



# Full Schedule

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## Tuesday, April 22, 2025

7:30 AM – 8:30 AM East Coast USA Time

Breakfast

Location: Franklin A – 2nd Floor

8:30 AM – 4:30 PM East Coast USA Time

The Device Design Change Life Cycle Experience

Location: Franklin B – 2nd Floor

Moderator: Bill Brodbeck – STERIS Corporation

Speaker: David Elder (he/him/his) – Eliquent Life Sciences

Moderator: Eric Henry – King & Spalding LLP

Speaker: Evan Markley – Eli Lilly and Company

Speaker: Chitra Nadig – KeborMed

Speaker: Tony Piotrkowski – STERIS Corporation

Speaker: Phil Pontikos – Retired, FDA

Speaker: Heather Rosecrans – Eliquent Life Sciences | Vice President Regulatory Affairs, MDMA

Workshop



5:30 PM – 6:30 PM East Coast USA Time

Opening Reception

Location: Delaware Ballroom – 2nd Floor

Networking Event

## Wednesday, April 23, 2025

7:00 AM – 8:00 AM East Coast USA Time

Breakfast

Location: Regency Ballroom Foyer – 3rd Floor

7:00 AM – 5:00 PM East Coast USA Time

Registration

Location: Regency Ballroom Foyer – 3rd Floor

8:00 AM – 8:20 AM East Coast USA Time

**Let's Make a Difference!**

Location: Regency Ballroom – 3rd Floor

Speaker: Kim Belsky – AFDO/RAPS Healthcare Products Collaborative

Speaker: Steven Mandernach – Association of Food and Drug Officials (AFDO)

Speaker: Bill McMoil – Regulatory Affairs Professionals Society, RAPS (Welcome)

Plenary

8:25 AM – 8:55 AM East Coast USA Time

**Patient Experience Plenary #1**

Location: Regency Ballroom – 3rd Floor

Moderator: Aaron Dunbar – Boston Scientific

Speaker: John Sperzel, III – T2 Biosystems, Inc.

Plenary



9:00 AM – 9:45 AM East Coast USA Time

**The Solutions Exchange – Culture of Quality**

Location: Regency Ballroom – 3rd Floor

Moderator: John Krug – Eli Lilly and Company

Moderator: Kim Trautman – Medical Device, IVD and Combo Product Expert

Moderator: Jessica Zeller – Edwards Lifesciences

Plenary



9:45 AM – 10:05 AM East Coast USA Time

**BREAK**

Location: Regency Ballroom Foyer – 3rd Floor

10:05 AM – 10:50 AM East Coast USA Time

**FDA Medical Device Inspections**

Location: Regency Ballroom – 3rd Floor

Moderator: Susan Matthias – FDA (Virtual)

Moderator: Phil Pontikos – Retired, FDA

Speaker: Anne Reid – FDA (Virtual)

Speaker: Rhonda Mecl – FDA (Virtual)

Plenary



10:55 AM – 11:40 AM East Coast USA Time

**Fostering Medical Device Improvement: FDA's Voluntary Improvement Program**

Location: Regency Ballroom – 3rd Floor

Moderator: Aaron Dunbar – Boston Scientific

Speaker: Kim Kaplan – ISACA

Speaker: Erin Keith (she/her/hers) – FDA (Virtual)

Speaker: Roseanne Leaupepe – Fisher & Paykel Healthcare

Speaker: Keisha Thomas, MS, MHS, CQA, RAC – FDA (Virtual)

## Plenary



11:40 AM – 12:45 PM East Coast USA Time

## LUNCH

Location: Franklin A-C – 2nd Floor

12:45 PM – 2:00 PM East Coast USA Time

## Breakout #1: International: Experience and Challenges With MDR/IVDR and EUDAMED

Location: Delaware AB – 2nd Floor

Moderator: Gert Bos – Qserve Group

Moderator: Kim Shoemaker – Johnson & Johnson MedTech

Speaker: Sabina Hoekstra-van den Bosch – TÜV SÜD Medical Health Services

Speaker: Nick-Roy Green – Johnson & Johnson MedTech

## Breakout



12:45 PM – 2:00 PM East Coast USA Time

## Breakout #2: What's New in CDRH Premarket Programs

Location: Delaware CD – 2nd Floor

Moderator: Heather Rosecrans – Eliquent Life Sciences | Vice President Regulatory Affairs, MDMA

Speaker: Mark Leahey – Medical Device Manufacturers Association (MDMA)

Speaker: Dan Schultz – Eliquent Life Sciences

Speaker: Sean Boyd – QualityHub, Inc.

## Breakout



2:00 PM – 2:15 PM East Coast USA Time

## BREAK

Location: Delaware Foyer – 2nd Floor

2:15 PM – 3:15 PM East Coast USA Time

## Breakout #1: Optimizing Regulatory and Design Strategies for LDTs and IVDs with Different International Requirements

Location: Delaware AB – 2nd Floor

Moderator: Kim Trautman – Medical Device, IVD and Combo Product Expert

Speaker: Balazs Bozsik – SGS North America Inc.

Speaker: Ken Fuh (he/him/his) – ACT-IVD

Speaker: David Murray – Illumina

Speaker: Michelle Zaharik – MLZ Biotech Consulting Inc

Breakout



2:15 PM – 3:15 PM East Coast USA Time

**Breakout #2: Are You Correctly Assessing Quality System Activities When Quality System Functions Are Spread Out Across Different Locations?**

Location: Delaware CD – 2nd Floor

Moderator: Gert Bos – Qserve Group

Speaker: Monica Wilkins – Abbott

Speaker: Kim Shoemaker – Johnson & Johnson MedTech

Breakout



2:15 PM – 3:15 PM East Coast USA Time

**Breakout #3: Supply Chain Resiliency: Evolving Challenges and Best Practices**

Location: Regency Ballroom – 3rd Floor

Moderator: Bill Brodbeck – STERIS Corporation

Speaker: Michael Gallucci – Edwards Lifesciences

Speaker: Matt Graf – Cook Medical

Breakout



3:15 PM – 3:30 PM East Coast USA Time

**BREAK**

Location: Regency Foyer – 3rd Floor

3:30 PM – 4:15 PM East Coast USA Time

**FDA's QMSR Implementation Status**

Location: Regency Ballroom – 3rd Floor

Moderator: Phil Pontikos – Retired, FDA

Speaker: Keisha Thomas, MS, MHS, CQA, RAC – FDA (Virtual)

Speaker: Karen Masley-Joseph – FDA (Virtual)

Plenary



4:15 PM – 4:55 PM East Coast USA Time

Location: Regency Ballroom – 3rd Floor

Speaker: Bill Brodbeck – STERIS Corporation

Speaker: Aaron Dunbar – Boston Scientific

Speaker: Shannon Hoste – Pathway for Patient Health

## Plenary

## Close-Out

Location: Regency Ballroom – 3rd Floor

Speaker: Kim Belsky – AFDO/RAPS Healthcare Products Collaborative

## Plenary

## MedCon Annual Dinner - Ticketed Event

## Networking Event

Thursday, April 24, 2025

## Breakfast

Location: Regency Ballroom Foyer – 3rd Floor

## Registration

Location: Regency Ballroom Foyer – 3rd Floor

## Opening Day 2

Location: Regency Ballroom – 3rd Floor

Speaker: Kim Belsky – AFDO/RAPS Healthcare Products Collaborative

## Plenary

## Breaking Barriers: The Power of Regulatory Reliance

Location: Regency Ballroom – 3rd Floor

Moderator: Fatemeh Razjouyan – Medtronic

Speaker: Karen Noffs – Anvisa - Brazil

Speaker: Tammy Steuerwald – Roche

## Plenary



9:30 AM – 9:50 AM East Coast USA Time

### BREAK

Location: Regency Ballroom Foyer – 3rd Floor

9:55 AM – 11:25 AM East Coast USA Time

### Breakout #1: One Year Into FDA's New Regulatory Authority of Medical Device Cybersecurity + A Cybersecurity Regulatory Landscape Update

Location: Delaware AB – 2nd Floor

Moderator: Eric Henry – King & Spalding LLP

Speaker: Axel Wirth – MedCrypt

Speaker: Chris Reed – Medtronic

#### Breakout

9:55 AM – 11:25 AM East Coast USA Time

### Breakout #2: Due Diligence – Are You Doing Enough? What About After Acquisition?

Location: Delaware CD – 2nd Floor

Moderator: Monica Wilkins – Abbott

Speaker: Braulio Ortiz – BioTeknica

Speaker: Dennett Kouri – Edwards Lifesciences

#### Breakout



11:25 AM – 12:25 PM East Coast USA Time

### LUNCH

Location: Franklin A-C – 2nd Floor

12:30 PM – 2:00 PM East Coast USA Time

### Breakout #1: QMSR - Are You Ready?

Location: Delaware AB – 2nd Floor

Moderator: Monica Wilkins – Abbott

Moderator: Kim Shoemaker – Johnson & Johnson MedTech

Speaker: Meera Bhatia – Abbott

Speaker: Patrick Weixel – Abbott

#### Breakout



12:30 PM – 2:00 PM East Coast USA Time

### Breakout #2: Are You Processing and Investigating Complaints to the Right Level?

Location: Delaware CD – 2nd Floor

Moderator: Kim Trautman – Medical Device, IVD and Combo Product Expert

Speaker: Monica Wilkins – Abbott

Speaker: Aaron Dunbar – Boston Scientific

Speaker: Phil Pontikos – Retired, FDA

## Breakout



12:30 PM – 2:00 PM East Coast USA Time

### Breakout #3: Addressing 510(k) Review Challenges

Location: Regency Ballroom – 3rd Floor

Moderator: Bill Brodbeck – STERIS Corporation

Moderator: Heather Rosecrans – Eliquent Life Sciences | Vice President Regulatory Affairs, MDMA

Speaker: Clarence Murray, III – STERIS Corporation

Speaker: Tony Piotrkowski – STERIS Corporation

Speaker: Lisa Griffin Vincent (she/her/hers) – GT Metabolic Solutions, Inc. (virtual)

Speaker: Liz Claverie-Williams (she/her/hers) – Claverie & Associates Consulting, LLC

## Breakout



2:00 PM – 2:20 PM East Coast USA Time

### BREAK

Location: Regency Ballroom Foyer – 3rd Floor

2:25 PM – 3:55 PM East Coast USA Time

### Risk Management - Systems Perspective

Location: Regency Ballroom – 3rd Floor

Moderator: Shannon Hoste – Pathway for Patient Health

Moderator: Kim Trautman – Medical Device, IVD and Combo Product Expert

Moderator: Bill Brodbeck – STERIS Corporation

Speaker: Brian Siroka (he/him/his) – MEDIcept

Speaker: Evan Markley – Eli Lilly and Company

Speaker: David Murray – Illumina

## Plenary



4:00 PM – 4:30 PM East Coast USA Time

### Patient Experience #2 Exploring Patient Experience


Location: Regency Ballroom – 3rd Floor

Moderator: Shannon Hoste – Pathway for Patient Health

Speaker: Lane Berlin – Grandview Heights Division of Fire

## Plenary



<div>4:30 PM – 4:40 PM East Coast USA Time</div> <div>Day 2 Close</div> <div>Location: Regency Ballroom – 3rd Floor</div> <div>Speaker: Kim Belsky – AFDO/RAPS Healthcare Products Collaborative</div> <div>Plenary</div>
<div>4:45 PM – 6:00 PM East Coast USA Time</div> <div>Networking Reception</div> <div>Location: Regency Ballroom Foyer – 3rd Floor</div> <div>Networking Event</div>
Friday, April 25, 2025
<div>7:00 AM – 11:00 AM East Coast USA Time</div> <div>Registration</div> <div>Location: Regency Ballroom Foyer – 3rd Floor</div>
<div>7:00 AM – 8:00 AM East Coast USA Time</div> <div>Breakfast</div> <div>Location: Regency Ballroom Foyer – 3rd Floor</div>
<div>8:00 AM – 8:05 AM East Coast USA Time</div> <div>Opening Day 3</div> <div>Location: Regency Ballroom – 3rd Floor</div> <div>Speaker: Kim Belsky – AFDO/RAPS Healthcare Products Collaborative</div> <div>Plenary</div>
<div>8:10 AM – 9:25 AM East Coast USA Time</div> <div>Global Shift in Clinical Expectations</div> <div>Location: Regency Ballroom – 3rd Floor</div> <div>Moderator: Aaron Dunbar – Boston Scientific</div> <div>Moderator: Gert Bos – Qserve Group</div> <div>Speaker: Mindy McCann – Qserve Group</div> <div>Speaker: Matt Albert – Boston Scientific</div> <div>Speaker: Andrew Webster – Zimmer Biomet</div> <div>Plenary</div> <div></div>
<div>9:25 AM – 9:45 AM East Coast USA Time</div> <div>BREAK</div> <div>Location: Regency Ballroom Foyer – 3rd Floor</div>
<div>9:50 AM – 11:20 AM East Coast USA Time</div>



Investigator Insights

Location: Regency Ballroom – 3rd Floor

Moderator: Monica Wilkins – Abbott

Speaker: Laureen Geniusz – FDA (Virtual)

Speaker: Susan Matthias – FDA (Virtual)

Speaker: CDR Tom Peter – FDA (Virtual)

Speaker: Katelyn Staub-Zamperini – FDA (Virtual)

Speaker: LCDR Mary Millner – FDA (Virtual)

Plenary



11:25 AM – 11:30 AM East Coast USA Time

Conference Close-Out

Location: Regency Ballroom – 3rd Floor

Speaker: Kim Belsky – AFDO/RAPS Healthcare Products Collaborative