SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

2022 SDRAN RAC Drugs Preparatory Session Program Schedule

Format: Zoom (Video) Conferencing Platform. *Attendees are encouraged to update to the latest version of Zoom.*

Reading Assignment: RAPS Fundamentals of Pharmaceutical and Biologics Regulations (Fourth Edition)

Session No.	Region	RAPS Textbook Chapter & Topic	Speaker
1	All	Pre-session: Introduction to Device and Drug RAC Program RAPS: Study Tools, Testing Readiness and Strategies in Preparation for the RAC Exam	Michelle Sands, Theresa Falls-Velazquez, Lequina Myles
2	US	US Chapter 4: Current Good Manufacturing Practices and Quality System Design	Duane Mauzey
3	US	US Chapter 7: Generic Drug Submissions US Chapter 8: Patents and Exclusivity US Chapter 14: Biosimilars	Michael Swit
4	EU	EU Chapter 3: Overview of Drug and Biologic Regulatory Pathways EU Chapter 13: Overview of Authorisation Procedures for Medicinal Products	Stephen Thompson
5	US	US Chapter 12: Biologics Submissions US Chapter 13: Biologics Compliance US Chapter 15: Biologics Labeling, Advertising and Promotion	Amanda Richter
6	EU	EU Chapter 16: Medicinal Product Clinical Trials EU Chapter 17: Registration Procedures for Medicinal Products	Jenny Grodberg

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7	EU Intl	EU Chapter 14: Adaptive and Alternative Pathways EU Chapter 29: Orphan Medicinal Products Intl Chapter 22: Principles of Rare Diseases and Orphan Products Development	Barney King
8	US	US Chapter 10: Prescription Drug Labeling, Advertising and Promotion US Chapter 11: Pharmacovigilance and Risk Management (**complement to above*) US Chapter 9: Over-the-Counter (Nonprescription) Drug Products	Michael Swit
9	EU Intl	EU Chapter 20: Biosimilar Medicinal Products EU Chapter 22: Marketing Authorisations for Products Derived From Biotechnology Intl Chapter 19: Biosimilars: Basics and Recent Developments	Barney King
10	EU Intl	EU Chapter 27: Vaccines EU Chapter 30: Combination Products Intl Chapter 20: Vaccines	Duane Mauzey
11	EU Intl	EU Chapter 8: The Pediatric Regulation Intl Chapter 26: Global Pediatric Drug Development	Jenny Grodberg
12	EU Intl	EU Chapter 19: Generic Medicinal Products Intl Chapter 15: Generic Drug Products	Barney King
13	EU Intl	EU Chapter 21: Nonprescription Medicinal Products Intl Chapter 16: Over-the-Counter (OTC) Products	Barney King
14	US Intl	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	Jenny Grodberg

US = United States, EU = European Union; Intl = International

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Chapters for independent reading and self-study

US
Chapter 1: History of Food, Drug and Cosmetic Laws
Chapter 2: Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways
Chapter 5: Prescription Product Drug Submissions
Chapter 6: Postapproval Submissions and Compliance: Prescription Drugs and Biologics
Chapter 11: Pharmacovigilance and Risk Management

EU
Chapter 1: EMA and Other Regulatory Bodies
Chapter 2: History of EU Regulations
Chapter 4: Preparing for EMA Meetings Prior to Submission of a Marketing Authorization Application
Chapter 5: Preparing for EMA Meetings During Review of a Marketing Authorization Applications
Chapter 6: EU Pricing and Reimbursement
Chapter 7: Health Technology Assessment (HTA)
Chapter 9: Advertising and Promotion
Chapter 10: Enforcement and Competent Authorities
Chapter 11: European Union Falsified Medicines Directive: Requirements and Implications for Multi-Stakeholder Healthcare Delivery
Chapter 12: Regulatory Strategy
Chapter 15: Preclinical Testing and Good Laboratory Practice Regulations
Chapter 18: Quality Systems and Inspectorate Process—Pharmaceuticals
Chapter 23: Pharmaceutical Post Authorisation Requirements and Compliance With the Marketing Authorisation
Chapter 24: Pharmacovigilance
Chapter 25: Regulatory Framework for Advanced Therapy Medicinal Products
Chapter 28: Products Manufactured from Human Blood or Plasma

International
Chapter 1: Introduction to International Regulatory Affairs

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Chapter 2: Crisis Management for the Healthcare Product Industry
Chapter 4: In-Country Representation
Chapter 5: International Advertising and Promotion
Chapter 6: Compliance and Enforcement
Chapter 7: International Counterfeit Regulations
Chapter 8: Regulatory Reliance
Chapter 9: Pricing and Reimbursement
Chapter 10: Health Technology Assessment (HTA)
Chapter 11: Premarket Requirements/Dossier Requirements
Chapter 12: Authorization Procedures for Pharmaceutical Products
Chapter 13: Stability Test Requirements
Chapter 14: Quality Systems and Inspectorate Process for Pharmaceuticals
Chapter 17: Pharmaceutical Postmarketing and Compliance
Chapter 18: High-Risk Products: Products Derived from Biotechnology
Chapter 21: Products Manufactured from Human Blood and Plasma
Chapter 23: Combination Products
Chapter 24: Regulatory Considerations for Cell-Based Medicinal Products
Chapter 25: Botanical Drug Products and Traditional Medicine