




Regulatory Clinic - Organized by BRBC -

Potential gains	<ul style="list-style-type: none"> The event is an R Clinic organized by BRBC. This clinic will focus on New European Medical Device Regulation (MDR) – Changes from the old MDD & Implications for Indian manufacturers. <div style="text-align: center;">  </div>
Organized by	<ul style="list-style-type: none"> BIRAC Regional BioInnovation Center (BRBC) @ Venture Center
Supported by	<ul style="list-style-type: none"> BIRAC (Biotechnology Innovation Research Assistant Council) Venture Center
For whom	<ul style="list-style-type: none"> CEOs/CTOs of innovative technology startups. Individual Inventors. Inventors from R&D institutes, medium/ large enterprises
Mentor	<ul style="list-style-type: none"> Mr. Atonu Dutta
When	<ul style="list-style-type: none"> Wednesday, 14 Aug 2019 14:00-15:00 hrs Regulatory talks on new European Medical Device Regulation (MDR) – Changes from the old MDD & Implications for Indian manufacturers.
Where	<ul style="list-style-type: none"> Training room @Venture Center 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune, Maharashtra, 411008
Contact	Technical queries and registrations: Navnath Kadam 020-25865877/76; rifc@web.venturecenter.co.in

Workshop Outline			
Time	Duration	Session title	Mentor
14:00 – 15:00	60 min	New European Medical Device Regulation (MDR) – Changes from the old MDD & Implications for Indian manufacturers	Atonu Dutta

Slots for Mentoring (15:30-18:30)

Serial #	Time	Entrepreneur	Company Name
1	3:30 - 4:15pm	Tanuj Gigras	Nayam Innovations Pvt Ltd
2	4:15 - 5:00pm	Milind Chaudhary	Welnnovate Biosolutions Pvt Ltd
3	5:00 - 5:45pm	Amol Chaudhari	Synthera Biomedical Pvt Ltd
4	5:45-6:30pm	Ashish Gawade	Jeevtronics Pvt Ltd

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Mentors



Mr. Atonu Dutta

Mr Atonu Dutta
Consultant to European Notified Bodies

Mr. Dutta is associated for over a decade with European Notified Bodies as a Senior Assessor and Lead Auditor for medical devices. Has an experience of over 27 years in areas of project management, operations and quality management in several large corporate houses.

He is currently working as a consultant to European Notified Bodies for technical documentation review and quality system audits, as well with several other large organizations and start-ups in the sector of healthcare and medical devices.


Mr. Dutta is a graduate in electrical engineering and a post-graduate in mathematics and operations management.

Core areas of consultation include:

- Developing strategies and plans to meet regulatory requirements, in areas like technical documentation, clinical evaluation, risk management, post-market surveillance.
- Helping organizations to develop and implement their quality management systems to fulfill regulatory requirements like CE, US FDA, Brazil ANVISA and others.



About the Organizers

 <p>A BIRAC - Venture Center Initiative</p>	<p>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/</p>
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	<p>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/</p>
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Supported by

	<p>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</p>
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	<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>
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