

DIA MedTech Conclave - 2025

MedTech Next:
Innovate, Regulate, Elevate

10-11 October 2025

Welcomhotel by ITC Hotels, Gurgaon-Delhi
Expressway, New Delhi, India

For the first time, presenting The DIA MedTech Conclave 2025, specially designed program in medical devices, from the house of DIA. This program intends to be an august gathering of torchbearers of the medical device industry in India leading it to the global. Leaders, regulatory experts, healthcare professionals and focused specialists who are contributing their every bit in advancing medical technology. This is a perfect blend of learning and contribution for all, with well-crafted content, thoughtfully designed interactive sessions, participating opportunities and experience centers for trying solutions and platforms of your choice hands-on. The session envisages taking a walk-through leading trends, evolving regulations, discussion about compelling best practices and journey through the leaders. It will cover medical devices, in vitro diagnostics, combination products, and software medical devices including artificial intelligence. The Conclave will be a two-days dedicated extensive session with regulatory affairs, quality system, clinical evidence and risk management practices, and post-market surveillance frameworks.

With a focused single-track format for maximum engagement, the event will feature multiple sessions and discussions on key challenges and opportunities in 3D (*Devices, Diagnostics, and Digital*). Attendees will *gain actionable insights on regulatory compliance, design validation, patient safety, and global market access*, shaping the future of MedTech innovation.

This conclave offers an excellent networking *opportunity* with industry pioneers, regulators, start-ups, and academia, fostering collaboration and driving excellence in the MedTech ecosystem.

WHAT TO EXPECT

Learning Objectives

DIA MedTech Conclave 2025 is designed to provide participants with in-depth knowledge and practical insights into the evolving MedTech landscape. By attending, participants will:

- **Understand Global & Indian Regulatory Pathways** – Navigate marketing authorization and compliance for medical devices, IVDs, and combination products.
- **Master Quality System & Risk Management** – Learn best practices for design validation, verification, and conformity assessment.
- **Explore AI & SaMD Regulations** – Gain insights into compliance, standards, and evaluation of Software as a Medical Device in EU and US.
- **Strengthen Clinical & Post-Market Strategies** – Enhance knowledge of clinical evaluation, post-marketing surveillance, and materiovigilance.
- **Network & Collaborate** – Connect with regulators, industry leaders, start-ups, and academia to drive MedTech innovation.

This conclave is a must-attend for professionals in regulatory affairs, quality, clinical research, and MedTech development aiming for global excellence.

Featured Topics

DIA MedTech Conclave 2025 will cover key areas shaping the future of medical devices, in vitro diagnostics, combination products, and Software as a Medical Device (SaMD). The sessions will provide expert insights, regulatory updates, and best practices across the MedTech ecosystem.

- **Regulatory Pathways for Market Authorization** – India & global requirements for medical devices and diagnostics.
- **Quality & Risk Management** – Design validation vs. verification, conformity assessment, and compliance strategies.
- **Fundamentals and Emerging Regulatory Perspectives in AI and Software as Medical Device** – Decoding the EU vs US requirements.
- **Why are emerging cybersecurity trends and updates in medical devices so important** (Software as Medical Device & AI in MedTech)?
- **Regulatory & Clinical Considerations for SaMD** – Standards, compliance & evaluation of Software as a Medical Device.
- **Clinical Evaluation & Evidence Generation** – Strategies for regulatory submissions and market access.
- **Risk Management for Medical Devices** – Implementation of ISO 14971 and best practices.
- **Safety & Post-Market Surveillance** – Materiovigilance, complaint management, and post-marketing clinical follow-up.
- **Challenges and Opportunities for Indian MedTech Companies** while going global.

This conclave provides a comprehensive learning experience, addressing critical aspects of MedTech innovation, regulation, and patient safety.

Who Should Attend

The **DIA MedTech Conclave 2025** is designed for professionals involved in the development, testing, regulation, and commercialization of medical devices, in vitro diagnostics, combination products, and Software as a Medical Device (SaMD).

- **R&D and Product Development Teams** – Understand the latest trends in MedTech innovation and regulatory expectations
- **Regulatory Affairs & Compliance Professionals** – Stay updated on evolving global and Indian regulatory requirements and effectively implement key updates and actionable items
- **Quality Assurance & Risk Management Experts** – Learn best practices in QMS, design validation, and conformity assessment.
- **Clinical Research & Medical Affairs Professionals** – Gain insights into clinical evaluation, post-market surveillance, and materiovigilance.
- **Healthcare & Policy Experts** – Engage in discussions on safety, compliance, and market access.
- **Start-ups & Entrepreneurs** – Connect with industry leaders and explore pathways to global markets.

This conclave offers a unique opportunity for networking, learning, and collaboration, making it essential for stakeholders shaping the future of MedTech.

PROGRAM COMMITTEE



Dr Ashish Indani
Program Chair
General Manager – Clinical and Medical Affairs, Advance MedTech Solutions (AMS), Mumbai / Vadodara



Dr Srirupa Das
Healthcare Industry Leader,
Independent, Mumbai



Dr Priyadarshini Arambam
Director, Cliebo Solutions Pvt Ltd, New Delhi



Sundeep Agarwal
Sr. Vice President, Regulatory Affairs & Quality Assurance, Remidio, Delhi/Bengaluru

SESSION CHAIRS



Omprakash Sadhwani
Director XPLORE Healthcare Solutions LLP. Ex-Joint Commissioner (HQ) and Drugs Controller, Maharashtra Food and Drug Administration.



Rajendran Varadharaj
General Manager Operations - MHS, TUV SUD India

AGENDA: Day 1, 10 October 2025; Friday

8:00-9:00AM **Registration and Welcome Coffee**

9:00-9:05 AM **Welcome Remarks from DIA: [5 min]**

Dr Ashok Swain, General Manager – DIA India
- Welcome the audience, house rules, and introduce Program Chair

9:05- 9:15 AM **U.S. FDA Welcome Remarks**

Mr. Gregory Smith, Director, FDA India Office [10 mins]

9:15 – 9:30 am **Meeting Opening Remarks by Program Chair: [15 min]**

Dr Ashish Indani, General Manager & Head – Clinical and Medical Affairs, AMS

9:30-11:00AM D1.S1: Advancing MedTech in India: A Roadmap for Scalable Impact

Session Chair:

Dr Srirupa Das, Healthcare Industry Leader, Mumbai

Session Overview: The Opening Session sets the stage for a dynamic exploration of how technology, AI, and MedTech start-ups are revolutionizing healthcare delivery and access. It will spotlight emerging innovations, highlight India's growing MedTech ecosystem, and bring together thought leaders in a panel discussion to chart a collaborative roadmap for advancing medical technology. Join us to uncover how these forces are shaping the future of healthcare in India and beyond.

9:30-10:00 AM **D1.S1.T1: Tech and AI – Transforming and Democratizing Healthcare**

Dr Moni Abraham Kuriakose, Co-Founder, Medical Director and CEO Kerala Operations, Karkinos Healthcare

10:00 -10:30AM **D1.S1.T2: Role of MedTech Start-up Ecosystem in Healthcare Transformation**

Prof. (Dr) Sucheta Banerjee Kurundkar, Director Research, KLE Academy of Higher Education & Research

10:30-11:00AM **D1.S1.T3: Panel Discussion: Advancing Medical Technology in India – Way forward**

Moderator: **Dr Srirupa Das**, Healthcare Industry Leader, Mumbai

Panelist: Speakers with the additional presence of

3. **Prof. Dinesh Kalyansundaram**, CBME- IIT Delhi, Principal Investigator at mPragati at IIT Delhi.

4. **Goutam Bhattacharya**, CEO, Life Sciences Sectors Skill development Council

5. **Kamal Shahani**, Managing Director- Cliniminds; Founder & Managing Director - Tenet Health Edutech.

11:00-11:30AM **Tea / Coffee & Networking Break**

11:30-1:00PM D1.S2: Regulatory requirements for Marketing Authorization from Design to Commercial - India and Global Perspective

Session Chair:

Sundeep Agarwal, Senior Vice President – Regulatory Affairs & Quality Assurance, Remidio Innovative Solutions Pvt. Ltd.

Session Overview: This session provides critical insight into the complex regulatory pathways shaping the global MedTech sector. In India, CDSCO regulates devices under the Medical Devices Rules, 2017, enforcing a risk-based classification (Class A–D), mandatory licensing, ISO 13485-compliant quality systems, and adherence to ISO 10993 biocompatibility standards. Recent updates, including the April 2025 FAQs, emphasize clearer documentation protocols, clinical evidence requirements, and vigilance mechanisms. Globally, the rise of digital health technologies, including Software as a Medical Device (SaMD) and AI, adds complexity. Internationally, regulatory frameworks are becoming more rigorous and harmonized. The EU MDR imposes comprehensive clinical evaluation, Unique Device Identification (UDI),

and lifecycle-based post-market surveillance. The U.S. FDA's Center for Devices and Radiological Health (CDRH) and Digital Health Center of Excellence supports innovation through programs like the Breakthrough Devices Program and, yet demands robust premarket submissions, cybersecurity controls, transparency, adaptive AI, continuous learning models and real-world evidence, especially for Software as a Medical Device (SaMD). For industry professionals, proactive regulatory alignment from design through commercialization is essential to mitigate compliance risk. For investors, a strong digital health regulatory strategy enhances market readiness, supports scalable growth, and de-risks capital deployment in a competitive, innovation-driven sector.

11:30-11:50AM

D1.S2.T1: Building a Future-Ready Regulatory Ecosystem - CDSCO's Role in India's MedTech Growth and Global alignment

Aseem Sahu, DDC, CDSCO, India (*invited*)

11:50-12:10 PM

D1.S2.T2: Navigating Regulatory Pathways for Software and Artificial Intelligence Medical Devices under the EU Medical Device Regulation (MDR) vs US FDA vs Indian MDR

Sundeep Agarwal, Senior VP – RA& QA, Remidio Innovative Solutions Pvt. Ltd

12:10 – 1:00 PM

D1.S2.T3: Panel Discussion: Accelerating Innovation While Managing Risk: Global Regulatory Trends in MedTech"

Moderator: **Sudhakar Mairpady**, Director, Regulatory Affairs & Government Affairs, BD

Panelists: Speakers with the additional panelists

3. **Prof. (Dr) Sucheta Banerjee Kurundkar**, Director Research, KLE Academy of Higher Education & Research

4. **Anil Chaudhari**, Founder and CEO, Operon Strategist

1:00-2:00PM

Lunch Break

2:00-3:30PM

D1.S3: QMS in Medical Device Development: Design & Development, Verification & Validation, and Compliance Requirement in India, US & EU

Session Chair:

Rajendran Varadharaj, General Manager Operations - MHS, TUV SUD India

Session Overview:

This session will provide a comprehensive overview of Quality Management System (QMS) requirements across major regulatory jurisdictions including an emphasis on evolving demands in digital health and AI-enabled medical technologies Focusing on ISO 13485 as the global benchmark, the session will explore region-specific expectations, including India's Medical Devices Rules (2017), the U.S. FDA's proposed Quality Management System Regulation (QMSR), and the EU MDR's emphasis on lifecycle-based quality assurance. Key topics include design and development controls, verification and validation (V&V), documentation practices, and risk management. Verification and validation (V&V) ensure that a medical device is designed correctly (verification) and performs safely and effectively for its intended use (validation). This is critical for regulatory approval, patient safety, and product reliability. Attendees will gain actionable insights on aligning QMS strategies to support compliance, product integrity, and timely market access. This session is ideal for regulatory, quality, and R&D professionals seeking to navigate evolving global standards while driving innovation in medical device development.

2:00-2:20PM

D1.S3.T1: Redefining Quality: FDA's Alignment with ISO 13485 and Its Impact on Manufacturers

Rupam Chaudhury, GLOBAL HEAD – Lifesciences and Healthcare Engineering, TCS

2:20-2:40PM

D1.S3.T2: When Quality is the Key – Quality Management Systems, Conformity Assessment, and Compliance Strategies for Medical Devices.

Vareena Raina, Advisor/Trainer for Medical device QMS and regulatory requirements, Bhat Assurance International (BAI)

2:40-3:30PM

D1.S3.T3: Panel Discussion with Q&A:

Moderator: **Rajendran Varadharaj**, General Manager Operations - MHS, TUV SUD India

Panelists: Speakers with the additional panelists

3. **Leena Bera**, CEO, Zenith

4. **Kulveen Singh Bali**, Director - Regulatory and Quality, Philips

3:30-4:00PM

Tea/Coffee & Networking Break

4:00-5:30PM

D1.S4: Regulatory, Clinical and Cybersecurity Considerations for Software as a Medical Device (SaMD): Standards, AI Integration, Compliance, and Evaluation

Session Chair:

Sundeep Agarwal, Senior Vice President – Regulatory Affairs & Quality Assurance, Remidio Innovative Solutions Pvt. Ltd.

Session Overview:

The emergence of Software as a Medical Device (SaMD) introduces complex regulatory, clinical, and cybersecurity challenges requiring coordinated, multidisciplinary solutions. This session will delve into key aspects of SaMD development and oversight, with a focus on evolving global standards, artificial intelligence (AI) integration, and compliance strategies. Discussions will include international regulatory alignment efforts, regional implementation nuances, and the implications of AI on clinical validation, transparency, and bias mitigation. With health data at the core of SaMD functionality, the session will also address cybersecurity as a critical pillar—covering threat landscapes, data protection measures, risk management frameworks, and post-market surveillance mechanisms. By examining the entire lifecycle of SaMD, from design through deployment and monitoring, this session aims to equip participants with a robust understanding of current best practices, regulatory expectations, and evaluation methodologies. Attendees will leave with actionable insights into ensuring the safety, efficacy, and security of SaMD in real-world clinical settings.

4:00-4:20PM

D1.S4.T1: Navigating the future: Trends and Strategic path for Healthcare AI Regulation in the APAC region

4:20-4:40PM

D1.S4.T2: Connected, But Protected? Navigating the New Cybersecurity Mandates in MedTech

Srinivasa Reddy, Sr. VP - Operations, Regulatory and Govt. Affairs, SS Innovations International Inc.

4:40-5:00PM

D1.S4.T3: Designing for success: aligning QMS for SaMD and AI product development in MedTech

Sreejith Viswam, Director- Quality and Regulatory, Stryker Global Technology Centre and APAC NPD, Stryker

5:00-5:30PM

D1.S4.T4: Panel Discussion: Global Standards, Local Realities: Aligning SaMD & AI Development, Clinical Application with Evolving Regulations

Moderator: **Sundeep Agarwal**, Senior VP – RA& QA, Remidio Innovative Solutions Pvt. Ltd.

Panelists: Speakers

5:30 – 6:00 PM

D1.S4a: FDA Center for Devices and Radiological Health (CDRH) Fundamentals: Regulatory Pathways, Resources, and Innovation

Stephanie Shedd, Biomedical Engineer, International Policy Analyst, FDA CDRH

6:00-6:15 PM

Day End / Wrap Up

9:00-9:10 AM	Welcome to Day 2 – DIA [5 min] Recap of Day1 & Day 2 Opening Remarks by Program Committee Co-Chair [10 min]
09:10 – 9:30 am	D2.KNA.1. Keynote Address: Age of wearables - How widely are they deployable to enhance clinical conformity. C. Palani Palaniappan, Ph.D , CEO, Aridica Corporation, USA. DIA Global Board of Directors
9:30-11:00AM	D2.S5: Bridging the Gap: Globalizing Indian MedTech through Policy, Partnership, and Purpose Session Chair: Mr. Omprakash Sadhwani , Director, XPLORE Healthcare Solutions LLP. Ex-Joint Commissioner (HQ) and Drugs Controller, Maharashtra Food and Drug Administration, India Session Overview: The Day 2 Opening Session explores India's journey towards global MedTech leadership, focusing on policy, partnerships, and purposeful innovation. Industry leaders will share insights on overcoming globalization challenges, seizing emerging opportunities, and scaling innovations. A high-impact panel will delve into the collaborative potential of the Medical Device Policy 2023, highlighting the role of regulatory agencies and industry in shaping a globally competitive Indian MedTech ecosystem.
9:30-10:00AM	D2.S5.T1: Breaking the Barriers to Breakthrough– Challenges and Opportunities for Indian MedTech companies in their globalization
10:00-10:30AM	D2.S5.T2: A MedTech Business Leaders's Insights Chander Shekhar Sibal , CEO, SS Innovations Private Limited, Gurgaon
10:20-11:00AM	D2.S5.T3: Panel Discussion: Title: Collaborating between agencies and industry – the spotlight of Medical Device Policy 2023. Moderator: Omprakash Sadhwani Panelists: Speakers with the additional presence of 3. Rajiv Nath , Managing Director - Hindustan Syringes & Medical Device Ltd. Forum Coordinator, Association of Indian Medical Device Industry (AIMED) 4. Pavan Choudary , Chairman, Medical Technology Association of India (MTAI) 5. Dr Rajiv Chhiber , Vice President, External Affairs (Policy, Govt Relations & Outreach), Sahajanand Medical Technologies; FICCI representative. 6. Dr Ravi Rathod , General Manager- Policy and Strategic Affairs (Regulatory), Innvolution Healthcare Pvt. Ltd. Advisor-Health to PHD Chamber of Commerce and Industry
11:00-11:30AM	Tea/Coffee & Networking Break
11:30-1:00PM	D2.S6: Clinical Evidence for Medical Devices Session Chair(s): Priyadarshini Arambam , Director, Clicebo Solutions Pvt Ltd, New Delhi Session Overview: Clinical Evaluation is a critical area of medical devices. Not only the regulators, but other stakeholders such as reimbursement authorities, insurers and payers also ask for the clinical evidence. It is indeed the most critical aspect for the clinicians to get the confidence and reason for use of medical devices. However, with the changing landscape of regulation, clinical practices and their synergies, the clinical evidence also has significant adoptions. This session focuses on these synergies and adoptions.
11:30-11:50AM	D2.S6.T1: Clinical Evaluation: Current guidelines and how it should be done? Who needs what for regulatory submissions and market access- EU, India & Global. Aaditya Vats , Director - Regulatory Affairs and Quality Assurance, Terumo India Private Limited
11:50-12:20PM	D2.S6.T2: Realistic clinical evidence for medical devices – What, When, How much? Dr Ashish Indani , General Manager & Head – Clinical and Medical Affairs, AMS

12:20-1:00PM

D2.S6.T3: Panel Discussion: Clinical Evidence beyond Regulatory Requirements

Moderator: **Dr Priyadarshini Arambam**, Director, Clicebo Solutions Pvt Ltd, New Delhi

Panelists: Speakers with the additional panelists

3. **Dr. Rajlakshmi Borthakur**, CEO & Founder, TerraBlue XT.

1:00-2:00PM

Lunch Break

2:00-3:30PM

D2.S7: Risk Management for Medical devices

Session Chair:

Dr Ashish Indani, General Manager – Clinical and Medical Affairs, Advance MedTech Solutions (AMS)

Session Overview:

Risk Management is the most critical function in medical device lifecycle management. While there are several set guidelines in Medical Devices including ISO 14971, the width of diversity of devices compels use high level of discretionary efforts, deliberation and carefully individualized approach for each device. This requires critical intersecting expertise in Medical Devices, understanding of clinical use and human factors, thorough knowledge of Risk Management, and systematic approach of evidence-based compliances.

2:00-2:20PM

D2.S7.T1: Managing Risks or Risk Management? - A holistic approach to ensure that device risks are realistic and not realized.

Sushmita Roy Chowdhury, General Manager Regulatory Affairs, Romsons Groups Pvt. Ltd.

2:20-2:40PM

D2.S7.T2: Risk Communication: Pathway from Risk management to Labelling

Kalindi Hapani, Senior Manager - Medical Safety & Device Safety, COD Research

2:40-3:30PM

D2.S7.T3: Panel Discussion: Accelerating Innovation While Managing Risk: Global Regulatory Trends in MedTech

Moderator: **Dr Ashish Indani**, Advance MedTech Solutions (AMS)

Panelists: Speakers with the additional panelists

3. **Preeti Sharma**, Head - Regulatory Affairs, Edwards Lifesciences

4. **Dr Manoj Karwa**, Head of Clinical Trials & Pharmacovigilance, Auriga Research.

3:30-4:00PM

Tea/Coffee & Networking Break

4:00-5:30PM

D2.S8: Post-marketing surveillance to ensure product safety

Session Chair

Dr Srirupa Das, Healthcare Industry Leader, Independent

Session Overview:

Continuing safety assessment across the product life cycle is imperative to ensuring patient safety and welfare of the India population. This section delves into the current state of post-marketing safety surveillance of medical devices; and deliberates on how multisector collaboration can enhance the same.

4:00-4:20PM

D2.S8.T1: India's Experience with MvPI – Current State of Adverse Event Reporting of Medical Devices

Dr Shatrunjay Shukla, Assistant Scientist, Indian Pharmacopoeia Commission, MoH & GFW, GoI

4:20-4:40PM

D2.S8.T2: Post marketing safety surveillance – current practices and challenges

Vidhya G G, Lead Materiovigilance– Clinical Affairs, Helathium

4:40-5:30PM

D2.S8.T3: Panel Discussion: Transformational strategies for enhancing post-marketing safety surveillance

Moderator: **Dr Srirupa Das**

Panelists: Speakers with the additional panelists

3. **Dr Bishnu Panigrahi**, Group Head - Medical Strategy and Operations, Fortis Healthcare.

4. **Dr Ravi Rathod**, General Manager- Policy and Strategic Affairs (Regulatory), Innvolution Healthcare Pvt. Ltd. Advisor-Health to PHD Chamber of Commerce and Industry

5:30-5:45PM

Closing Remarks & Vote of Thanks

PAYMENT INFORMATION

Meeting registration for an individual participant with **ONLINE payment** can be completed directly through the DIA website.

For **DIA MedTech Conclave 2025**: [Register Online](#)

For group registrations, please contact the meeting manager (below table).

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Category	Early Bird Rate (Up to 10 Aug)	Advance Rate (11 Aug – 09 Sep)	Standard Rate (from 10 th Sep)
Industry – Member	INR 6,000 + GST	INR 9,000 + GST	INR 10,500 + GST
Industry – Non-member	INR 10,500 + GST	INR 13,500 + GST	INR 15,000 + GST
Academia*/ Non-Profit / Govt – Member	INR 5,250 + GST	DIA membership Discounts: 71% off for students (₹ 1,970 + GST) 50% off for academia/government (₹ 3,397 + GST)	
Academia*/ Non-Profit / Govt – Non-member	INR 9,750 + GST		
For Group Registrations: Please contact meeting manager. Email: nishank.nivedit@diaglobal.org Mob: +91 8178837734			

CHEQUE / DRAFT

Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:

Vinita Shetty | Finance Manager

DIA (India) Pvt. Ltd.

Cowork30, Office #201, ACME Plaza-2, Chakala

Andheri- Kurla Road, Andheri (East), Mumbai – 400059

Email: vinita.shetty@diaglobal.org Cell: +91 9769764645

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*Academia Category

The ACADEMIA category applies to individuals with primary, full-time affiliation to a bona fide academic institution, and includes STUDENTS. Proof of appointment or enrollment is required.

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- Transfer Policies:** Registrations may be transferred to a colleague at any time, but membership benefits are non-transferable. Please notify the DIA India office in writing. Substitute registrants will be charged any applicable non-member fees at the rate in effect on the transfer date.
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- Administrative Fee:** A 25% administrative fee will be deducted from all eligible refunds.
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Dd Month 2025

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