Annual Roundtable Dinner, November 12, 2026

At the Apella RTConference Center, 12 Davis Drive, Durham NC

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Table 1: Excelling as a Regulatory Professional

Speaker: Kevin Healy

Description of Talk

Regulatory professionals can have a tremendous impact on drug and device development and commercialization, paving the way for new therapies and products to reach patients in need. Whether you have just started your career or are a "seasoned professional", we all strive to continuously improve and maximize our contributions. This table will discuss what it takes to excel in Regulatory Affairs, and how different skillsets can be applied in different environments. The format will be interactive; contributions will be sought and welcomed from people of all experience levels.

Speaker Biosketch

Dr. Kevin Healy is Senior Vice President of Regulatory Affairs at Entrada, a biotech company focused on treating devastating diseases with intracellular therapeutics. As a member of the senior leadership team, Kevin is responsible for developing and executing global regulatory strategies. Kevin has extensive expertise in the development and commercialization of therapies for serious and rare diseases, and has led or participated in more than 30 formal Health Authority meetings. Prior to joining Entrada, Kevin oversaw Regulatory Affairs and other biotech-enabling functions, including Quality, Pharmacovigilance, and Compliance, at multiple biotech companies, including Enzyvant Therapeutics, Roivant Sciences, Mallinckrodt Pharmaceuticals, and Gilead Sciences. Kevin received his BS in Biological Sciences from Cornell University, a PhD in Biochemistry at the University of Wisconsin-Madison, and completed a postdoctoral research fellowship at the University of North Carolina at Chapel Hill.

Table 2: NOT AVAILABLE

Speaker:

Description of Talk

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Table 3: De-Risking the IV-to-SC Transition: An Integrated Development Approach to Formulation and Device Bridging

Speaker: Erica Peters

Description of Talk

Reformulation of monoclonal antibody therapies from IV to subcutaneous (SC) delivery is an increasingly important development strategy in oncology and chronic disease. This shift can improve patient convenience, reduce infusion burden, and enable more flexible administration options, including home-based use and device-enabled delivery such as prefilled syringes and autoinjectors. However, IV-to-SC transitions also introduce complex clinical, CMC, device, nonclinical, quality, and human factors considerations that must be integrated early to support development and regulatory success. This roundtable will discuss key regulatory and development considerations for IV-to-SC biologic reformulation, including supplemental BLA strategy, bridging approaches, comparability, nonclinical testing, combination product requirements, and human factors considerations. An integrated development timeline will be used to highlight cross-functional dependencies, critical path activities, and common regulatory risks from early development through FDA approval. The discussion is broadly applicable to regulatory affairs professionals involved in biologic and combination product development.

Speaker Biosketch

Dr. Erica Peters is a Senior Scientist in CMC and Biopharmaceutics at Kymanox, where she leads global regulatory strategy and cross-functional development programs for biologics and combination drug-device products, including IV-to-subcutaneous transitions and autoinjector platforms. She currently serves as Regulatory Lead on the MIT Catalyst Innovation Phase 2 team developing PRISM, an AI/ML-enabled imaging tool for early skin cancer detection. Dr. Peters holds a PhD in Biomedical Engineering from Duke University and completed postdoctoral training in polymer engineering and nanomedicine, focusing on peptide amphiphile nanofiber drug delivery systems. She has authored 17 peer-reviewed publications and holds one patent. Her work bridges quantitative modeling and regulatory strategy, supporting FDA, EMA, and PMDA engagement across the product development lifecycle.

Table 4: NOT AVAILABLE

Speaker:

Description of Talk

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Speaker:

Description of Talk

Table 6: AI in GMP: A Bioinformatician's Perspective on Validation

Speaker: Tom de Man

Description of Talk

As a bioinformatics scientist working at the intersection of computational methods and regulated life-science research, I will offer a scientific perspective on GMP validation of AI/ML systems. I will explain how these systems work under the hood to help translate technical characteristics into practical risk assessments. As AI enters GxP processes, how should organizations validate tools that may be probabilistic, adaptive, and a black box? This roundtable will explore technical controls, human oversight, data governance, change management, and how much model understanding is sufficient for effective validation and regulatory oversight. We will also discuss FDA, EMA, and regulatory developments and question reliance on legacy FDA software-validation paradigms that may burden modern AI without meaningfully improving quality or patient health.

Speaker Biosketch

Tom de Man is Head of the Omics and Machine Learning R&D Department at MilliporeSigma, supporting the BioReliance® services portfolio. His team develops and validates multi-omics bioinformatics algorithms, including machine-learning-based methods, for biosafety testing and biopharmaceutical product characterization. His work spans the translation of advanced computational approaches into robust, scientifically sound, and fit-for-purpose solutions for regulated life-science applications. Previously, Tom worked at the U.S. Centers for Disease Control and Prevention (CDC) and at several academic institutions, where he developed broad expertise in comparative genomics, software development, bioinformatics, and GxP data analysis. He has authored more than 20 peer-reviewed publications on molecular and bioinformatics topics, including pathogen detection and characterization. Tom holds both a Bachelor of Science (BSc) and a Master of Science (MSc) in Bioinformatics.

Table 7: AI as a Stress Test for Quality Culture: What Emerging Technology Reveals About Regulatory Readiness

Speaker: Elizabeth Gilbert

Description of Talk

Artificial intelligence is entering biotechnology industry at a pace that is testing more than technology controls. It is also testing quality culture. This roundtable will explore what AI adoption can reveal about the health of the quality system surrounding it. When new technology increases speed, uncertainty, and pressure, are accountability and oversight still clear? Can employees question AI-generated content or challenge implementation practices? Are concerns escalated openly? Are documentation and data-integrity expectations maintained? Does the organization learn from emerging risks, or respond only after a deviation, inspection finding, or failure? Using practical regulated-industry scenarios, participants will examine AI through a quality-culture lens, with emphasis on leadership accountability, speak-up and escalation behavior, human oversight, documentation integrity, organizational learning, and regulatory readiness. Participants will leave able to identify quality-culture conditions that can strengthen or undermine responsible technology adoption and consider how those conditions may become visible before they result in regulatory or operational failure.

Speaker Biosketch

Elizabeth Gilbert, DBA, ASQ CQA, is President of Trinity National Consulting and a Senior Advisor and Executive Consultant with PQE Group US. She brings more than 20 years of experience across pharmaceutical and biotechnology quality systems, investigations, CAPA and root-cause analysis, data integrity, validation, inspection readiness, and regulatory compliance. Her current consulting and research focus includes quality culture, organizational governance, responsible AI, leadership accountability, and workforce capability in regulated environments. Dr. Gilbert developed the Trinity Pillars® and PillarMetric® frameworks for examining quality culture and ethical readiness. She is also doctoral faculty, an ASQ Certified Quality Auditor, and a peer reviewer for the Journal of Pharmaceutical Innovation.

Table 8: Copilot in the Real Regulatory Medical Writing Workflow: Where It Saves Time, Improves Quality, and Falls Short

Speaker: Meagan Eldridge

Description of Talk

AI discussions often focus on drafting speed, but regulatory professionals and medical writers may realize greater value from Copilot for AI-assisted review, quality control (QC), and knowledge synthesis. This interactive roundtable will explore how Copilot can support regulatory medical writing through authoring, QC verification, and identification of scientific or regulatory imprecision. The discussion will also consider where AI adds little value or reduces efficiency, emphasizing its use where it improves quality or workflow while preserving human judgment and document ownership. Participants will be encouraged to share experiences, challenges, and metrics for evaluating success with Copilot and other AI platforms, including time savings, issue detection, QC depth, and workflow quality improvements.

Speaker Biosketch

Meagan Eldridge is President of Eldridge Writing, a regulatory medical writing firm specializing in partnered support for clinical-stage biopharma companies. Before founding the company, she held medical writing roles of increasing responsibility on both the sponsor and contract sides of the industry, supporting programs from early development through global marketing submissions. Meagan brings a strategic, execution-focused approach to medical writing leadership, partnering with clinical, regulatory, biostatistics, and operations teams to strengthen document quality, consistency, and submission readiness. Her experience spans all phases of development, multiple therapeutic areas, and deliverables including briefing documents, protocols, clinical study reports, and clinical modules for submissions.

Table 9: NOT AVAILABLE

Speaker:

Description of Talk

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Speaker:

Description of Talk

Table 11: Operationalizing ICH E6(R3): Translating Quality by Design from Protocol Concept to Regulatory Submission

Speaker: Matthew Barnes

Description of Talk

The final release of ICH E6(R3) marks a fundamental shift in clinical trial oversight, replacing reactive monitoring and "checklist compliance" with a proactive Quality by Design (QbD) approach centered on Critical-to-Quality (CtQ) factors. However, bridging the gap between theoretical guidelines and day-to-day clinical execution remains a key challenge for sponsors, CROs, and regulatory affairs professionals alike. This interactive roundtable discussion explores practical, cross-functional strategies for embedding QbD principles early in clinical development. Participants will examine how to align Clinical Operations, Regulatory Affairs, and QA teams prior to protocol freeze to identify true CtQs, eliminate non-essential data collection, and reduce avoidable post-approval protocol amendments. We will also address how to structure clinical study reports (CSRs) and trial documentation to demonstrate to health authority inspectors that data integrity and patient safety were built into the study architecture from concept to submission.

Speaker Biosketch

Matthew L. Barnes is a senior clinical development leader with 30 years of global clinical operations and executive leadership experience across the biotechnology, pharmaceutical, and CRO sectors. As the CEO and Principal Consultant at Praecur Consulting Services, he advises biopharmaceutical companies on optimizing clinical trial infrastructure, vendor governance, and risk-mitigation frameworks. Matthew specializes in operationalizing Quality by Design (QbD) methodologies and Risk-Based Quality Management (RBQM) to drive continuous inspection readiness across Phase I through Phase IV programs. His career includes executive and senior leadership roles at organizations such as Labcorp, UCB, Virpax, and Envisia. He is an active contributor to industry education on clinical trial execution and regulatory compliance, including recent presentations for the North Carolina Regulatory Affairs Forum (NCRAF) on clinical protocol design and development planning.

Table 12: NOT AVAILABLE

Speaker:

Description of Talk

Table 13: Bypassing PK Bridging Studies for Drug-Device Combination products via MIDBA: Global, Drug, Clinical, and Device considerations

Speaker: Rita Lee

Description of Talk

With the finalization of the Molecule Independent Bridging Approach (MIDBA) in March 2026, the European Medicines Agency (EMA) has introduced a landmark shift in regulatory science for drug-device combination (DDC) products, which may have global implications. This roundtable explores how sponsors can leverage MIDBA to omit molecule-specific pharmacokinetic (PK) bridging studies when transitioning from hand-held or pre-filled syringes (PFS) to autoinjectors. We will break down essential drug, clinical, and device considerations and conditions required to successfully bridge to pre-existing reference product data. Attendees will gain actionable insights on how to navigate this new regulatory pathway to potentially reduce clinical costs and accelerate time-to-market.

Speaker Biosketch

Rita Lee PhD RAC (US, Global) has 15+ years of regulatory affairs strategy experience in regulated combination products, medical devices, and drug products, in startups and large companies. She served for over five years as global regulatory device lead for combination products and devices. Rita is currently a Senior Manager in Regulatory Affairs, Devices at GSK, focused on combination products.

Table 14: NOT AVAILABLE

Speaker:

Description of Talk

Speaker Biosketch

Table 15: Building Better Evidence and Optimizing Market Access: Hidden Opportunities to Improve Regulatory Success

Speaker: Tara Kervin

Description of Talk

Successful regulatory submission and market adoption require more than regulatory expertise or statistical rigor alone. Many of the decisions that ultimately determine success are made before a single patient is enrolled, yet statisticians are often engaged only for data analysis after development decisions are finalized. This roundtable will explore the emerging discipline of "regulatory statistics" and how earlier collaboration between Regulatory Affairs, Clinical Development, Medical Writing, and Statistics can improve study design, evidence generation, regulatory interaction, and submission and market strategy. Participants will discuss practical examples involving dose optimization, patient-centricity, accelerated approval pathways, endpoint strategy, and evidence storytelling. Intended for regulatory professionals, clinical scientists, medical writers, and statisticians seeking to strengthen cross-functional decision-making and maximize the regulatory value of clinical evidence. Through open discussion, we will explore where Regulatory Affairs and Statistics intersect, common communication gaps between functions, and practical approaches for engaging earlier in development.

Speaker Biosketch

Tara A. Kervin, MPH, is Chief Strategy Officer & Managing Director US at IDDI, a global clinical data science organization specializing in regulatory strategy, biostatistics, and research methodology. She is a clinical trialist, biostatistician, and epidemiologist with two decades of experience supporting drug development from first-in-human through regulatory approval. Tara works at the intersection of science, operations, and business strategy, helping sponsors navigate complex development, regulatory, and commercialization challenges through innovative biometrics and regulatory-grade data. She has extensive experience in supporting FDA/EMA interactions and independent data monitoring across multiple therapeutic areas. Tara is an active contributor to research initiatives focused on improving clinical evidence generation and patient safety. She is passionate about bridging the gap between Regulatory Affairs and Statistics to get effective new treatments to patients faster.

Table 16: AI, AI, AI: Are Regulators Singing the Same Song for Global Product Development?

Speaker: Prem Narang

Description of Talk

What is similar, or different, between the two largest regulatory agencies—FDA and EMA—when it comes to artificial intelligence (AI)? How deeply should one understand the lyrics of the song they are singing and what are the important notes to remember? We will briefly review and compare the current approaches toward AI in medicines regulation, clinical development, and regulated product lifecycle management. While both agencies emphasize trustworthy AI, human oversight, transparency, and risk-based governance, they differ in regulatory philosophy and implementation. FDA and the EMA have converged on a common principle: AI can improve drug development, manufacturing, pharmacovigilance, and regulatory decision-making only if its outputs are reliable for a given regulatory decision. Neither regulator considers AI exempt from existing Good Practice (GxP) requirements; it is viewed as another computerized system whose outputs must be validated. We will discuss similarities and differences in evolving regulatory frameworks and contexts, and places where sponsors designing AI-enabled drug development programs could build a single global quality framework that can satisfy both.

Speaker Biosketch

Prem Narang ('P.K.') serves as the President of P.K. Narang Strategic Consulting, which provides advisory services to businesses on development-regulatory matters. He brings >35 years of experience and a track record of strategic, scientific and operational successes leading to 16 new drug approvals. He has held Global leadership roles in Regulatory & Quality domains. Prior to that, he was the US Head for the Clinical Pharmacology/PK function at a large pharma. He received his Ph.D. in Pharmacokinetics from University of Maryland. He currently serves as a Chief Scientific Officer/Advisor to Bloqcube, and Development Advisor to Ordaos. He is an EAC member to the MPS Program in Regulatory Science and an Adjunct Associate Professor at UNC-ESOP.

Table 17: Regulatory Intelligence - Why it matters on so many levels

Speaker: Kirsten Messmer

Description of Talk

Regulatory intelligence (Reg Intel) is more than tracking regulations and agency announcements. It is the process of finding, evaluating, interpreting, and connecting regulatory information to understand what it means for products, development programs, and business decisions. This discussion will explore what Reg Intel is—and what it is not—including the difference between information, intelligence, and regulatory strategy. We will look at where useful intelligence comes from, how to identify credible sources, and how to distinguish meaningful regulatory trends from isolated events or noise. Ultimately, effective Reg Intel helps organizations move from "What happened or is likely to happen?" to "What does it mean, what might happen next, and what should we do about it?"

Speaker Biosketch

Kirsten Messmer, PhD, RAC, is the owner of KM Intel LLC, which supports companies with actionable intelligence to inform their policy and regulatory strategy. She was previously a Senior Research Analyst and contributed to the research for AgencyIQ on regulatory issues affecting the bio-/pharmaceutical industry in the US and Europe. Before that, Kirsten was a Principal Regulatory Affairs Specialist at PPD providing global regulatory intelligence to support efficient, compliant, and successful clinical research and drug development for biopharmaceuticals and advanced therapies. Kirsten has held additional positions in university and biotechnology research and has 14+ years of experience in regulatory affairs with a particular focus on regulatory intelligence. Kirsten received her PhD in Neuroscience from the University of Sheffield (Sheffield, UK), and holds a Regulatory Affairs Certification (RAC) in US regulation.