Columbia Basin Section
ASQ Excellence Through Quality™

Invitation from
Temecula ASQ Section
January 21, 2026 Virtual Webinar

ASQ WE ACHIEVED SILVER LEVEL IN 2024! PERFORMANCE EXCELLENCE PROGRAM

This is a joint offering from Temecula ASQ and the Southern California Local Networking Group Regulatory Affairs Professionals Society (RAPS)

DATE:

Wednesday, January 21, 2026

This is a virtual/online (Webex) webinar.

Time: 6:00 pm to 8:00 pm PDT

There is no charge for ASQ members or non-members.

No advance registration is required – just go to the Webex link for the meeting.

Online Instructions:
https://asq.webex.com/asq/j.php?MTID=m22160a4f38a34cb147359d8bee9406f3

Webinar number:
2557 041 8152

Webinar password:
3dfMuFskQ83 (33368375 when dialing from a phone or video system)

Join by phone:
1-877-668-4490 Call-in toll-free number (US/Canada)
1-408-792-6300 Call-in toll number (US/Canada)

Access code: 255 704 18152

Attendance at this meeting earns RU credit toward ASQ recertification.

For more information about the Temecula ASQ section, click here.

For more information about the Southern California Local Networking Group RAPS, click here.

FDA's New Medical Device Quality Management System Regulation: What you Need to Know

Kim Trautman, M.S.
Medical Device, IVD and Combination Product Expert

FDA's Quality Management System Regulation (QMSR) comes into full effect in February of 2026. This is FDA's first revision of 21 CFR 820 since 1996. FDA has incorporated ISO 13485:2016 into the regulation by reference and has additional U.S. country-specific requirements. In addition, the Federal Register contained the concurrent amendment to Combination Product GMP requirements in 21 CFR Part 4.

Hear first-hand from the 1996 QS regulation author and ISO 13485 International TC 210 QMS expert about how these changes will affect medical device manufacturers - from the requirements to the comments in the Preamble, to FDA medical device inspections, MDSAP, and more.

- Nuts and Bolts
- By the Numbers
- Increase in FDA's Expectations
- Possible Surprises

Attendees will gain an understanding of the new FDA QMS requirements which are in addition to ISO 13485:2016 and learn some of the nuances and increased emphasis from the regulation's preamble. The presenter will also discuss the value of Gap Analysis and transition planning along with consideration of other regulatory obligations before the QMSR goes into effect.

About the Speaker: Kimberly A. Trautman is an International Medical Devices, IVD, and Combination Product Expert with over 40 years of experience. She worked at the US Food and Drug Administration for over 24 years and currently works with regulatory agencies around the globe. An expert in global medical device regulations, Kim wrote and harmonized the 1996 US FDA Quality System Regulation. She also served on authoring groups for ISO 13485, the 21 CFR Part 4 Combination Product GMPs, and many of the Combination Product guidance documents. Kim conceived and developed the Medical Device Single Audit Program and its consortium of five Global Regulators which she chaired for the initial four-years of the program. She is a 25-year veteran of the Global Harmonization Tasks Force, a foundational member of the International Medical Device Regulators Forum, and she established an Authorized MDSAP Auditing Organization and a new Notified Body for EU IVDR/MDR Designation.