




## e-Regulatory Clinic on Regulations, Standards and Certifications for PPEs and Medical Devices

- Organized by BRBC -

<b>Potential gains</b>	<p>This event is an e-R Clinic organized by BRBC. The goal is to; Expand understanding of the different standards, Importance of compliance, Expand understanding of the current harmonization initiatives in India, Provide an overview of the different types of standards, Provide an overview of the terminologies like certification, accreditation, registration, approval, licensing, Provide an overview of the Certification (Product, System), Provide an overview of using different standards (Fundamental standards, Test methods and analysis standards, Specification standards, Organization standards).</p> <div style="text-align: center;">  </div>
<b>Organized by</b>	<ul style="list-style-type: none"> <li>Regulatory Information and Facilitation Center (RIFC) @ Venture Center</li> <li>BIRAC Regional BioInnovation Center (BRBC) @ Venture Center</li> </ul>
<b>Supported by</b>	<ul style="list-style-type: none"> <li>BIRAC (Biotechnology Innovation Research Assistant Council)</li> <li>Venture Center</li> </ul>
<b>For whom</b>	<ul style="list-style-type: none"> <li>CEOs/CTOs of innovative technology startups.</li> <li>Individual Inventors.</li> <li>Inventors from R&amp;D institutes, medium/ large enterprises</li> </ul>
<b>When</b>	<ul style="list-style-type: none"> <li><b>Wednesday, 22 July 2020   Time: 1100 – 1320</b></li> </ul>
<b>Where</b>	<ul style="list-style-type: none"> <li>Online on Zoom/ WebEx.</li> </ul>
<b>Registration Details</b>	<p>Registration Process: Interested participants need to fill in registration form at the following link. <b>Register online at:</b> <a href="https://tinyurl.com/22july2020">https://tinyurl.com/22july2020</a> <b>Total number of seats: 100 Event is Free!!!</b></p> <p>Preference: Startup companies (LLC/PLC) vs. individuals if we receive more than 100 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. <b>NOTE: Registration closes once 100 seats are full or on 20 July 2020 (whichever is sooner).</b></p>
<b>Contact</b>	<p><b>Technical queries and registrations:</b> Navnath Kadam   020-25865877/76; <a href="mailto:rifc@web.venturecenter.co.in">rifc@web.venturecenter.co.in</a></p>

e-R Clinic Schedule			
Time	Duration	Session title	Lead
1100-1110	10 min	Introduction: e R Clinic, Organizers, Speakers	Navnath Kadam
1110-1130	20 min	Understanding the regulations for PPEs in Indian Scenario	Anil Jauhri
1130-1150	20 min	Overview of Indian Standards on Medical Devices	Prakash Bachani Chandan Kumar
1150-1210	20 min	National Certification Schemes& Current Harmonization initiative in India for Med Devices	Rajiv Nath
1210-1230	20 min	Management System and Product Certification	MG Sathyendra
1230-1250	20 min	SWOT of the PPE Industry	Sanjiv Relhan
1250-1320	30 min	Panel Discussion and Q&A moderator by Dr. Premnath V	All of the above

**RIFC****BRBC**  
A BIRAC - Venture Center Initiative**Speakers/faculty (in alphabetical order of last names)****Prakash Bachani,**  
**Scientist-F & Head (Medical Equipment & Hospital Planning Dept), Bureau of Indian Standards (BIS)**

Mr. Prakash Bachani Scientist F & Head (Medical Equipment & Hospital Planning Dept.). He has 37 years' experience in Bureau of Indian Standards, the National Standards Body of India, having worked in Standard Formulation, Laboratory and Certification Activities. At the Technical level, he has overseen Product Certification, System Certification (QMS), Hallmarking of Gold and Silver, Standards Formulation (Electrotechnical and Medical Equipment & Hospital Planning), Laboratory Management. He has participated in various international seminars and meetings organized in the country in the field of Electrotechnical as well as in Medical Equipment and Devices. He has also presented several papers on Standardization, Certification etc. in the field of Electrical Engg. And Medical Equipment at various National and International meetings/ seminars. He is GOLD MEDALIST in MIE (Electrical Engg.), Institution of Engineers, India.

**Anil Jauhri**

Mr. Anil has spent four decades in the government holding various positions like, scientist, director, advisor, CEO in NABCB/ QCI, BIS, IEC, etc. He is a member of UNFCC CDM Accreditation Panel; Member, Yoga Certification Board; Chairman, SC, GCPCS, CDSA. Member APO Technical Working Group on Accreditation, IAF Evaluator APAC, Lead Peer Evaluator NABCB Lead Assessor.

He has notably lead NABCB's achievement of international equivalences by signing the mutual recognition arrangements of regional bodies, Pacific Accreditation Cooperation, for Product certification, Food safety MS (FSMS), Information Security MS (ISMS), Global GAP, Energy MS (EnMS), Occupational Health & Safety MS (OHSMS).

Asia Pacific Accreditation Cooperation (APAC) for Personnel certification and Asia Pacific Laboratory Accreditation Cooperation for Inspection.

His international achievements and affiliation cover member of various working groups like Clean Development Mechanism (CDM) Accreditation Panel, UN Framework Convention on Climate Change (UNFCCC), ISO CASCO WG 21 and 42 and many more.

**Current affiliations**

- Member, UNFCCC CDM Accreditation Panel since July 2007
- Lead assessor NABCB (MS/PCB/PrCB/IB/GHG)
- Lead Peer Evaluator, APAC (MS/PCB/GHG/IB)
- Co-convener, IAF Task Force of Conformity Assessment Schemes since Oct 2018
- Member, Technical Working Group on Accreditation, Asian Productivity Organization, Tokyo
- Member, Yoga Certification Board, Ministry of AYUSH, Govt of India
- Member, Core Group to address regulatory gap in India, Department of Commerce, Govt of India
- Member, Standardization Cell, Department of Commerce, Govt of India
- Member, Team for Harmonization of standards in SA and ASEAN, Department of Commerce, Govt of India
- Member, Sub-Committee (for standards, testing and certifications) of the Vaccine Task Force, Office of Principal Scientific Adviser (PSA), Govt of India
- Convener, Committee to address quality and performance of PPEs set up by O/o PSA
- Co-convener, Committee to address standards for respiratory support systems set up by

**RIFC****BRBC**  
A BIRAC - Venture Center Initiative

O/o

- PSA
- Chairman, Steering Committee for GCP Professional Certification Scheme, CDSA-THSTI, Govt of India
- Chairman, Certification Advisory Group, Network for Forest Certification & Conservation, Scheme owner in India
- Member, National ASSOCHAM Letter of confirmation as Honorary Member of National Council for Green & Eco-friendly Movement
- Honorary Patron, Consumer Coordination Council, Federation of consumer organizations in India
- Honorary Member, Consultants Consortium of Chennai, an association of management systems consultants
- Honorary Member, Water Quality Association of India
- Member, CII International Trade Policy Council for the year 2020-21



**Navnath Kadam,**  
**Asst. Manager – RIFC at Venture Center.**

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.



**Chandan Kumar,**  
**Scientist-C, (Medical Equipment & Hospital Planning Dept), Bureau of Indian Standards (BIS)**

A graduate engineer in Electrical & Electronics Engineering currently working for the Bureau of Indian Standards (BIS), the National Standards Body of India.

Member Secretary of Health Informatics Sectional Committee which is responsible for formulation of Indian Standards in Health Informatics and related technologies to achieve compatibility and interoperability between independent systems.

Represented India in meetings of ISO technical committee on Health Informatics i.e. ISO/TC 215 and is a member of its working group WG2 on Systems and Device Interoperability.



**Rajiv Nath,**  
**Managing Director of Hindustan Syringes & Medical Devices Ltd &**  
**Forum Coordinator, Association of Indian Medical Device Industry (AiMed).**

Managing Director of Hindustan Syringes & Medical Devices Ltd. which is having a turnover of over 600 Crores & Trustee – Safe Point India – a CSR Initiative of HMD (Hindustan Syringes & Medical Devices Ltd.). He is the President of All India Syringes & Needles Mfg. Association. (AISNMA) and the Founder and Forum Coordinator – Association of Indian Medical Device Industry (AIMED) with over 350 Members nationwide whereby Medical Device Manufacturers all types of technologies have been attracted nationwide on one Platform. He has widely

**RIFC****BRBC**  
A BIRAC - Venture Center Initiative

traveled more than 52 countries and has attended various meetings of WHO/ UNICEF/ ICASA/SIGN. As the Forum Coordinator of AIMED, He has taken many initiatives to establish a Collaborative Framework with various departments of the govt. and media to bring to their attention the issues troubling the industry and attract investments into India in his quest to make India as the preferred manufacturing destination and the leading supplier of medical device worldwide.

**Sanjiiv Relhan,**  
**Chairman, Preventive Wear Manufacturers' Association of India (PWMAI)**



Dr. Sanjiiv, Chief Executive Officer of Shalex Overseas has an extensive experience of over 20 years working within Healthcare Industry across different verticals including Pharmaceutical & Surgical Products. His profound qualities of enthusiasm, perseverance, vision & live networking has made Shalex Overseas a preferred company for products related to Infection Prevention Clothing segment consisting of Single-use as well as Multiple-use products. He is an expert in Technical Textiles for Infection Control. He is Founder Chairman of Preventive Wear Manufacturers' Association of India (PWMAI), an association of Manufacturers of Preventive Wear Products of Indian Origin having more than 75 members PAN India. The association is founded with a vision to upgrade the technical skills of manufacturers, research in the sector of Preventive Wear Textiles and to spread awareness about role of Infection Control Practice.

He is member of following panels, associations, committees:

1. Founder Chairman, PWMAI
2. Member, AiMED
3. Member, FICCI-MSME
4. Member, FICCI Textile Committee
5. Member, BIS-TXD-36
6. Member, UNECE for Gender Specific Standards
7. Member, AORN (Association of perioperative Registered Nurses)
8. Member, APIC (Association of Professionals in Infection Control & Epidemiology)
9. Member, ISHA India (Indian Sterile Healthcare Association)

**MG Sathyendra,**  
**Member, Consultants Consortium of Chennai (CCC)**  
**Consultant and Expert, Medical Devices**



Major work

- Educating manufacturers on Global compliance to Indian and International standards.
- Training on ISO/IEC 17025,17020, ISO9001, ISO13485 and 80079-34 for new and existing labs.
- As technical expert and assisting in pre-compliance of CE projects/other Global conformities and training for third-party inspections as per 17020.
- Assessing Labs for NABL. Faculty for IMTMA for training on Global conformances.
- Technical Expert /Assessor for MDQMS for NABCB. (17021- trained by NABCB)
- Trainer/ faculty for FICCI for 17025,13485.
- Faculty for BIS NITS

39 years in national and internal certifications and testing! 1981-2008. Served with Standards and certification bodies

- BIS (final posting as Director CMD III),
- Canadian Standards, (Started the organization in India - Headed Indian operations)
- Intertek (Head-south & West),
- Was involved also in 3 KEMA projects for MCB (IEC 60898)

A BIRAC - Venture Center Initiative  
VENTURE  
CENTER  
Bio-NEST  
BIRAC  
ignite innovate incubate

Handled UL-USA, SABS (South Africa) certification inspections In India.  
Trained in North American and EU compliances in Canada, China, Japan, Singapore and Medical Devices at Malaysia.

Training programmes on global compliance for IEEMA, FKCCI, Coddisia, Sri Lankan electrical manufacturer's association, AIEMMA, Europe-India SME development programmes, ITPO, GMCI, Govt of Kerala (Dept of industries, Dept of Technical education), CII, Exim bank.  
Training on ISO/IS 17025,17020. Faculty for Indian Machine Tool Manufacturers Association (IMTMA) for training on machinery directive.

Faculty for FICCI and NITS (BIS) for 17025 accredited programs.  
Trainer for the INDO-EU capacity development program on Lighting & Medical devices.  
Trained in ISO 13485 by SGS UK (2003 version) and Pacific Accreditation Committee – Malaysia for 2016 version.

Technical Assessor NABL (National accreditation board for Laboratories), several labs trained / assessed in the past 15 years.

For electrical and electronics:

Secretary of Indian Society of Lighting Engineers (ISLE) Karnataka - engaged in conducting various programmes for the lighting industry and educational programmes. Member on ET23 committee of Bureau of Indian Standards on Lamps.

Past Chairman of Quality division of IEEMA (Indian Electrical and Electronics Manufacturers Association). Assessor for Business excellence for IEEMA ISQA award, training / arranging visits to TQM awardees for Electrical industries.

Third Party inspections for BHEL (from 2009 – 2013) for electrical/mechanical industries in Karnataka Approved by NTPC and performed more than 100 joint inspections with NTPC. Third party inspections also done for Haryana/Gujarat EB, GETCO, Power Grid, GE, Alstom.

More than 50 training programmes conducted for ISO/IEC17025, about 10 internal auditors 4-day program after 2017 version. (In-house as well as open).

Faculty for the BIRAC, CDSA, CDSCO (medical device regulator in India) joint programmes under NITI Aayog. Speaker for Validation and testing of Medical devices.

**V. Premnath**

**Director, Venture Center | Head, NCL Innovations | Head, IP Group, NCL**



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. More information at:

[www.premnath.org](http://www.premnath.org)











	 A BIRAC - Venture Center Initiative	 VENTURE CENTER		 ignite innovate incubate
---	---	---	--	--

### About the Organizers

 A BIRAC - Venture Center Initiative	<p><b>BIRAC Regional Bio-Innovation Center (BRBC)</b> 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: <a href="http://www.brbc.venturecenter.co.in/">http://www.brbc.venturecenter.co.in/</a></p>
	<p><b>The Regulatory Information and Facilitation Center (RIFC)</b> 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: <a href="http://www.rifc.venturecenter.co.in">www.rifc.venturecenter.co.in</a></p>

### Supported by

	<p><b>Venture Centers</b> 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 &amp; Technology's National Science &amp; Technology Entrepreneurship Development Board (DST-NSTEDB) and BIRAC. For more information, visit: <a href="http://www.venturecenter.co.in">www.venturecenter.co.in</a></p>
	<p><b>Biotechnology Industry Research &amp; Assistance Council (BIRAC)</b> 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: <a href="http://www.birac.nic.in">www.birac.nic.in</a></p>
	<p><b>Bureau of Indian Standards (BIS)</b> is the National Standard Body of India established under the BIS Act 2016 for the harmonious development of the activities of standardization, marking and quality certification of goods and for matters connected therewith or incidental thereto. BIS has been providing traceability and tangibility benefits to the national economy in a number of ways – providing safe reliable quality goods; minimizing health hazards to consumers; promoting exports and imports substitute; control over proliferation of varieties etc. through standardization, certification and testing. For more information, visit: <a href="https://bis.gov.in/">https://bis.gov.in/</a></p>
	<p><b>Association of Indian Medical Device Industry (AiMED)</b> is an Umbrella Association of Indian Manufacturers of Medical Devices covering all types of Medical Devices including Consumables, Disposables, Equipments, Instruments, Electronics, Diagnostics and Implants. With a Primary Membership of over 300 Manufacturers and additionally of over 200 Associate Members representing the interest of over 1200 Manufacturers of Medical Devices to address the manufacturer's problems.</p> <p>The aim behind forming AiMED is allow the Indian Government to access a single point of contact and provide various services to the manufacturers like Advocacy on policy issues, Information services, Regulations for Medical Devices, Education and Training, services, Testing Assistance and guidance for Quality Certification (ISO, CE, GMP), Lobbying for funding for R&amp;D from the Government, encourage innovations from member units, Improve clinician and patient access to the modern, innovative and reliable Medical Device technologies through organizing and supporting Meeting, Seminars, Symposia, Exhibitions and Demonstrations and also, to promote global harmonization and respect for the Indian Device Industry.</p> <p>AiMED ensures convergence at a one common platform, when needed, for ensuring overall growth of Indian Medical Devices Industry and further address the needs of all members of the Medical Device Industry irrespective of their affiliation or their company size. It also helps in wider dissemination of</p>

				
	<p>information to each player of the industry. AiMeD has been horizontally divided into common groupings like – R&amp;D and Product Development, Legal &amp; Tax Issues, Export Related Issues, Medical Device Regulatory Issues common to all vertical groups of different families of product lines with Zonal Representations.”</p> <p>For more information, visit: <a href="https://aimedindia.com/">https://aimedindia.com/</a></p>			
	<p><b>Consultants Consortium of Chennai (CCC)</b> is an Association of Management Systems Consultants, registered under the Tamil nadu Societies Registration Act, 1975.</p> <p>The Key Objective of CCC is to work in alignment with the National Quality Mission launched by the Government of India by educating the industry about the role and importance of Standards, Certifications and Regulations in the country as well as in the global markets.</p> <p>CCC strives to encourage Responsible Consulting through Members of its Association and focus is to Standardize Consulting Practices in alignment with changing market and industry needs in a dynamic manner.</p> <p>The focus is also to identify areas and industries in which the consultants in the profession of Management Systems Consulting can contribute to the betterment of the society and the country and to promote Management Systems Consulting in such areas or industries.</p> <p>One of the core objectives is to collaborate with various Industry platforms, Trade Associations, Chambers of Commerce, Management Associations, Apex Bodies of Government or Quasi Government Organization to contribute to the betterment of the industry initiatives, which will in turn contribute to the betterment of the society.</p> <p>For more information, visit: <a href="http://ccc-consultants.org/">http://ccc-consultants.org/</a></p>			
	<p><b>PWMAI– Preventive Wear Manufacturers’ Association of India</b> is a team of people engaged in manufacturing of Preventive Wear products. Primary domain of manufacturers of this group is Surgical Gowns &amp; Drapes which are used for infection control in Healthcare Settings.</p> <p>For more information, visit: <a href="https://aimedindia.com/">https://aimedindia.com/</a></p>			