



Regulatory & Clinical Research Institute (RCRI) offers its expertise in presentation format on many different topics on medical device, IVD, biologic, and combination products. A list of major workshops is listed below with an estimate of time for each presentation, but many can be customized to meet your specific needs. Please contact Juli Denny, Vice President of Business Development at 952-224-2263 or jdenny@rcri-inc.com for more information.

RCRI Speakers Bureau Presentations

		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Biostatistics					
Statistics for Non-Statisticians	Common statistical issues, common errors in study conduct and study interpretation, types of statistics in routine analysis, interpreting basic statistical output.	x	x	x	x
What is Statistics	What statistics is and what it is not, and statistics in clinical (drug) studies and device studies.	x	x	x	
Bayesian Statistics	What is Bayesian statistics and how it works, Bayesian statistics for medical device trial and when to use it.	x	x	x	
Conducting, Documenting, and Reporting Statistical Analysis	US and OUS regulations, data flow in clinical trials, validation, introducing modules, two types of statistical programs, documenting and reporting.	x	x	x	
Statistical Agreement Between Two Methods	Theory of method comparison studies, method comparison in practice, and possible pitfalls.	x	x	x	

		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Database Development					
Data Collection for CMS and FDA purposes			x		
Electronic Randomization		x			
Software Validation	An overview of regulated software types, and software standards and guidance documents. Risk management in software development, quality aspects, user interface impacts and typical design and validation documentation.	x			

		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Regulatory - General and History					
GLP 101: Good Laboratory Practices	History and background of the FDA, overview of Quality System Regulation, overviews of 510(k) and commercialization processes.	x	x	x	x
BiMO Audit Overview	Review current FDA requirements and key FDA regulations that apply to medical devices and understanding the role of guidance documents.	x	x	x	x
Medical Device Reporting and Reports of Corrections and Recalls	Better understanding of the overall product development process and how to plan and prepare regulatory submissions that will result in timely product approvals.	x	x	x	x
Effectively preparing your device for FDA review	Regulatory strategy including product strategy, device classifications, 510(k) submissions, PMA, IDEs and meeting with the FDA.	x	x	x	x
FDA Legislation		x	x	x	x
Introduction of Food and Drug Administration (FDA)	When is an IDE applicable, IDE Submissions, Elements and Amendments, Pre-IDEs, and Investigation Plan contents.	x	x	x	x
Introduction to FDA Requirements		x	x	x	x
Introduction to Medical Device Regulations	Definitions of IVD and Classifications, IVD Labeling and Quality System Requirements, Clinical IVD studies, and IVD premarket clearance.	x	x	x	x
US FDA Approval Process: Devices	Definitions, background, and information flow of product labeling. SPL Standard Product Labeling (SPL) and how it can help.	x	x	x	x
Overview of Federal Requirements for Medical Device Clinical Studies	Overview of device regulation, structure of the FDA, facility regulation and device listing, animal and human product testing, marketing clearances, GMPs/QSR, and medical device reporting.	x			
US FDA Regulatory Training	History of device regulations, device classifications, marketing clearance, quality system regulation, device tracking, post-market surveillance, hot issues.	x			
Medical Device Regulations	When is and IDE applicable, IDE elements, submissions, and amendments, Pre-IDE meetings, and FDA IDE and Pre-IDE statistics.	x	x	x	
Regulatory Responsibilities of Medical Device Manufacturers	Product strategy and approval process, device classification and definition, marketing and regulatory requirements, device submission process. Regarding marketing claims: labeling and claims violations.		x	x	x

Regulatory - Labeling		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Labeling, advertising, and promotion in a regulated environment	Understanding what "off-label" and "on-label" mean and how they relate to medical device labeling, advertising, and promotion.	X	X	X	
Medical Device Marketing Claims	Product strategy and approval process; Device classification and definition; Marketing and regulatory requirements; Device submission process.	X	X	X	
Labeling and Advertising in a Regulated Environment	Regarding marketing claims: labeling and claims violations.	X	X		
Structured Product Labeling	Objectives: Awareness of laws and regulations; Understanding definitions and boundary established by law/reg; Potential consequences when in violation; Typical pitfalls and how to avoid them	X			
Regulatory - IDE		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
IDE Annual Reports	Brief overview in relation to RCRI SOPs.	X			
Management Considerations in the Design of Clinical Studies for Medical Products	How to design your clinical strategy, and objectives using regulatory considerations.	X	X	X	
Transitioning from the IDE to the PMA	When is an IDE applicable; IDE elements, submissions and amendments; Pre-IDE meetings; FDA IDE and pre-IDE statistics.	X			
IDE & Pre-IDE Submissions: Regulatory Affairs 101	Elements; Investigational Plans; Submission types; Approval types; Problems; Pre-IDE meetings; Pre-IDEs; Expanded use of IDEs; Types of meetings; Review times.	X			
IDE Submissions 21 CFR 812, Investigational Device Exemptions,	When is an IDE applicable; IDE Submissions; Elements and Amendments; pre-IDEs; and Investigation Plan contents.	X			
Investigations Device Exemption (IDE) 21 CFR 812	All things IDE: Identify internet links; Strategy and planning; Interacting with the FDA; IDE submission elements; What separates a better submission from an adequate submission.	X			
Regulatory - PMA		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
PMA Basics	Requirements; Structure; Review; Approval; Supplements/post-market requirements	X	X	X	
Premarket Approval (PMA) Applications	Complete overview of the PMA application to include application structure, contents, types, review process, meetings, conditions of approval, post-approval requirements, supplements, role of standards, Device Master Files, etc.	X	X	X	
Premarket approval applications	Legislative history and the Modernization Act; Device classifications; Methods for gaining pre-market approval.	X	X	X	
Regulatory - Biologics		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Cellular therapy and tissue engineering, Regulatory guidance	Biologics basics, the role of CBER and recent FDA regulations.	X	X	X	
Cellular therapy and tissue engineering, Cell, Tissue and Gamete Preservation	Biologics basics; The tipping point – New Regulations.	X	X	X	
Regulatory - US and OUS Combination Products		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Combination Products brown bag	What are they; Examples; Recently approved; US, EU; Animal material; Human blood material; Competent Authority; Strategy; Guidance documents	X			
Regulatory Challenges in the EU - Combination Products	Challenges; Using MDD; Using MEDDEV 2.1/3; 93/42/EEC; 65/65/EEC; Examples; Notified Body; Competent Authority; Strategy; Guidance documents	X	X		
Drug/Device/Biological - Combination Products	What are they; Categories; Examples; Recently approved; ; Product assignment within CBER, CDER and CDRH; Request for designation; How can RCRI help?	X	X		
Issues Regarding EU Combination Products	Determining classification (mode of action vs. ancillary action; assess claims); Regulatory process / registration requirements (current regs/updates; NBs/CAs); Challenges	X	X		
Combination Products and the Regulatory Process	Product Regulation; Primary mode of action; Intended use; Jurisdiction; Strategy; Product assignment within CBER, CDER and CDRH.	X			
Regulatory - US and OUS IVD		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation

Issues and Challenges for IVD technologies – Predictability is power	How to identify and reduce the ambiguity that comes from seeking medical device approval and insurance coverage.	x			
In Vitro Diagnostics Directive (IVDD)	Background of EU and IVD Directive; Definition of IVD and classification; Labeling requirements (Annex I, item 8); Quality system requirements; Clinical/Performance studies; Premarket clearance/approval requirements	x	x		
Technical Files, RAPS IVD Conference	Requirements; Control and structure; Most important elements of technical files; Typical compliance issues from Notified Body audits		x		
US and EU IVD Regulations	Definitions of IVD and classifications; IVD labeling and Quality System requirements; clinical IVD studies; and IVD premarket clearance.				
Regulatory - European regulations		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
International Submissions Training	Europe; Australia/New Zealand; Canada; Japan; Asia Pacific; Latin America; Useful websites; Reference pages.		x	x	
Reviewing Design Control and Process Validation Compliance Issues from European Directive Audits	MDD/AIMDD/IVDD highlights and compliance issues; Quality system requirements and compliance issues; IVDD additional hints;	x	x		
The Role and Challenges of European Notified Bodies Regarding Medical Technology: Global Opportunities: the Knowledge You Need to Access Key Markets	Role and Challenges of Notified Bodies.	x	x		
European Union Medical Device Directive Training	History of the EU and Directives; Important EU Directives; EU Roles and Responsibilities; History of the MDD; MDD Structure and Definitions;				x
Regulatory - Standards General		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Use of Standards Overview	History and structure of MDD 93/42/EEC; Definition and examples of medical devices; conformity assessment procedures; QS requirements; Clinical evaluations and EN ISO 14155; Essential requirements (Annex I); Technical File and Design Dossier requirements; Medical Device Vigilance; Devices incorporating material of human or animal origin; drug/device combinations			x	
Use of Standards Overview	Origin, MDD and Links; Clinical Evaluation Standards; Tech Files; FDA Submissions; EU and US Standards Organizations; Revision and Transition periods; Typical Standards for Medical Devices		x	x	
Are All Standards Created Equal?	Types of consensus standards and their limitations; FDA recognition of consensus standards.	x			
Regulatory - Standards General		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Topics in Software Risk Management for Medical Devices	Software in medical devices; Components of software risk management; Regulatory Expectations	x			
ISO 14971 Overview	Overview of Risk and ISO 14971; Changes in the 2007 version; Where do we start; RM file/report; Example.	x			

Clinical		1-hour Webinar	2-hour Webinar	1/2 Day Presentation	1-1+ Presentation
Clinical 101 of Medical Devices	FDA overview, types of clinical studies, study design, defining study objectives, understanding research error, and conducting site selections and initiations.		x	x	
Clinical Research Paradigms		x			
ClinicalTrials.gov	What is ClinicalTrial.gov, why register, requirements and deadlines.	x		x	
Performing Medical Device Clinical Research	Defining study objectives and endpoints, controlling potential research errors, and selecting a clinical study design.	x			
DSMBs and CEC in Medical Device Trials	Identify criteria for using a DMC and/or CEC, identify how DMCs/CECs can assist the sponsor in data analysis, and identify FDA's recommendation for working on DMCs and CECs.	x			
Analysis of Adverse Events	Documenting, classification, and coding of events, and characterizing frequency of occurrence.		x		
Practical Challenges of Clinical Trial Design	Determining the needs for a study, pinpointing the audience for results, selecting objectives, identifying study values, defining criteria for success, and choosing a study design.	x			
Clinical Trial Management	Identify and refine research questions, review objectives, protocol creation, identify financial and personnel resources, select safety and monitoring committees, and determine logistics of study conduct.	x			
Case Report Form Design	Definition of a documentation and source data, identifying the need for CRFs, and complete CRF layout, format, design.	x			

Pretesting Case Report Forms	The purpose, scope, and definitions of pretesting your CRFs and methodologic considerations.	x			
Clinical Trial Data Management Tips & Techniques			x		
Safety First: Tips for Adverse Event Management in IDE Studies	Sponsor responsibilities, adverse event definition, monitoring and protocol considerations, site management, CRF design, and the DSMB and CEC roles.		x		
Clinical Study Planning	Goals of planning phase, regulatory environment, areas of preparation, and keys to success.		x		
Overview Federal Requirements for Medical Device Clinical Studies	FDA overview and Federal Regulations.			x	
International Standard for Clinical Investigation of Medical Devices for Human Subjects: ISO 14155-1:2003 and ISO 14155-2:2003	ISO 14144 introduction, history, and purpose and a breakdown of the criteria in Part 1 and Part 2.		x		
BIMO Audit Overview	Overview of FDA and BiMO Audits, critical issues during inspection, common deficiencies, duration of inspections, BiMO communication of results, influence on approval, and inspection authority.		x		
Adverse Event Reporting and Management	Adverse event definitions, responsibilities, common challenges, and safety management plan.	x	x		
US Regulatory Requirements for Clinical Trial			x		
FDA Wants Clinical Data to Support Your 510(k); Now What?		x	x		

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Quality Systems					
Quality System Regulation Compliance CAPA IVD Directive		x	x		
Quality System Training	History and role of the Food and Drug Administration and an overview of the Quality System regulation.	x	x	x	x
ISO 13485	What is an ISO, a quality system, ISO 13845: 2003 and its requirements, and why you want to remain certified.	x	x	x	x
Medical Device Directive	Review ISO 9001 and ISO 13485 requirements, the role of quality systems in product approvals in the European Union and USA, audits for ISO 9001/13485 and Medical Device Directives 93/42/EEC.	x	x	x	x
Changes to Medical Device Directive	Review ISO 9001 and ISO 13485 new 2010 requirements	x			
Internal Auditing	Requirements for internal audits FDA QSR and ISO 9001: 1994 and ISO 13485: 1996. What will the notified body want to see, what guidance documents are available on auditing, latest ISO updates.	x	x	x	x
IVD Technical Files		x	x	x	x
IVD US and EU regulations		x	x	x	x
Design and Document Control	FDA Requirements: PMA application and the approval process, PMA supplements, IVDD highlights, 510(k), Quality System Requirements and Compliance Issues, and Design Control Procedures	x	x	x	x
Design Control and Process Validation Compliance Issues from European Directive Audits	MDD, AIMDD, and IVDD highlights and EN ISO 9001 requirements.	x	x	x	x
Global Opportunities: the Knowledge You Need To Access Key Markets - The Role and Challenges of European Notified Bodies Regarding Medical Technology	History of the Single Market, European Union Members, EU, EEA, EFTA, and the challenges and roles of Notified Bodies.	x	x		

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Reimbursement Strategy					
Integrating Regulatory, Clinical & Reimbursement Strategies	Definition of clinical endpoints, publication strategy, and new/revised code and other applications.		x		
The Reimbursement Triad: Overview and Policy Update	The background of health care costs and the history of payment reforms. Understanding of the reimbursement triad: coding, coverage, and payment and their trends and challenges.	x			
Introduction to Health Economic & Outcomes Research	Differentiate basic types of cost-effectiveness analysis, study components, and basic process for analysis.	x			
Publication Planning	The importance of publication planning to gain coverage, topic planning, publication committee development, key audiences and key topics and journal identification.	x			
Clinical Trial Reimbursement	Coding, Coverage, and Payment, 510(k) vs. PMA coverage, CPT requirements, and procedure coding.	x			