 min)** • Planning for Clinical study design, statistics, Clinical studies, ethical approvals, hospital partners and ethics committee.	**Slot 6** Ravindra Ghooi
1300-1400	60 min	Lunch break	

One-on-One Mentoring

Time	Duration	Room 1	Room 2	Room 3	Room 4
		Mukul Pore **Pre-clinical**	**Ravindra Ghooi** **Clinical**	**Kiran Sonaje** **Predicate/ Substantial Equivalence**	**Anil Chaudhari** **QMS& Facility**
1400-1440	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.
1440-1520	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.
1520-1540	20 min	Tea break			
1540-1620	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.
1620-1700	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.
1700-1740	40 min	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.	Mentoring slots. Work at your station when not in mentoring.

Workshop Schedule cont..

DAY 3: 7 Feb 2019 – Thursday
CONCEPTS, OVERVIEW& ROADMAP PRESENTATION

Time	Duration	Session title	Lead
0930-1100	90 min	**Session 5: Manufacturing, QMS, Facility** **(45 min each)** • Planning manufacturing process and facility for devices. • Planning for Quality Management System.	**Slot 7** Manickam P. **Slot 8** Saurabh Rawat
1100-1130	30 min	Tea break	
1130-1300	90 min	**Session 6: Approvals and Post Market Regulations (Regulatory Perspective) (45 min each)** • Planning for marketing approvals and certifications. • Post-market requirements in India.	**Slot 9** Rubina Bose
1300-1400	60 min	Lunch break	

ROADMAP PRESENTATIONS

Download template at: https://bit.ly/2AGG0M1

Time	Duration	Panel 1	Panel 2
		Slot 10 Nikita Jhaveri Priya Nagaraj Rubina Bose Saurabh Rawat	**Slot 11** Navnath Kadam Premnath V P. Manickam Anil Chaudhari
1400-1515	75 min	Presentation slots 5 X 15 min each (10 min presentation, 5 min comments)	Presentation slots 5 X 15 min each (10 min presentation, 5 min comments)
1515-1545	30 min	Tea break	Tea break
1545-1600	75 min	Presentation slots 5 X 15 min each (10 min presentation, 5 min comments)	Presentation slots 5 X 15 min each (10 min presentation, 5 min comments)
1600-1630	30 min	Closure & High Tea	

BEST REGULATORY STRATEGY PRESENTATION AWARD WORTH ≈50, 000 INR

In the form of following standards – for two participants from slot 10 and 11

ISO 13485:2016 Medical devices — Quality management systems -- Requirements for regulatory purposes (≈ 12, 000 INR)

ISO 14971:2007 Medical devices — Application of risk management to medical devices (≈15, 000 INR)

ISO/ TR 24971:2013(en) Medical devices — Guidance on the application of ISO 14971 (≈5, 000 INR)

IEC 62366-1:2015(en) Medical devices — Part 1: Application of usability engineering to medical devices (≈20, 000 INR)

Note: The licensed copies of the standards will be purchased on the registered company name of the winner.

Anchor Faculty and Venture Base Camp Director

Prof. Ravindra Ghooi

Current positions held:
Director, Scientia Clinical Services.
Chairman, Institutional Ethics Committee, Jehangir 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: Haffkine Institute, (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.

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

Dr. 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, 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.

 **Mr. Anil Chaudhari**	Founder & CEO at Operon Strategist Private Limited, Pune. Anil Choudhari has over 18 years of experience in the field of Regulatory and Quality assurances of medical devices. Operon Strategist offers service in the areas of Quality management systems, Design and development of medical devices, Regulatory approvals, Marketing authorizations, Validations and Manufacturing setup of Medical devices.
 **Ms. Nikita Jhaveri**	Project Associate, BRBC - Venture Center, Pune. 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.
 **Mr. Navnath Kadam**	Asst. Manager at RIFC - Venture Center, Pune. Navnath Kadam provides leadership to the RIFC at Venture Center, Pune. He regularly advises startups on planning their regularly roadmap and facility planning. He is developing a suite of services and resources of use to startups. He has multifaceted working experience in managing Quality and Regulatory operations at Medical Device startup 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.
 **Ms. 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.

 **Mr. Manickam P.**	Freelancer consultant / Advisor and trainer for Quality Management System implementation and practices. He is a mechanical engineering graduate with post-graduation in materials management. He has 33 years of manufacturing experience in various organizations, followed by 16 years in training, consultancy and certification services. His manufacturing experience relates to engineering products and medical devices. Qualified Lead Auditor for: Quality Management Systems standards ISO 9001, ISO 13485, ISO/TS 16949 Standards. He has experience in regulatory assessment for Medical devices directives of EU, Canadian Conformity Assessment Systems and PAL JGMP, Japan Trained for Third Party Inspection for US FDA, ISO 9001 and ISO13485 Lead Auditor and Internal Auditor, Risk Management as per ISO 14971, Medical Device Single Audit program (MDSAP) implementation, Experienced in Technical reviews against Medical Devices Marketing Authorization program of SFDA. Extensive global audit experience, including for Medical Devices and In-vitro Diagnostic Devices. Currently supporting manufacturers for documentation, implementation for QMS and regulatory requirements.
 **Dr. Mukul P. Pore**	Co-Founder & Director, INTOX Private Limited, Pune. Dr. M. P. Pore is one of the founders of INTOX, and is the whole time Director of INTOX Pvt. Ltd. He looks over the responsibility of the Technical Director in the GLP organization of INTOX. Dr. Pore is a Diplomate of the American Board of Toxicology (DABT) and is also a European Registered Toxicologist (ERT) since 2009. With a degree in Veterinary Medicine (BVSc & AH) in 1986, Dr. Pore earned his Master's degree (M.V.Sc.) in Veterinary Pathology in 1989 from the Department of Pathology, Bombay Veterinary College, Mumbai. Dr Pore briefly worked for Bombay Veterinary College and later in toxicology CRO for about 7 years (1989-1996) before co-founding INTOX in 1995-1996. Dr. Pore has designed and conducted toxicology studies for diverse kinds of products - Pharmaceuticals, Agrochemicals, Biotechnology Products, Specialty chemicals, Vaccines, Medical Devices, Industrial chemicals etc. during his experience of over 26 years in regulatory toxicology. Dr. Pore has undergone several trainings in Regulatory Toxicology, GLP, and is also a GLP trainer. Also active in Animal Welfare issues, he is a Fellow & Associate of 'Academy of Sciences for Animal Welfare, India' and is an Ad Hoc Specialist for AAALAC International, USA (2010-2013; 2013-2016). He is a member of many professional bodies/ societies including the Indian Society of Toxicology (STOX), Chinese Society of Toxicology, and Japanese Society of Toxicology (JST). Dr. Pore received the 'Fellow of Society of Toxicology' (FST) award by Society of Toxicology (STOX), India, for the year 2009.

 **Dr. V Premnath**	Founding Director - Venture Center and Head, NCL Inovations. 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.
 **Mr. Saurabh Rawat**	Manager – Quality Assurance at Axio Biosolutions Private Limited, Ahmedabad. Saurabh is documentation expert in designing and implementation of Quality Management System (QMS). He has hands-on experience on phase wise QMS up-gradation, deviation & change management, Product Quality Reviews, Gap Analysis, Quality Inspections & Audits, Complaint Management, Team Management, CAPA Management, Document Design, Control &Review, Vendor Audit & Qualification, Quality Risk Management and Impact Assessment. He is a Qualified Internal Auditor for Quality Management System Standard ISO 13485: 2016. He holds masters in pharmacy – Pharmaceutics, MBA – General Studies, 6+ Years of experience in Quality Management. He worked at, Zydus Cadila, Teva Pharmaceuticals, TPL Biologicals.
 **Dr. Arvind Savargaonkar**	Founder & CEO at Streben Healthcare Private Limited, Chennai. Arvind is a Med Tech specialist with 25 years of experience. He is an early entrepreneur to venture into Med Tech space in 1993, before the globalization and digital era reached India. He founded and built medical devices SME taking it to a customer base of 3000+ hospitals across India through indigenous development of affordable medical products. He has also founded and built an embedded software technology venture that catered to embedded and communications technology leaders in the USA. Arvind currently leads a Med Tech startup in the mental stress measurement technology domain. He is passionate about building affordable and scalable solutions to deliver benefits of advancements in medical technology and help the cause of prevention of lifestyle diseases. He is also part of the mentoring team at IIT Madras Incubation Cell and is mentoring IIT Madras incubated startups and aspiring student entrepreneurs. By training, Arvind is an Electronics and Telecommunication Engineer with M Tech from IIT Madras in Solid State Technology.

 **Dr. Kiran Sonaje**	Principal Scientist at Axio Biosolutions Private Limited, Ahmedabad. Dr. Kiran is a seasoned R&D manager with a bench to bedside product development and tech transfer experience. He is working as a Principal Scientist at Axio Biosolutions Private Limited, Ahmedabad. He holds 10+ years of research experience in biomaterials, novel drug delivery systems, and medical devices. He has over 21 US patents and 20 research articles to his name with over 2500 citations. He is an expert in design and development planning, verification and validation and clinical evaluation of medical devices. He was instrumental in receiving FDA-510(k) approval for Axiostat, the first wound-care product from India to receive the US-FDA approval. Prior to joining Axio, he worked as a Senior Post-doctoral fellow at the University of Geneva and as a Consulting research scientist for Nanomega Medical Corporation. He has completed Ph.D. in Chemical Engineering from National Tsing Hua University, Taiwan and Masters degree in Pharmaceutics from National Institute of Pharmaceutical Education and Research, Mohali.
Mrs. 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 a 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).

RIFC	BRBC A BIRAC - Venture Center Initiative	VENTURE CENTER	birac Ignite Innovate Incubate

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. More on: http://www.brbc.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. More on: http://rifc.venturecenter.co.in/

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