SDRAN Winter 2024 RAC Device Preparatory Sessions (Pre-recorded)

Session access starts November 1, 2024 and ends February 28, 2025.

OCRA members are also eligible to register for these sessions at the SDRAN member rate.

SESSION #	CHAPTER(S)
1	Introduction to Device and Drug RAC Program RAPS: Study Tools, Testing Readiness and Strategies in Preparation for the RAC Exam
2	US Chapter 4: Current Good Manufacturing Practices and Quality System Design
3	US Chapter 1: History of Food, Drug and Cosmetic Laws US Chapter 2: Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways. US Chapter 3: Clinical Trials: GCPs, Regulations and Compliance for Drugs, Biologics and Medical devices (DEVICES ONLY) US Chapter 5: Medical Device Submissions US Chapter 7: In Vitro Diagnostics Submissions and Compliance
4	US Chapter 7: In Vitro Diagnostics Submissions and Compliance (cont'd) US Chapter 6: Medical Device Compliance and Postmarketing Activities US Chapter 8: Advertising, Promotion and Labeling for Medical Devices and In Vitro Diagnostics (IVDs)
5	EU Chapter 3: Advertising and Promotion EU Chapter 5: Regulatory Strategy
6	EU Chapter 6: The New Medical Device Regulation and In Vitro Diagnostic Device Regulation EU Chapter 7: The European Medical Devices Legal System
7	EU Chapter 8: Medical Devices: Legislation and Classification EU Chapter 9: In Vitro Diagnostic Medical Devices EU Chapter 13: Medical Device Conformity Assessment Procedure
8	EU Chapter 10: General Safety and Performance Requirements and Technical Documentation (MDR, IVDR) EU Chapter 11: Medical Device Preclinical Testing EU Chapter 12: Clinical Evaluation and Clinical Evaluations (EU Chapter 9: (complement to above)*
9	EU Chapter 14: Medical Device Compliance: Postmarket Requirements EU Chapter 15: Medical Device National Particularities EU Chapter 16: Combination Products EU Chapter 4: Enforcement and Competent Authorities
10	Intl Chapter 9: In Vitro Diagnostic Medical Devices
11	Intl Chapter 1: Introduction to International Regulatory Affairs Intl Chapter 2: Compliance and Enforcement Intl Chapter 3: International Counterfeit Regulations
12	Intl Chapter 4: Pricing and Reimbursement Intl Chapter 5: Health Technology Assessment (HTA)
13	Intl Chapter 10: Active Implantable Medical Devices Intl Chapter 11: Software Intl Chapter 12: Postmarket Requirements Intl Chapter 13: Combination Products