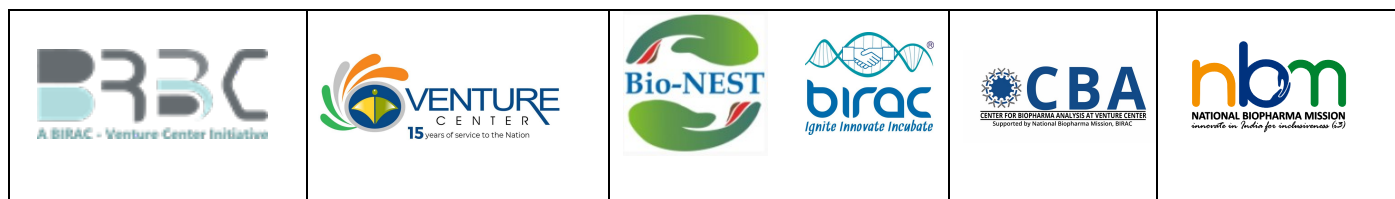


Symposium on Taking BioPharma Products to Global Market (Hybrid Mode)

- Organized by BRBC-

POTENTIAL GAINS	The objective is to introduce Biopharma professionals working in biopharmaceutical development and manufacturing to FDA, EMEA and equivalent international regulatory requirements. It is useful for managers, researchers and for everyone working with Biologics to understand the importance of quality assurance and regulations for biopharmaceuticals.
ORGANIZED BY	<ul style="list-style-type: none"> BRBC- A BIRAC and Venture Center, Pune Initiative
CO-ORGANIZED BY	<ul style="list-style-type: none"> Center for Biopharma analysis- A NBM and Venture Center, Pune Initiative
SUPPORTED BY	<ul style="list-style-type: none"> Venture Center National Biopharma Mission BIRAC
FOR WHOM	Startups, Researchers, Indian companies, and multinationals that are working or wish to work on Novel Biologics/Biosimilars/Vaccines.
WHEN	Friday, 22 Apr 2022 Event Time: 04:00 pm – 7:00 pm Meet & Greet: 7:00 pm – 8:30 pm
WHERE	<ul style="list-style-type: none"> This Event will be available to attend Online (Zoom) & Offline (Venture Center) Link to the Event & Details will be shared with selected participants. Kindly Choose option as suitable in registration form
CONTACT	Technical queries: Meghana Bhandari Email: meghana.bhandari@venturecenter.co.in Registration queries: Lipika Biswas Email: eventsdesk@venturecenter.co.in
REGISTRATION	<p>Registration is free but Mandatory</p> <p>Steps for registration:</p> <ul style="list-style-type: none"> Step 1: Interested participants need to fill in registration form at the following link. Register online at: https://tinyurl.com/ycy2vway Step 2: Attendance only on confirmation from organizers. <p>Note: -</p> <ul style="list-style-type: none"> Organizers reserve the right to select participants to maximize learning and networking opportunities for the group Session will be conducted using ZOOM online & offline. Only registered participants will be allowed to participate in the event.









Introduction







The biopharmaceuticals market is expanding far more rapidly than the overall pharmaceutical industry. Regulations and quality assurance principles play an important and mounting role in the biopharmaceutical industries. Companies with biologics in the development pipeline are advised to study, implement, and enforce regulations; otherwise, they will not get approval to market the biologics. This symposium aims to help the interested companies to focus on regulatory compliance as one of the critical aspects of drug development and manufacturing. The symposium includes an overview of the Biopharmaceutical industry and the global regulations, case studies, and experience sharing by multinational pioneer companies, consultants and start-ups.





Session Schedule







Time	Duration	Session Title	Lead
4.00 -4:15	15 min	About the Symposium Introduction to Venture Center	Narendra Chirmule Smita Kale
4.15 -4.45	30 min	Overview Biopharmaceutical Development Pathway	Taruna Arora
4.45 -5.15	30 min	CMC Strategy for Biologic	Jyoti Iyer
5.30- 6.00	30 min	Key Regulatory Guidelines for the Development	Samir Sangitrao
6.00- 6.10	10 min	Overview of Center for Biopharma Analysis	Sreekanth Rouduri
6.10-7.00	50 min	Panel Discussion: Global Regulations in Biopharma	Moderator: Narendra Chirmule Panelists: Taruna Arora, Jyoti Iyer, Samir Sangitrao
7.00- 8.30	90 min	Networking & Dinner	

					
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Speakers (in alphabetical order of last names)	
	<p>Taruna Arora Vice President, Biotherapeutics Discovery & Translational Research</p> <p>She is a R&D leader with a passion for immunology, drug hunting, and drug development to enable effective solutions for treatment of diseases. In 20+ years of working in large and small biopharma, biotech, academic institutes, and VC firms she has led initiatives and team efforts to deliver on multiple biologics IND candidates, inventions and approved drugs in I/O, heme-onc, inflammation, cardio/metabolic, and neuroscience areas. Her interests lie in disruptive thinking, accelerated advancement of therapeutics to clinic for patients' benefit, and shaping corporate strategies by connecting science, people, functions, and cultures. She is an active contributor to EU/US/AUS filings, BLA/MAA approvals, F2F FDA meetings.</p>
	<p>Narendra Chirmule Chief Scientific Officer, AculImmune. Freelance</p> <p>Narendra Chirmule is a Biotechnology professional and a music enthusiast. He has published and presented seminars on subjects of immunology, biologics and vaccines and contributed to development of vaccines and biologics. The drug development experiences include Vaccines for cervical cancer [HPV], shingles [Varicella zoster], childhood diarrhoea [Rotavirus]), and Biologics for osteoporosis [Prolia], rheumatoid arthritis [Enbrel], platelet loss (NPlate) breast cancer (Ogrivi) among many others. He has worked on basic concepts of gene therapy using viral vectors. He did his PhD on development of a leprosy vaccine, from Cancer Research Institute, Mumbai; post-doctoral studies on pathogenesis of AIDS from Cornell University Medical College-North Shore Hospital, and taught immunology at the University of Pennsylvania.</p>
	<p>Jyoti Iyer Consultant and Researcher (Ex-Biocon RND)</p> <p>She has a technical expertise of all aspects of CMC in developing therapeutic biosimilar molecules from early stage until regulatory approvals. She has worked on purification process development, Scale-down and Process characterization, Scale-up, Technology-transfer, Process Validation, Viral validation and Troubleshooting, Defining Critical Quality Attributes, QTPP and steering process development around this knowledge, Analytical and characterization tools and technologies, analytical similarity report, etc. She enjoys work-around challenges by creating or influencing creation of systems and processes within and outside my span of control. She has a talent to build a connect at a personal and professional level, thus managing complex challenges through active participation, can engage closely with stakeholders and senior management and is passionate about teamwork and mentoring people.</p>
	<p>Samir Sangitrao Vice President, Head Regulatory Affairs and R&D QA, Biologics</p> <p>He is an experienced Regulatory Affairs Professional with 24 years of experience in the leading biotech and pharmaceutical companies. He is skilled in Strategic Planning, Project Management, R&DQA, and Regulatory Affairs (Domestic, EMB and Regulated market). He is a strong healthcare professional with Regulatory Affairs Certification (US) from Regulatory Affairs Professional Society, USA. He actively works in regulatory reforms & policy shaping – and has represented ABLE, OPPI, IPA, FICCI for several regulatory reforms in India.</p>

					
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Organizers (in alphabetical order of last names)	
	<p>Meghana Bhandari Associate- Bioincubation, Venture Center</p> <p>Meghana is responsible for planning & co-coordinating activities of BRBC. She studied M.Tech in Biomedical engineering from IIT Ropar. During her Masters she did her project work on intranasal drug delivery system for treating Alzheimer's Disease. Previously she has worked as a medical writer for a biopharma company.</p>
	<p>Smita Kale Manager –Bioincubation, Venture Center</p> <p>Smita as part of incubation team, facilitates incubator operations by interacting with incubatees, infrastructure and facilities creation and development of the ecosystem. She is leading Bio-incubation activities, Center for Biopharma Analysis (CBA) and BIRAC's Regional Bioinnovation Center (BRBC) projects at Venture Center. She is actively involved in mentoring startups at Venture Center. She is Ph. D in Pharmaceutical Chemistry from Institute of Chemical Technology, Mumbai and prior to joining Venture Center has had academic experience of 12 years which includes research experience of 3.6 years.</p>
	<p>Sreekanth Rouduri Chief Scientific and Business Officer, Venture Center</p> <p>Sreekanth has over 20 years of Pharma R&D experience in leadership roles in the USA and India (Vertex, Advinus, Sai Life, Venture Center), with a successful track record of establishing state of the art labs and high performing teams, and leading multiple cross functional drug discovery efforts some of which have reached clinical development/approval stages in diverse therapeutic areas. His experience includes both small molecules and large molecule biotherapeutics. During this tenure, he worked in innovator as well as contract research organizations where he collaborated effectively with many pharma, biotech and academia partners across the globe. Dr. Rouduri received his Ph.D. from CCMB, Post-doctoral training from Harvard Medical School, and Business Management certificate from North-Eastern University.</p>
	<p>Premnath V Director, Venture Center Head, NCL Innovations</p> <p>Premnath V is currently the Head, National Chemical Laboratory (NCL) Innovations - the group within NCL charged with the responsibility of championing the cause of technology innovation within NCL. Dr Premnath is also the Founding 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 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. He brings with him considerable experience in technology development and commercialization (two successfully commercialized families of products), working with start-up companies (in Cambridge-UK and India) and engaging with large corporations on research and consulting projects as project leader.</p>

 A BIRAC - Venture Center Initiative	 15 years of service to the Nation		 Ignite Innovate Incubate	 CENTER FOR BIOPHARMA ANALYSIS AT VENTURE CENTER Supported by National Biopharma Mission, BIRAC	 NATIONAL BIOPHARMA MISSION innovate in India for inclusiveness (i3)
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Organized by	
 A BIRAC - Venture Center Initiative	<p>BIRAC Regional Bioinnovation 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 Centre; Bio Incubation Practice School.</p> <p>More on: http://www.brbcc.venturecenter.co.in/</p>
Supported by	
 NATIONAL BIOPHARMA MISSION innovate in India for inclusiveness (i3)	<p>National Biopharma Mission (NBM) is a Mission of the Government of India approved by the Cabinet for implementation in May 2017. The NBM's mission is to make India a hub for design and development of novel, affordable and effective biopharmaceutical products and solutions. The NBM has an allocation of US\$ 250 million and is jointly funded by the Government of India and the World Bank in equal measure. The NBM is officially known as "An Industry-Academia Collaborative Mission of Department of Biotechnology (DBT) for Accelerating Early Development for Biopharmaceuticals". Biotechnology Research Assistance Council (BIRAC) is the implementation partner of the Government of India for the Mission. For more information, visit: https://birac.nic.in/nbm/</p>
 Ignite Innovate Incubate	<p>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</p>
 CENTER FOR BIOPHARMA ANALYSIS AT VENTURE CENTER Supported by National Biopharma Mission, BIRAC	<p>Center for BioPharma Analysis (CBA) is an initiative of Venture Center supported by the National BioPharma Mission, BIRAC (Government of India). The Venture Center is a technology business incubator hosted by CSIR-National Chemical Laboratory, Pune. It is a state-of-art GLP compliant facility with high-end instrumentation and industry-linked personals provides globally acceptable analysis of biopharmaceuticals. It provides open access cutting-edge technologies for Biopharmaceutical Analysis and would emerge as resource center for Characterization of Biopharmaceuticals. The facility aims to cater all academics, small to medium size biosimilar developers through-out the India and the world.</p> <p>More on: https://www.venturecenter.co.in/biopharma/</p>
 15 years of service to the Nation	<p>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: http://www.venturecenter.co.in/</p>