

2026 Device RAC Study Group

UPDATED August 22, 2026

Schedule: Tuesdays 6:00 - 8:00 PM (with 2 exceptions)

Format: Live Virtual (Zoom) Sessions and access to session recordings for 6 months

Cost: \$200.00 for SDRAN members

(OCRA, RAPS SoCal LNG, RAPS San Francisco Bay Area Chapter, and RAPS members may register at the SDRAN member rate)

\$300.00 for Non-Members

Device RAC Prep Sessions Agenda – Chapters from RAPS Device Fundamentals Book (2025 edition) Added and update schedule on for last few sessions.

Session	Date	Topic	Speaker
Device 1	Tues 7/7/2026	Device Basics- What is a Device/How to develop a Global Device Regulatory Strategy Chap. 1, 2, 3, 4, 5	Diane King
Kick-Off Joint Session**	Wed 7/8/2026	Overview of Device & Drug RAC Exams, Study Tools, Test Taking Strategies, and GLP Regulations Chap. 12	Kim Walker & Anya Bekhtel
Devices 2	Tues 7/14/2026	QMS/ISO 13845 -Quality Management System Design Controls, Risk management, Testing Strategy Chap 6, 7, 8	Roger Greenwald
Devices 3	Tues 7/21/2026	U.S. Medical Device Pre-Market – how do study and obtain market access Chap 17, 20, 21, 22, 25 (partially 12, 13, 14, 15, 16)	Natalie Kennel
Devices 4	Tues 7/28/2026	EU Medical Device Pre-Market – how do study and obtain market access (Includes Medical devices and IVDs intro) Chap 23, 24	Natalie Kennel
Joint Session** #5	Wed 8/12/2026	US & EU GCP Regulations Chap 18, 20	Jenny Grodberg – Drugs & Kim Walker - Devices
Device 6	Tues 8/11/2026	US & EU Post Market Controls Chap 26, 27, 28, 29, 30, 31	Gabriela McCoole
Device 7	Tues 8/18/2026	US & EU In Vitro Diagnostics (IVDs) Unique Aspects Compare/contrast with Medical Devices Chap 33 (and as it is pertains to IVDs, 21, 22, 23, 27)	Robert Kovelman
Device 8	Tues 9/1/2026	Misc. Topics -More on non-clinical testing, import/export, reimbursement, combination products, Software, Cybersecurity AI-ML, Pre-approved Change Requests Chap 13, 14, 15, 16, 32, 37, 38, 39, 40	Natalie Kennel/Kim Walker
Device 9	Tues 9/8/2026	Practice Question Session	Natalie Kennel, Kim Walker, & Other Invited Speakers

**** Joint sessions will include cohorts from the Drug and Device prep courses; please note date and day of the week.**