SDRAN Winter 2024 RAC Drug 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 7: Generic Drug Submissions US Chapter 8: Patents and Exclusivity US Chapter 14: Biosimilars
4	EU Chapter 3: Overview of Drug and Biologic Regulatory Pathways EU Chapter 13: Overview of Authorisation Procedures for Medicinal Products
5	US Chapter 12: Biologics Submissions US Chapter 13: Biologics Compliance US Chapter 15: Biologics Labeling, Advertising and Promotion
6	EU Chapter 16: Medicinal Product Clinical Trials EU Chapter 17: Registration Procedures for Medicinal Products
7	EU Chapter 14: Adaptive and Alternative Pathways EU Chapter 29: Orphan Medicinal Products Intl Chapter 22: Principles of Rare Diseases and Orphan Products Development
8	US Chapter 10: Prescription Drug Labeling, Advertising and Promotion US Chapter 11: Pharmacovigilance and Risk Management (*complement above) US Chapter 9: Over-the-Counter (Nonprescription) Drug Products
9	EU Chapter 20: Biosimilar Medicinal Products EU Chapter 22: Marketing Authorisations for Products Derived From Biotechnology Intl Chapter 19: Biosimilars: Basics and Recent Developments
10	EU Chapter 27: Vaccines EU Chapter 30: Combination Products Intl Chapter 20: Vaccines
11	EU Chapter 8: The Paediatric Regulation Intl Chapter 26: Global Pediatric Drug Development
12	EU Chapter 19: Generic Medicinal Products Intl Chapter 15: Generic Drug Products
13	EU Chapter 21: Nonprescription Medicinal Products Intl Chapter 16: Over-the-Counter (OTC) Products
14	US Chapter 3: Clinical Trials: GCPs, Regulations and Compliance for Drugs, Biologics and Medical Devices Intl Chapter 3: Clinical Trials, Good Clinical Practice, Regulations, and Compliance