REGULATORY, PAYMENT & POLICY CONFERENCE

CONFERENCE AGENDA

June 12-13, 2025 | Mintz, Boston, MA

DAY 1: JUNE 12

8:15 AM

NETWORKING & BREAKFAST

NETWORKING

9:00 AM

OPENING REMARKS

9:15 AM

GLOBAL MARKET COMPARATIVE ANALYSIS

PANEL

Healthcare is a global industry and medtech products have broad marketability the world over. What regions currently hold the clearest opportunities for medtech?

Where is demand increasing and pricing strong? Where are payment and reimbursement regimes tractable? Where are regulatory frameworks stable and reasonably navigable?

This session will look at how various European, Asia/Pacific, Middle East, and Latin American markets compare to the US; and share the most up-to-date knowledge of global markets' strengths and weaknesses for US-based medtech companies.

10:00 AM

MASTERING FDA INTERACTIONS

HOT TOPIC

Navigating the FDA's processes requires more than just compliance–it demands a strategic approach. This session will highlight the importance of understanding the people behind FDA reviews, audits, and inspections. Each individual involved has their own set of priorities and incentives that shape their decisions. By recognizing patterns in these dynamics, you can tailor your approach to optimize the results of your current interaction, minimize unnecessary friction, and foster collaboration that will smooth future interactions.

10:30 AM

NETWORKING BREAK

NETWORKING

11:00 AM

THE STATE OF MDR

HOT TOPIC

An overview of key updates to EU MDR and the impact for medical device companies.

11:30 AM

CHINA MARKET ENTRY

HOT TOPIC

China is the world's second-largest MedTech market, offering significant opportunities with policies like total foreign ownership of private hospitals. The upcoming medical device law, along with Volume-Based Purchasing (VBP), will impact foreign manufacturers.

This session covers China's first medical device law, updated guidance, key regulatory factors to speed market entry, leveraging foreign clinical data to avoid in-China trials, and "Made-in-China" policies for foreign startups.

Key topics include:

- Latest healthcare policies
- China's first medical device law and updates
- Innovation policies for premium pricing and reimbursement
- China clinical evaluation pathways
- "Made-in-China" policies for startups and manufacturers

12:00 PM

NETWORKING LUNCH

NETWORKING

1:15 PM

COORDINATING PAYMENT AND REGULATORY STRATEGY

PANEL

In the constantly evolving landscape that is medtech, payment and regulatory policy interact in ways that are often complex and sometimes non-obvious.

This session will explore the manners in which these two critical functions intersect and influence each other. By examining the overlap and divergence of priorities in these disciplines, we'll highlight the practicalities for organizations in smoothing the path from promising technology to successful product.

2:00 PM

DRIVING PRODUCTION ADOPTION IN THE POST-KOL ERA

PANEL

Traditional key opinion leaders (KOLs) no longer hold the sway in purchasing decisions that they once did. As the marketing influence of KOLs diminishes, companies must adapt their strategies for driving product adoption.

In this session, we'll discuss the changing landscape of individual influence, explore evolving strategies for increasing product adoption, and examine whether these approaches are universal or vary across different global markets.

Join us for a deep dive into the future of product promotion in a world where traditional KOL power is no longer the dominant force.

2:45 PM

IN OUR BACKYARD: THE STATE OF HOSPITAL IN MA

PANEL

This panel will explore the current state of Massachusetts-owned hospitals, focusing on their operations and the impact of recent policy changes, including the Steward Health Bill and its effects on medical devices.

We'll discuss the rising costs pressuring hospitals, leading to layoffs, and how this is affecting the hospital workforce—ultimately influencing the buyer landscape.

Additionally, we'll dive into the impact of rising drug prices, particularly GLP-1 medications, on Medicare and Medicaid budgets, and how these changes are influencing the medical device market.

3:30 PM

CLOSING REMARKS

4:00 PM

NETWORKING RECEPTION AT STILLWATER

NETWORKING

6:00 PM

EVENT CONCLUDES FOR THE DAY

DAY 2: JUNE 13

8:30 AM — **BREAKFAST NETWORKING** — NETWORKING

9:05 AM — **OPENING REMARKS**

9:15 AM — **EUROPE IS NOT ONE PLACE** — PANEL

The EU and European common market are often spoken about as single entity. While the regulatory framework and free movement policy make this true in some respects, healthcare payment models are a different tale entirely. Across the 27 EU member states, medical products are paid for with a heterogeneous mix of public and private insurance; healthcare is delivered through a diversely structured array of public, private, and non-profit provider institutions; and payment models include fee-for-service, capitation, value-based methods, and blended methods.

This panel will discuss the specific markets that are most attractive within Europe for certain types of medical products and identify commonalities in addressing these to make the approach more manageable.

10:00 AM — **STATE OF TELEHEALTH PAYMENTS** — HOT TOPIC

10:30 AM — **NETWORKING BREAK** — NETWORKING

10:45 AM

ALIGNMENT BETWEEN FDA CLINICAL TRIAL REQUIREMENTS AND CMS REQUIREMENTS FOR IDE COVERAGE

PANEL

This panel will explore the growing disconnect between FDA clinical trial requirements and CMS IDE coverage criteria.

Recent trends show CMS imposing additional requirements not covered by FDA approvals, leading to delays, repeated resubmissions, and slower patient access to new technologies.

Panelists will share case studies from manufacturers, discussing the time gap between FDA protocol approval and CMS coverage, and offer strategies to navigate these challenges.

11:30 AM

VIGILANCE: HOW/WHEN TO PRIORITIZE INSPECTION PREPARATION

PANEL

This panel will bring together medical device manufacturers to discuss best practices for managing global sites and preparing teams for audits and unannounced inspections. Experts will share tips on navigating regulatory challenges across different regions, ensuring compliance, and fostering a culture of readiness to handle inspections smoothly and efficiently.

12:15 PM

NETWORKING LUNCH

NETWORKING

1:15 PM

STATE OF GOVERNMENT WITH CONGRESSMAN JAKE AUCHINCLOSS

SPECIAL

1:30 PM

MODERATED Q&A WITH CONGRESSMAN JAKE AUCHINCLOSS

SPECIAL

1:45 PM

GOVERNMENT AFFAIRS IN ACTION: WHAT MEDTECH IS FACING

PANEL

This panel will explore the real-world impact of government policies on companies, providing insights into what businesses are actually experiencing. Panelists will share firsthand accounts of how recent legislative and regulatory changes are affecting operations, compliance strategies, and market access. Attendees will gain a clearer understanding of how companies are navigating the evolving landscape of government affairs and the challenges they face.

2:15 PM

IMPACT OF AI ON THE REGULATORY FUNCTION

PANEL

This session will explore the transformative impact of AI on the regulatory profession and organizations. Experts will discuss how AI is reshaping the role of regulatory professionals, streamlining processes, and enhancing decision-making. Attendees will learn how regulatory managers can prepare for these changes, adapt to new technologies, and leverage AI to improve efficiency, compliance, and strategic planning in the evolving regulatory landscape.

3:00 PM

CLOSING REMARKS