North Carolina Regulatory Affairs Forum

2021 RAC Workshop Syllabus

	Pharmaceuticals and Biologics		Medical Devices and In Vitro Diagnostics	
Date	**Lecture** & Suggested Book Chapters	**Lecturer**	**Lecturer**	**Lecture** & Suggested Book Chapters
1-Jun	Introduction Sect.I-Chapter 1 History of Food, Drug and Cosmetic Laws Sect.I-Chapter 2 Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways Sect.II-Chapter 1 Health Canada Organization and Its History of Regulating Health Products in Canada Sect.III-Chapter 1 Overview of Drug and Biologic Regulatory Pathways Sect.IV-Chapter 1 Clinical Trials, Good Clinical Practice, Regulations and Compliance	David Shoemaker	Kevin Barber	Introduction Sect.I-Chapter 1 History of Food, Drug and Cosmetic Laws Sect.I-Chapter 2 Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways Sect.I-Chapter 3 Clinical Trials: GCPs, Regulations and Compliance for Drugs, Biologics and Medical Devices Sect.II-Chapter 1 The New Medical Device Regulation and In Vitro Diagnostic Device Regulation Sect.II-Chapter 2 The European Medical Devices Legal System Sect.II-Chapter 3 Medical Devices: Legislation and Classification Sect.IV-Chapter 1 Health Canada
8-Jun	Clinical Development and GCPs Sect.I-Chapter 3 Clinical Trials: GCPs, Regulations and Compliance for Drugs, Biologics and Medical Devices Sect.II-Chapter 3 Clinical Trial Applications, Good Clinical Practices Sect.III-Chapter 5 Medicinal Product Clinical Trials Sect.IV-Chapter 1 Clinical Trials, Good Clinical Practice, Regulations and Compliance	Liz Moore		Clinical Development and GCPs Sect.I-Chapter 3 Clinical Trials: GCPs, Regulations and Compliance for Drugs, Biologics and Medical Devices Sect.II-Chapter 7 Clinical Evaluation and Clinical Investigations Sect.IV-Chapter 2 Investigational Testing and Special Access Programme
15-Jun	Preclinical Development and GLPs Sect.II-Chapter 2 Good Laboratory Practice for Nonclinical Laboratory Studies Sect.III-Chapter 4 Preclinical Testing and Good Laboratory Practices	Brenda Faiola		Preclinical Development and GLPs (Device biocompatibility) Sect.II-Chapter 6 Medical Device Preclinical Testing

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22-Jun	CMC/Quality System Design & Development Sect.I-Chapter 4 Current Good Manufacturing Practices and Quality System Design Sect.II-Chapter 4 Good Manufacturing Practices and Establishment Licensing in Canada Sect.III-Chapter 7 Quality Systems and Inspectorate Process - Pharmaceuticals Sect.IV-Chapter 5 Stability Test Requirements Sect.IV-Chapter 6 Quality Systems and Inspectorate Process for Pharmaceuticals	Scott Burian		CMC/Quality System Design & Development Sect.I-Chapter 4 Current Good Manufacturing Practices and Quality System Design Sect.II-Chapter 5 General Safety and Performance Requirements and Technical Documentation Sect.III-Chapter 3 Device Quality Systems Sect.IV-Chapter 5 Medical Device Quality System Requirements Sect IV-Chapter 9 Medical Device Establishment Licensing
29-Jun	Compliance, Regulatory Inspections, and Enforcement Sect.I-Chapter 2 Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways Sect.I-Chapter 3 Clinical Trials: GCPs, Regulations and Compliance for Drugs, Biologics and Medical Devices Sect.I-Chapter 6 Postapproval Submissions and Compliance: Prescription Drugs and Biologics Sect.I-Chapter 13 Biologics Compliance Sect.III-Chapter 7 Quality Systems and Inspectorate Process - Pharmaceuticals Sect.IV-Chapter 6 Quality Systems and Inspectorate Process for Pharmaceuticals	Sandy Kennedy		Compliance, Regulatory Inspections, and Enforcement Sect.I-Chapter 2 Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways Sect.I-Chapter 3 Clinical Trials: GCPs, Regulations and Compliance for Drugs, Biologics and Medical Devices Sect.I-Chapter 5 Medical Device Submissions Sect.II-Chapter 8 Medical Device Conformity Assessment Procedure Sect.II-Chapter 9 Medical Device Compliance: Postmarket Requirements Sect.III-Chapter 3 Device Quality Systems Sect.IV-Chapter 5 Medical Device Quality System Requirements
6-Jul	Clinical Pharmacology	Mark Shelton	Cheng Li	Medical Device Design Process (Design Controls) Sect.I-Chapter 4 Current Good Manufacturing Practices and Quality System Design Sect.II-Chapter 5 General Safety and Performance Requirements and Technical Documentation Sect.III-Chapter 3 Device Quality Systems Sect.IV-Chapter 5 Medical Device Quality System Requirements

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13-Jul	Biologics and Biosimilars Sect.I-Chapter 12 Biologics Submissions Sect.I-Chapter 14 Biosimilars Sect. II-Chapter 11 Biologics Submission, Approval and Postmarketing Sect.III-Chapter 10 Marketing Authorisations for Products Derived From Biotechnology Sect.IV-Chapter 10 High-Risk Products Derived from Biotechnology Sect.IV-Chapter 11 Biosimilars: Basics and Recent Developments Sect.IV-Chapter 12 Vaccines Sect.IV-Chapter 13 Products Manufactured from Human Blood and Plasma	Charity Schuller	David Jensen	IDEs, etc (ex-US device clinical trial submissions) Sect.I-Chapter 5 Medical Device Submissions Sect.II-Chapter 7 Clinical Evaluation and Clinical Investigations Sect.III-Chapter 2 Technical and Regulatory Requirements Sect.IV-Chapter 2 Investigational Testing and Special Access Programme
20-Jul	Regulatory Authority Meetings Sect.I-Chapter 2 Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways Sect.I-Chapter 12 Biologics Submissions Sect.II-Chapter 3 Clinical Trial Applications, Good Clinical Practices Sect.II-Chapter 5 New Drug Submission Process Sect.III-Chapter 1 Overview of Drug and Biologic Regulatory Pathways Sect.III-Chapter 6 Registration Procedures for Medicinal Products	Kevin Barber		Regulatory Authority Meetings Sect.I-Chapter 5 Medical Device Submissions
27-Jul	Clinical Protocols and Clinical Development Plans	Nick Kenny, Jack Modell, Ben Vaughn		Clinical Protocols and Clinical Development Plans
3-Aug	Pharmaceuticals, Generics, and OTC Drugs Sect.I-Chapter 7 Generic Drug Submissions Sect.I-Chapter 8 Patents and Exclusivity Sect.I-Chapter 9 Over-the-Counter (Nonprescription) Drug Products Sect. II-Chapter 8 An Overview of Pharmaceutical Intellectual Property Protection in Canada	Catherine Maher	TBD	Device Classification and Regulatory Controls Sect.II-Chapter 1 The New Medical Device Regulation and In Vitro Diagnostic Device Regulation Sect.II-Chapter 3 Medical Devices: Legislation and Classification Sect.IV- Chapter 6 Medical Device Classification

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	Sect. II-Chapter 10 Nonprescription Drugs Sect.III-Chapter 8 Generic Medicinal Products Sect.III-Chapter 9 Nonprescription Medicinal Products Sect.IV-Chapter 7 Generic Drug Products Sect.IV-Chapter 8 Over-the-Counter (OTC) Products			
10-Aug	INDs, IMPDs, CTAs, & CTXs Sect.I-Chapter 5 Prescription Product Drug Submissions Sect.I-Chapter 12 Biologics Submissions Sect.II-Chapter 3 Clinical Trial Applications, Good Clinical Practices Sect.II-Chapter 13 electronic Common Technical Document (eCTD) Sect.III-Chapter 2 Overview of Authorisation Procedures for Medicinal Products Sect.III-Chapter 3 Adaptive and Alternative Pathways Sect.IV-Chapter 3 Premarket Requirements/Dossier Requirements	Karl Whitney	Maria Oyaski	In Vitro Diagnostics, "LDTs"/CLIA, Companion Diagnostics Sect.I-Chapter 7 In Vitro Diagnostics Submissions and Compliance Sect.II-Chapter 4 In Vitro Diagnostic Medical Devices Sect.III-Chapter 4 In Vitro Diagnostic Medical Devices Sect.IV-Chapter 4 In Vitro Diagnostic Medical Devices
17-Aug	NDAs/BLAs, MAAs, JNDAs, NDSs Sect.I-Chapter 5 Prescription Product Drug Submissions Sect.I-Chapter 12 Biologics Submissions Sect.II-Chapter 5 New Drug Submission Process Sect. II-Chapter 9 Abbreviated New Drug Submissions Sect. II-Chapter 11 Biologics Submission, Approval and Postmarketing Sect. II-Chapter 13 electronic Common Technical Document (eCTD) Sect.III-Chapter 2 Overview of Authorisation Procedures for Medicinal Products	Rob Woolson & David Shoemaker	Ken Butz	510(k)s, PMAs, Canada, EU (CE mark, etc), Int. Sect.I-Chapter 5 Medical Device Submissions Sect.II-Chapter 8 Medical Device Conformity Assessment Procedure Sect.II-Chapter 10 Medical Device National Particularities Sect.III-Chapter 1 Medical Device Premarket Requirements Sect.IV-Chapter 3 Medical Device Submission and Approval Process Sect.IV-Chapter 9 Medical Device Establishment Licensing

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	Sect.III-Chapter 3 Adaptive and Alternative Pathways Sect.III-Chapter 6 Registration Procedures for Medicinal Products Sect.IV-Chapter 4 Authorization Procedures for Pharmaceutical Products			
24-Aug	Advanced Medicinal Therapeutic Products	Tom Class	Kevin Barber	Special Programs (HDEs, Special Access, etc) Sect.I-Chapter 5 Medical Device Submissions Sect.II-Chapter 8 Medical Device Conformity Assessment Procedure Sect.II-Chapter 10 Medical Device National Particularities Sect.III-Chapter 1 Medical Device Premarket Requirements Sect.IV-Chapter 2 Investigational Testing and Special Access Programme Sect.IV-Chapter 3 Medical Device Submission and Approval Process Sect.IV-Chapter 9 Medical Device Establishment Licensing
31-Aug	Pediatric, Orphan Product and Expanded Access Development for Rare Diseases Sect.IV-Chapter 14 Principles of Rare Diseases and Orphan Products Development Sect.IV-Chapter 15 Global Pediatric Drug Development	Susan Watts	TBD	Medical Device Software Sect.III-Chapter 6 Software
7-Sep	Combination Products Sect.I-Chapter 2 Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways Sect.I-Chapter 4 Current Good Manufacturing Practices and Quality System Design	TBD		Combination Products Sect.I-Chapter 2 Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways Sect.I-Chapter 4 Current Good Manufacturing Practices and Quality System Design Sect.I-Chapter 5 Medical Device Submissions Sect.II-Chapter 3 Medical Devices: Legislation and Classification

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				Sect.IV-Chapter 2 Investigational Testing and Special Access Programme
14-Sep	Prescription Product Labeling Sect.I-Chapter 10 Prescription Drug Labeling, Advertising and Promotion Sect.I-Chapter 15 Biologics Labeling, Advertising and Promotion Sect. II-Chapter 12 Labelling, Advertising and Promotion: Prescription Pharmaceutical Drugs, Biologics and Radiopharmaceuticals	Diana Fordyce & Theresa Scocca		Prescription Product Labeling Sect.I-Chapter 8 Advertising, Promotion and Labeling for Medical Devices and In Vitro Diagnostics (IVDs) Sect.IV-Chapter 7 Medical Device Labelling, Advertising and Promotion
23-Sep	Pharmacovigilance and Risk Management Sect.I-Chapter 11 Pharmacovigilance and Risk Management Sect.II-Chapter 7 Health Product Vigilance and Risk Management Sect.II-Chapter 14 Product Lifecycle Management Sect.III-Chapter 12 Pharmacovigilance	Lisa Hornick		Pharmacovigilance and Risk Management No chapters dealing with this topic.
28-Sep	Postmarketing Sect.I-Chapter 6 Postapproval Submissions and Compliance: Prescription Drugs and Biologics Sect.II-Chapter 6 Postmarketing and Other Activities Sect.III-Chapter 11 Pharmaceutical Postauthorization Requirements and Compliance with the Marketing Authorisations Sect.IV-Chapter 2 International Advertising and Promotion Sect.IV-Chapter 9 Pharmaceutical Postmarketing and Compliance	Karin McIntosh & David Shoemaker	Richard Vincins	Postmarketing Sect.I-Chapter 6 Medical Device Compliance and Postmarketing Activities Sect.II-Chapter 9 Medical Device Compliance: Postmarket Requirements Sect.III-Chapter 7 Postmarket Requirements Sect.IV-Chapter 8 Medical Device Postmarketing

Legend:

Blue text = US (1st 4 chapters in pharmaceuticals and biologics & devices are the same)
Green text = Canada

Red text = EU
Teal text = International

TEXTBOOKS available on the RAPS.org website:

Pharmaceuticals and Biologics:

VOL 1 Fundamentals_of_Pharmaceutical_and_Biologics_Regulations

VOL 2 Fundamentals_of_Pharmaceutical_and_Biologics_Regulations

Medical Devices and In Vitro Diagnostics:

Fundamentals_of_Medical_Device_Regulations__Second Edition