

North Carolina Regulatory Affairs Forum

2020 Regulatory Affairs Certification Training Course Syllabus

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

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23-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
30-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
7-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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14-Jul	<p>Biologics and Biosimilars</p> <p>Sect.I-Chapter 12 Biologics Submissions</p> <p>Sect.I-Chapter 14 Biosimilars</p> <p>Sect. II-Chapter 11 Biologics Submission, Approval and Postmarketing</p> <p>Sect.III-Chapter 10 Marketing Authorisations for Products Derived From Biotechnology</p> <p>Sect.IV-Chapter 10 High-Risk Products Derived from Biotechnology</p> <p>Sect.IV-Chapter 11 Biosimilars: Basics and Recent Developments</p> <p>Sect.IV-Chapter 12 Vaccines</p> <p>Sect.IV-Chapter 13 Products Manufactured from Human Blood and Plasma</p>	Charity Schuller	David Jensen	<p>IDEs, etc (ex-US device clinical trial submissions)</p> <p>Sect.I-Chapter 5 Medical Device Submissions</p> <p>Sect.II-Chapter 7 Clinical Evaluation and Clinical Investigations</p> <p>Sect.III-Chapter 2 Technical and Regulatory Requirements</p> <p>Sect.IV-Chapter 2 Investigational Testing and Special Access Programme</p>
21-Jul	<p>Regulatory Authority Meetings</p> <p>Sect.I-Chapter 2 Overview of Drug, Biologic, Device, Combination Product or Food Regulatory Pathways</p> <p>Sect.I-Chapter 12 Biologics Submissions</p> <p>Sect.II-Chapter 3 Clinical Trial Applications, Good Clinical Practices</p> <p>Sect.II-Chapter 5 New Drug Submission Process</p> <p>Sect.III-Chapter 1 Overview of Drug and Biologic Regulatory Pathways</p> <p>Sect.III-Chapter 6 Registration Procedures for Medicinal Products</p>	Kevin Barber		<p>Regulatory Authority Meetings</p> <p>Sect.I-Chapter 5 Medical Device Submissions</p>
28-Jul	Clinical Protocols and Clinical Development Plans	Nick Kenny, Jack Modell, Ben Vaughn		Clinical Protocols and Clinical Development Plans
4-Aug	<p>Pharmaceuticals, Generics, and OTC Drugs</p> <p>Sect.I-Chapter 7 Generic Drug Submissions</p> <p>Sect.I-Chapter 8 Patents and Exclusivity</p> <p>Sect.I-Chapter 9 Over-the-Counter (Nonprescription) Drug Products</p> <p>Sect. II-Chapter 8 An Overview of Pharmaceutical Intellectual Property Protection in Canada</p>	Catherine Maher	Sheila Hemeon-Heyer	<p>Device Classification and Regulatory Controls</p> <p>Sect.II-Chapter 1 The New Medical Device Regulation and In Vitro Diagnostic Device Regulation</p> <p>Sect.II-Chapter 3 Medical Devices: Legislation and Classification</p> <p>Sect.IV- Chapter 6 Medical Device Classification</p>

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

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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			
25-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
1-Sep	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	Sheila Hemeon-Heyer	Medical Device Software Sect.III-Chapter 6 Software
8-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	Vicki Gunto		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
15-Sep	<p>Prescription Product Labeling</p> <p>Sect.I-Chapter 10 Prescription Drug Labeling, Advertising and Promotion</p> <p>Sect.I-Chapter 15 Biologics Labeling, Advertising and Promotion</p> <p>Sect. II-Chapter 12 Labelling, Advertising and Promotion: Prescription Pharmaceutical Drugs, Biologics and Radiopharmaceuticals</p>	Diana Fordyce & Theresa Scocca		<p>Prescription Product Labeling</p> <p>Sect.I-Chapter 8 Advertising, Promotion and Labeling for Medical Devices and In Vitro Diagnostics (IVDs)</p> <p>Sect.IV-Chapter 7 Medical Device Labelling, Advertising and Promotion</p>
22-Sep	<p>Pharmacovigilance and Risk Management</p> <p>Sect.I-Chapter 11 Pharmacovigilance and Risk Management</p> <p>Sect.II-Chapter 7 Health Product Vigilance and Risk Management</p> <p>Sect.II-Chapter 14 Product Lifecycle Management</p> <p>Sect.III-Chapter 12 Pharmacovigilance</p>		Lisa Hornick	<p>Pharmacovigilance and Risk Management</p> <p>No chapters dealing with this topic.</p>
29-Sep	<p>Postmarketing</p> <p>Sect.I-Chapter 6 Postapproval Submissions and Compliance: Prescription Drugs and Biologics</p> <p>Sect.II-Chapter 6 Postmarketing and Other Activities</p> <p>Sect.III-Chapter 11 Pharmaceutical Postauthorization Requirements and Compliance with the Marketing Authorisations</p> <p>Sect.IV-Chapter 2 International Advertising and Promotion</p> <p>Sect.IV-Chapter 9 Pharmaceutical Postmarketing and Compliance</p>	Karin McIntosh & David Shoemaker	Richard Vincins	<p>Postmarketing</p> <p>Sect.I-Chapter 6 Medical Device Compliance and Postmarketing Activities</p> <p>Sect.II-Chapter 9 Medical Device Compliance: Postmarket Requirements</p> <p>Sect.III-Chapter 7 Postmarket Requirements</p> <p>Sect.IV-Chapter 8 Medical Device Postmarketing</p>

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