REGULATORY ROUNDUP

MassMEDIC
THE HEART OF HEALTHTECH

arena®

WEDNESDAY, NOVEMBER 13TH

8:00 AM **NETWORKING & BREAKFAST**

8:30 AM **OPENING REMARKS**

8:35 AM **ACCELERATE REGULATORY APPROVALS & TIME TO MARKET WITH AI-POWERED CLINICAL DATA AND VIRTUAL TWINS**

Learn about the groundbreaking U.S. FDA and Dassault Systèmes collaboration using virtual twins and generative AI in support of the In Silico Clinical Trial (ISCT) Enrichment Project.

Speaker:
John McCarthy, Life Sciences & Healthcare Industry, Business Consulting, Dassault Systèmes

9:20 AM **DRIVING VALUE WITH THE ADOPTION OF AI IN HEALTHCARE QARA SYSTEMS**

AI technologies have the potential to be broadly applied across the healthcare industry to yield benefits for patient health and company commercial growth. However, any solution needs to be mindful of healthcare regulation and navigate an environment where data availability, data congruence and the cost of the solution may be prohibitive for broad industry uptake.

This session will cover:

- How a customer centric approach to adopting AI technologies in healthcare QARA systems is beneficial
- Specific use cases where value can be derived
- Explore where a 'human in the loop' and healthcare grade AI data are critical

Speakers:
Michael King, Sr. Director Product & Strategy, IQVIA Technologies
Chris Escobedo Hart, Partner, Co-Chair, Privacy & Data Security Practice, Foley Hoag LLP

10:05 AM **NETWORKING BREAK**

10:30 AM **FDA KEYNOTE & MODERATED Q&A**

This session will provide a keynote address from the newly appointed Director of the Center for Devices and Radiological Health, FDA, Dr. Michelle Tarver. This will be followed by a moderated Q&A session led by Veeva MedTech where you will get the chance to ask your questions directly to Dr. Tarver!

Speakers:
Dr. Michelle Tarver, Director, CDRH, FDA (virtual)
Amra Racic, MBA, Vice President, Government Strategy, Medtech, Veeva Systems

11:30 AM **FDA'S NEW QUALITY MANAGEMENT SYSTEM REGULATION (QMSR) – WHAT'S NEW AND HOW TO GET READY FOR THE FEB 2026 IMPLEMENTATION DEADLINE**

The FDA issued an updated 21 CFR 820 on Jan. 31, 2024 and it has a two-year effective date. All medical device manufacturers subject to the requirements of 21 CFR 820 must be in compliance with the new rule by Feb 2, 2026. With the issuance of the new rule, the FDA continues its focus on global harmonization by incorporating by reference ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

With this interactive presentation we will review the major differences between the 1996 version of 21 CFR 820 and the 2024 version, discuss any questions from the audience, and outline what companies need to do to ensure they are compliant on day one.

Speakers:
Marion Cappadona, Senior Product Manager, Arena by PTC
Aaron Snyder, VP Quality Assurance, Allotex
Alexis Compton, Medical Device Quality Engineer, Allotex

12:15 PM **LUNCH & NETWORKING**

1:15 PM

LESSONS FROM THE FRONT LINES

Featuring industry regulatory professionals living regulatory challenges daily, this roundtable discussion will highlight the pain points and opportunities those working on the "front lines" are experiencing, including best practices and lessons learned.

Speakers:
Marie Buharin, Director, Regulatory Affairs, Medtronic
Chris Cain, VP, Clinical & Regulatory Affairs, Hyalex Orthopaedics, Inc.
Mrunmayee Satam, Director of Quality and Regulatory Affairs, Podimetrics, Inc.
Sharon Timberlake, VP of Clinical, Quality, & Regulatory Affairs, Gentuity

2:00 PM

INSIGHTS INTO THE DEVELOPMENT OF IEC 60601-1 4TH EDITION

As the primary global standard for electrical safety in medical devices, IEC 60601-1 has undergone numerous changes, with the upcoming 4th Edition set to bring the most significant updates in nearly 20 years. In this presentation, Intertek's medical experts, who actively participate on the IEC technical committees, will provide a behind-the-scenes look into the development of this critical standard.

Speakers:
Yaqing Liu, Global Chief Engineer, Medical, Intertek
Todd Konieczny, Quality Supervisor, Technical Laboratory Manager, Intertek Boxborough

2:45 PM

NETWORKING BREAK

3:00 PM

LABORATORY DEVELOPED TESTS AS IN VITRO DIAGNOSTICS: REGULATION, LITIGATION, & LEGISLATION

On April 29, 2024, the FDA issued its controversial final rule affirming the Agency's position that LDTs are in vitro diagnostic products regulated as medical devices under the Federal Food, Drug, and Cosmetic Act. Shortly thereafter, organizations representing clinical laboratories and molecular pathologists filed lawsuits challenging the rule in federal court. Meanwhile, the U.S. Supreme Court decided Loper Bright v. Raimondo, overruling the decades-old Chevron doctrine, which had required federal courts to defer to reasonable agency interpretations of ambiguous statutory provisions. This session will address the LDT rule's implementation provisions, the likelihood of the rule being upended by litigation, and the prospects for Congress ultimately deciding the issue of FDA's authority through legislation. It will also cover the potential implications of Loper Bright more generally for device companies that might consider challenging an FDA legal interpretation.

Speakers:
Greg Levine, Partner, Life Sciences Regulatory & Compliance Group, Ropes & Gray
Beth Weinman, Member, Life Sciences Regulatory & Compliance Group, Ropes & Gray

3:45 PM

WHICH MEDTECH COMPANIES WILL SURVIVE THE COMING PCCP SHAKEOUT?

Medtech companies face a shakeout now that the FDA's Predetermined Change Control Plan (PCCP) guidance is out, allowing manufacturers to update their devices without repeated approvals. While adapting procedures to the guidance is challenging, the PCCP directive exposes that the IT aspect is even more daunting since so many companies are hindered by outdated IT infrastructures, developed in the 1990s, which fail to support the demands of modern applications, user volumes, and advanced technologies like Cloud and AI.

This talk presents strategies and case studies for RA, QA and C-level executives to design medical device infrastructures with PCCPs in mind, enabling companies to surpass competitors stuck in traditional regulatory frameworks.

Speaker:
Erez Kaminski, Founder & CEO, Ketryx

4:30 PM

CLOSING REMARKS