June 24-26, 2025 | Boston, MA

www.medicaldevice-software-development.com



5th Annual

Medical Device Software Development Summit

Benchmark & Fuse Knowledge from Software, QA, RA & Product Teams to Align Innovation in Software with **Evolving Processes, Cybersecurity,** & Global Regulatory Frameworks in **New & Legacy Devices**

Expert Speakers Include:



Adam Heroux Vice President of Quality & Regulatory Affairs Kheiron Medical



Attrayee Chakraborty **Quality System** Engineer **Analog Devices**



Brian Schick Director, Digital Product Strategy & **Development Lead**



Jason Gorman Director, Global Product Regulatory Affairs



Eleonora Chakraborty Associate Director, Regulatory Affairs, Strategic Global Labeling, Combination Products & Devices



Dinendra Ramachandran Vice President Digital Health Solutions Convate

Proud to Partner With:











Welcome to the 5th Medical Device Software Development Summit



As the FDA continues to release updated regulatory and cybersecurity guidance, and validation of Al/ML-enabled medical devices remains uncharted territory, the challenges of building robust SBOM infrastructure and managing legacy device updates have never been more critical. Staying ahead of these demands is essential to efficiently validate, secure, and futureproof both new and legacy medical device software.

The **5th Medical Device Software Development Summit** is dedicated to tackling these pressing challenges head-on. This event will demystify the complexities of U.S. and global regulatory landscapes, address vulnerabilities in cybersecurity, and share actionable strategies for updating and maintaining legacy devices. By bringing together industry leaders from medical device giants to innovative start-ups, the summit offers an unparalleled opportunity to exchange case studies, insights, and best practices for developing compliant, secure, and future-ready software.

Join 120+ CTOs, Heads of Software, Product Development, Regulatory Affairs, and Quality Assurance to:

- Benchmark practical applications of evolving compliance frameworks
- Optimize threat modeling for systematic security risk analysis
- Navigate SBOM for enhanced transparency and operational efficiency
- Break cross-functional siloes to streamline testing and regulatory processes

Don't miss your chance to stay ahead of the curve and lead the way in delivering innovative, compliant medical device software solutions.

What past attendees have to say:

The workshops and roundtable discussions throughout the conference were a great way to brainstorm best practices and learn from how other teams solved similar problem

Software System Engineer, Abbott Laboratories

■ The topics that were discussed were very relevant to the industry. The utility of the discussions stood out

Software Engineer, CardioQuip

KEY BENEFITS OF ATTENDING



Optimize SBOMs & Change Control for Seamless Compliance:

Discover best practices for integrating SBOMs into your development to ensure end-to-end traceability with

Straumann Group



Master the Technical Implementation of FDA

Cybersecurity Regulation:

Uncover how to address cybersecurity risks in connected medical devices through best-inclass technical practices



Establish Practical Al Validation Frameworks:

Kheiron Medical

will uncover how to bridge the gap between highlevel AI principles and actionable validation steps for medical devices



Accelerate
Medical Device
Approvals
with Agile
Development:
Reduce timeto-market by
integrating agile

integrating agile methodologies with regulatory frameworks, ensuring rapid iteration without compromising compliance with

IMVARIA



Enhance
Approvals through
FDA's Product
Change Control
Plans (PCCPs):
Streamline
product changes

with FluxErgy to
ensure compliance
and accelerate
time-to-market for
Al-powered medical
devices



2





with Abbott

Laboratories





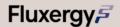


What's New in 2025?



NEW COMPANIES FOR 2025









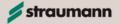












NAVIGATING THE EVOLVING MEDTECH LANDSCAPE: NEW CHALLENGES IN 2025

In 2025, the MedTech industry is grappling with heightened regulatory uncertainty, driven by evolving FDA guidelines, shifting international trade policies, and emerging tariffs. At the same time, cybersecurity and AI regulations are becoming increasingly critical, as standards for AI integration and data protection evolve. As new frameworks and compliance requirements are introduced, companies face the dual challenge of ensuring regulatory alignment while safeguarding patient data and leveraging Al-driven innovations. Staying ahead of these shifting regulations and optimizing processes for both compliance and innovation is crucial to navigating the complex landscape of 2025.



20+ brand-new speakers from leading device developers and regulators sharing cutting-edge strategies and case studies.

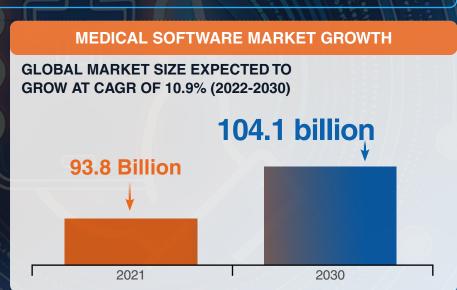


8+ hours of networking, including a dedicated speed

networking session to connect you with the whole room of 120+ Medical Device Software Experts



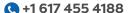
Al Integration Mastery - Understand the key strategies for leveraging AI in medical device development while ensuring compliance and security across the product lifecycle.



Peers are knowledgeable and shared different perspectives, insights, experiences, and practices including case studies

Associate Director, Merck







Your Expert Speakers







Andrew O'Keeffe Executive Director, Global Digital Quality



Andrew Wichmann Senior IP & Licensing Manager, Digital Manago., Technology Hopkins



KHEIRON

Attrayee Chakraborty Quality Systems Engineer **Analog Devices**



Brian Schick Director, Digital Product Strategy & Development



Dinendra Ramachandran Vice President Digital **Health Solutions**



Don Bigler Vice President, Engineering



Eleonora Chakraborty Associate Director, Regulatory Affairs, Strategic Global Labeling, Combination Products & Devices



Ephrat Most Director, Software Quality Program



James Asimah Director and Head of Cyber Security & Government, Risk & Compliance Highridge Medical



Jason Domask Director, Software Engineering Heart Sciences



Jason Gorman Director, Global Product Regulatory Affairs



Associate Director, Emerging Technologies Regulatory & Quality Lead

Joshua Guo



Joshua Kupke Director, Research & **Product Development**



Joshua Park Chief Executive Officer Global Biomedical



Manil Asija Principal Éngineer Quality Engineering



Michael Iglesias Associate Director, **Quality Assurance**



Neeraj Mainkar Vice President, Software Engineering Proprio Inc









Phani Bidarahalli Senior Director, Surgical Innovations, Research & Development



Richard Jackson Director of Platform Engineering FluxErgy



Sarah Rickert Director of Quality & Regulatory Affairs Werfen



Seth Kuzdzal Former Senior Vice President, Quality Assurance & Regulatory Affairs **Biofourmis**



Stephen Odaibo Founder, Chief **Executive Officer &** Software Architect **RETINA-AI Health**



Srutiparna Lahkar Senior Quality Lead



Timothy Ruchti Director, Algorithms Nihon Kohden Corporation



Tura Oullette Director of Regulatory



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Pre-Conference Workshop Day Tuesday, June 24



Check-In & Coffee 8.00

Workshop A

9.00

Harmonizing Global Regulatory Strategies to Simplify Medical Device Submissions & Expand Market Reach

- Navigating complex regulatory landscapes across key global markets by discussing advanced strategies for interpreting and applying the regulatory requirements and submission processes for the FDA, EU, Japan, and other regions
- Harmonizing global submissions by gaining insights into streamlining regulatory submissions across multiple regions, minimizing redundancy, and optimizing time-to-market
- Managing cross-jurisdictional challenges by exploring common hurdles in managing multi-market regulatory approvals, including varying requirements for clinical trials, risk management, and post-market surveillance, and discovering strategies to overcome these challenges effectively

Workshop Leaders



Eleonora Chakraborty
Associate Director, Regulatory
Affairs, Strategic Global
Labeling, Combination
Products & Devices
Abbyie



Michael Iglesias
Associate Director, Quality
Assurance
Merck

Joshua Guo



Technologies Regulatory & Quality Lead
Biogen

Associate Director, Emerging

Morning Break 11.00

Workshop B

12.00

Harnessing AI in Medical Device Software Development: Innovation, Efficiency & Ethical Boundaries

- Explore how AI is currently being integrated into medical device software to improve automation, efficiency, and quality - and where the ethical and regulatory boundaries lie
- Move beyond high-level guidance with actionable steps for validating Al systems, including incorporating PCCPs to manage model updates effectively
- Balance innovation and oversight by addressing ethical considerations, regulatory readiness, and the long-term adaptability of AI systems in a changing global landscape
- Learn how leading teams are building systems and frameworks that ensure Al tools are safe, compliant, and continuously evolving with future standards

Workshop Leaders



Ephrat Most
Director, Software Quality
Program
Medtronic



Adam Heroux
Senior Vice President of
Quality & Regulatory Affairs
Kheiron Medical

Lunch Break & Networking

2.00









Pre-Conference Workshop Day Tuesday, June 24

Medical Device Software Development Summit

June 24-26, 2025 | Boston, MA

Workshop C 3.00

Building Resilient Al-Cybersecurity Frameworks: Practical Strategies for Development teams Amid Regulatory Gaps

- · How to fit Al development into a traditional secure product development lifecycle
- Explore how development teams can proactively secure Al-driven medical devices, focusing on unique risks at the intersection of cybersecurity and Al when regulatory guidance is unclear
- Gain insights into structuring software development workflows to anticipate future cybersecurity and AI compliance requirements, ensuring systems are audit-ready without overengineering

Workshop Leaders



Andrew O'Keeffe
Executive Director, Global
Digital Quality
Olympus



Stephen Odaibo
Founder, Chief Executive
Officer & Software Architect
RETINA-AI Health











Conference Day One Wednesday, June 25





8.00 Registration & Morning Coffee



Stephen Odaibo Founder, Chief Executive Officer & Software Architect RETINA-AI Health

8.50 Chair's Opening Remarks

Enhancing Device Software Security for Long-Term Success

Manil Asija Principal Engineer Quality Engineering

9.00 Securing Cloud-Connect Medical Devices: Interoperability & Data Privacy

- Addressing cybersecurity challenges in cloud-connected medical devices and ensuring secure data exchange across diverse ecosystems
- Adhering to regulatory standards like HIPAA and GDPR while ensuring data privacy and security in cloud integrations
- Navigating the complexities of interoperability between devices, cloud systems, and healthcare technologies, while safeguarding against cybersecurity risks

Sarah Rickert
Director of Quality &
Regulatory Affairs
Werfen

Analog Devices

9.30 Overcoming Challenges in Modernizing Legacy Devices: Bridging Cybersecurity & Regulatory Compliance

- Addressing cybersecurity vulnerabilities in legacy medical devices
- Ensuring compliance with evolving global regulations (FDA, EU MDR, etc.) for legacy software
 - Strategies for assessing design and regulatory gaps in outdated software systems
- Determining regulatory strategy for release of updated version of legacy medical device software



James Asimah
Director & Head of
Cyber Security &
Government, Risk &
Compliance
Highridge Medical

10.00 Threats, Attacks, & Vulnerabilities

- Understanding different threat actors, their motivations, and common attack surfaces
- · Exploring various vulnerability types and their impact on medical device software
- Analyzing malicious activity indicators and implementing effective defense mechanisms to protect enterprise systems



10.30 Morning Break & Speed Networking

Join our speed networking session tailored for medical device software experts, like yourselves, to connect with industry peers & facilitating rapid yet meaningful exchanges of insights and expertise. Elevate your networking experience during this session designed for impactful connections within the space of medical device software



11.30 Session Reserved for Ketryx

Building Trustworthy & Scalable AI: From Development to Global Regulatory Approval

12.00 Building Al Capabilities within a Medical Device



Dinendra
Ramachandran
Vice President Digital
Health Solutions
Convatec

- Finding the right AI use case by balancing technical feasibility, commercial potential, clinical impact, and regulatory challenges
- Ensuring high-quality, curated, and regulation-compliant data including synthetic data to drive Al success
- Navigating regulatory challenges such as bias, transparency, accountability, and safety to secure approval and maintain compliance
- Adapting post-market with continuous learning and leveraging Gen AI for enhanced performance and innovation









Conference Day One Wednesday, June 25

2.00





Neeraj Mainkar Vice President of Software Engineering & Advanced Technology **Proprio Inc**

Building Efficient Data Pipelines: Accelerating AI Model Training & 12.30 **Validation in Regulated Environments**

- Discussing strategies for designing robust data pipelines to streamline collection, processing, and storage
- Leveraging automation for data cleaning, feature engineering, and validation to optimize
- · Ensuring adherence to industry standards while maintaining data integrity and traceability



Lunch & Networking 1.00



Seth Kuzdzal Former Senior Vice President, Quality Assurance & Regulatory Affairs **Biofourmis**

 Addressing the challenges of designing and developing AI/ML enabled medical devices that ensure transparency and meet FDA global regulatory expectations

Demystifying Al Transparency: Building Systems That Regulators Trust

- · Navigating multi-region submission complexities, including FDA, EU MDR, and Japan, with a focus on Al-specific guidelines and clinical data requirements
- Integrating post-market surveillance insights to refine AI models, mitigate risks, and enhance regulatory readiness in real-world applications

Navigating Software Change Control: Ensuring Compliance from Development to Post-Market

Navigating Product Change Control: Balancing Innovation & Regulatory Compliance



Joshua Kupke Director, Research & Product Development **Enovis**

- Insights into the new FDA guidance, its objectives, and its implications for medical
 - device submissions which include software · Navigating the shift from traditional change processes to a forward-looking compliance
 - strategy including regulatory strategies and optimizing documentation Practical strategies for managing change justification and maintaining compliance in a
 - rapidly evolving regulatory landscape



3.00 **Poster Session & Refreshments Break:**

> This poster session is your go-to session to obtain competitive insights and present your most innovative work to medical device thought leaders and decision makers. For more information or to submit your abstract, please email info@hansonwade.com

Accelerating Approvals: Leveraging the FDA's Product Change Control Plans (PCCPs)



- · Streamlining product changes by using PCCPs to accelerate approvals for Al-powered medical devices while maintaining compliance with the FDA
- Optimizing change documentation by understanding best practices for creating comprehensive change control plans that align with FDA expectations for medical devices with AI components
- Avoiding approval delays through real-world case studies that demonstrate how leveraging the PCCP process can reduce time-to-market for Al-driven medical devices

4.15 Optimizing SBOMs & Change Control Management for Regulatory **Compliance in Medical Device Software**



Tura Oulette Director Regulatory Straumann Group

- Best practices for integrating SBOMs into the software development lifecycle to meet FDA, EU MDR, and other regulatory requirements, ensuring end-to-end traceability
- Establishing robust procedures to handle software changes post-market, ensuring compliance with change control regulations while maintaining device safety and performance
- Understanding regional differences in SBOM requirements and change management practices, and how to manage these complexities in the context of global submissions



Stephen Odaibo Founder, Chief **Executive Officer &** Software Architect **RETINA-AI** Health

Chair's Closing Remarks 4.45

4.50 **End of Conference Day One**



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Conference Day Two Thursday, June 26





8.00 Check In & Coffee



Stephen Odaibo
Founder, Chief
Executive Officer &
Software Architect
RETINA-AI Health, Inc

8.40 Chair's Opening Remarks

Advancing Collaboration Between Engineers & Regulators

8.45 Panel Discussion: Aligning Engineers & Regulators for Seamless Collaboration

- Tackling communication barriers in highly regulated environments and creating a shared language between engineering and regulatory teams
- Overcoming common misalignments in goals and timelines, with practical strategies to enhance collaboration without compromising technical and regulatory integrity
- Real-world case studies on how leading companies have successfully aligned engineering and regulatory teams to achieve faster approvals and innovation



Attrayee Chakraborty
Quality System Engineer
Analog Devices



Eleonora Chakraborty
Associate Director Regulatory Affairs, Strategic Global
Labeling, Combination Products & Devices
AbbVie





Brian Schick
Digital Product Strategy
& Development Lead
Takeda

9.15 Collaborative Risk Assessment for Faster Approvals

- Ensuring a streamlined risk assessment process that involves both engineering and regulatory teams
- Revealing how to conduct joint risk assessments that satisfy both compliance and development needs without delays
- Outlining techniques for maintaining regulatory timelines while addressing engineering challenges

9.45 Key Considerations for Sponsors & Manufacturers of SaMDs & Medical Devices in Clinical Trials



- Understanding risk management requirements, regulatory frameworks, and compliance standards such as ISO 14155 and ISO 13485
- Aligning software development, clinical validation, and regulatory compliance to streamline approval and trial success
- Implementing fit-for-purpose strategies to balance patient safety, data collection, and usability in clinical study protocols

10.15 Harmonizing Quality Management with Regulatory Expectations: Bridging the Gap



Jason Gorman
Director, Global
Product Regulatory
Affairs
ResMed

- Aligning quality systems with regulatory standards by ensuring quality management systems (QMS) are designed to meet both regulatory and internal quality expectations
- Managing software and hardware integration by integrating regulatory compliance into hybrid systems where software and hardware components interact seamlessly in medical devices
- Optimizing Post-Market Surveillance and Compliance through strategies that harmonize regulatory expectations with post market activities, ensuring ongoing compliance and quality management



10.45 Morning Break & Networking









Conference Day Two Thursday, June 26



Accelerating Safe, Compliant Innovation to Get Devices to Market Faster



Andrew Wichmann Senior IP & Licensing Manager, Digital Technology John Hopkins

Don Bigler Vice President,

Engineering IMVARI

- 11.30 Leveraging Open-Source Tools for Medical Device Software Development
 - Improving speed and flexibility by utilizing open-source tools to streamline development and enable faster iterations
 - Ensuring regulatory compliance by integrating open-source solutions that meet industry standards
 - Building collaborative ecosystems by tapping into open-source communities for innovation and shared expertise while managing risks

12.00 Efficient Iterations: Reducing Time-to-Market for Medical Devices



- Integrating agile processes with regulatory requirements to avoid bottlenecks in approval timelines
- Highlighting how iterative testing and validation have expedited product launches without compromising safety or compliance
- Real-world examples: Fibresolve (de novo) and ScreenDx (510k)

Driving Better Patient Outcomes Through Smarter, Al-Enabled Technologies

12.30 Roundtable: The Role of Edge Computing in Real-Time Healthcare: Opportunities & Challenges



Joshua Park
Chief Executive Officer
Global Biomedical



- How can AI integration on the edge enhance real-time decision-making for clinicians and improve patient outcomes?
- What are the key technical and regulatory challenges when integrating edge computing in medical devices, and how can they be addressed to ensure compliance and functionality?
- How should the healthcare industry approach the ethical implications of real-time Al decision-making in medical devices?



1.00 Lunch Break & Networking

2.00 Transforming Patient Care with Predictive Algorithms & Real-Time Physiological Data



- Adding value by developing predictive algorithms for real-time detection of patient deterioration before clinical recognition
- Avoiding bias through the harnessing of continuous physiological data to create unbiased, data-driven solutions
- Overcoming the last mile by focusing on deployment and clinical integration

2.30 HeartSciences Pillars of Excellence: A Story About how we Built a Medical Device Data System (MDDS) & Class II Cardiovascular Machine Learning-Based Notification Software in Record Time



Jason Domask
Director, Software
Engineering
HeartSciences

- Collaborating regularly with clinicians to validate designs, gather feedback, and align solutions with real-world clinical needs
- Integrating AI seamlessly into clinical workflows while addressing data access challenges and regulatory requirements
- Leveraging agile development and strategic partnerships to enhance cybersecurity, streamline processes, and accelerate high-quality product delivery



Phani Bidarahalli Senior Director, Surgical Innovations, Research & Development Medtronic

3.00 Data-Driven Innovation: Leveraging Big Data & Al in Development & Validation

- Building a data-driven ecosystem to enhance software validation, optimize testing processes, and accelerate iterative development
- Exploring how big data and Al-driven analytics can identify software flaws, improve accuracy, and optimize device functionality
- Navigating the regulatory landscape for integrating AI into software development while ensuring compliance with medical device standards



Stephen Odaibo
Founder, Chief
Executive Officer &
Software Architect
RETINA-AI Health, Inc

3.30 Chair's Closing Remarks

3.40 End of Conference



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2025 Partners





Ketryx Corporation – Expertise Partner

Ketryx is the first and only Al-powered connected lifecycle management platform for the life sciences industry. Our automation-based software enables companies building regulated software to accelerate development through modern cloud-based tools while improving quality and compliance. By overlaying and connecting existing product development and quality tools, Ketryx creates a real-time, traceable, single source of truth. Teams expedite time to market by automating documentation while enforcing SOPs across connected systems.

www.ketryx.com





QMB's QualiVerse is a Vertical SaaS, Al-native platform revolutionizing regulatory workflows in medical devices. By transforming the traditionally manual, consultant-heavy process into an intelligent, data-driven system; QualiVerse accelerates approvals, reduces errors, and turns regulatory affairs into a strategic advantage. With a proprietary Al-powered knowledge graph, smart document co-pilot, and patent-pending algorithms, we slash FDA rejection risks, empowering MedTech companies to bring life-saving innovations to market faster

https://www.qmbdevices.com/

discussions and insights based on hands-on experience

Director of Software, Luma Vision

GET INVOLVED



Molly Biggin
Partnerships Director
Tel: +1 617 455 4188

Email: sponsor@hansonwade.com









Why Partner?



The Leading Platform to Build Strong Partnerships & Drive Innovation in Medical Device Software Development

The 5th Medical Device Software Development Summit in June 2025 will bring together leading medical device manufacturers and pioneering start-ups to explore cutting-edge solutions in cybersecurity, software development, compliance, testing, and quality management. By partnering with us, you'll position your company at the forefront of innovation, connect with an engaged audience of senior decision-makers, and showcase your expertise as a key solution provider in the medical device software space.

Opportunities for Partnership:



Software Development Platforms:

As companies race to bring devices to market, they rely on robust development platforms to enhance efficiency, scalability, and integration capabilities.



Cybersecurity Software:

With increasing threats of data breaches and device vulnerabilities, developers need cutting-edge security solutions to protect patient safety and maintain regulatory compliance



Regulatory Consultants:

Navigating the ever-changing landscape of global medical device regulations requires expert guidance to ensure compliance, accelerate approvals, and mitigate risks

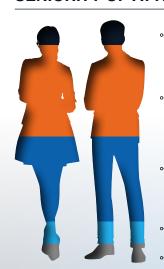


Testing & Quality Management:

From verification and validation to risk assessment and post-market surveillance, ensuring product reliability and regulatory approval is a top industry priority

Let's create a tailored sponsorship package that aligns with your objectives, whether through thought leadership sessions, one-on-one meetings, exhibit booths, or exclusive networking opportunities. Connect with us today to explore how you can maximize your impact at the summit.

SENIORITY OF ATTENDEES*



VP/CXO: 10%

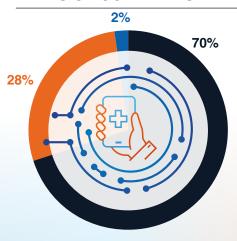
Head/Director: 38%

Manager/Lead: 35%

Principal Engineer: 9%

Other: 8%

TYPES OF COMPANIES ATTENDING*



Medical Device Manufacturers

> Service Providers

Not For Profit

Statistics Taken from the 4th Medical Device Software Development Summit

GET INVOLVED



Molly Biggin
Partnerships Director
Tel: +1 617 455 4188

Email: sponsor@hansonwade.com









Ready to Register?

3 Easy Ways to Book



www.medicaldevice-software-development.com/take-part/register/



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Email: info@hansonwade.com



Future-Proof Your Medical Devices with AI & Next-Gen Technologies: Explore how leading companies are optimizing AI, software validation, and change management to build safer, smarter, and faster-tomarket medical devices.



Turn Regulatory Complexity into a Competitive Advantage/ Stay Ahead in the Ever-Evolving Regulatory Maze/ Gain Actionable Insights on Navigating Complex Regulatory Landscape: Gain expert insights on navigating FDA, EU MDR, and global requirements to streamline approvals and accelerate time-to-market



Network with the Industry's Best: From global leaders to innovative startups, engage with a diverse mix of medical device software professionals, ensuring you leave with contacts and insights that deliver immediate value

Device Developer Pricing	Register & Pay By Friday, May 30	On the Door Price
Conference + Workshop Day	\$3,897	\$4,197
Conference Only	\$2,799	\$2,999

Standard Pricing	Register & Pay By Friday, May 30	On the Door Price
Conference + Workshop Day	\$4,797	\$5,097
Conference Only	\$3,499	\$3,699

^{*}To qualify for the device developer pricing your company must have a public pipeline. Please visit the website for full pricing options or email info@hansonwade.com Do you work for a Not-for-Profit or academic organization? Email us at info@hansonwade.com to inquire about attending at a discounted rate **To qualify for academic & research rate you must be full time academic. Please visit the website for full pricing options or email info@hansonwade.com

Team Discounts**

- 10% discount 2 Attendees
- 15% discount 3 Attendees
- 20% discount 4 + Attendees

***Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Discounts cannot be used in conjunction with any other offer or discount. Only one discount offer may be applied to the current pricing rate.

Contact: register@hansonwade.com

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Venue

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TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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