

## Compliance Workshop for Software as a Medical Device (SaMD) on Quality Management System (QMS), Risk and Cybersecurity Management

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| Expected Outcomes | <ul style="list-style-type: none"> <li>• Clarity on product classification (medical vs. wellness) and the QMS structure, evidence, and records required before scale-up.</li> <li>• Integrated understanding of how standards interlink, with real-world mapping of design file → risk matrix → PMS → regulatory filing, including cybersecurity documentation.</li> <li>• Clear view of cybersecurity-by-design requirements, how attacks impact safety and data, and the controls needed across design, development, operations, and post-market stages.</li> <li>• Awareness of cybersecurity tools and harmonized QMS-ISMS SOPs (access control, incident management, risk management, change control, supplier management, and document control).</li> </ul> |
| Organized by      | <ul style="list-style-type: none"> <li>• Regulatory Information and Facilitation Center (RIFC) @ Venture Center</li> <li>• Social Innovations @ Venture Center</li> <li>• BFI-BIOME Networks</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Supported by      | <ul style="list-style-type: none"> <li>• Venture Center, Pune</li> <li>• Blockchain for Impact</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| For whom          | <ul style="list-style-type: none"> <li>• Technology developers and innovators in SaMD domain</li> <li>• Early-stage inventive enterprises and science-based start-ups having software integrated in the medical device</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| When              | <b>Starting from Saturday, 6 December 2025 (+ 2 more Saturdays)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Where             | <b>Lecture Theatre, Venture Center, 900 NCL Innovation Park, Dr. Homi Bhabha Road, Pune</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Organization Lead | <ul style="list-style-type: none"> <li>• Mr. Akash R. Dhade</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Contact           | <b>Technical queries:</b> Mr. Akash R. Dhade   <a href="mailto:akash.dhade@venturecenter.co.in">akash.dhade@venturecenter.co.in</a>   9511903743<br><b>Registration queries:</b> Ms Aishwarya Varpe   <a href="mailto:aishwarya.varpe@venturecenter.co.in">aishwarya.varpe@venturecenter.co.in</a>   9156465137                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Registration      | <b>Registration Fee: Rs. 1000/- for each Day</b><br><br>*Registration fees for startups in the current cohort of BFI BIOME at Venture Center will be <b>waived</b> .<br><br>For registration: <a href="https://forms.gle/nqJrMJRgz8ayGbUM6">https://forms.gle/nqJrMJRgz8ayGbUM6</a><br>Event website and details: <a href="https://www.venturecenter.co.in/events">https://www.venturecenter.co.in/events</a>                                                                                                                                                                                                                                                                                                                                                     |

### Regulatory Information and Facilitation Center [RIFC]

(Managed by BRBC at Venture Center, Entrepreneurship Development Center)  
 MB1, 100, NCL Innovation Park, Dr Homi Bhabha Road, Pashan, Pune: 411008, India

## Workshop Agenda:

| Sr. No.                                                                                       | Session                                                          | Topic                                                                                                                                                 | Duration | Time        | Format                         | Key Takeaway                                                                                                                 |
|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------|--------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>Day 1: Quality Management System for Medical Device and eQMS tools (6th December 2025)</b> |                                                                  |                                                                                                                                                       |          |             |                                |                                                                                                                              |
| 0                                                                                             | Introduction to VC and RIFC                                      | <ul style="list-style-type: none"> <li>Overview of Venture Center</li> <li>Overview of RIFC</li> <li>Overview of Social Innovation and BFI</li> </ul> | 30 min   | 1000 -1030  | Talk                           | -                                                                                                                            |
| 1                                                                                             | Setting the Stage: SaMD Landscape & Global Expectations          | Understand how SaMD is defined and regulated under EU MDR, FDA, and CDSCO.                                                                            | 30 min   | 1030 - 1100 | Interactive Talk + Poll        | Clarity on where your product fits — medical vs. wellness software                                                           |
| 2                                                                                             | Why QMS Matters for SaMD                                         | Map ISO 13485 QMS processes to software lifecycle; learn design control and documentation flow.                                                       | 1 Hr     | 1100 - 1200 | Presentation + Q&A             | Learn the QMS structure needed before product scale-up                                                                       |
| 3                                                                                             | Standards Overview: ISO 13485, ISO 14971, IEC 62304, IEC 82304-1 | How the standards connect — risk, safety, lifecycle, usability, and post-market processes.                                                            | 4 Hrs    | 1200 - 1600 | Presentation + Exercises + Q&A | A mapped framework showing how the standards interlink                                                                       |
| 4                                                                                             | Using Jira / Confluence of for SaMD Development                  | Understand the tool offerings and map their relationship for compliance                                                                               | 1 Hr     | 1600 - 1700 | Discussion + Homework          | Participants Understand the needs for evidences / records from session 2 & 3                                                 |
| 5                                                                                             | Case Study: From Prototype to Audit Ready SaMD                   | A start-up journey — how compliance turned into a growth advantage.                                                                                   | 1 Hr     | 1700 - 1800 | Group Case Analysis            | Real-world mapping of design file → PMS → regulatory filing                                                                  |
| <b>Day 2: Risk Management System</b>                                                          |                                                                  |                                                                                                                                                       |          |             |                                |                                                                                                                              |
| 6                                                                                             | Integrating Risk Management in SaMD                              | Practical walkthrough of ISO 14971 and IEC 62304 risk control application.                                                                            | 6 Hrs    | 1000 - 1600 | Workshop /Exercise             | Risk matrix and hazard analysis linked to software components                                                                |
| <b>Day 3: Cybersecurity Management</b>                                                        |                                                                  |                                                                                                                                                       |          |             |                                |                                                                                                                              |
| 7                                                                                             | Overview of Cybersecurity & risks                                | Understand basics of cybersecurity and risks to product, organization, and patient / medical service providers                                        | 1 Hr     | 1000 - 1100 | Presentation + Q&A             | Clear understanding of how cyberattacks impact device safety, clinical performance, data confidentiality, and patient trust. |

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|----|--------------------------------------------------------------|--------------------------------------------|---------|-------------|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8  | Regulations related to Cyber Security                        | Brief overview of regulations : FDA and EU | 30 min  | 1100 - 1130 | Presentation + Q&A             | Clarity that cybersecurity is now a regulatory submission requirement, including documentation, threat models, and verification evidence.                 |
| 9  | Key Standards ISO 27001, 2017, 18, HIPAA, GDPR, FedRAMP, SOC | Overview of requirements and controls      | ~4 hrs  | 1200 - 1600 | Presentation + Exercises + Q&A | Secure design controls<br>Secure development practices<br>Technical controls<br>Operational controls<br>Post-market controls                              |
| 10 | Security Tools & tech                                        | Brief overview of tools and tech           | ~30 min | 1600 - 1630 | Presentation + Q&A             | Overview of the Code security tools:<br>Identity & access tools:<br>Cloud security:<br>Vulnerability management tools:<br>Testing tools:                  |
| 11 | Integrating QMS & ISMS                                       | How to harmonize QMS and ISMS SOPs         | ~30 min | 1630 - 1700 | Discussion + Homework          | Clarity on shared SOPs:<br>Access control<br>Incident management<br>Risk management<br>Change control<br>Supplier management<br>Document & record control |

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**Speaker Detail**

**Anand Paropkari**

Expertise in design and development of medical device, SaMD (Software As Medical Device) QMS aligned to organisation's strategy and regulatory compliances such as 21 CFR Part 820, 21 CFR Part 11, ISO 13485, ISO 14971 & IEC 62304, EU-IVDR, and information security compliances covering ISO 27001, HIPAA, GDPR, SOC and FedRAMP. He helps seamlessly blend agile software development for SaMD compliances making it easier for development teams to comply with. He brings in over two decades of industry inexperience in IT services as well as product development. He has helped several small, mid and large sized organizations achieve competitive advantage by integrating regulatory requirements in the business processes. Anand holds MS from BITS, and BE from University of Pune.

**Organizing Team**

**Akash Dhade**
Associate Manager – Regulatory Services

Akash works for the Regulatory Information and Facilitation Center (RIFC) at Venture Center and assists multiple organizations in choosing regulatory pathways, creating technical documentation, and submitting the documentation to the notified bodies for the European market. He has experience drafting over 20 technical documentation for different types of medical devices and also has the lead auditor certification for ISO 13485 QMS by BSI Academy.


**Niruta Killedar**
Senior Associate - Social Innovations

Niruta is primarily responsible for assisting in the implementation of the Social Innovation Immersion Program at Venture Center. Overall she assists in driving the Social Innovations portfolio at Venture Center and coordinates events and related mentoring activities. She is a Microbiologist by training and has more than 7 years of experience in interdisciplinary areas of science. She has been passionately working in border areas for the last 15 years as a volunteer through the NGO Aseem Foundation, which adds value to the Social Innovations portfolio at Venture Center.

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**Mugdha Lele**
Head – Social Innovations

Mugdha is currently Head – Social Innovations at Venture Center, Pune. She has done Ph.D from School of Health Sciences, University of Pune and has teaching and research experience in a State Government medical university. At Venture Center, she is responsible for driving the Social Innovations activities and providing technical mentoring for startups at Venture Center. She has been a Fellow of the Chevening Rolls Royce Science, Innovation, Policy and Leadership Programme (CRISP) at the Said Business School, University of Oxford, UK in 2016. In 2018 she has also been part of the Aritra Accelerator Program for Leadership in the Social Sector at IIM Bangalore with Phicus Solutions and Dr. Reddy's Foundation. She serves as the nominee director on the boards of Synthera Biomedical Pvt Ltd (a dental biomaterials startup), Pragmatech Healthcare Solutions Pvt Ltd (a medical diagnostics startup) and Spot Healthcare Solutions Pvt Ltd (a medtech startup).


**Aishwarya Varpe**
Associate – Regulatory Services

Aishwarya works for the Regulatory Information Facilitation Center (RIFC) at Venture Center. Aishwarya is responsible for providing support for regulatory advisory services for MedTech Startups. She is also involved assisting and supporting operations for ISO 13485 certified MedTech Cleanroom Facility at venture center. She is responsible for assisting in conducting workshops, training and events for startups to understand regulatory affairs. She has completed her Master of Technology in Biomedical Engineering from Ajeenkya DY Patil University, Pune. She holds a Bachelor of Technology in Bioengineering from MIT School of Bioengineering Science and Research, Pune. She has a internal auditor certification for ISO 13485 QMS by BSI Academy.

**Organized by**


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/>

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| <br>Social Innovations<br>at Venture Center | <p>Venture Center is committed to Social innovation and entrepreneurship. We actively nucleate and nurture enterprises that focus on solving socially important problems and build sustainable entities (for profit or not-for-profit) to deliver the solutions to society. Focus areas at Venture Center include affordable health and nutrition, empowering farmers, clean energy, sustainable resource utilization, environment and circular economy, water, sanitation, hygiene and any other social sectors that can leverage Venture Center's innovation ecosystem. More:</p> <p><a href="http://www.venturecenter.co.in/socialinnovations">http://www.venturecenter.co.in/socialinnovations</a></p> |
| <br>BFI BIOME NETWORK                       | <p>BFI-BIOME's mission cuts across traditional boundaries by encompassing both upstream and deep science, driving innovation that leads to transformative health solutions. BFI-BIOME aims to bring leading researchers, technologists, and innovators together in the form of a network to discuss, identify, collaborate and innovate in the biomedical sector to solve pressing health challenges. More:</p> <p><a href="https://www.venturecenter.co.in/bfi-biome/">https://www.venturecenter.co.in/bfi-biome/</a></p>                                                                                                                                                                                 |

#### Supported by

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| <br>VENTURE<br>CENTER          | <p>Venture Center is a national award winning deep tech and science-based business incubator approved by the Ministry of Science and Technology, Govt of India. It aims to nucleate and nurture knowledge based enterprises. It does this by creating and maintaining a rich and supportive ecosystem for inventive enterprises that includes a large mentor network, funding options including 4 seed funds, scientific/ analytical/ prototyping facilities, specialized advisory capabilities, numerous events etc. It empowers scientists, engineers, clinicians and other knowledge workers to take their ideas from lab to market. It is structured as an independent, non-profit company and charitable organization that is hosted by CSIR-National Chemical Laboratory, Pune. The Venture Center was founded in 2007. Venture Center has been recognized with the National Award for Technology Business Incubators (2015), AABI (Asian) Incubator of the Year Award (2018), National Entrepreneurship Award under Ecosystem Builder Category (2019), Biospectrum No 1 Bioincubator of India (2022) and National Award for Incubators for Nurturing IP (2021 &amp; 2022). More: <a href="http://www.venturecenter.co.in/">http://www.venturecenter.co.in/</a></p> |
| <br>BLOCKCHAIN FOR<br>IMPACT | <p>'Blockchain for Impact' carries forward the baton of the Crypto Relief Fund, a phenomenon that came to the fore at the peak of the second COVID wave in 2021. The relief fund mobilized resources from the global blockchain community and managed to make a positive dent in the healthcare system of India. More:</p> <p><a href="https://www.blockchainforimpact.in/">https://www.blockchainforimpact.in/</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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