













Regulatory Clinic Regulatory Clinic for Medical Devices and Diagnostics at KIIT-Technology Business Incubator, Kalinga Institute of Industrial Technology (KIIT), Bhubaneswar

- Organized by BRBC -

| Potential gains | This event is an R Clinic organized by BRBC. The goal is to understand regulatory requirements and roadmap for securing regulatory approval for medical products in India. The Clinic will also focus on understanding the relevant Acts/ Laws/ Rules and standards applicable to medical devices and diagnostics. The Clinic will provide a | | | | |
|----------------------|--|--|--|--|--|
| | practical understanding of regulatory pathways and timelines for approvals. | | | | |
| | BRBC | | | | |
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| | Regulatory | | | | |
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| Organized by | BIRAC Regional BioInnovation Center (BRBC) @ Venture Center | | | | |
| | KIIT – Technology Business Incubator, Bhubaneswar | | | | |
| Supported by | BIRAC (Biotechnology Innovation Research Assistant Council) | | | | |
| | Venture Center | | | | |
| For whom | CEOs/CTOs of innovative technology startups. | | | | |
| | Individual Inventors. Inventors from BSD institutes madium/large enterprises. | | | | |
| Mentor | Inventors from R&D institutes, medium/ large enterprises Dr. Ravindra Ghooi | | | | |
| Welltoi | Navnath Kadam | | | | |
| | Wednesday, 23rd Oct 2019 09:00 – 17:00 Hrs | | | | |
| When | | | | | |
| | Conference Hall 6, KIIT Technology Business Incubator | | | | |
| Where | Kalinga Institute of Industrial Technology (KIIT), | | | | |
| | Campus – 11, Patia, Bhubaneswar, Odisha, India | | | | |
| | Pin: 751024 | | | | |
| Registration Details | | | | | |
| | Total number of seats for talk: 50 | | | | |
| | Total number of mentoring slots: 12 | | | | |
| | Registration Process: | | | | |
| | Step 1: Interested participants need to fill in registration form at the following link. | | | | |
| | Register online at: http://bit.ly/RClinic-23Oct Step 2: Email invite will be sent post screening of registration details. | | | | |
| | Preference: Startup companies (LLC/PLC) vs. individuals if we receive more than | | | | |
| | 50 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 50 seats are full or on 15 th Oct 2019 | | | | |
| | (whichever is sooner). | | | | |
| Contact | Technical queries and registrations: | | | | |
| Contact | Navnath Kadam/Neha K. 020-25865877/76; rifc@web.venturecenter.co.in | | | | |
| | Venue queries: | | | | |
| | Dr. Nivedita Jena nivedita@kiitincubator.in +91-9556716477 | | | | |















| R Clinic schedule | | | | |
|-------------------|----------|--|---|--|
| Time | Duration | Session title | Lead | |
| 0900- 0930 | 30 min | Registration and refreshments | | |
| 0930 - 0945 | 15 min | Session 1: Welcome note Opening remarks | Dr. Nivedita Jena Chief Scientific Officer (KIIT) | |
| 0945 - 1045 | 60 min | Session 2: Introduction to medical products regulations in India Pathway Assessment – Development, Approvals | Navnath Kadam | |
| 1045 - 1115 | 30 min | Networking and tea break | | |
| 1115 - 1245 | 90 min | Session 3: Awareness on current medical requirements for medical products and clinical trials in India Clinical research/clinical investigation/performance evaluation | Ravindra Ghooi | |
| 1245 - 1345 | 60 min | Lunch | | |

Slots for Mentoring

| Session 4: One-on-one meetings | | | | | | |
|--------------------------------|--------|----------------|---------------|--|--|--|
| | | Ravindra Ghooi | Navnath Kadam | | | |
| 1400 - 1700 | 30 min | | | | | |
| | 30 min | | | | | |
| | 30 min | | | | | |
| | 30 min | | | | | |
| | 30 min | | | | | |
| | 30 min | | | | | |















Speakers/faculty (in alphabetical order of last names)

Dr Ravindra Ghooi



Dr. Ravindra Ghooi

Dr. Ravindra B. Ghooi, is a pharmacologist with over 46 years of experience, in the field of drug discovery and development. He holds a Masters in Pharmacology and a Doctorate in Medicine, and has trained at Haffkine Institute in Mumbai and Max Planck Institute in Gottingen, Germany. Dr. Ghooi spent over twenty years in the pharmaceutical industry, heading the medical department as a Medical Advisor. He has been involved in clinical research for the last 35 years, in the role of a sponsor, CRO, regulatory expert and advisor. He has been teaching clinical research for over a decade and has authored two books on the subject. He presently is a consultant in research, serves a number of ethics committees, and editorial boards of two journals. He has over 65 research papers to his credit, and guides students at the Ph. D level.

Navnath Kadam

Navnath Kadam

Navnath Kadam provides leadership to the RIFC at Venture Center, Pune. He regularly advises startups on planning their regulatory 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.















About the Organizers



BIRAC Regional Bio-Innovation Center (BRBC) is a resource intensive center set up by BIRAC at Venture Center. Through its diverse initiatives, BRBC aims to significantly impact the translation of high quality innovative ideas across diverse ecosystems into viable and sustainable business enterprises. BRBC Initiatives: Venture Mentoring Service; Venture Base Camps; Regulatory Information and Facilitation Center; BioIncubation Practice School

For more information, visit: http://www.brbc.venturecenter.co.in/





KIIT Technology Business Incubator (KIIT-TBI) was started in 2009 as an initiative of Kalinga Institute of Industrial Technology (KIIT) Deemed to be University and supported by National Science & Technology Entrepreneurship Development Board (NSTEDB), Dept. of Science & Technology (DST), Govt. of India. Since its inception, KIIT – TBI has provided a vibrant ecosystem for promoting innovations and entrepreneurship development. Having established as a premier university based incubation centre, KIIT – TBI has expanded its verticals in health care, Life sciences and social incubation. Our status as an emerging social innovation hub in the country is reinforced by DFID INVENT seed fund.

Supported by



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



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.

For more information, visit : http://rifc.venturecenter.co.in/



Biotechnology Industry Research & Assistance Council (BIRAC) 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.

For more information, visit: www.birac.nic.in