**Roundtables Archive from 2023 back to 2010**

| Year | # | TOPIC | Speaker | Company |
|---|---|---|---|---|
| **2023** | **2023-11-09 Roundtable Dinner** | | | |
| 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 |
| **2022** | **2022-11-16 Roundtable Dinner** | | | |
| 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** | | | |

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|---|---|---|---|---|
| **2019** | **2021-11-07 Roundtable Dinner** | | | |
| 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 |
| **2018** | **2018-11-08 Roundtable Dinner** | | | |
| 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 |

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| **2017** | **2017-11-09 Roundtable Dinner** | | | |
| 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 |
| **2016** | **2016-11-09 Roundtable Dinner** | | | |
| 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 |

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| **2015** | **2015-11-12 Roundtable Dinner** | | | |
| 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 |
| **2014** | **2014-11 Roundtable Dinner** | | | |
| 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 |

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|---|---|---|---|---|
| 2014 | 15 | Inspection Readiness | Joseph Knight-McKenna | Quintiles |
| **2013** | **2013-11 Roundtable Dinner** | | | |
| 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 | |
| **2012** | **2012-11 Roundtable Dinner** | | | |
| 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-Sumission 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** | | | |
| 2011 | 1 | Companion Diagnostics | Susan Watts - drugs, Don Kafader - IVD | |
| 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 | Advisory Committee Meetings: 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 | |

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|---|---|---|---|---|
| 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** | | | |
| 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 | |