WHY? SUMMITS

Updated: 27 February, 2026
for the latest programe update,
please download agenda on
conference website

1 - 2 April, 2026

Chicago, USA

3RD AMERICAN MEDTECH SUMMIT 2026

Premium Gold Partner: FINN

Gold Partner: ALWIS A NEXTGEN SOLUTIONS

INTRODUCTION

This exclusive conference brings together senior leaders in **medical device safety, vigilance, and compliance** to address the most critical post-market and regulatory challenges shaping 2025–2026. Over two focused days, participants will gain practical insights into **global vigilance harmonization, integrated risk management, clinical evidence alignment, and inspection readiness** directly from top industry experts. With regulators demanding stronger governance, faster signal detection, and real-time safety accountability, this event offers a rare opportunity to benchmark against leading device manufacturers and prepare for what's next. Missing it means falling behind on the evolving expectations that define **the future of patient safety and medical device compliance.**

OUR NEWEST EDITION TO OUR PV WORLD TOUR 2026

- Meet America's leading MedTech professionals responsible for QA, safety & compliance
- Taking the discussions from surface to practical applications, results and challenges
- Take a glimpse into the future with the industry shapers and innovators
- What have we learnt in 2025? Case-studies and review the will shape 2026 priorities
- Listen to the most crucial current topics selected & presented by industry leaders
- Enjoy education & networking focused event in a non-vendor-driven environment
- Create lasting work groups and friendships with the possibility of meeting regularly on the next stops of our world tour

ALWAYS ASK WHY?

Our Chicago meeting will be focusing on topics of:

- Evolving Post-Market Surveillance (PMS) and Vigilance Expectations
- Global Regulatory Divergence and Reporting Complexities
- Integration of Risk Management and Post-Market Data
- Signal Detection and Trending: From Manual to Predictive
- Complaint Handling Quality and CAPA Effectiveness
- Clinical Evaluation and Performance Data Integration
- Human Factors and Usability-Driven Safety Risks
- Field Safety Corrective Actions (FSCA) and Recall Readiness
- Digitalization of Safety Systems and PMS Workflows
- Inspection Readiness and Enforcement Trends
- Third-Party / Contract Manufacturer Safety Accountability
- Data Quality and Traceability in Safety Documentation
- Global Safety Data Sharing and Real-World Evidence Integration
- Leveraging Safety Governance for Cross-Functional Excellence

TESTIMONIALS

Karen Forsha Ph.D.
L&D Change Management and Training Leader
Terumo Medical Corp.
★★★★★

„I had the opportunity to offer participants insight on how to positively impact others' well-being and influence organizational outcomes by viewing resilience, grit, and growth mindset as their leadership superpower! The dialogue afterwards was inspiring."

Surinder Dhillon
Head of Commercial PMO, International
Hologic
★★★★★

„I found the sessions were well organized, with an interesting mix of attendees from across the industry. Various key topics were covered, all pertinent to the current MedTech landscape with good discussions on common challenges and sharing of useful lessons, practical applications and future proofing strategies."

Gunther Lenz
Vice President Software R&D
Biosciences BD
★★★★★

„Digital Transformation in PPM at the #MedTechSummit! It's always inspiring to connect with fellow professionals who are equally passionate about harnessing digital tools to revolutionize project and portfolio management in healthcare. Let's continue this conversation and keep the ideas flowing!"

Renea Olsen
Post-Market Surveillance Manager, Scientific Affairs
3shape
★★★★★

„The fact that the conference is relatively small generates a very open dialog and it makes it easy to network"

Susanna Girard, MBA, PMP, ACP
Senior R&D Program Manager
J&J MedTech
★★★★★

„Great discussions! It was my pleasure to be a part of it and get to know so many great people working in the industry."

Arite Wildau
Director Patient Safety
BIOTRONIK
★★★★★

„Great open dialogue in an expert community. Many valuable presentations, panel discussions and time for networking to share best practices and different views on similar challenges. Warm atmosphere to grow as team over two fabulous days. Also excellently organized and moderated by the WHY SUMMIT TEAM. Happy to join next year as well!"

Sarah Paro
Global QMS Associate
Director
★★★★★

„Last week I had the opportunity to share my experiences and learn from industry experts at Why Summits MedTech Summit. It was an incredible experience!"

Benjamin Rochette
Vice President, Global Regulatory Affairs
Coloplast
★★★★★

„I joined the conference in Spring 2023 and really enjoyed it. The program covered several topics of direct relevance to my daily activities, while also giving me perspectives on 'macro trends' of the medical devices industry. Speakers were experts and participants motivated to interact between sessions."

INDUSTRY PIONEERS ATTENDING FROM

WHY? SUMMITS

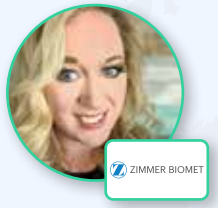
OUR SPEAKERS

WHY? SUMMITS

Pat Baird
Regulatory Head of Global Software Standards
Philips

Melissa Pieplow
Director, Complaints Vigilance
Intuvie

Guy Starbuck
Co-Founder and CTO
AIQ Solutions



Sarah Paro
Global QMS Associate Director
Zimmer Biomet

Tina O'Brien
Director of Regulatory Affairs - Global
Paragon 28

Vee Arya
Associate Director Quality Assurance
bioMérieux

Michelle Schiltz-Taing
Regulatory Affairs Manager
Hollister Incorporated

Dan Xuan Nguyen
Director, Medical Affairs
ZETA Surgical

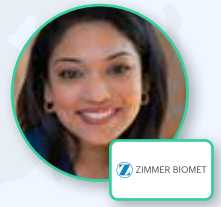
Mehul Desai
Vice President, Medical Affairs | Executive Team Member
Enable Injections

Ankush Raj Gaur
Director of Medical Affairs, IGTD
Philips

Humberto Valbuena
Director, Medical Affairs-US & LATAM
Alcon

Edward Chekan
Vice President of Medical Affairs & Professional Education
Asensus Surgical

Leo Park
Sr. Director of Cyber Security
Click Therapeutics



Ras Viswanadha
Associate Director of Research (Biological Safety)
Zimmer Biomet

Abdul Rahim
Founder & CEO
Alwis Group

Sudhir Shandilya
Director (SDSM) - Digital Strategy, Transformation, and Operations
Sanofi

Subhadip Jana
Sr. Director, Global Regulatory Affairs
ADC Therapeutics

Mike Xie
VP of Quality and Regulatory Affairs
Sol-Millennium Medical Group

Richard Matt
Principle Consultant
Aspen Medical Risk Consulting

Aparna Ahuja
Divisional Vice President Medical, Clinical and Scientific Affairs ID Rapid Diagnostics
Abbott

CONFERENCE AGENDA

DAY 1

6:00PM MEET & GREET

Informal meeting in the Lobby of the hotel for all attendees coming to the conference the night before. Register and receive your badge in advance, and enjoy a pre-event meet and greet with a few attendees before we kick-off Day 1.

8:30

MORNING REGISTRATION AND EARLY BIRDS NETWORKING COFFEE

9:00

OFFICIAL START WITH OPENING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

9:10 NEXT-SEAT- MEET & GREET

STATE OF MEDTECH SAFETY: 2025–2026 LANDSCAPE & EXECUTIVE PRIORITIES

9:20

STRATEGIC IMPERATIVES FOR 2026: WHAT SAFETY LEADERS MUST PRIORITIZE NOW

- Building end-to-end safety visibility across complaints, CAPA, risk and clinical evidence
- Investing in data integrity, PMS system upgrades, and inspection readiness
- Driving a safety-first culture that enables compliance, performance, and patient protection

9:50

REGULATORY MOMENTUM: FDA, MDR, AND GLOBAL AUTHORITIES TIGHTEN POST-MARKET CONTROLS

- Intensified oversight of PMS plans, vigilance reporting timelines, and documentation traceability.
- Practical implications of MDR/IVDR, FDA's TPLC direction, and emerging UK/MHRA frameworks.
- What regulators expect going forward

10:20

OPENING ROUND-TABLE DISCUSSIONS: NAVIGATING TOWARDS THE FUTURE

- What are the main challenges that we need to focus on?
- Key trends and technologies

Round-table Leader:

10:50 MORNING BREAK: COFFEE, CAKE & NETWORKING

POST-MARKET EXCELLENCE & VIGILANCE EVOLUTION

11:20

EVOLVING POST-MARKET SURVEILLANCE (PMS) AND VIGILANCE EXPECTATIONS

- Transition from passive to active and predictive post-market models
- Regulatory alignment between FDA and MDR vigilance frameworks
- Continuous surveillance as the foundation of patient safety

11:50

THE NEW POST-MARKET REALITY: RISING EXPECTATIONS FOR SAFETY LEADERS

- Current status of the industry
- Shift toward active, predictive surveillance as the new baseline expectation.
- Greater accountability placed directly on Safety Directors for data accuracy and decision-making

CONFERENCE AGENDA

DAY 1

12:20

GLOBAL REGULATORY DIVERGENCE AND REPORTING COMPLEXITIES

- Navigating multi-regional vigilance timelines and definitions
- Managing global field safety corrective actions and trend reports
- Harmonization vs. localization — what global leaders must prioritize

12:50 LUNCH BREAK

13:50

PANEL DISCUSSION: FUTURE PROOFING THE WORKFORCE

- Upskill for data literacy and AI fluency
- Emphasize cross-functional adaptability

14:30

AUTOMATING THE DETECTION OF ADRS FROM DIVERSE DATA SOURCES

- Introduction and description of a new probabilistic method for causality assessment
- Automation of the tool by means of Large Language Models and predefined data-sheets
- Comparing the outcomes of automated (AI driven) vs manual (human) assessment
- Exploring future use of the tool for conducting an automated semi-quantitative signals detection

15:00

COMPLAINT HANDLING QUALITY AND CAPA EFFECTIVENESS

- Enhancing complaint triage and root cause analysis.
- Measuring CAPA effectiveness and linking to PMS outcomes.

15:30 COFFEE & CAKE BREAK

16:00

PANEL DISCUSSION: REGULATORY UPDATES IN FDA AND ISO 10993-1

- Key FDA shifts affecting post-market safety decisions, documentation traceability, and complaint-driven risk updates
- Latest ISO 10993-1 interpretations that influence biological evaluation, risk–benefit justification, and ongoing safety evidence
- Practical implications for safety directors: aligning PMS data, clinical evidence, and risk management files to meet updated global expectations

17:00 END OF DAY 1 & CLOSING REMARKS FROM THE CHAIRPERSON

CONFERENCE AGENDA

DAY 2

8:50 OPENING REMARKS FROM CHAIRPERSON

INNOVATION, DIGITALIZATION AND AI'S INCREASING ROLES

9:00

ROUND-TABLE DISCUSSION: WHAT'S STOPPING YOU FROM EXTRACTING VALUE FROM EMERGING TECHNOLOGIES?

9:30

DIGITALIZATION OF SAFETY SYSTEMS AND PMS WORKFLOWS

- Transition to integrated electronic vigilance systems & sensors.
- Ensuring validation and data integrity (21 CFR Part 11 / Annex 11).
- Automation trends in complaint handling and signal tracking.

10:00

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING: PRACTICAL CONSIDERATIONS

- Data Quality & Training: The Foundation for Success
- Human-in-the-Loop: Augmentation, Not Automation
- Performance Metrics: Proving AI's Value

10:30 NETWORKING BREAK

11:00

DIGITAL INNOVATION FRAMEWORKS & CHANGE MANAGEMENT

- From Pilot to Platform: Driving Digital Innovation in a Regulated Environment

11:30

HOW TO SELECT THE RIGHT VENDOR FOR YOUR AI PROJECTS

- The most important step for any outsourcing project is vendor selection: this is especially the case for PV and AI activities
- Vendor oversight during a project

SAFETY GOVERNANCE, DATA INTEGRITY & FUTURE READINESS

12:30

GLOBAL SAFETY DATA SHARING AND REAL-WORLD EVIDENCE INTEGRATION

- Integrating RWD and registry data into safety signal analysis.
- Managing cross-border data access, privacy, and interoperability.
- Using global safety data to drive regulatory and clinical collaboration.

13:00 LUNCH BREAK

14:00

LEVERAGING GENERATIVE AI IN QUALITY MANAGEMENT: ENHANCING EFFICIENCY

- Role of generative AI in PV Quality data/trend analysis
- Use prompts with relevant datasets or information in generating relevant responses using generative AI.

14:30

REGULATORY MOMENTUM: FDA, MDR, AND GLOBAL AUTHORITIES TIGHTEN POST-MARKET CONTROLS

- Intensified oversight of PMS plans, vigilance reporting timelines, and documentation traceability.
- Practical implications of MDR/IVDR, FDA's TPLC direction, and emerging UK/MHRA frameworks.
- What regulators now expect to see in safety files, PMCF updates, and audit trails.

15:00

Strategic Imperatives for 2026: What Safety Leaders Must Prioritize Now

- Building end-to-end safety visibility across complaints, CAPA, risk and clinical evidence.
- Investing in data integrity, PMS system upgrades, and inspection readiness.
- Driving a safety-first culture that enables compliance, performance, and patient protection.

15:45 NETWORKING COFFEE BREAK

16:10

PRIORITIZATION OF ICSRS: MOVING BEYOND MANUAL TRIAGE

- Risk Scoring Frameworks for Case Management
- Integrating AI into enterprise risk frameworks

CONFERENCE AGENDA

DAY 2

16:40

CLOSING ROUND-TABLE DISCUSSION: REFLECTIONS AND NEXT STEPS: SHAPING THE FUTURE

- Wrap-up and outline actionable steps
- An open plenary discussion, with chairperson introducing the most interesting & unanswered questions. The conference will end as a free interactive networking and discussion setting goals for 2025.

17:00 CLOSING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

OUR PAST PARTNERS

WHY? SUMMITS

IQVIA™

Syneos™ Health

ETHICARE Clinical Trial Services
Science | Quality | Integrity

drugcard

PREVAIL INFOWORKS

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eNNOV
Software for Life

PHARMORA

Quark

4C PHARMA SOLUTIONS

SPONSORSHIP

Additional sponsorship opportunities are available for those who wish to further customize their involvement.

Exhibiting

With a large and senior audience and decision makers, thoroughly selected, exhibiting at any Summit at 2025 FoP SUMMIT WORLD is a popular sponsorship option with great value for solution providers.
Sponsorship includes
- Selected Summit Three Access Passes
- Exhibition space
- Helping to prearrange face to face meetings with selected participants

Dinner Sponsorship

2025 FoP SUMMIT WORLD TOUR will host a series of dinners These dinners bring together thoughtfully selected groups of 15-20 peers from established pharma, biotech, healthcare, and medtech companies. The dines start with a 30-minute networking reception followed by a 60-minute seated dinner, with the option for participants to remain afterward to continue networking.
- Selected Summit Three Access Passes
- 30-minute reception, and 60 minute seated dinner

Speaking

Limited speaking opportunities are available for our sponsoring partners to demonstrate the expertise of their organization. Be sure to ask about these early so we can ensure your presentation flows seamlessly with the overall content. Speaking sponsorships has several options – keynote presentations, case study presentations, expert presentations, panel discussions, workshops, or roundtable leadership. Speaking opportunities are available for experts in the field of Drug safety specialists, QPPVs, Safety Heads, C-level pharmaceutical and biotech executives, hospital management, clinicians, epidemiologists, pharmacologists, Project and Portfolio Management, Contract Management, Consultancy, CROs, Data Management, Artificial Intelligence, Robotics and Digital Innovation experts

CONTACT US

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WHY? SUMMITS

Attending:

Jan Cizek
jan.cizek@whysummits.com

Attending and Sponsoring:

Rakesh Multani
rakesh@whysummits.com

REGISTER HERE

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SOLUTION-PROVIDERS & VENDORS

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Disclamer:
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"Always be Curious"

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