2018 Spring Schedule

		ASSIGNMENT	TOPICS
Orientation		Program Orientation	• Program Overview • Virtual Sessions • Calling In • Study Groups • Instructor Access • Assignments • RegEx Community • Find a Mentor • Test-Taking Tips • Practice Exam
General Information		**Read:** Chapters 1-12 **Watch On Demands:** General Information Part 1-2	• FDA & Related Regulatory Agencies • History of Food, Drug & Cosmetic Laws • Overview of Drug, Biologic & Device Regulatory Pathways • FDA Communications & Meetings • Preparing for Key FDA Meetings & Advisory Committee Meetings • Crisis Management • Health Technology Assessment • Good Laboratory Practice Regulations • Clinical Trails: GCPs, Regulations & Compliance • Current Good Manufacturing Practices & Quality System Design • FDA User Fees • Regulatory Strategy
1	**20 February (Tues) 3:00pm EST**	**General Information**	**Live Q&A Webcast (30 minutes)**
Drugs		**Read:** Chapters 13-19 **Watch On Demands:** Parts 1-4	• Prescription Drug Submissions • Postapproval Prescription Drug Submissions & Compliance • Generic Drug Submissions • Patents & Exclusivity • Over-the-Counter Drug Products • Prescription Drug Labeling, Advertising & Promotion • Pharmacovigilance & Risk Management
2	**1 March (Thurs) 3:00pm EST**	**Drugs**	**Live Q&A Webcast (30 minutes)**
Medical Devices		**Read:** Chapters 20-23 **Watch On Demands:** Parts 1-2	• Medical Device Submissions • Medical Device Compliance & Postmarketing Activities • Advertising, Promotion & Labeling for Medical Devices & *In Vitro* Diagnostics • *In Vitro* Diagnostics Submissions and Compliance

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3	**8 March (Thurs) 3:00pm EST**	**Medical Devices**	**Live Q&A Webcast (30 minutes)**
Biologics		**Read:** Chapter 24-26 **Watch On Demand**	• Biologics Submissions • Biologics Compliance • Biologics Labeling, Advertising & Promotion
4	**15 March (Thurs) 3:00pm EST**	**Biologics**	**Live Q&A Webcast (30 minutes)**
Other Product Classifications		**Read:** Chapters 27-38 **Watch On Demands:** Part 1-4	• Combination Products • Products for Small Patient Populations • Blood & Blood Products • Human Cell & Tissue Products • Regulating Regenerative Medicine: Cell Therapy, Gene Therapy & Tissue Engineering • Laws & Regulations Pertaining to Pediatrics • Dietary Supplements & Homeopathic Products • Cosmetics • Veterinary Products • Food Products • Companion Diagnostics • Medical Foods
Inspection & Enforcement		**Read:** Chapters 39-40 **Watch On Demand**	• FDA Inspection & Enforcement • Healthcare Fraud & Abuse Compliance
5	**29 March (Thurs) 3:00pm EST**	**Other Product Classifications, Inspection & Enforcement**	**Final Live Q&A Webcast (30 minutes)**

NOTE: The RAC (US) Prep Virtual Program agenda is subject to change.