North Carolina Regulatory Affairs Forum (NCRAF)_Roundtables Archive from 2024 back to 2010

Year	#	TOPIC	Speaker(s)	Company
2024	**2024-11-14 Roundtable Dinner (11 tables)**			
2024	1	Transitioning to a Career in Regulatory Affairs	Linda Bowen	Temple University
2024	2	Lab Developed Tests - US and EU Perspectives	Stefan Burde	TÜV SÜD
2024	3	Bridging Science and Compliance: The Synergy between Medical Writing and Regulatory Affairs	Stefanie Byrd	SynerG Biopharma Group
2024	4	Tip and tricks for uncomplicated collaborative authoring	Meagan Eldridge	Eldridge Writing & Consulting LLC
2024	5	Mine Your Business (and Others Too) - Searching for Relevant Data to Guide Regulatory Decision-Making	Michael Lance	United Therapeutics
2024	7	Leveraging DHTs For Enhancing Innovations in Regulatory Science	Prem Narang	P.K. Narang Strategic Consulting
2024	9	Assessment of the Effects of Drugs on Cardiac Repolarization	Rachel Rozakis	Allucent
2024	11	Unlocking Hope: Regulatory Innovations in the Treatment of Rare Diseases	Jason Mercer	Facet Life Sciences
2024	12	Cell and Gene Therapy Regulatory Affairs: Applying Recent FDA Guidance	Scott Burger	Advanced Cell & Gene Therapy, LLC
2024	13	Regulatory Considerations in Development of Opthalmic Products (and other Localized Delivery Routes)	Olu Aloba	Premier Research International
2024	14	De-Risk Submissions: Increase your IQ for Right 1st Time Submissions	Khyati Desai, and Mayra Marquez	Moderna, and LaSalle Group International
2023	**2023-11-09 Roundtable Dinner (12 tables)**			
2023	1	eSTAR and PreSTAR – Experiences with CDRH's Electronic Submission Template	Cynthia Nolte	ICON
2023	2	Digital Health Technologies (DHTs) used with Combination Products - Regulatory Considerations	Rita Lee	Suttons Creek
2023	4	Empowering Innovation in Generative AI and Digital Health: Exploring FDA Guidelines	Shilpa Gampa	Freyr
2023	5	Regulatory approaches to Cell, Gene, and Tissue Therapies	Kevin Healy	Kevin Healy
2023	6	Exploring FDA's Focus Areas of Regulatory Science	Patricia Termini	UNC
2023	7	Decentralized Clinical Trials: Things to Consider	Prem Narang	P.K. Narang Strategic Consulting
2023	8	When a single pivotal trial might be sufficient - FDA's thoughts	Sathya Ganesan	UCB
2023	9	IND gap analysis, requirements, and filing How-to	Prabodh Kumar Kandala	Syneos Health
2023	10	Mind the Gap - For a Successful NDA or BLA, Early Identification of Issues is critical!	Sheila Plant	Allucent
2023	11	Regulatory Medical Writing: Who, What, and Why	Nancy Gasper Smith	Syner-G
2023	12	Briefing Document Development from a Medical Writer's Perspective	Meagan Eldridge	Meagan Eldridge Writing and Consulting
2023	13	Everything everywhere all at once - The European Commission's thicket of issues	Kirsten Messmer	Agency IQ

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2022	**2022-11-16 Roundtable Dinner (9 tables)**			
2022	1	EU Clinical Trial Regulation	Clare Matti	The FlexPro Group
2022	3	Notified Body interactions during the review of technical documentation remediated to MDR and IVDR	Cynthia Nolte	ICON plc
2022	4	Regulatory Intelligence – Medical Devices	Charles Jagun	Merz Aesthetics
2022	7	Manna from Heaven - PDUFA VII	Drusilla Scott	Sobi
2022	10	Advanced Therapies – Lessons learned from regulatory challenges	Kirsten Messmer	POLITICO
2022	12	Making the Switch: Transitioning your career into Regulatory Writing	Demetrius Carter	Synchrogenix
2022	13	The Logistics of Starting Your Own LLC/Consulting Company	Marissa Berry	Embee Regulatory Consulting
2022	14	Regulatory Affairs Influence in Investment Decisionmaking	Devin Rosenthal	NovaQuest Capital Management
2022	15	Storytelling, Hypnosis, and Vulcan Mind Melds: The Art and Science of Persuasion in Regulatory Interactions	Kevin B Johnson	Ring Therapeutics
2021	**No Roundtable event in 2021, due to COVID pandemic**			
2020	**No Roundtable event in 2020, due to COVID pandemic**			
2019	**2021-11-07 Roundtable Dinner (12 tables)**			
2019	1	It Takes a Village to Author a Briefing Document: Working with Cross-Functional Teams to Author Pre-IND and EOP2 Briefing Documents	Fatima Larry	FBL Clinical and Regulatory Consulting
2019	2	Benefit vs. Risk: Expedited development of therapeutics for serious and life-threatening diseases	Dana Minnick	SciLucent
2019	3	From Benchtop to Desktop: Transitioning into Regulatory Writing	Brandi Schuster	Impact Pharmaceutical Services
2019	4	Artificial Intelligence in Medical Devices	Tammy Carrea	Baebies
2019	5	Global Approach to Software as a Medical Device (SaMD)	Yuan Xu and Cindy Nolte	Focus 42 and ICON
2019	6	Advanced Therapies – Scientific Progress, Regulatory Requirements and Ethical implications	Kirsten Messmer	PPD
2019	9	Going it Alone: The Benefits and Risks of Transitioning from Full Time Employee to Independent Contracting/Consulting	Erin O'Reilly	Independent Regulatory Consultant and Medical Writer
2019	10	Quality from an RA Perspective	Susan Speicher	Network Partners
2019	11	Navigating Drug Development Under the Animal Rule (21 CFR 314.600-650)	Gina Grossi	Chimerix
2019	13	Creating Effective Data Visualizations for Regulatory Submissions	Chris Miller	3D Communications
2019	14	Stem cell therapies	Zachary Swan and Becky Sundseth	Cato
2019	15	Mind the Gap(s): Early Identification of Issues is Key for a Successful NDA or BLA	Sheila Plant and Michelle Villasmil	Cato

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2018	**2018-11-08 Roundtable Dinner (14 tables)**			
2018	1	GDPR and the New World of Data Privacy	Kylie Opel	Duke Clinical Research Institute
2018	2	How to Kill your Biotech Startup	Maria Oyaski	Metabolon
2018	3	Regulatory Intelligence – Building Strategies for Drug Development in the Changing Regulatory Landscape	Kirsten Messmer	PPD
2018	4	CHMP Oral Explanations and FDA Advisory Committee Meetings – Understanding Similarities and Differences to Optimize Your Meetings	Bert Regeer	3D Communications
2018	5	Due Diligence in GxP Supplier Selection	Michelle Holbrook Thompson	FDA Quality and Regulatory Consultants
2018	6	Orphan Drug Development: U.S. Regulatory Landscape	Colleen Johns	Dova Pharmaceuticals
2018	7	FDA Policy: Are the Incentives Right for Orphan Drugs?	Marian Rhodes	UCB
2018	8	Artificial Intelligence in Medical devices	Tammy Carrea	Baebies
2018	9	How is your company preparing for the MDR/IVR?	Cindy Nolte	ICON
2018	10	Right-to-Try or Right-to-Ask? Understanding Right-to-Try and FDA's Expanded Access	David Shoemaker and Kevin Barber	Rho
2018	11	Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics	Sathya Ganesan	G1 Therapeutics
2018	12	How to write a good audit report	Celine Clive	Polaris Compliance Consultants
2018	13	Gene Therapies and Advanced Tissue Therapies: FDA and EMA Pathways	Kevin Healy	Enzyvant
2018	14	Best Practices for Preparing for FDA Meetings	Will Lee	Cato Research
2017	**2017-11-09 Roundtable Dinner (14 tables)**			
2017	1	Global perspective on orphan drug regulations - compare/contrast process in US, EMA, Australia, and Japan	Sathya Ganesan	PPD
2017	2	EU CT Regulations	Bhargavi Rao	PPD
2017	3	Getting Started: Requirements for First time in Human Studies	Greg Hileman	Cato
2017	4	CAR-T Cells – Development and Approval Play-by-Play	Kirsten Messmer	PPD
2017	5	Regulatory Innovation and the RMAT Designation	Kevin Healy	Roivant
2017	6	Communicating Benefit-Risk is Fundamental to Device Approval and Market Adoption	Jim DiBiasi	3D Communications
2017	7	Seeking Yes. Effective communications in job search and beyond	Don Alexander	Recruiter
2017	8	Privacy Please! Data privacy rules for medicine and research in the US and the EU	Maria Oyaski	Metabolon
2017	9	What's in the Mix for PDUFA VI?	Drusilla Scott	BioDelivery Sciences
2017	10	Leveraging Real World Evidence in Regulatory Approvals	Nicole Baker	Roivant
2017	11	eCTD - What's the Big Deal	Margaret Schubert	Cato
2017	13	Priority Review Vouchers	Kelly Roney	Consultant
2017	14	IND Submissions: Past, Present, and Future	Rudy Fuentes	Quintiles IMS
2017	15	5 Years after GAIN: QIDP Progress	Joan Drucker	IQVIA

Year	#	TOPIC	Speaker(s)	Company
2016	**2016-11-09 Roundtable Dinner (13 tables)**			
2016	1	Winning Strategies for Success in the FDA and EMA Panel Review Processes	Jim Kelley	3D Communications
2016	2	Advanced Therapies – Hot topics and what you need to know	Kirsten Messmer	PPD
2016	3	Spotlight: Hiring Trends in Regulatory Affairs	Don Alexander	Recruiter
2016	4	Meeting the Challenges of Device Trial	Rob Romanchuk	Schulman IRB
2016	5	Biosimilars - A Challenging Global Landscape	Charity Schuller	PPD
2016	6	Combination Products vs. Companion Diagnostics, Aren't They the Same Thing?	Jocelyn Jennings	(plasma proteins company)
2016	7	Pediatric Regulatory Environment: The Importance of Early Planning	Robin Huff	Quintiles
2016	8	Will Your Study Data Meet FDA's Technical Requirements for Submission?	Dawn Edgerton	Edgerton Data Consulting
2016	9	FDA's Regulatory Science Approach to Nanotechnology	Nasrin Habibi	Duke
2016	10	What Does It Take to Become an Independent Contractor?	Celine Clive	Polaris Compliance
2016	11	Do Tell - Registering and Reporting under the clinicaltrials.gov Final Rule	Drusilla Scott	Cempra Pharmaceuticals
2016	12	CTA in Europe: Is VHP Right for your Study?	Sathya Ganesan	PPD
2016	13	Proposed Environmental Compliance	Susan Bostian and Andy Rodak	Duncklee & Dunham
2015	**2015-11-12 Roundtable Dinner (16 tables)**			
2015	1	Career Development	Brian McMerty	Carlyle Conlan
2015	2	cGMPs and inspections: Overview from FDA's recent SBIA meeting	Poonam Pande	Integrated CMC Solutions
2015	3	Bio Like Me: Recent Events & Current Regulatory Considerations for Biosimilars	Kevin Healy	
2015	4	Oh Baby! The new Pregnancy and Lactation Labeling Rule	Drusilla Scott	
2015	5	Making a List and Checking it Twice: Using Checklists to Ensure High Quality Regulatory Submissions.	Evan Richardson	GlobalSubmit
2015	6	Who's on First? The new Module 1	BJ Witkin	Impact Pharma
2015	7	Name that Drug! (How pharma companies name their assets)	Elvis Tutu	GSK
2015	8	Regulatory Intelligence - Building Strategies for Drug Development	Kirsten Messmer/ Charity Schuller	PPD
2015	9	pre-IND 12-step: Recipe for IND filing success	Larry Hofmann	LMH Associates
2015	10	Growing Pains - Making Pediatric clinical trials better!	Valerie Amspacher	FDA (ORISE fellow)
2015	11	Medical Device Regulations	Cynthia Nolte	ICON
2015	12	Creating to spec: the Design Control process	Jim Clinton	
2015	13	Split Personalities: Combination Products	Sandra Boyd	Biogen
2015	14	Diagnostics across borders: Key differences of IVD regulations in the EU vs US	HE Sengoku	GSK
2015	15	FDA's Golden Tickets: Priority Review Vouchers for Rare Pediatric and Tropical Disease Drugs	Matt Medlin	Chiesi USA
2015	16	Medical Writing for Regulatory Affairs Professionals	Jennifer Moen	Impact Pharma

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2014	**2014-11 Roundtable Dinner (15 tables)**			
2014	1	Regulatory Affairs Profession	Don Alexander	Carlyle Conlan
2014	2	Risk based monitoring vs. Risk based auditing	Celine Clive	Polaris Compliance Consultants
2014	3	Plant biotechnology product development, safety evaluation and regulatory approval	Jingwen Chen	Syngenta Biotechnology
2014	4	GLP and Data Quality in Containment: Studies Conducted Under The Animal Rule	I.M. Grossi (gina)	Chimerix
2014	5	Sling back shoes and the changing landscape of clinical trial applications in the EU: what's in store under Regulation (EU)536/2014	Denise Sturdy	DCRI
2014	6	What's Mine is Mine, and What's Yours is Yours (DMFs)	Amy Blawas	Cato Research
2014	7	Unapproved Drugs Available at a Pharmacy Near You!	David Jensen	DCRI
2014	8	FDA's recent changes to the substantial equivalence decision making process for 510(k)s	Tammy Carrea	RegMatters LLC
2014	9	Global Vaccine Supply & Regulation	Diya Abdeljabbar	Merck & Co.
2014	10	BioCryst's NDA for Peramivir: regulatory & publishing challenges	BJ Witkin	Impact Pharmaceutical Services
2014	11	Regulatory Intelligence	Emily Huddle	GlaxoSmithKline
2014	12	Breakthrough Therapies and Expedited Programs	Kevin Healy	Mallinckrodt
2014	13	Writing the CSR Synopsis: Reduce, Recycle, Reuse	Susan Sisk	Spf consulting
2014	14	Help! I need an IND!	Nancy Chew	Regulatory Affairs North America
2014	15	Inspection Readiness	Joseph Knight-McKenna	Quintiles

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2013	**2013-11 Roundtable Dinner (11 tables)**		
2013	1	New FDA Guidances for 2013	Susan Watts
2013	2	Sunshine Act Uncertainties	Matt Medlin
2013	3	From Crisis to Legislation to Regulation: The compounding pharmacy case	Rachel Hardy
2013	4	Affordable Care Act's Medical Device Excise Tax.	Michael Hinkle
2013	5	Breakthrough Therapies - Are we fabulous enough yet?	Maria Oyaski
2013	6	ClinicalTrials.gov Results Reporting… It's Not A Choice Anymore!	Lorna Dula
2013	7	If I only knew then what I know now...or how to plan for your first CE mark EU Technical File.	Linda Charles
2013	8	Submission of Datasets using CDISC Standards	Diane Wold
2013	9	SOPs, Training and Auditing	Brooke Moody
2013	10	Regulatory Affairs Careers	Don Alexander
2013	11	Preparing for a Successful FDA Advisory Committee or Device Panel Meeting	Cari Newton and Jamie Blackburn

Year	#	TOPIC	Speaker(s)
2012	**2012-11 Roundtable Dinner (12 tables)**		
2012	1	Advertising and promotion review. FDA hot buttons	Susan Zecchini
2012	2	PreIND/IND Wonder Submissions: Your Bread and Butter	Nancy Chew
2012	3	Working in the twilight zone: "GMP" and quality elements for non-regulated R&D Labs	Michelle Pruett
2012	4	ICH M7: Qualification of impurities and everything else in that goop you call a drug	Dana Minnick
2012	6	ClinicalTrials.gov Registrations. Big Brother wants your data	Erin O'Reilly
2012	7	Risk Based Monitoring: Sanity returned or cheap trials?	Celine Clive
2012	8	PDUFA V: Get with "The Program"!	Drusilla Scott
2012	9	Clinical Studies in Africa and S. America	Aida Cancel
2012	10	Regulatory Affairs Careers. Get One.	Don Alexander
2012	11	Hey! I'm talking here! Device Pre-Submission discussions and meetings with FDA.	Ken Edds
2012	1	Advertising and promotion review. FDA hot buttons	Susan Zecchini
2012	2	PreIND/IND Wonder Submissions: Your Bread and Butter	Nancy Chew
2011	**2011-11 Roundtable Dinner (12 tables)**		
2011	1	Companion Diagnostics	Susan Watts, Don Kafader
2011	2	Quality Risk Management	Joe Knight-McKenna
2011	3	Challenges in Migrating eCTDs from Multiple Tools and Format	Karteek Sandadi
2011	4	Pre-IND/IND free-for-all	Nancy Chew
2011	5	The Steps to a Successful FDA Advisory Committee	Cari Newton/3D Communications
2011	6	Adaptive Clinical Trial Designs	Jeff Sorbel
2011	7	Regulatory Intelligence	Rebecca Sagosz
2011	8	Pediatrics / consent	Bob Kunka
2011	9	CDISC	Jeff Abolafia
2011	10	Special Protocol Assessment	Maria Oyaski
2011	11	Medical Devices	Ken Edds
2011	12	Career	Don Alexander
2010	**2010-11 Roundtable Dinner (14 tables)**		
2010	1	Orphan Drug Designation	Drusilla Scott
2010	2	Device Related	Suzanne Schwaller
2010	3	ESG	Bob Rhode
2010	4	REMS	Frank Gallo, Charity Metz Schuller
2010	5	Social Networking in Promotional Advertising	Lorna Wilson
2010	6	Pre-IND / IND	Nancy Chew
2010	7	Preparing for a Successful AdCom	Cindy DeBassi
2010	8	Investigator fraud	Celine Clive
2010	9	Pharmacovigilance OR Regulatory Compliance: Consequences of PV inspections and compliance	Joe Knight-McKenna
2010	10	CAPA plans	Rita Griffin
2010	11	IVD	Maria Oyaski
2010	12	Drug Safety Monitoring Boards	Linda Charles
2010	13	GLP, CLIA	Susan Meeker
2010	14	cGMP	David Houck