Annual Roundtable Dinner, November 12, 2026

At the Apella RT Conference Center, 12 Davis Drive, Durham NC

Contents

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: Navigating Career Transitions from Academia to Medical Writing

Speaker: Stephanie Byrd

Description of Talk

This roundtable will offer an in-depth examination of the speaker's professional evolution from academia to the clinical research industry—as a project manager and medical writer—and ultimately to independent medical writing and consulting. Through this structured discussion, participants will gain insight into how each transition required a recalibration of identity, a reconfiguration of core competencies, and a reconsideration of what constitutes professional achievement. The session will outline the expectations of academic life, the operational tempo and collaborative demands characteristic of CRO and pharmaceutical medical writing, and the entrepreneurial autonomy central to freelance medical writing. By comparing each of these environments, the roundtable will highlight the different pressures, performance metrics, and opportunities within each stage of the speaker's career.

Speaker Biosketch

Stephanie Byrd, PhD, RAC is an independent medical writer and formed her firm, Carolina Lily Medical Writing & Consulting, LLC, in 2026. Most recently she was a Principal Medical Writer at Syner-G BioPharma Group where her primary responsibilities as a medical writer included authoring CSRs, protocols and amendments, IBs/IB updates, briefing documents, submission documents, and regulatory responses and project management tasks that accompany these projects. Prior to this, Stephanie was a Project Manager at Nuventra Pharma Sciences and an Analytical Development Specialist at Medicago. Stephanie received her BS in Biology from Wake Forest University in 2008, her PhD in Plant Biology with a minor in Biotechnology from North Carolina State University in 2013, and has had her RAC since 2019.

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: When the Protocol Meets the Real World: Regulatory Challenges in Clinical Trial Execution

Speaker: Dong Hodgkins

Description of Talk

Clinical trial protocols are designed to provide clear instructions for study conduct, but real-world execution often presents situations that are not explicitly addressed in the protocol. This interactive roundtable will explore common regulatory and operational challenges encountered when translating protocol requirements into clinical practice. Through practical examples, we will discuss protocol interpretation, protocol deviations, safety reporting, IRB considerations, documentation practices, and the responsibilities of sponsors, CROs, and investigative sites. Participants will be encouraged to share experiences and discuss approaches for managing regulatory gray areas while maintaining patient safety, data integrity, GCP compliance, and inspection readiness.

Speaker Biosketch

Dong Hodgkins, PhD, MBA, is the Founder and CEO of Wakefield Clinical Research, an integrated CRO and clinical trial site based in North Carolina. She has extensive experience supporting clinical development programs for drugs, biologics, and medical devices, spanning clinical operations, regulatory affairs, study start-up, site management, monitoring, and sponsor oversight. Dr. Hodgkins works closely with biotechnology and pharmaceutical companies to translate clinical development plans and regulatory requirements into practical study execution. Her experience from both CRO and investigative-site perspectives provides insight into real-world regulatory and operational challenges. Her areas of interest include GCP compliance, protocol implementation, regulatory strategy, IRB oversight, inspection readiness, and clinical research quality systems.

Table 5: EMA Policy 0070: the 6-month project hiding inside your MAA

Speaker: Evan Richardson

Description of Talk

EMA Policy 0070 and Health Canada's PRCI make sponsors publish clinical documents that once stayed between them and the regulator. Most regulatory professionals know they exist. Far fewer have worked one. A primer on what happens after the notification arrives. You will leave able to describe what 0070 and PRCI require, and where they diverge; build a timeline, staffing plan, and budget for a redaction package; and spot the failure modes that cost sponsors time, including starting late, thin anonymization methodology, and CCI claims that will not survive review. EMA's relaunch pulls in more sponsors every quarter, and the work gets underestimated because it looks like redaction and behaves like a submission. This discussion is for regulatory professionals at any level who know 0070 by name but have not run one.

Speaker Biosketch

Evan Richardson began his career in the pharmaceutical industry 20 years ago and today serves as Senior Director of Regulatory Operations & Clinical Disclosure at Veristat. His experience includes drugs, biologics, and medical devices, and he has worked for both service providers and industry organizations of all sizes. Evan has held many roles throughout his career, including regulatory affairs, regulatory operations, quality management, and project management. In his current role, Evan leads a global team of subject matter experts at Veristat, helping clients navigate electronic regulatory submissions and clinical data disclosure requirements.

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: Application of Safety Standards and Market Access as Design Inputs

Speaker: Rahul Baria

Description of Talk

How often do we discover a compliance or market access requirement after the design is already well underway? This discussion will focus on moving those considerations upstream and treating safety standards and market access requirements as foundational design inputs, not afterthoughts. With increasing regulatory complexity and pressure to launch products globally, integrating compliance requirements early has never been more important. This discussion will be valuable for R&D, Systems Engineering, Quality, Regulatory Affairs, Product Development, and Design Assurance professionals.

Speaker Biosketch

Ex UL, Rahul Baria is a Principal Compliance Specialist with a passion for helping teams integrate compliance, safety, and regulatory requirements into product development from the outset. Throughout his career, he has worked closely with engineering, quality, and regulatory professionals to translate safety standards and market access requirements into practical design inputs that support successful global product launches. His experience spans product compliance, standards application, risk management, design controls, and international market access strategies. He enjoys fostering cross-functional collaboration, sharing lessons learned, and helping organizations reduce compliance risks while improving development efficiency. His focus is on enabling teams to view compliance not as a hurdle, but as a key enabler of safe, effective, and globally marketable products.

Table 10: Revising EU Device Regulations - Boon or Bane?

Speaker: Stefan Burde

Description of Talk

On December 16, 2025, the European Commission published a proposal to update the medical device and in vitro diagnostics regulations (MDR and IVDR). The stated goals are simplification, proportionality, reduction of administrative burden and encouraging innovation, while maintaining patient safety. In this session, we will take a look at some of the proposed changes and evaluate their potential impact on various stakeholders in the CE-marking process for medical devices. The session will be of interest to manufacturers of medical devices who want to market or continue to market their devices in the European Union.

Speaker Biosketch

Stefan Burde, PhD is the founder and principal consultant of IVDR Solutions, a regulatory consultancy focused exclusively on helping IVD manufacturers master the CE-marking process. Stefan holds a PhD in Pathology from the University of Rochester, and has over 13 years of experience in the in vitro diagnostic industry and over 10 years of Notified Body experience as an auditor, technical documentation reviewer, and strategic director. He has spoken extensively at international conferences on topics related to IVDR implementation and compliance.

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: Roundtable Q&A on Recent FDA Guidance on Cell and Gene Therapy Products

Speaker: Scott Burger

Description of Talk

Cell and gene therapy is in a remarkable growth phase, with more than 750 active INDs in the US alone and a surge of FDA approvals. In support, FDA has stepped up release of CGT-specific guidance documents, nine since the beginning of 2025. Helpful as these guidances are, interpreting and applying them can be a challenge. This roundtable will discuss common questions—including participants' own—about recent CGT guidance. We will focus on 2025–26 guidances, but others are fair game too. Examples of guidance to be discussed include potency assessment of active immunotherapy products vis-à-vis the draft guidance on potency assurance for CGT products; leveraging prior knowledge in development of human gene therapy products incorporating genome editing; CMC flexibilities for developing human CGT products for BLA; the plausible mechanism framework for individualized therapies; and the FAQ on developing potential CGT products. The session is intended to provide practical insights into how to interpret and apply recent FDA guidance to CGT products of interest to participants. This will be particularly useful for those involved in CGT development, regulatory strategy, CMC, and quality.

Speaker Biosketch

Scott R. Burger, MD, is founder and principal of Advanced Cell and Gene Therapy, a consulting firm focused on cell and gene therapy product development, manufacturing, regulatory affairs, and commercialization. With more than 30 years of experience, Dr. Burger has supported more than 200 companies worldwide, helping advance therapies at all stages of development. He is widely recognized for his expertise in regulatory affairs and has advised on over 150 regulatory submissions for cell and gene therapy products. Dr. Burger has served on the USP Cell, Gene and Tissue Therapies Expert Committee, chaired the ISCT Global Regulatory Perspectives Workshop organizing committee, been an invited speaker at FDA workshops, and authored more than 200 scientific publications and presentations. He earned his MD from the University of Pennsylvania School of Medicine and completed training in clinical pathology and transfusion medicine at Washington University in St. Louis.

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: The submission is becoming Data, not Documents: Verification Infrastructure, Not Generation Quality, Determines the Value of AI in Regulatory Writing

Speaker: Tim Spaeder

Description of Talk

Filing timelines have compressed sharply: a 62-company benchmark study authored by McKinsey puts best-in-class submission timelines at 8.0 weeks from database lock and 18.6 weeks for median organizations. That 10+ week difference equates to roughly $60 million in NPV per month for a $1B asset. Yet only 10–13% of companies in the McKinsey study have scaled any portion of the regulatory submission process with AI automation. Regulators have industrialized their side of submission approval in the US. For example, the FDA has consolidated 40+ submission data sources into one AI-accessible platform, and they have run structured, rules-and-risk quality assessment since 2021, compared to sponsors who still send roughly 14,000 unstructured PDF submissions a year to the FDA. This talk will focus on AI solutions that are available and best practices to utilize AI based on verification of prose as opposed to the quality of the draft.

Speaker Biosketch

Tim Spaeder is an Account Executive at Weave Bio, where he helps CROs, Sponsors and CDMOs use AI to accelerate IND and NDA submissions specifically for the pharma and biotech part of the life science industry. Prior to working at Weave he was at Dassault Systèmes supporting Enterprise Life Science companies in early preclinical research utilizing AI drug discovery tools. With over 25 years in the Life Science industry experience Tim brings a unique perspective to how AI has been and is being used in both upstream and downstream drug development. Tim holds a Ph.D. from Penn State University and currently lives in Apex, NC with his wife and two daughters.

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.