RAC EU Study Sessions, Jan 2012 – March 2012

Sessions will meet on Tuesdays at 6:00 p.m. and will last for 90 minutes each.

Location: Duke Clinical Research Institute (DCRI), North Pavilion, Room 7015
2400 Pratt Street, Durham, NC 27705

If you are planning to take the RAC exam in 2012, purchasing the *Fundamentals of EU Regulatory Affairs*, 5th Edition (2011) published by RAPS, is highly recommended. If you have no immediate plans to take the exam, suggested readings and course materials will supply sufficient background. Chapter numbers from the 2008 version of the *Fundamentals* text are provided below as a courtesy.

Syllabus is flexible, based on the needs and interests of participants and the availability of speakers.

DATE	WEEK	SUBJECT	2008 Text	2011 Text
January 10	1	• History of EU regulation of healthcare products • Enforcement and National Authorities • Overview of Authorization Procedures for Medicinal Products • Overview … for Medical Devices	1 2 3 21	1 30 13 4
January 17	2	• Introduction to EU regulation of Medical Devices: Overview of Authorization Procedures; Institutional Players • Classification of Medical Devices; • Medical Devices: Conformity Assessment	3, 5, 6, 8	2, 3, 4 5 8, 9
January 24	3	• Regulation of In Vitro Diagnostic Products • Postmarket requirements for Medical Devices	 7	10 11
January 31	4	• John Hille, Underwriters Laboratories, guest speaker, Notified Bodies		
February 7	5	• Medicinal Products Registration • Registration Procedures for Medicinal Products--Past, Present and Future • Quality Systems and Inspectorate Process—Pharmaceuticals • Pharmaceutical Postmarketing and Compliance with the Marketing Authorization, Pharmacovigilance and Changes to a Marketing Application	2 12 4 13	 15 16 17
February 14	6	• Marketing Authorizations for Products Derived from Biotechnology • Orphan Medicinal Products	9 15	19 22
February 21	7	• Human Medicinal Products: Products Manufactured from Human Blood or Plasma • Human Tissue Regulation • Generic Drug Products • Over-the Counter (Nonprescription) Products • *Combination Products * 2011 text only*	10 11 14 19	20 21 18 23 *25*
February 28	8	• Clinical Trials of Medicinal Products; Clinical Evaluation and Clinical Investigation of Medical Devices • Pediatric Regulation	22, 23 24	14,6, 7 24
March 6	9	• Veterinary Medicinal Products • Cosmetic Products • Advertising and Promotion • Food Supplements and Health Claims	18 16 20 17	24,28 26 29 27
March 13	10	• Wrap-up and Review		