Detailed Agenda

MONDAY, April 15, 2024

Devin Hughes, Keynote

The Human-Centered Workplace: Establishing Belonging Through Authenticity, Collaboration, and Respect

Our world has changed, and your organization needs to reflect these changes. By being aware of those around you, showing respect, and appreciating both individuals and their unique qualities, you'll create the right environment to foster true belonging.

Workplaces are increasingly disconnected. It is vital that individuals feel authentic, valued for their contributions, and have a strong sense of connection and community. All of us must build these environments when our plates are already full.

Devin will offer research-backed strategies for building an inclusive mindset, implementing best practices, and creating a work environment where people feel like they belong. He will explore our role at work and how we can develop empathy and understanding for others' experiences.

In this session, you will:

- Learn more about organizations' unique role in creating places of belonging and encouraging authentic connections.
- Explore the latest research to understand workforce trends and dive into what it means for employees to be connected.
- Learn the specific actions necessary to create a culture of connection and belonging.

Devin Hughes is a bestselling author, award-winning speaker, and an internationally recognized expert in workplace culture. He has lectured and worked with a variety of Fortune 100 companies, as well as the Secret Service, the IRS, and an assortment of profit and nonprofit organizations. He was recently recognized as one of the Top 100 thought leaders to follow in 2024. He lives in San Diego, California, with his wife, and their loved rescue dog, Tyson.

John Buschiazzo

Failing Forward: Is Your Culture Holding You Back?

We are taught from an early age that failure is bad. From school to work, from graded tests and papers to job performance management, people go to great lengths to avoid or hide their failures. Given the widely held belief that we learn best from our failures, organizations and individuals struggle to integrate these disparate points of view.

Organizations recognize the need to create psychological safety but struggle to do so in a world where success is money, and failure can negatively impact the bottom line. And most, if not all, employees will try desperately to avoid the blame for failure.

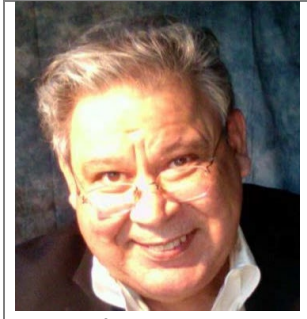
How do you overcome these hurdles, especially in highly regulated organizations where failure can be catastrophic? In this workshop, we will use a case study approach to understand the hurdles you will face, and offer suggestions to support building a truly safe learning culture.

Objectives:

- Identify organizational forces that prevent learning from failure
- Identify the reasons people fail
- Create plans to address

Remember, the question is not if you will fail, but how you and your organization will deal with failure. Always fail forward!

John Buschiazzo has over 20 years of Talent Development experience across multiple industries. John spent more than 10 years within the Pharmaceutical industry partnering closely with Discovery, Development, and GXP organizations to create innovative solutions that added business value and achieved behavior change within those employee populations.
John has been recognized by Brandon Hall Group for excellence in blended learning design, learning strategy and governance, and integrated talent management. Among many awards, John's work at Capital BlueCross led them to be named to the Training Magazine Top 100 Hall of Fame. John has been certified in Lean Six Sigma, Project Management, Change Management, Learning & Development, and Organizational Development.



Jesus Rivera

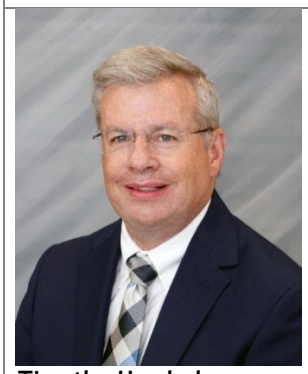
The Art and Science of Receiving & Giving Thanks

In this session, you will learn the benefits of adopting a daily gratitude attitude and how it can improve your career and personal life. We will explore the science behind practicing gratitude and appreciation and learn some techniques for incorporating these into our daily lives.

Jesús is an accomplished learning and development professional with over 25 years of diversified business operations, performance improvement, and organizational development experience in the pharmaceutical and financial services industries.

Before joining BMS, Jesús worked as a senior consultant to Fortune 500 clients, including repeat consulting engagements with BMS to provide a range of services and solutions, including Strategic Planning, Competency Models & Frameworks, Project / Change Management, Instructional Design, Coaching, and Mentoring.

He holds a Bachelor of Science in Business Management / Computer Applications from the State University of New York, and a Master of Science in Narrative Medicine from Columbia University.



Timothy Urschel

Data Privacy and Protection – Regional Differences and Requirements in the Conduct of Clinical Trials

Provide overview of the requirements for data protection and privacy of main ICH regions in the clinical trial environment and requirements placed on organizations to meet regulations (ie - EU requires Data Privacy Officer) and where future regulations, specifically FDA, may be heading.

Objectives are to enable a clear understanding of the various regulations and objectives regarding data protection and data privacy in the clinical research setting in its current state and possible future directions and provide some best practices to be compliant with regulations

Tim Urschel has over 30 years of experience working in the pharmaceutical industry within Regulatory Affairs and Quality Assurance. He has worked in small biotechs, large international pharmaceutical companies, and CROs. He has experience interacting with numerous health authorities and understands the nuances of global regulatory activities. He has been involved in the successful filing and approval numerous INDs/CTAs and NDAs/MAAs across a range of therapeutic areas.

Prior to joining DP Clinical as VP of Regulatory Affairs & QA, Mr. Urschel held Quality Assurance and Regulatory positions at Onoconova Therapeutics, Daiichi Sankyo Pharmaceuticals, Asubio Pharmaceuticals, Transave, Inc. (now Insmed, Inc.), and Celgene Corporation to name a few.

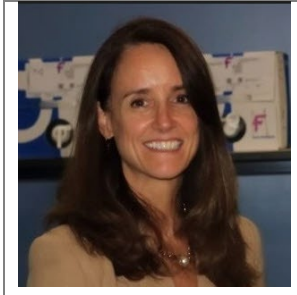
Mr. Urschel holds an MBA in Pharmaceutical Studies from Farliegh-Dickinson University in Rutherford, New Jersey and a BS in Medicinal Chemistry from State University of New York at Buffalo in Buffalo, New York. He also holds a current certification from the Society of Quality Assurance as a Registered Quality Assurance Professional in GCPs, and Pharmaceutical Quality Assurance Certification in GMPs from the New Jersey Pharmaceutical Quality Control Association.

Tim Bolus

Enabling GxP Compliance Solutions & Services: Molecular Devices Compliance Portfolio

This presentation will provide a high level overview of how Molecular Devices portfolio of compliance products and services enables regulatory compliance and how they are designed from the regulations in select parts of 21 CFR and the EudraLex standards in Annex 11: Computerized Systems and Annex 15: Qualification and Validation. The speaker will also demonstrate how their microplate reader software, SoftMax® Pro - GxP Edition, enables data integrity with elements from 21 CFR Part 11 for electronic records and electronic signatures.

Tim is the Senior Compliance Product/Program Manager at Molecular Devices. Over the past 25 years, Tim has developed his expertise working in diagnostic labs, manufacturing, clinical development, and in the GxP space bringing the customer perspective to the new Compliance Portfolio Marketing team. He works closely with Sales and Marketing teams with strategies to promote GxP products and services, and works with software engineering teams as the product manager to develop innovative software solutions, enhancements and features. He obtained his dual Master's in Business Administration and Project Management from DeVry University in San Francisco (California) and his BS in Biology from Angeles University Foundation in the Philippines.



Judy Carmody

Harmonizing Quality Management Systems and Training Across GxP Functions

This presentation discusses areas of harmonization within your quality management systems and training program across GxP functions. We discuss how harmonization can improve efficiencies affording you the opportunity to accelerate your drug development, reduce costs and protect patients.

Judy Carmody, Ph.D., is the Founder and Principal Consultant of Carmody Quality Solutions, LLC, a quality solutions provider to life science startups and global Fortune 500 organizations who are as passionate as we are about keeping patients safe and delivering quality products. Dr. Carmody has 30+ years of specific expertise driving vision in quality and operations. She is the former founder and president of Avatar Pharmaceutical Services, an FDA-registered contract research organization and manufacturer which was acquired by Vertex Pharmaceuticals in 2010.

Prior to founding Avatar, Dr. Carmody spent 10 years in the Life Sciences industry, developing and validating methods for small molecules and oligonucleotides, and managing QC, Analytical, and Validation groups.

Dr. Carmody holds a Bachelor of Science degree in Chemistry from Worcester State University, and a Master of Science degree and a Ph.D. in Analytical Chemistry from Clark University in Worcester, Massachusetts.

Pamela Hurley

Fundamentals of SOPs

In this session, we'll talk about five of the most common mistakes SOP writers make and discuss strategies to improve SOPs.

Objectives: At the conclusion of this session, participants will be able to

- Discuss the five most common mistakes SOP writers make
- Describe five strategies to improve

Pam Hurley, PhD is the founder and president of Hurley Write, Inc., a certified women-owned small business. For over 35 years, Pam has developed and taught courses for writing SOPs, deviations, and CAPAs, and in technical and scientific writing.

She has taught at Duke University, George Washington University, and several universities in the NC system.

Pam's philosophy about writing is simple: she believes that anyone can learn to write well if given the proper tools.

Hurley Write, Inc.'s clients include Genentech, Pfizer, Biogen, Gilead, and Novartis, among others.

Christine Cavalieri

Leadership and Innovation – The Value of Rewarding Vulnerability

Unlocking the nexus between leadership and innovation lies in embracing vulnerability as a cornerstone of growth. As Timothy Clark emphasizes, teams and organizations are a reflection of their leaders, highlighting the pivotal role of leadership in fostering innovation. Brené Brown underscores that genuine leadership transcends titles, emphasizing the importance of recognizing and nurturing potential in individuals and processes. Through a journey encompassing self-leadership, team leadership, and organizational leadership, the value of rewarding vulnerability emerges as a catalyst for fostering high-performing, innovative environments.

This interactive presentation will provide tools and techniques for empowering high performance and increased innovation while exploring what gets in the way of accountability.

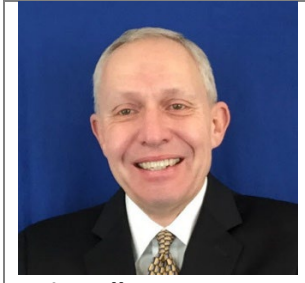
Learning Outcomes:

- Explore the concept of rewarded vulnerability.
- Understand the link between vulnerability, innovation, and high performance.
- Identify barriers to accountability and learn strategies to overcome them.
- Explore practical tools and techniques for fostering a culture of openness and innovation.

As a Leadership Coach, **Chris** partners with leaders seeking to increase performance, encourage teamwork and spark innovation. She's coached leaders and their teams through high-stakes challenges, from role expansions to performance leaps, and she's guided many companies on their journeys toward adopting and embracing changes in corporate culture.

With more than 20 years of experience, Chris integrates her knowledge and experience of system and design thinking, group dynamics, and organizational culture to inform the contextual landscape of coaching conversations.

Chris leads powerful team building processes for executives, teams and boards and regularly facilitates creative retreats. Believing in the impact of "helping others help themselves", Chris mentors high performing women in tech transitioning into leadership roles.



Rui Coelho

Navigating Change in the Advent of AI

Rui Coelho will lead a thought-provoking session titled "Navigating Change in the Advent of AI." His presentation will address the reality that technological change is not just coming; it's already here, and it's accelerating. In an era where artificial intelligence (AI) is rapidly evolving, the ability to adapt and adopt new technologies is critical. Failure to do so risks being left behind. As someone who is in the latter stages of his career, Rui is a testament to the power of continuous learning. Having developed some of the first BOTs for regulatory affairs, he continues to refine these capabilities and push the boundaries of AI in his function. His session will underscore the importance of embracing change, investing in AI training, and understanding the capabilities and limitations of AI to remain competitive and future-proof careers and businesses.

Objectives for the Session:

- Be a Continuous Learner: Encourage attendees to adopt a mindset of lifelong learning, highlighting how this has been integral to his career and ongoing regulatory affairs contributions.
- Embrace Change: Instill a sense of urgency and a positive attitude towards change, emphasizing that adaptability is key to leveraging AI for business and professional growth.
- Invest in AI Training: Advocate for the time investment in AI training, ensuring that individuals and organizations have the skills necessary to harness the power of AI effectively.
- Learn AI's Capabilities and Limitations: Provide insights into the practical aspects of AI, including its strengths and weaknesses, to enable informed decision-making about where and how to implement AI solutions.

Through this session, participants will gain valuable insights from Rui Coelho's recent experience and leadership in navigating the transformative landscape of AI. They will leave the session inspired and equipped with actionable strategies to drive change and capitalize on the opportunities presented by AI in their respective functions.

Rui Coelho is a Director of Business Process Excellence in Global Regulatory Affairs at Takeda Pharmaceuticals. In his current role, he is building out a Business Process Management Network, developing Performance Metrics, and accelerating Improvement Opportunities for Global Regulatory Affairs along with the required cultural adoption.

Throughout his career, he has led efforts to drive operational performance and engage the workforce to enable the cultural shift required for continuous improvement. He draws upon his experience in multiple industries – defense, consumer, OEM, and life sciences – with one common denominator, sustainable change depends on one key factor – people.

Rui has Chemical and Material Engineering BS degrees from UConn and an MBA in HR and Leadership from Rensselaer Polytechnic Institute. He has multiple Quality, Lean, and Six Sigma certifications. He holds board or leadership roles in several academic, professional, and service organizations.

Matt Kurtin

Let’s Talk Learning Technology Trends

Matt will lead a conversation about seven technology trends in the learning and performance space.

- Artificial intelligence
- Virtual reality
- Augmented reality
- Virtual Assistants / Smart Speakers
- Learning systems, platforms, and portals
- Gamification
- Accessibility

For each, participants will be able to:

- Define the trend
- Describe examples of using the trend for training or performance support
- Determine whether the trend is just hype or here to stay
- Determine how to get started learning more

Matt Kurtin, Learning Group’s senior director of technology and visual design, provides leadership for ILG’s programmers, animators, and graphic designers who make every learning solution more robust. His deep understanding of technologies connects ILG’s project teams to creative, innovative ideas for truly interactive, engaging client learning experiences. Matt is consultative with clients and consistently applies the latest advances in digital capability with practical application in learning.

For nearly 30 years, he has advised client organizations on their overall technology strategy for learning and performance improvement. Matt provides insight into leading best practices for use of augmented reality, virtual reality, mobile solutions, gamification, serious games, learning portals, and learning management systems. Matt is also proficient in Unity, C#, HTML, JavaScript, Articulate, and Captivate, and he has led the authoring of thousands of e-learning courses. In 2022, Matt received a VR developer certificate demonstrating proficiency in the use of the Unity engine, based on experience working on several VR projects.

Matt is a member of The Learning Guild and is a frequent speaker at this and other national and local professional associations, including various Association for Talent Development (ATD) chapters, ATD TechKnowledge, Realities360, the Chicago eLearning & Technology Showcase, the Association for GXP Excellence Conference, DevLearn, and the Central Indiana ATD Learning Summit. Additionally, Matt is the co-host of ILG's podcast series, LT2: Let's Talk Learning Technology.

Matt has a bachelor’s and master’s degree in electrical engineering from Virginia Polytechnic Institute and State University.

Nicole Benjamin

Jessica Sampson

Imminent Challenges with the Great Resignation & Impact to Organizations

This presentation aims to address the imminent challenges organizations face with the retiring generation and the potential knowledge loss they take with them.

First, we will explore the various risks and consequences organizations may face due to knowledge loss as the Boomer generation leaves the workforce

We will demonstrate the impact of knowledge loss on decision-making, problem-solving, and innovation within organizations.

We will also discuss the use of Bloom's taxonomy as a potential framework for evaluating institutional knowledge, and assessing the ways to ensure the tactical knowledge involved in effective analysis and evaluation strategies are maintained in the organization

Second, we will focus on the practical implementation of AI-driven solutions as part of a knowledge management strategy

We will also explore how to ensure that we are able to identify, assess, validate, and propagate the accumulated wisdom within an organization, both solidifying the foundations of an organization and providing a strong basis for future endeavors.

Nicole holds two Bachelors of Science degrees in Biology and Education from Delaware Valley University and a Master's of Science degree in Instructional Technology Management from LaSalle University. She has over 15 years' experience in learning and development. Prior to joining the Global Development Quality organization at Merck, Nicole was a Site Learning Specialist for MMD West Point, supporting learning for both production and support areas. She has extensive experience in learning needs analysis, learning design, and facilitation. In her free time, Nicole spends time with her four children, Reilly (23), twins Amelia and Angelo (9), and Carl (5), her spouse Colin, our dog Rosie, 6 cats, bearded dragon, axolotl, and chickens.

Jessica graduated from Arcadia University as a double major in Biology and Psychology, with a concentration in Neuroscience. She spent several years performing spinal cord injury research at Thomas Jefferson Hospital for Neuroscience before moving over to the Children's Hospital of Philadelphia where she engineered mouse embryonic stem cells to study psychiatric disorders such as schizophrenia and autism. From there, she moved into a position in Merck's Manufacturing Division where she spent several years as a Vaccine Formulation Scientist before taking on roles of increasing responsibility in the Learning organization. Jessica is currently a Senior Learning Automation specialist in Merck's HR Learning Operations organization where she strives to incorporate her love for neuroscience and all things learning into potential automation solutions for our clients.

William Coble

Attaching Capability Building to a Productivity Engine: Clinical Research Professional Case Study

Senior Leadership wants to build capability across the group and wants to know how you plan to do it. Come learn how to link this effort to a productivity engine with the added bonus of showing how it links to strategy:

- Use a Needs Assessment approach through interviews (uncovering gaps in knowledge and skills)
- Conduct affinity mapping with an established Competency Model (off the internet shelf from the Multi-Regional Clinical Trial Center) with the added bonus of having knowledge management activities and training tied to competencies
- Develop the Capability Plan

William Coble brings over 15 years of pharmaceutical experience from big pharma (Wyeth, Pfizer, Novartis) to small/medium pharma (Alexza, Pharmacyclics, Ultragenyx, Summit, Exelixis) and across the GxP's – GCP, GVP, GDocP, GDP, and GMP from a quality systems perspective. His biggest quality accomplishment was the remediation of a 2011 483 finding, Deficiency in GMP Training/Lack of Training, at the Novartis manufacturing plant in Lincoln, NE that gained Lachman concurrence and acceptance at the FDA Kansas City Office.

Most recently, William has been building and developing fit-for-purpose, sustainable quality system management framework across the GxP's. An area of intense focus is centralizing or integrating the quality processes to platforms – Quality Management and Document Management Systems (Veeva) and Learning Management Systems (ComplianceWire & Veeva Quality Vault Training).

William enjoys collaborating, sharing, and developing common goals, knowledge base, and ways of working. He looks forward to being a partner and accomplishing diverse outcomes. He has led many working groups to write SOPs, build/deliver training, map processes, and implement quality systems.

Detailed Agenda

TUESDAY, April 16, 2024

John Constantine

Building a Value Story for You (and Your Department)

In any support function (Quality, L&D, etc.) we often resort to giving or taking orders in our day-to-day routine. This workshop will explore how to become a valued Business Partner with your internal clients.

Objectives:

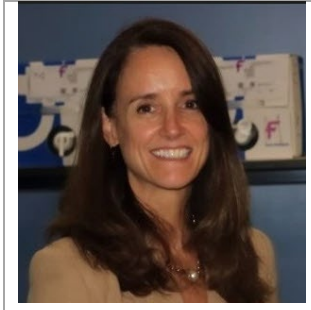
- Explore why many professionals primarily 'take orders', without focusing on business outcomes.
- Gain a high-level familiarity of Business Partnership end-to-end process.
- Discuss (and practice a little) the basic skills of customer/client-facing roles. You will NOT become an expert…that will happen over time, dependent on role & experience.
- Learn about other resources to help on your journey. Write the beginning of your personal journey.

John has 30 years in the life sciences industry, first at GlaxoSmithKline, then at Merck as Executive Director, Merck Polytechnic Institute in 2008, and joining Orchestrall, Inc. as Senior VP in 2016.

Background in Sales, Marketing, Corporate Staffs, Information Technology, Human Resources, Research and Development, and 25 years in Learning & Development. Expertise in application of learning to business strategy to drive workforce effectiveness and the application of technology to learning to drive learning effectiveness and efficiency. Other areas of expertise include:

- Learning strategy
- SOP training optimization
- Training organizational design & development
- Technology solutions including training systems integration
- Business Partnership Focus on Business Outcomes
- Services to support strategy and technologies
- Measurement of training effectiveness – quantifying return on training spend

He is a long-term member and served on the Board of Directors of the Life Sciences Trainers and Educators Network (LTEN) for 14 years, including 2 years as president. He serves on the Board of Directors of the Association for GxP Excellence. John is also a member of the Association for Talent Development, the Society of Human Resources Management, Chair of the Board of the Asia (Global) Training Consortium, served as Advisor, National Board of Medical Examiners Clinical Research Certification, and is an advisor to the Smart Healthy City Alliance.



Judy Carmody

Jonathon Vaught

Using a Modern Risk Management Tool to Meet ICH E6 Requirements

Use contemporary risk management tools to align with ICH E6 guidelines. This approach ensures adherence to international standards in clinical research, enhancing overall risk management strategies. Embracing modern tools optimizes compliance and fosters a robust framework for meeting the stringent requirements set forth by ICH E6 in clinical trials.

Judy Carmody, Ph.D., is the Founder and Principal Consultant of Carmody Quality Solutions, LLC, a quality solutions provider to life science startups and global Fortune 500 organizations who are as passionate as we are about keeping patients safe and delivering quality products. Dr. Carmody has 30+ years of specific expertise driving vision in quality and operations. She is the former founder and president of Avatar Pharmaceutical Services, an FDA-registered contract research organization and manufacturer which was acquired by Vertex Pharmaceuticals in 2010.

Prior to founding Avatar, Dr. Carmody spent 10 years in the Life Sciences industry, developing and validating methods for small molecules and oligonucleotides, and managing QC, Analytical, and Validation groups.

Dr. Carmody holds a Bachelor of Science degree in Chemistry from Worcester State University, and a Master of Science degree and a Ph.D. in Analytical Chemistry from Clark University in Worcester, Massachusetts.

Jonathan is a dynamic and passionate business leader with a deep technical background and over 20 years of experience in the development and commercialization of new technologies spanning multiple industries including clinical diagnostics, food safety, and agriculture. He is currently the CEO of QI Path, a SaaS company with a unique and highly effective risk management platform that works with pharma, CRO's, and government agencies. He also serves as an advisor to several companies in the Life Sciences. Prior to that he was CEO and Founder of a Biosciences company which was a Denver Business Journal Fast 50 small business category winner in 2020. He also helped develop and commercialize the core biomarker discovery technology behind the SomaScan platform at SomaLogic, which listed on the NASDAQ in 2021 and is the largest protein biomarker discovery platform in the world. Jonathan received his PhD in Chemistry from CU Boulder and is an author of multiple peer reviewed publications and an inventor on several patents.

John Misock

The Modernization of Cosmetic Regulation Act of 1922

The session will explain the seven elements of MoCRA with an emphasis on the new compliance tools given to FDA and their effect on the cosmetic industry in general. Attendees will gain a unique insight into the new requirements and suggestions for compliance based on John's 40 plus years of regulatory experience including 20 years in cosmetics regulation with industry and FDA.

As an accomplished leader across multiple FDA regulated industries, John uses his broad experience industry and government to obtain the best possible outcomes when faced with regulatory challenges John is recently retired from FDA and previously worked in industry and state government. John is an expert in regulatory compliance (including international), microbiological and chemical safety, toxicology, and risk analysis. His education is in microbiology and biochemistry. John has degrees from The Ohio State University and The University of Wyoming.

James Vesper

Knowledge Management: The Other Enabler of a Pharma Quality System

Knowledge Management (KM) is one of the two "Enablers" of the Pharma Quality System described in ICH Q10 but little has been done to expand on what KM is, how it can benefit an organization, and ways that the KM lifecycle can be used. The new version of the ICH Q9 Quality Risk Management guideline speaks to how KM can contribute to better decisions, but with little detail about the what and the how. This presentation provides an overview of KM, describes the KM life cycle, what is currently happening with KM and the industry, how trainers are important in knowledge transfer, and resources available for more information.

James Vesper, PhD, MPH develops and provides training courses for pharma and biopharma organizations world-wide and delivers workshops on advanced GMPs, root cause investigations, and quality risk management. He has worked in the pharma industry for 40 years, starting out at Eli Lilly where he headed the global GMP training efforts. He has provided training for health care authorities and the WHO in the Americas, Europe, and Asia. He has authored six books and dozens of technical, peer-reviewed articles. Currently Jim is Director of Learning Solutions at ValSource, Inc. He is co-lead of the PDA task force on knowledge management. He's excited to be part of another AGXPE conference!

Nikki Miller

GXP Accessibility: Making Learning More Accessible to All

In our learning framework, diversity and inclusion is foundational to recognizing that a singular approach does not optimize learning efficiency and effectiveness. Discover the transformative power of prioritizing accessibility in learning. During this session, we will unlock the concept of GXP Accessibility and its profound impact on fostering an inclusive and effective learning environment.

OBJECTIVES:

1. Develop an enhanced understanding of accessibility standards and guidelines
2. Gain expanded awareness of how accessibility improves learning in a GXP environment
3. Identify actions we can take to make L&D more accessible, TOGETHER

Nikki L. (Miller) Bland is an Associate Director of Learning & Development at AstraZeneca and most of all a big lover of learning. She works extensively in the pharmaceutical sector with expertise in GXP learning. Nikki dedicates her career to helping employees traverse complex regulatory landscapes efficiently and in compliance. She is driven by her enthusiasm for equipping employees with the information and skills they need to flourish in regulated situations. As a strong inclusion and diversity advocate, Nikki ensures the multifaceted learner voice is heard and used to develop impactful learning experiences.

Christian Torstensson

Critical Areas of Focus for a Successful GxP Training Program

In this session, we will dissect the current challenges facing GxP Training departments. Discussion will include a debate of the intent of this group's core mission from both organizational and Quality Systems perspectives. We'll then propose a revolutionary, albeit often unpopular, approach to improving compliance, sustainability, and overall success for training in a regulated organization: Focus.

Objectives for this session include:

- Differentiating Training and Education from Learning and Development
- Clarifying the expectation of personnel qualification
- Highlighting critical areas of focus
- Proposing priorities for maturing Training groups

Christian embarked on his career over three decades ago in the public school system teaching Kindergarten through High School across various subjects. Earning degrees in Education and the Sciences, he not only taught but also mentored new and seasoned educators while honing their craft.

Transitioning into the corporate world, Christian's journey traversed software, hardware, and pharmaceutical landscapes at companies like Novartis, GlaxoSmithKline, and Sanofi as well as early-stage companies Seres Therapeutics and Idenix. During his tenure with these companies, Christian led Training and Documentation teams through times of growth and maturity with transition from paper to digital, new systems implementation and migration, and archival.

- Now, as Principal at The Atlantec Group, Christian's current mission is to help maturing companies meet the demanding needs of growth and commercial manufacturing. As a consultant, Christian provides his customers guidance and hands-on support:
- Building GxP Training organizations and phase appropriate governance;
- Implementing sustainable curricula models;
- Ensuring onboarding framework delivers effective and timely "Door to Do" for new hires;
- Guiding change management and implementation of electronic systems to support mission critical Quality Systems;
- Rethinking metrics and KPIs to maintain focus on productivity and compliance.

Beyond his professional endeavors, Christian finds solace in family life and enjoys sailing, swimming, hiking, and tinkering with automobiles during colder months.

Mark Lee

Compliance Learning Benchmarking Study

UL Solutions ComplianceWire team has been conducting an annual Benchmarking Study since 2011. The survey covers audit trends, training, and training technology trends in the Life Sciences industry. Attendees will learn the latest sentiment on topics like AI, VR, Micro Learning, and what people see as their corporate objectives for the coming year.

Objective – Keep AGXPE attendees of latest trends in GxP Compliance Training

Mark Lee, Ph.D. is the Head of Research, Analytics, and Business Development - UL Solutions ComplianceWire, and Adjunct Professor, in People Analytics, NYU Tandon School of Engineering. The common theme in Dr. Lee's career has been combining psychology and engineering to improve business results the well-being of people. Mark worked as a Human Factors Engineer for Lockheed Martin, AT&T, NCR, Pitney Bowes and Siemens. Mark has worked in the Life Science Industry since 2004 (EduNeering, UL ComplianceWire, Certara and Medidata's Acorn AI). His experience includes Medical Device Design, GxP Training in Manufacturing, Clinical, Drug Discovery and Development, and Biosimulation. Dr. Lee has 30+ publications in a variety of topics, mostly centered on learning and skill development.

Vijay Anandraj

Gen AI Strategies for Innovative SOP Training

This insightful 60-minute session will delve into the transformative potential of Generative AI in Standard Operating Procedures (SOP) training in context to GLP and GMP in pharma and will discuss the challenges faced in traditional SOP training and explore how Generative AI helps to create innovative solutions to overcome these challenges. In this presentation, we will demonstrate some of the real-world applications of generative AI strategies for innovative SOP trainings, such as, using AI to automate interactive SOP training module creation (video and text formats), the possibilities of human co-authoring with GPT systems for real-time updates to training materials, automate creation of test items from SOP documents for assessment and certification of GLP/GMP/Quality associates.

Session Objectives:

- Understand the Challenges: Identify the key challenges in current SOP training practices within GLP and GMP contexts.
- Discover Generative AI: Introduce the fundamentals of Generative AI and its relevance to enhancing SOP training.
- Explore Gen AI Applications: Delve into specific generative AI strategies that can automate and personalize SOP training materials and assessment methods.
- See Gen AI in Action: Briefly illustrate practical applications of these strategies, using SkillFLO as an example, to demonstrate the real-world potential of Gen AI in SOP training.
- Learn Implementation Best Practices: Provide guidelines and best practices for successfully integrating generative AI into SOP training processes.
- Anticipate Future Trends: Discuss future advancements in Gen AI technologies and their implications for SOP training.
- Engage with the Audience: Facilitate a Q&A session to address any questions.

Vijayanandraj VR, PhD, Head, New Tech Solutions (AI/AR/VR) at Sify Technologies North America Corp.

Vijayanandraj VR serves as the Head of New Tech Solutions, specializing in AI, AR, and VR technologies, at Sify Technologies North America Corp. Known affectionately as Vijay, he is a visionary in solution strategy and business intelligence, focusing on AI-enhanced human augmentation and extended reality (XR). Over a decade, he has played a pivotal role in creating and implementing technologically advanced solutions for Fortune 500 clients of Sify using innovative XR and AI technologies and has led to the development of 7 award-winning solutions that address complex business challenges related to people and processes, providing significant ROI and value to clients.

With a PhD in Microbiology and experience in the pharmaceutical industry, Vijay's deep-seated passion for technology has fueled his contributions across a spectrum of knowledge domains. His interdisciplinary skill set seamlessly integrates the principles of biological sciences with the forefront of technological innovation, delivering significant insights and progress. He has authored research papers in esteemed peer-reviewed journals and contributed chapters to foundational texts in biological research, highlighting his influence and thought leadership in bridging diverse fields.

Carrie McKeague

Designing Unforgettable Training Content

Do you have responsibilities for the design and delivery of training in your current job role, but question the effectiveness of the training?

In this session, participants will learn about different knowledge types and specific strategies to support the delivery of each knowledge type. By pairing the knowledge type with the correct strategies, your training will be optimized for delivery and retention. Practical examples from course interactivity to games will be shared. Participants will complete an interactive card game aid to support retention of this content and for future reference. You will leave this session with strategies and ideas on how to design unforgettable training for your employees.

Objectives

- Review the learning theory around how people encode, retain, and recall content.
- Discuss the types of knowledge (i.e., facts, concepts, procedures, and problem solving) that make up all content that employees need to learn.
- Identify strategies that support each specific knowledge types.

Carrie is the Manager of the Content Solutions department at UL ComplianceWire. She has over 25 years' experience designing and developing results-driven training programs. Carrie has a PhD in Instructional Design and Educational Psychology from Penn State University and has taught instructional design courses and authored several articles on learning topics.

As the manager of the Content Solutions department at ComplianceWire®, Carrie is responsible for the eLearning courses portfolio focused on the following topic areas: pharmaceuticals, medical devices, clinical, data integrity, ethics and corporate compliance, and human resources. Her team of adult learning experts and external Subject Matter Experts completes annual course reviews and necessary maintenance on the 400-course offering. Additionally, Carrie works with our customers on client specific eLearning courses and the implementation of the CreateTM authoring tool.