GLOBAL MEDTECH CONNECT

11 - 12 July 2025
Bharat Mandapam,
New Delhi (formerly Pragati Maidan)

informa markets

Empowering Global Patient Care Through MEDICAL TECHNOLOGY

Co-located with India Health

ABOUT THE **CONFERENCE**

Over the past decade, the medical device industry has undergone transformative innovation, driven by evolving patient needs, regulatory shifts, and advancements in AI, SaMD, and cybersecurity. As we move into 2025, navigating this dynamic landscape requires a strong foundation in quality assurance and regulatory affairs to ensure successful device development, approval, and commercialization across global markets. This conference will bring together MedTech leaders, regulatory experts, and industry pioneers to explore critical topics such as global regulatory harmonization, AI-driven medical technologies, cybersecurity in SaMD, drug-device combination product compliance, and sustainable MedTech manufacturing. Sessions will provide deep insights into regulatory frameworks like the eSTAR applications for US FDA approvals, and India's evolving regulatory landscape under CDSCO and IMDRF alignment. Key discussions will focus on integrating risk management in product lifecycle planning, optimizing quality management systems (QMS), post-market surveillance, and ensuring data privacy and security in medical devices. Attendees will also gain actionable strategies to navigate geopolitical trade challenges, strengthen supply chain resilience, and leverage AI in medical device localization and compliance.Designed for MedTech professionals, this conference will deliver the latest regulatory intelligence, practical compliance tools, and forward-looking strategies to accelerate market entry while fostering innovation and patient safety.

KEY **FEATURES**

15 hours of engaging content across 2 days

25+ Speakers

150+ MedTech Professionals under one roof

Panel discussions, Roundtables and fire side chats

Networking sessions

KEY TOPICS

- Navigating Geopolitical Storms: How Indian MedTech Leaders Are Adapting to U.S. Tariff Pressures
- Cultivating a Culture of Excellence in Medical Device Manufacturing
- The Role of QMS for MedTech Organizations in India: ISO 13485 and Indian MDR Alignment
- Refurbished Medical Devices: Unlocking Potential Through Regulatory Clarity and Ensuring Patient Safety
- Strengthening India's Medical Device Regulatory System through IMDRF Membership

WHO CAN ATTEND

Departments:

- REGULATORY AFFAIRS
- REGULATORY
- REGULATORY STRATEGY
- QUALITY
- QUALITY ASSURANCE
- QUALITY CONTROL
- CLINICAL
- POST MARKET SAFETY / SURVEILLANCE

Designations:

- Director
- HOD
- President
- VP
- AVP
- GM

Associations:

Departments:

Development | Regulatory Research

Designations:

Chairman | Director President | Researchers

SPEAKERS 2025

Rajiv Nath
Managing Director &
Forum Coordinator (AiMeD)
Hindustan Syringes & Medical Devices

Bivash Chakraborty
Head - Regulatory, Quality &
Government Affairs - South Asia
Biomerieux India Pvt.Ltd

Sreejith Viswam
Director - Quality and Regulatory,
APAC NPD
Stryker

Parveen Jain
Senior Director, Quality and
Regulatory Affairs, Asia Pacific
Fresnius Medical Care

Preety Sharma
Head - Regulatory Affairs
Edwards Lifesciences

Himanshu Baid
Managing Director
Poly Medicure

Sundeep Agarwal
Vice President–Regulatory Affairs &
Quality Assurance
Remidio Innovative Solutions

Dr. Muthu Dhandapani
Vice President- Quality & Regulatory Compliance
Tricog Health

Jhankhana Gyani
Head – QRA
Draeger India Private Limited

Aaditya Vats
Director Regulatory Affairs and
Quality Assurance
Terumo India Private Ltd.

SPEAKERS 2025

Dr. Rajiv Chhibber
Vice President - External Affairs
Sahajanand Medical Technologies Ltd.

Dr. Ashish Indani
(Author - Essentials of Medical Device Clinical Research) General Manager Clinical and Medical Affairs
Advanced MedTech Solutions

Sailesh YHNB
Associate Director
Novo Nordisk

Malte Knowles Schmidt
Manager Global Service Portfolio SW, AI and Cybersec. for medical devices
TÜV SÜD

Shri Katipally Karthik Reddy
Scientist-B/Assistant Director,
Bureau of Indian Standards (BIS)
Ministry of Consumer Affairs, Food and Public

Somesh Rasal
Global Service Line Manager MHS– Cyber Security
TÜV SÜD

Dr. Ravi Rathod
General Manager - Policy & Strategic Affairs, (Regulatory Division)
Innvolution

Rupam Chaudhary
Global Head – MedTech & LifeScience
TCS

Nitin Gupta
Managing Director India & South Asia
Fujifilm Sonosite India Pvt. Ltd.

Sushmita Roy Chowdhury
General Manager -
Global Regulatory Affairs
Romsons Group Pvt. Ltd.

SPEAKERS 2025

Goutam Bhattacharya
Chief Executive Officer
Life Sciences Sector Skill Development Council

Anil K Srivastava
Chief Operating Officer
Nihon Kohden India Private Limited

Venkatesh Barat
Senior Manager,
Quality- Digital Solutions,
Wipro GE Healthcare

GLOBAL MEDTECH CONNECT

11th & 12th JULY 2025|BHARAT MANDAPAM, NEW DELHI

Transforming MedTech: Pioneering Innovation and Global Compliance

DAY 1: FRIDAY, 11th July 2025

10:00 – 11:00	**Registration and Refreshments**
11:00 – 11:30	**Opening Remarks by Informa Markets**
11:30 – 12:30	**Leadership Panel Discussion: Navigating Geopolitical Storms: How Indian MedTech Leaders Are Adapting to Tariff, Regulatory, and Supply Chain Disruptions to Ensure Global Resilience and Local Relevance** • Balancing global demand with domestic healthcare priorities • Ensuring seamless pharma supply chains despite geopolitical tensions and trade restrictions • Streamlining regulatory pathways for cross-border collaboration **Moderator: Parveen Jain**, Senior Director, Quality and Regulatory Affairs, Asia Pacific, **Fresenius Medical Care** **Panellist**: **Rajiv Nath,** Managing Director **Hindustan Syringes & Medical Devices** Forum Coordinator (**AiMeD)** **Himanshu Baid,** Managing Director**, Poly Medicure** **Dr Rajiv Chhibber,** Vice President - External Affairs**, Sahajanand Medical Technologies. Ltd.** **Anil K Srivastava,** Chief Operating Officer, **Nihon Kohden India Pvt. Ltd.**
12:30 – 13:00	**The Role of QMS for MedTech Organizations in India: ISO 13485 and Indian MDR Alignment** • Harmonization of standards between ISO 13485:2016 and the Indian Medical Device Rules (MDR) 2017 • Highlight how adherence to ISO 13485 supports compliance with Indian regulatory requirements for quality management • Challenges and benefits of integrating global standards into local regulatory frameworks **Sreejith Viswam**, Director- Quality and Regulatory, APAC NPD, **Stryker**

13:00 – 13:30

Role of BIS in the MedTech Quality Ecosystem

- Overview of BIS
- Standard Formulation Process
- National Standards and Harmonization with International Standards
- Role of Standards in Innovation, Quality, and Regulatory Frameworks

Karthik Reddy Katipally, Scientist-B/Assistant Director,
Bureau of Indian Standards (BIS), Ministry of Consumer Affairs, Food and Public Distribution

13:30 – 14:30

Networking Lunch Break

14:30 – 15:15

Panel Discussion: Cultivating a Culture of Excellence in Medical Device Manufacturing

- QMS integration to ensure tracking, documentation, and training to adapt to regulations & consistent quality
- AI-Powered advanced manufacturing systems streamline track maintenance and complex monitoring
- Strategies for minimizing human error
- Strategic localization

Moderator:
Bivash Chakraborty, Head - Regulatory, Quality & Government Affairs - South Asia, **Biomerieux India Pvt. Ltd**

Panellist:
Sreejith Viswam, Director- Quality and Regulatory, APAC NPD, **Stryker Global Technology Centre**
Dr Rajiv Chhibber, Vice President - External Affairs**, Sahajanand Medical Technologies. Ltd.**
Jhankhana Gyani, Head – QRA**, Draeger India Private Limited**

15:15 – 15:45

Strength In Collaboration: Sourcing Quality Raw Materials for Manufacturers'

- Developing long-term partnerships with suppliers for quality materials
- Implementing rigorous verification process for sourced materials adhering to industry standards
- Prioritize environmentally sustainable and ethically sourced materials

Jhankhana Gyani, Head – QRA**, Draeger India Private Limited**

15:45 – 16:15	**Streamlining Labelling Compliance in India: A Unified Approach** • Addressing dual compliance requirements under the Ministry of Health and Legal Metrology • Crafting a cohesive labelling framework to reduce complexities and enhance transparency • Best Practices **Rajiv Nath,** Managing Director **Hindustan Syringes & Medical Devices** Forum Coordinator (**AiMeD)**
16:15 – 16:30	**Networking Coffee Break**
16:30 – 17:00	**Strengthening India's Medical Device Regulatory System through IMDRF Membership** • Explore the significance of India's membership in the International Medical Device Regulators Forum • Understand how alignment with IMDRF frameworks can enhance CDSCO's regulatory system and ensure global harmonization • IMDRF guidelines to tackle emerging technical challenges in the Indian MedTech sector **Sushmita Roy Chowdhury**, General Manager - Global Regulatory Affairs, **Romsons Group Pvt. Ltd.**
17:00 – 17:30	**Medical Device Cybersecurity: A Checklist or a Culture?** • What is Cybersecurity in Medical Devices • Regulatory Landscape • Are we overdoing the cybersecurity? • Current and Ideal (appropriate) practice • Current Challenges and Solutions **Somesh Sanjay Rasal**, Global Service Line Manager – Cybersecurity, **TÜV SÜD South Asia Pvt. Ltd.**

END OF THE CONFERENCE DAY 1

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DAY 2: SATURDAY, 12th July 2025

10:00 – 10:30	**Registration And Refreshments**
10:30 – 11:00	**Fireside Chat: Global Harmonization of Medical Device Standards: A Roadmap for India** • Integrating ISO, European, and U.S. standards into India's regulatory framework • Opportunities for Indian manufacturers in global markets through standard harmonization • Leveraging IMDRF membership to align India's regulations with international best practices **Moderator: Dr Ashish Indani** (Author - Essentials of Medical Device Clinical Research), General Manager Clinical and Medical Affairs, **Advanced MedTech Solutions** **Speakers:** **Preety Sharma,** Head - Regulatory Affairs**, Edwards Lifesciences** **Aaditya Vats,** Director Regulatory Affairs and Quality Assurance**, Terumo India Private Ltd.** **Sailesh YHNB**, Associate Director, **Novo Nordisk**
11:00 – 11:30	**Clinical Evaluation vs. Clinical Investigation: Key Differences in Medical Device Compliance** • Defining clinical evaluation and clinical investigation • Regulatory expectations and requirements: • Strategic planning for transitioning between evaluation and investigation to meet global compliance standards **Aaditya Vats,** Director Regulatory Affairs and Quality Assurance**, Terumo India Private Ltd.**
11:30 – 12:00	**Post-Market Risk Assessment and Management for SaMD: Lessons for Indian Manufacturers** • Understanding the Unique Risks of SaMD • Leveraging data analytics and AI tools for predictive risk assessment and proactive issue resolution • Collaborating with stakeholders to ensure compliance, patient safety, and product reliability **Dr Ashish Indani** (Author - Essentials of Medical Device Clinical Research), General Manager Clinical and Medical Affairs, **Advanced MedTech Solutions**
12:00 – 12:30	**Networking Coffee Break**

12:30 – 13:15

Panel Discussion: Emerging Cybersecurity Trends in Medical Devices: Addressing Risks for SaMD and AI Devices

- Identifying Key Cybersecurity Risks for SaMD and AI Devices
- Overview of global standards like the FDA's cybersecurity guidance and ISO/IEC 27001
- Leveraging AI and machine learning for proactive threat detection and adaptive security measures

Moderator: Venkatesh Barat, Senior Manager, Quality- Digital Solutions**, Wipro GE Healthcare**

Panellist:
Dr Muthu Dhandapani, Vice President – Quality & Regulatory Compliance**, Tricog Health**
Dr Ravi Rathod, General Manager- Policy & Strategic Affairs, (Regulatory Division)**, Innvolution**
Malte Knowles Schmidt, Global Portfolio Manager SaMD, AI and Cybersecurity, **TÜV SÜD**

13:15 – 13:45

Fundamentals and Emerging Regulatory Perspectives in AI and SaMD: Decoding EU vs US Requirements

- Understanding the classification systems, approval pathways, and key documentation requirements
- Examine recent updates in regulatory guidelines - EU's AI Act and the FDA's guidance on AI/ML-based SaMD
- Explore the role of international harmonization efforts and how these are shaping future regulatory landscapes

Sundeep Agarwal, Vice President–Regulatory Affairs & Quality Assurance**, Remidio Innovative Solutions**

13:45 – 14:45

Networking Lunch Break

14:45 – 15:15

Data Privacy and Security in Medical Devices

- Managing patient health data under GDPR while exporting medical devices to the EU
- Role of data localization and its impact on multinational MedTech firms
- Implications for Indian companies conducting clinical trials for EU regulatory submissions

Dr Muthu Dhandapani, Vice President – Quality & Regulatory Compliance**, Tricog Health**

15:15 – 15:45

Fireside Chat: Upskilling Healthcare Professionals for the Evolving MedTech Landscape

- Exploring training programs and initiatives to equip healthcare professionals
- Fostering industry-government collaborations
- Leveraging digital tools and simulation technologies to provide hands-on training

Moderator: Sailesh YHNB, Associate Director, **Novo Nordisk**

Speakers:

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	Goutam Bhattacharya, Chief Executive Officer**, Life Sciences Sector Skill Development Council** **Dr Arijit Guha,** Head-Medical Affairs, India & Subcontinent**, Boston Scientific** **Nitin Gupta,** Managing Director India & South Asia, **Fujifilm Sonosite India Pvt. Ltd.**
15:45 – 16:00	**Networking Coffee Break** 
16:00 – 16:30	**AI-Enabled Medical Devices and How to Bring them to European Markets** • Understand the current regulatory framework for AI-enabled medical devices under the EU MDR • Learn how to navigate the EU MDR requirements to prepare a CE submission effectively • Discover the types of supporting materials needed to strengthen your CE submission **Malte Knowles Schmidt**, Global Portfolio Manager SaMD, AI and Cybersecurity, **TÜV SÜD**
16:30 – 17:00	**Innovating MedTech: Harnessing Circularity and Sustainable Design for a Greener Future** • Exploring the shift from linear to circular models to reduce waste and extend product lifecycles • Sustainable design strategies to enhance device longevity and environmental impact • Aligning circular practices with global compliance standards and cost-effectiveness • Building partnerships for material recovery, refurbishment, and recycling **Dr Ravi Rathod,** General Manager- Policy & Strategic Affairs, (Regulatory Division)**, Innvolution**
17:00– 17:30	**Refurbished Medical Devices: Unlocking Potential Through Regulatory Clarity and Ensuring Patient Safety** • Overview of CDSCO and Indian MDR guidelines for refurbished devices • Environmental benefits of refurbished devices: Reducing e-waste and conserving resources • Ensuring patient safety and regulatory compliance **Rupam Chaudhary**, Global Head Lifesciences Engineering, **TCS**
NETWORKING COFFEE BREAK & END OF THE CONFERENCE	

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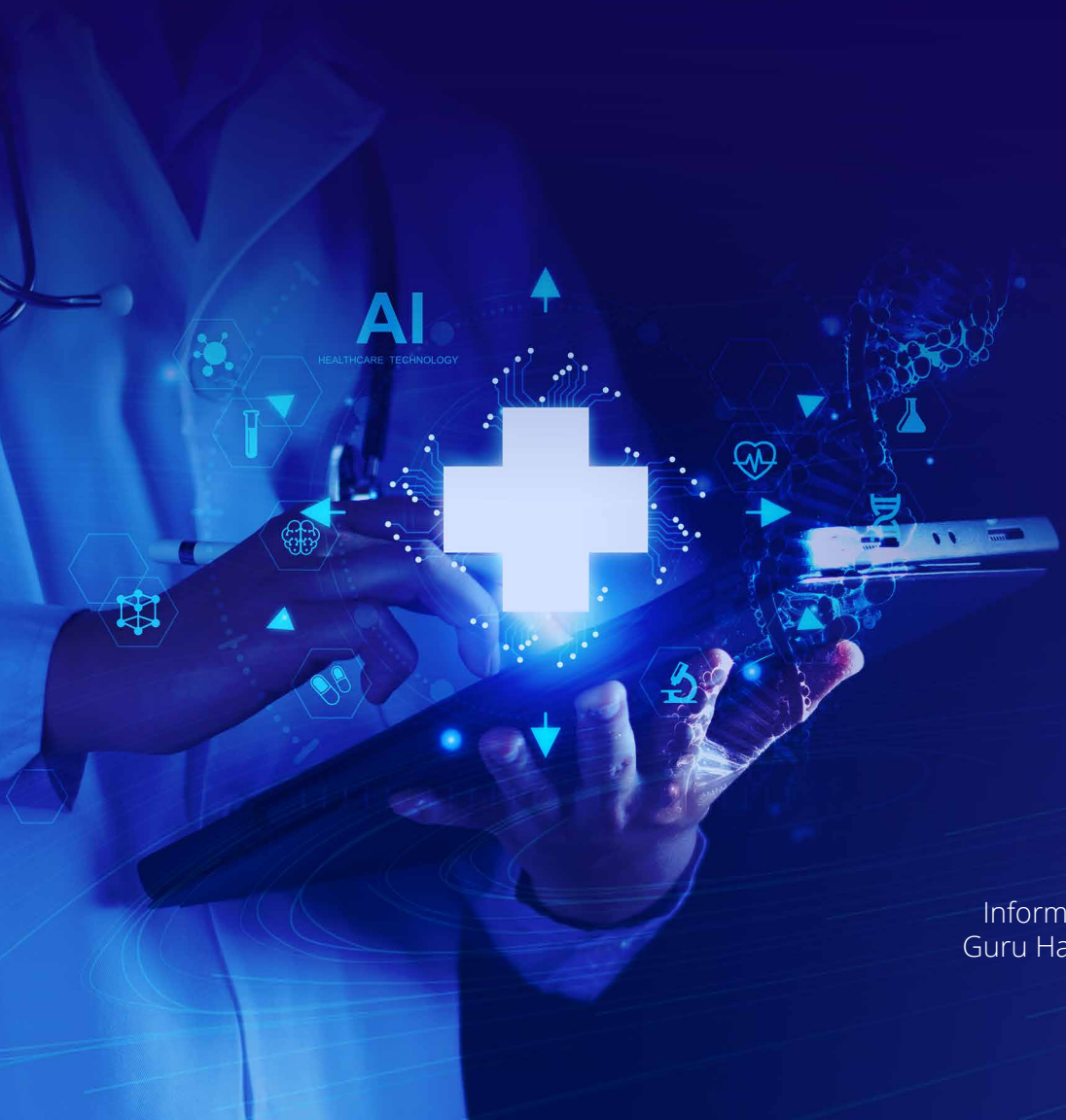

PRICING

Standard Pricing
INR 12,000 per delegate

18% GST applicable

FOR DELEGATE REGISTRATIONS

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informa markets

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