SPEAKER BIOS

John Avellanet

Managing Director and Principal, Cerulean Associates LLC

John Avellanet is the author of *Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine* (2010, Logos Press) and founder of the FDA compliance consulting firm, Cerulean Associates LLC. Prior to founding Cerulean, John was a Fortune 500 combination device C-level executive who created, developed and ran his company's compliance programs to achieve ISO, FDA, DEA, and HIPAA compliance. During his career, he has had to defend decisions to inspectors, auditors and litigators alike. John is also an expert member of the ISPE Data Integrity Working Group. He now brings that real-world experience and practical advice to his consulting clients, articles and speeches.

David Borasky

Vice President of IRB Compliance, WIRB-Copernicus Group (WCG)

David Borasky Jr. serves as Vice President of IRB Compliance for the WIRB-Copernicus Group (WCG). In this role, he is responsible for leading the quality and compliance activities for all of the WCG institutional review boards (IRBs). David has 20 years of experience in managing IRBs in global public health organizations, large academic medical centers and independent IRBs. He has facilitated training activities on basic research ethics and IRB operations and management for IRB staff and members for institutions and IRBs throughout the U.S. and abroad. He has served as a consultant for the Office for Human Research Protections, the U.S. Department of Energy, the World Health Organization, and numerous other institutions. David currently serves as co-chair of the subpart A subcommittee of the HHS Secretary's Advisory Committee on Human Research Protections. Borasky is a Certified IRB Professional and former member of the board of directors of Public Responsibility in Medicine and Research (PRIM&R). In 2018, he was named a distinguished leader of PRIM&R. David received his undergraduate education at Le Moyne College and his master's degree in public health leadership from the University of North Carolina at Chapel Hill.

Alonza Cruse

Director, Office of Pharmaceutical Quality Operations, ORA, FDA

Alonza Cruse is director of the Office of Pharmaceutical Quality Operations within the Office of Regulatory Affairs (ORA) in the Food and Drug Administration (FDA). His office is responsible for all pharmaceutical quality inspections and investigations, working in conjunction with FDA's Center for Drug Evaluation & Research and the Center for Veterinary Medicine. Additionally, Alonza is leading ORA's pharmaceutical collaboration efforts under our program alignment initiative. From 2013 – 2015, Alonza served as the acting director of the Office of Medical Products & Tobacco Operations within ORA, overseeing activities such as implementation of the Generic Drug User Fee Amendments, of pharmacy compounding, and the development of a new inspection protocols program. Prior to that, Alonza was the director of the Los Angeles District Office, where his responsibilities included providing executive leadership to implement, manage and evaluate FDA's regulatory operations. Mr. Cruse first joined ORA in 1983 as a microbiologist. He received his bachelor's of science degree in medical technology from York College (City University of New York).

Chalana Damron

Counsel, Crowell & Moring

Chalana N. Damron is a counsel in the firm's Mass Tort, Product, and Consumer Litigation Group. Chalana represents clients across numerous industries, in a diverse array of litigations, including commercial, antitrust, class action, and product liability. Chalana's litigation practice spans numerous industries including aviation, healthcare, pharmaceutical and food & beverage. Chalana also provides counseling regarding product liability, risk management, and consumer product regulatory compliance, with a focus on products regulated by the Food and Drug administration. Chalana assists clients with preparing for FDA inspections, evaluating quality systems and responding to FDA 483 observations. Chalana also develops and conducts comprehensive training programs to assist regulatory executives and marketing teams with understanding and complying with U.S. food regulations. In addition, she regularly evaluates and offers commentary on litigation and regulatory developments impacting FDA-regulated industries and provides clients with mechanisms to limit the risk of marketing-related challenges by plaintiffs and regulators.

David Elder

Executive Vice President, Greenleaf Health

David Elder brings more than 30-years of extensive regulatory experience to his role as Executive Vice President for Regulatory Compliance at Greenleaf Health. A 23-year veteran of the U.S. Food and Drug Administration (FDA) and U.S. Public Health Service (USPHS), David served as a senior FDA official with prominent roles in domestic and foreign inspections, recalls and emergencies, and compliance actions involving hundreds of situations. He has testified in federal court and before Congress, initiated and approved enforcement actions, and represented the FDA during national media events. Additionally, David has received numerous honors, including the Distinguished Service Medal. David began his FDA career as an investigator in the Boston District Office where he conducted domestic and foreign inspections and investigations in various program areas. He was selected as a compliance officer and later as the director of the compliance branch with responsibility for assessment of inspection reports, initiation of compliance actions and evaluation of compliance action effectiveness. David transferred to FDA headquarters when he was selected as the director of the FDA Office of Enforcement in 2003, a position he held for the next six years. In this senior executive service position, David led the Office with responsibility for agency enforcement policy, agency recall policy and operations, and enforcement strategy and case review

Kristen Grumet

Senior Vice President, Regulatory Compliance, Greenleaf Health

Kristen Grumet is an expert in the field of medical device compliance, with nine years of experience as an FDA field investigator specializing in medical devices and 21 years of quality systems compliance management and consulting for the industry. As a member of FDA's Design Control Inspection Strategy (DCIS) Team and FDA's Pacific Region Design Control Training Cadre, Kristen contributed to the development and implementation of the DCIS questionnaire for medical device inspections and trained companies in the use of the questionnaire. She was a Phase II-certified performance auditor in the area of medical devices at FDA and has the distinction of being part of the first cadre of certified medical device investigators in FDA history, conducting numerous inspections of European medical device facilities during her six-year tenure with the FDA foreign inspection cadre. In her work with medical device companies, Kristen has managed successful third-party certifications for companies under consent decree. She has led projects across the spectrum of quality assurance and regulatory compliance activities, including: compliance assessments, internal audits and investigations, quality systems and validation program development and implementation, corrective action planning and quality system remediation, and QSR and FDA inspection readiness training. As senior vice president of regulatory compliance at Greenleaf Health, Kristen continues to provide medical technology clients with customized guidance and support in developing and implementing strong corporate quality systems and regulatory strategies for compliance.

Connie Hoy

Consultant, Hoy & Associates Regulatory Consulting

Connie Hoy, founder of Hoy & Associates Regulatory Consulting, has over three decades of experience in the medical device industry. Time and again Connie and Hoy & Associates have helped companies obtain important global regulatory approvals and pass foreign and domestic audits. She and the firm are well-versed in the workings of the FDA, helping companies of all sizes with pre-submission meetings and submission preparation. The firm offers internal auditing and gap analysis for quality management systems and provides full-scope audits including FDA 21 CFR, ISO 13485:2016, Medical Device Single Audit Program (MDSAP) and electronic product reporting, providing audit reports for regulatory agencies that will withstand the most rigorous scrutiny. Connie is intimately familiar with the day-to-day challenges of developing strategies and obtaining approvals, developing and maintaining quality management systems and encouraging a culture of compliance. Before forming Hoy & Associates, Ms. Hoy was executive vice president of regulatory, quality and clinical development at Cynosure, a division of Hologic. Prior to that, she served as senior vice president of global regulatory affairs and quality assurance at Cynosure, Inc. and vice president, regulatory affairs and quality assurance, Cutera, Inc.

Susan Leister

Vice-President of Quality & Compliance of Technical Resources International

Dr. Susan Leister, Vice-President of Quality & Compliance of Technical Resources International, boasts 20-plus years of industry experience and holds CQA and CSSBB certifications from the American Society for Quality. Susan serves on the ASQ Section 509 Executive Committee and served as a 2012 and 2013 Maryland Performance Excellence Award examiner and a 2013 ASQ International Team Excellence award judge. She has served as a part-time faculty member of the University of Phoenix Undergraduate and Graduate School of Business for the past five years.

Brian Ludovico

Executive Director, MDSAP Regulatory Certification, NSF Health Sciences

Brian Ludovico has more than 20 years' experience in medical quality systems and regulatory certification requirements. He is currently the executive director of the Medical Device Regulatory Certification Program at NSF International which includes the global Medical Device Single Audit Program (MDSAP). Brian represented the Auditing Organizations (AO) group during the development and implementation of the MDSAP and currently sits as the chair of the AO group that interfaces with the participating regulatory authorities. He is an active board member of the American Society for Quality (ASQ) Biomedical Section New England Discussion Group (NEDG) and a member of RAPS (Regulatory Affairs Professionals Society). He was formerly with the Certification Body/Notified Body TUV Rheinland Group for 21 years, most recently as the certification manager of the Americas. In that capacity, Brian was also responsible for the global management of the Canadian Medical Devices Conformity Assessment System (CMDCAS) and the Medical Device Single Audit Program (MDSAP), and represented all Certification Bodies under CMDCAS as the Chair of the Health Canada-Registration Body Forum held with the Regulatory Authorities. He was active in issues concerning the Global Harmonization Task Force, the FDA AP (Accredited Persons) and Third-Party Review Programs, and the PMAP (Pilot Multipurpose Audit Program) between the U.S. and Canada.

Steven Lynn

Principal GxP Consultant/Owner, Lynn Consulting

Steve Lynn has over 20 years of quality and regulatory compliance related experience in the pharmaceutical, biopharmaceutical, medical device, blood, plasma and tissue industries. He served in executive leadership roles with global accountability in both the private sector, as well as at the U.S. FDA. Steve is an expert in cGMP compliance related matters and has significant experience with other GxP quality compliance and regulatory issues. Steve is currently the principal consultant/owner for Lynn Consulting, LLC, which provides expert GxP consulting services to the life sciences industry. Prior to this role, he was the global head of group (corporate) compliance and audit at Novartis AG. In this role, Steve led the corporate compliance and audit functions for Novartis. Prior to joining Novartis, Steve was the inaugural vice president of global quality compliance at Mylan, Inc. in Canonsburg, PA.

Prior to Mylan, he was the director of the CDER Office of Manufacturing and Product Quality within the Office of Compliance. In this role he was responsible for the global cGMP oversight of all drugs manufactured and/or imported into the U.S. to assure compliance with cGMPs. In addition, in his last year at the FDA he served in a dual position as the Operations Transition Lead for CDER's new Office of Pharmaceutical Quality reporting to CDER's Center Director where he was responsible for setting up OPQ operations.

Steve received his bachelor's of science degree in Biology from Bethany College in Bethany, WV, and his master's of Science Degree in quality systems management from the National Graduate School in Falmouth, MA. He is an Eagle Scout, senior member of the American Society for Quality (ASQ) and an Excellence in Government Program Senior Fellow.

Chris Markus

Partner and Deputy Chair, FDA & Life Sciences Practice, King & Spalding

Chris Markus focuses on federal and state regulation of drugs, biologics, biotechnology and related products. As a partner in our FDA and Life Sciences practice and Deputy Practice Group Leader, Chris represents clients in a range of regulatory strategy and compliance evaluations, enforcement matters, and business transactions. She represents drug, biologic and other healthcare products companies and investors with compliance and enforcement under the Food and Drug Administration, the Drug Enforcement Administration (DEA) and related state agencies such as boards of pharmacy. She also represents clients in business transactions, including strategic planning, due diligence and assessment, that involve product development and approval, safety, labeling, marketing and advertising, manufacturing and supply chain. Based on her experience, Chris was chosen to serve as the legal member of the Institute of Medicine's Committee on Pediatric Studies conducted under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. IOM evaluated studies of drugs and biologics performed under two statutory regimes that provide incentives and, in some instances, mandate pediatric research through the drug approval process. The Committee assessed the findings and offered recommendations and briefings to FDA and the U.S. Congress. Committee findings and recommendations were considered during the reauthorization of BPCA and PREA in July of 2012.

John McKay

CEO and Chief Compliance Officer, Q1 Associates LLC

John McKay has 34 years of global executive and senior management experience, training, and knowledge working for small, medium, and large companies in the following industries: pharmaceutical, medical device, combination products, biotechnology, chemical, healthcare, energy, automotive, aerospace, IVD. John brings a wealth of global training, experience, knowledge, leadership, certification, and senior management achievements working in the following functional areas: quality, compliance, regulatory Affairs, clinical affairs, operational excellence, validation, EHS, project management, manufacturing, engineering, training, auditing, maintenance, reliability, supply chain management, distribution, warehousing, continuous improvement, lean manufacturing, Six Sigma, and product development. Starting as a chemical engineer, John has achieved company objectives and contributed through global job positions at the following levels: manager, regional manager, global manager, director, vice president, senior vice president, and chief compliance officer. John has helped to implement every version of various ISO Standards, has successfully hosted regulatory agency inspections from the FDA, EMA, MHRA, Health Canada, TGA, China NMPA, PMDA, ANVISA, WHO, EPA, OSHA, DOT and other global regulatory agencies. John has served as the management representative for ISO Standards for over 30 years, and is an expert in GMP, GCP, GLP, GDP, GVP, QMS. LMS, DCS, CSV, SQC, SPC, validation, and these ISO Standards: ISO 9001, ISO 13485, ISO 14971, ISO/IEC 17025, ISO 15189, ISO 14001, OHSAS 18001, ISO/TS 16949, ISO 45001, AS 9100.

John McKay has completed various GxP projects, product approvals, product launches, audits, operational excellence/ISO/QEHS implementations, or expatriate assignments in the following countries: U.S., Mexico, Canada, UK, Ireland, Wales, Czech Republic, Austria, France, India, Brazil, Australia, Germany, Netherlands, Italy, Belgium, Indonesia, Japan, Taiwan, Singapore, Israel, China, Portugal, Spain, Macau, Sweden, and South Africa. John has the following Quality and EHS certifications: ASQ CMQ/OE, CQA; exemplar global lead QMS auditor, Lead ISO 13485 medical device auditor; lead EMS auditor (ISO 9001); NREP registered environmental Manager (REM), certified environmental auditor (CEA). John completed his B.S. in chemical engineering from Pennsylvania State University, is a graduate of the Wharton Management Program, Wharton School of Business, University of Pennsylvania, and is completing the Master's of Science (MS) Degree in Regulatory Affairs and Quality Assurance (RAQA) at Temple University Graduate School of Pharmacy. John also completed the following: Drug Development Certificate at Temple University Graduate School of Pharmacy, Certification for Engineer-in-Training (EIT), and the Project Management Institute Certificate at the Katz Business School, University of Pittsburgh for training as a Project Management Professional (PMP®).

Steve Niedelman

Lead Quality Systems and Compliance Consultant, King and Spalding LLP

Steve Niedelman serves as lead quality systems and compliance consultant to the FDA & Life Sciences practice team at King & Spalding, specializing in regulatory, enforcement and policy matters. He provides strategic advice, insight and guidance to the medical device, pharmaceutical, biologics and food industries to ensure FDA compliance. Steve retired from the FDA in 2006 after a 34-year distinguished career, serving as the deputy associate commissioner for regulatory affairs and as chief operating officer of the Office of Regulatory Affairs. He ensured consistent interpretation of the FDA's regulatory policies by directly overseeing offices at the headquarters of ORA, including the Office of Regional Operations, Office of Enforcement and Office of Criminal Investigations. Additionally, Steve assisted in the day-to-day management of the FDA's nearly 3,400 field staff responsible for investigative and laboratory operations. While at ORA, Steve served as the principle liaison to the CDRH and was a member of the GHTF Steering Committee, FDA/Medical Device Industry Grassroots Initiative Steering Committee and the CDRH Post Market Initiative Steering Committee. He also served on the steering committee to the pharmaceutical cGMP for the 21st Century Initiative as well the Counterfeit Drug Task Force. Prior to joining the Office of the Associate Commissioner, he was the director and deputy director of the FDA's Office of Enforcement, where he was responsible for oversight and consistency of compliance policy, enforcement and recall activities. Steve currently participates as a member of the Medical Devices Committee at FDLI and as a member of the editorial review boards for FDAnews' GMP publications.

Dan O'Leary

President, Ombu Enterprises LLC

Dan O'Leary has more than 30 years of experience in quality, operations and program management in regulated industries, including aviation, defense, medical devices and clinical labs. Dan is now president of Ombu Enterprises LLC, a consultancy focused on operational excellence and regulatory compliance serving small manufacturing companies. He has a master's degree in mathematics, is an ASQ-certified biomedical auditor, quality auditor, quality engineer, reliability engineer, Six Sigma Black Belt, and is certified by APICS in resource management.

Sharon Reinhard

Executive Director, Merck

Sharon Reinhard has over 20 years of industry experience comprised of a unique blend of roles in clinical development, operations, compliance and quality assurance. She has worked for large companies such as Wyeth, mid-sized companies such as Shire and Endo and small biotech companies like Solstice Neurosciences and iCeutica. Prior to joining the industry, Sharon spent four years working in academic research at the University of Pennsylvania. She has developed expertise in GCP, risk-based approaches, quality by design and inspection readiness. During her career, she has supported 10 NDA filings, over a dozen sponsor regulatory inspections and performed countless vendor, site, document and process audits. Sharon has published over a dozen abstracts and articles related to clinical research. She has also served as chair and/or speaker at numerous industry conferences. She earned her undergraduate degree from the University of Pennsylvania in biology and english and her master's of science in pharmaceutical sciences from Temple University School of Pharmacy. In 2014, Sharon transitioned to independent consulting to provide "right-sized" clinical development and QMS services to a variety of pharmaceutical and biotechnology companies. In November, 2018, she joined Merck in the quality assurance division after supporting the company in a consulting role the previous two years.

CAPT Helen Saccone

Senior Advisor, Office of Strategic Programs, CDER, FDA

CAPT Helen Saccone serves as a senior advisor within CDER's Office of Strategic Programs. Helen was part of the inaugural team that initiated the US-EU Mutual Reliance Initiative in 2014, that led the negotiations and implementation of the US-EU Mutual Recognition Agreement for the FDA.

Helen joined FDA in 2008 as a program management officer within CDER's Office of Compliance, then served as the associate director of Global Policy within FDA's Office of Commissioner. Prior to joining FDA, she worked as a pharmacy inspector for the DC Department of Health and a senior manager of education at the American Pharmacists Association. CDR Saccone received her doctorate of pharmacy from Rutgers University and was commissioned into the U.S. Public Health Service in 2009.

Marc Scheineson

Partner, Alston & Bird LLP

Marc Scheineson is a Partner in the Washington, DC, office of Alston & Bird. He heads the firm's food and drug law practice. Marc previously served as associate commissioner for legislative affairs at the FDA. He came to Washington to work as legislative assistant and counsel to Rep. Bill Gradison (R-OH), the ranking member of the Health Subcommittee of the House Ways and Means Committee. In addition, he worked as a regulatory FDA lawyer for another national law firm, and senior vice president of Ketchum Communications and as a principal in its government relations unit. Marc is a former Co-Chairman of the American Bar Association's Committee on Food and Drug Law; chaired the Task Force on FDA Reform and is a former Chair of the Young Lawyers Section of the Bar Association of the District of Columbia. He received his B.A. and J.D. from the University of Cincinnati and its College of Law and his L.L.M. from the Georgetown University Law Center.

Cynthia Schnedar

Executive Vice President, Regulatory Compliance, Greenleaf and former Director of the Office of Compliance, CDER, FDA

With more than 25 years of experience as an expert in compliance issues – including more than 20 years in leadership positions in the government – Cynthia Schnedar adds to Greenleaf Health's prestige as executive vice president, regulatory compliance. Cynthia was formerly Director of the Office of Compliance for CDER, where she led a staff of more than 300 doctors, scientists, manufacturing experts, pharmacologists, attorneys and administrative staff. During her time at the FDA, she spearheaded efforts to protect the American public from unsafe and ineffective drug products by ensuring that companies comply with federal standards for quality and safety. Among her many duties, Cynthia advised the FDA commissioner, the CDER director and other senior FDA officials on significant enforcement issues. Before joining the FDA in 2014, Cynthia spent more than two decades at the DOJ, where she specialized in compliance and enforcement issues. Her most recent position was as deputy inspector general and acting inspector general, where she led a nationwide staff in investigating allegations of corruption and misconduct concerning DOJ's employees and in conducting independent audits of the department's operations and programs. She communicated significant findings from the investigations and reviews to the attorney general and to Congress. Cynthia's other positions at DOJ also provided her with an extensive background in criminal and civil enforcement work. They included counselor to the Inspector General, deputy chief of the Sex Offense and Domestic Violence Section in the U S Attorney's Office for the District of Columbia, assistant U.S. attorney, and trial attorney in the Civil Fraud Section of the civil division. Previously, Cynthia clerked for a federal judge on the Ninth Circuit and worked as a television reporter in New Mexico and Texas. Cynthia earned a B.A., with distinction, from the University of New Mexico and a J.D., with honors, from the University of Texas School of Law.

Susan Schniepp

Fellow, Regulatory Compliance Associates, Inc.

Susan Schniepp is a fellow at Regulatory Compliance Associates, Inc. As a pharmaceutical quality assurance thought leader with 35 years' experience, Sue has held leadership roles in industry at Allergy Laboratories, Inc., OsoBio Pharmaceuticals, LLC, Searle, Abbott and Hospira. She is a member of the PDA Board of Directors and has served as PDA / FDA Joint Regulatory Affairs Conference Chair, conference presenter and chair of the PDA's Regulatory Affairs / Quality Advisory Board. Sue was awarded PDA's Distinguished Service Award in 2008.

Ibim Tariah

Vice President, EU MDR and IVDR Consulting Services, Regulatory & Quality Solutions (R&Q)

Dr. Ibim Tariah is the vice president, EU MDR and IVDR Consulting Services, Regulatory & Quality Solutions. Most recently he was technical director for BSI Healthcare with more than 23 years of experience in the medical device industry. In the last 14 years, since coming to BSI, Ibim has been providing regulatory expertise in the area of long term implantable devices for clients needing technical documentation assessment and reviews in compliance with the European Medical Device Directive (MDD). He also acts as a liaison with regulatory authorities including MHRA, EMA, Medical Products Agency (Sweden), FDA, Health Canada and Therapeutic Goods Administration (TGA).

John Taylor

President/Principal, Compliance and Regulatory Affairs, Greenleaf Health

John Taylor joined Greenleaf following a distinguished career of more than 20 years at the Food and Drug Administration (FDA). During John's time at the agency, he led several of its priority initiatives. At Greenleaf, John continues his commitment to healthcare innovation as the firm's president and principal of compliance and regulatory affairs, providing strategic consultation to FDA-regulated clients on enforcement and compliance matters. From 2009–2014, John held three high-profile positions at FDA: counselor to the commissioner, acting deputy principal commissioner, and acting deputy commissioner for global regulatory operations and policy. As counselor to the commissioner, John served as the principal advisor to commissioner Margaret Hamburg on issues that affected the agency's programs, policymaking, management, budget, and administration. In his role as acting deputy commissioner for global regulatory operations and policy, John provided leadership and direction to more than 4,000 employees in FDA's Office of Regulatory Affairs and Office of International Programs. John began as an attorney within FDA's Office of the Chief Counsel in 1991. During this time, John was responsible for all phases of criminal and civil litigation related to violations of the Federal Food, Drug, and Cosmetic Act and other federal laws. In 1997, John was promoted to senior advisor for regulatory operations and policy within FDA's Office of the Commissioner. He was later named director of the Center for Drug Evaluation and Research's Office of Compliance. In 2000, John accepted the position of Director of ORA's Office of Enforcement. Two years later, John was promoted to associate commissioner for regulatory affairs.

Karl Vahey

Vice President Manufacturing Quality, Cardinal Health

Karl Vahey is currently the vice president of manufacturing quality with medtronic. Karl has 25 years of experience in the medical device industry and has worked in manufacturing, quality assurance, regulatory affairs and quality systems compliance. His current responsibilities include overseeing quality operations and quality compliance for 16 manufacturing facilities in North and South America and Europe. Prior to this, Karl was senior director of regulatory compliance for Covidien. This role included the following responsibilities: quality compliance activities, such as conducting audits, development of best practices and providing general support as appropriate to Covidien facilities (manufacturing, distribution centers and technical service centers) and third-party suppliers in EMEA, Latin America and Asia Pacific. Karl was also heavily involved in the development of corporate quality system training programs, such as process validation, CAPA, internal audits, change management and the implementation of these corporate training programs to all international sites.

Liz Wool

President, Wool Consulting Group

Liz Wool has 28 years of clinical research experience and is a recognized industry subject matter expert, trainer, and international speaker with a focus on solutions and added value results for clients. Liz's expertise is in the areas of clinical research, trial management, monitoring, clinical quality management systems, vendor management and oversight, compliance, operations, personnel training and development, and, performance management methods. Liz's expertise produces results in both organizational effectiveness and efficiencies (design, re-design, modifications for growing companies, and post-mergers and acquisitions) in support of the organization's goals. She has provided consulting services to six of the TransCelerate Biopharma, Inc. companies during her consulting tenure in the areas of department level strategic support, SOPs and performance management (post-merger/acquisitions), vendor program gap analyses, enterprise wide training strategy, and framework gap analyses, training course design, development and delivery, and metrics.