

PDA Biennial Training Conference
Speaker Biographies
As of October 3, 2012

Kristina Barkhouser

Excelen Performance, Inc.

Kristina has over 20 years of experience in technical and interpersonal skills development, with a background in presentation skills and instructional design, quality assurance, regulatory compliance, and active learning techniques. With nearly ten years of direct training experience in the Pharmaceutical industry, she specializes in designing training to meet the needs of a variety of educational levels and learning styles, while ensuring regulatory compliance. Kristina has a background in Human Resources, Quality Assurance, Education, and Instructional Design and has earned the American Society for Training and Development (ASTD) Certified Professional in Learning and Performance (CPLP®) credential. Kristina has a talent for designing interactive learning experiences to improve employee effectiveness and increase organizational performance.



Sonja Broyles

Genzyme Corporation

Sonja Broyles is Manager, Technical Training for the Development and Training Department at Genzyme Corporation where she currently provides training support for the Framingham Biologics site in Framingham, MA. Her main responsibilities include designing and delivering classroom training on regulatory, technical and skill topics, and providing support to the functional groups in the areas of improving compliance, OJTs, and OJT Trainer qualification. Sonja earned her M.A.T. in Science Education from the University of Louisville and an M.S. in Pharmaceutical Biotechnology from Northeastern University. She is a member of BETA, GMP TEA, and PDA.

Joanne Cochran

JWC Training Associates

Joanne W. Cochran is a training professional with 25 years of industry experience with expertise in the fields of Regulatory Compliance and GMP Training, Aseptic Processing, Quality, and Training Strategies. Joanne has presented training around the world from China and Korea to local programs in Pennsylvania. As the principal of JWC Training Associates, she has spoken to FDA to present a session on “cGMP Training as Part of the Quality System in a Risk-based Environment” at their Risk and Quality GMP Conference. She currently provides technical consulting to clients in the areas of training and training systems, analysis and development. She was the Chair for the 2006 PDA Biennial Training Conference. She is also active in the GMP Training and Education Association, the American Society of Quality, and the American Society of Training and Development.



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Paul Corbin

Pfizer, Inc.

Paul joined Cardinal Health in January 2011. He is responsible for quality and regulatory training for 32+ domestic PET manufacturing facilities. Paul recently served as a Process Lead that successfully launched Cardinal Health's first-ever enterprise-wide FDA-approved LMS ("myLearning" July 2011). He is currently working with the NPS Training Team to design and implement a New Hire Program (NHP) across PET Manufacturing to meet regulatory 212 cGMP training compliance. Paul was formerly a Manager of Training and Continuous Improvement at Pfizer Consumer Healthcare in Richmond, Virginia. He joined the training department at Pfizer (legacy Wyeth Pharmaceuticals) in June 2001. Paul served as the change management lead for the implementation of the Pfizer Global Manufacturing (PGM) Plateau Learning Management System. In this role he successfully delivered oversight of the organizational and individual transitions. He has also served as the project lead for the development and implementation of a technical training program for the Packaging Production Technicians. As project lead, Paul supervised the design and delivery of a competency-based training program that produced 60+ technical training guides used as supplemental tools for training and evaluation.



His work received Corporate Global Recognition Awards for "High Performance Work System Design" and "Sustainable Compliance". Additionally, his efforts were awarded two "Employee Development" All-Star Awards from the Richmond Human Resources Management Association (HRMA) and the Greater Richmond Chamber of Commerce.

Instructional certifications include Human Performance in the Workplace, Targeted Selection, Employment Law, Quality Management Skills, and Expert On-the-Job Trainer.

Prior to Pfizer, he worked in secondary vocational education for fourteen years as a Business and Marketing Teacher-Coordinator.

Paul is currently pursuing his Masters degree in Instructional Technology from Virginia Tech University. He received his BS in Marketing Education from Virginia Tech, and he is an avid "Hokie". Paul and his wife, Linda, have two children, Andrew and Olivia, and the family resides in Mechanicsville, VA.

Jill Drummond

Blood Systems

Jill Drummond is a "cutting edge" learning management professional with over 20 years' experience directing training initiatives in FDA regulated industries. She has varied training experience in the pharmaceutical industry and currently directs the corporate office Training Department for Blood Systems, a leading blood banking organization. She has a broad range of expertise in adult learning theory, instructional design, program assessment, facilitation and e-learning methodologies which she has shared in past PDA conferences and numerous other national professional organization meetings.



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Eric Flasck

Advantage Performance Group

Eric Flasck has been a partner with Advantage Performance Group (APG) since 2003 and has been consulting for over 16 years. Eric is responsible for helping organizations create, implement and measure training and performance initiatives. Eric works with pharmaceutical and biotech companies as well as large organizations in other industries throughout North America, Asia, and Europe. As a partner at APG, Eric utilizes the *High Impact Learning* methodology and *Success Case Method* process to help organization increase the impact they receive from training and to effectively and efficiently measure the ROI of training. Eric also works with clients to transfer this capability thus enabling them to embed these processes and methods into ongoing and new training initiatives.



Paula Fritsch

Eli Lilly and Company

Ms. Fritsch has over 20 years' experience in corporate Learning & Development (L&D). She has spent ten of her eleven years at Lilly in the global manufacturing/quality L&D organization. In her current role, she helps business partners identify and develop the people capabilities needed to deliver their business plans. Her customers include the global manufacturing/quality lab group, and the scientific/technical function that supports Lilly's manufacturing sites. Aside from her experiences with distance learning and other "formal" training solutions, Ms. Fritsch views "informal" training solutions (e.g., electronic performance support systems) as integral to L&D's future success. She holds a M.Ed (Instructional Design, Indiana University, Bloomington, IN), a B.A. (English, Marian University, Indianapolis, IN), a Distance Learning Systems Planning and Management Certificate (IUPUI, Indianapolis, IN) and a Professional in Human Resources (PHR) Certification (Society of Human Resources Management {SHRM}).



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Joanna Gallant

Joanna Gallant Training Associates, LLC

Joanna Gallant has spent 20 years in the pharmaceutical, biotech, and medical device industries. Her background includes eight years in Drug Product Development, where her responsibilities included creating new product submissions to regulatory agencies, laboratory data reviews, developing and transferring processes between Development and QA/QC, supporting investigational product manufacturing and safety assessment study needs, and creating, validating, and managing a controlled product storage facility.



She spent eleven years in QA, performing and managing the function that designs, develops, and delivers training programs in Current Good Manufacturing Practices and technical training, supporting all GMP-related functions at her sites. In 2011, she launched her own company, and now provides a range of training services to her clients, including design and delivery of training, packaged training materials, and training system audits and remediation.

Joanna regularly speaks at industry meetings on interactive training, OJT, investigations and root cause analysis. Joanna has been a member of the GMP TEA, Inc. Board of Directors since 2008, president of BETA, a member of PDA since 2001, and a member of ASTD. She was involved in developing and teaches in WPI's Biomanufacturing Certificate Program, and is an Adjunct Professor in the BU School of Medicine.

Tim Gillum, PhD

Baxter Healthcare

Tim Gillum, Ph.D. has worked both in academic and business environments for more than 15 years focusing on learning and change management within regulated environments.

Tim has designed and implemented end-to-end training systems for start-up facilities in both the U.S. and Europe and rebuilt training systems for organizations under Consent Decree with the FDA. His area of expertise centers on aligning learning organizations to the company's overall strategy.



Tim has a Bachelor of Science degree in Chemistry from St. Louis University, a MBA from Webster University and a Doctor of Philosophy in Educational Leadership from the University of Missouri – St. Louis.

In his current role at Baxter, Tim is responsible for the Global Quality Training Process/System.

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Reni Gorman

Performance Development Group

Reni Gorman is the Senior Director of Strategic Engagements. Her strengths lie in analyzing business needs and consulting with key leaders to design strategies and deliver solutions that enable the firm's talent to develop the qualities and behaviors needed to meet business goals. She has consulted with key leaders of Fortune 100 firms, one of whom described her as "uniquely linking learning and business."

Reni Gorman is a dynamic leader whose passion is contagious to colleagues and clients alike. She is a true believer in creating continual learning strategies for the impatient, busy professional of the 21st century. She has designed intelligent push/pull strategies and systems that deliver bite-sized knowledge objects through various delivery mechanisms such as e-Learning, mobile learning and performance support.

Reni holds a graduate degree in Cognition and Intelligent Technologies from Columbia University Teachers College and an undergraduate degree in Communication from Rutgers University.



Jan Gray

Blood Systems

Jan Gray has 25+ years' experience in education and training and has a Master's degree in Educational Technology from Arizona State University. Her hands-on experience with authoring tools includes the Articulate suite, Adobe Flash, Adobe Captivate, Camtasia, and Raptivity. In her current position as Instructional Design Manager, she is leading the transition from an environment of primarily instructor-led training to one that includes a significant amount of e-learning, especially for software programs, soft skills training, and regulatory topics such as basic safety and cGMP.



Patty Jurgensen

Merck Manufacturing Division

Patty Jurgensen is an Associate Director in Learning & Development for the Merck Manufacturing Division. Patty is passionate about learning and instructional design for "head, heart and hands" experiential learning. Believing that the heart leads the head and hands, she encourages learning solution design that incorporates "Ah Ha" moments that change learner's perspective forever and encourages passion.

During her 23 years in the learning field she gained experience in sales and marketing training and sterile vaccine and solid-dose pharmaceutical manufacturing training. She has a Masters of Education at Penn State in Adult Learning and Instructional Systems Design.

For the Global Vaccines and Sterile Manufacturing (GVSM) Learning Academies, Patty supported the project from Needs Analysis to Piloting the Academies and finally to the Implementation and Sustainment phase. Overseeing much of the development of the workshops, she ensured that they were designed using highly experiential adult learning techniques resulting in memorable and rewarding experiences.

Prior to her work on the Academies, she led a development team to create a highly acclaimed learning curriculum for a National Launch of the Merck Engage Health Partnership Program.

On a personal side, Patty, a mother of two boys, is a Juvenile Diabetes Research Foundation (JDRF) Coach for several Philadelphia area families with children recently diagnosed with Type 1 Diabetes. She has also led TEAM MERCK for the JDRF "Walk for a Cure" for which she has personally raised over \$35,000 through book fairs and good old fashioned fund raising.



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Sukon Kanchanaraksa, PhD

Johns Hopkins Bloomberg School of Public Health (JHSPH)

Sukon Kanchanaraksa, PhD is Director of the Center for Teaching and Learning (CTLT) at the Johns Hopkins Bloomberg School of Public Health (JHSPH). The Center supports JHSPH educational programs by producing online academic courses, training courses, and open educational resources. More than 100 full online courses are now offered for Master's and Doctoral students, while materials from select academic and training courses are freely available to the public through the JHSPH OpenCourseWare site. Dr. Kanchanaraksa is also Associate Scientist in the Department of Epidemiology and Associate Chair of the Master of Public Health Program. As a faculty member in the Department of Epidemiology, he has taught the online 'Fundamentals of Epidemiology' course for the past 15 years, and is faculty sponsor or cosponsor for two online certificate programs – Training Certificate in Public Health Practice and Training Certificate in Quantitative Methods in Public Health. He has particular interest and expertise in program and curriculum development in the health and public health disciplines, and has served on numerous committees, task forces, and groups, responsible for review, revision, and development of public health curriculums. He is currently the chair of the Council on Learning Futures, one of the councils of the Association of Schools of Public Health.



Ümit Kartoğlu, PhD

World Health Organization

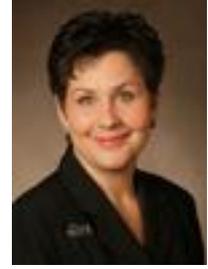
Dr Kartoğlu is a scientist at the World Health Organization, Department of Immunization, Vaccines and Biologicals, Quality, Safety and Standards team. He is responsible for learning programmes and coordinates the work of Global Learning Opportunities for Vaccine Quality (GLO/VQ) and Strengthening and Expanding Immunization Staff Capacity (SEISC) project. Prior to his WHO work, Dr Kartoğlu worked with UNICEF as health officer in Central Asian Republics and Kazakhstan Area Office and as health coordinator for Operation Lifeline Sudan based in Kenya. Earlier he was Associate Professor in Public Health at the Institute of Pediatrics of Istanbul University and also held positions as permanent advisor in Public Health to the Ministry of Health in Turkey, and worked in different positions in rural health delivery system for 10 years. He is the founder of the Human Rights Branch of the Turkish Medical Association and WEBCOM (Communication Web for Health). He was elected to serve in the Executive Council of the Turkish Medical Association for a term in 1988. Since 1974 he professionally draws cartoons, had various exhibitions, published his works in books and postcards, and received 10 international/national cartoon awards. Dr Kartoğlu has over 50 professional publications in public health including 11 books/manuals targeting primary health care professionals used as learning materials, and received two international research awards in research design and communication. Dr Kartoğlu also received IQPC (International Quality & Productivity Center) Cool Chain Excellence Award in 2010 and Ludwig Rajchman 2011 Science Award. Ümit was recently named one of the "*Temperature Controlled Logistics Leaders for 2012*" by the IQPC's Temperature Control Logistics & Quality Network, an international industry peer group recognizing 15 of the most influential and inspiring thought leaders in global pharmaceutical supply chain. Dr Kartoğlu has over 25 years of experience in authentic learning, and has developed various creative learning tools and materials.



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Wendy Kouba

Merck and Company, Inc.



Wendy Kouba is a dynamic executive who has successfully repositioned global companies and driven organizational performance and effectiveness in intensely competitive, high-growth industries. At Wyeth, a \$22 billion global healthcare company, she initially led public affairs and issues management for the global manufacturing network. After one year she was promoted to head global Corporate Communications and serve as an officer of the corporation. Only one year later she was offered an opportunity to lead Operational Excellence across Wyeth's global manufacturing network. She viewed it as a pivotal moment in her career -- an opportunity to gain operations experience that broadened her own skills while driving a new culture of employee engagement throughout the organization. She and her team exceeded all expectations. Together they helped build Operational Excellence into a cultural transformation within Wyeth's manufacturing facilities and enabled the reduction of overall operating costs by 25 percent -- or \$400 million -- across 25 worldwide sites supporting Pharma and Consumer businesses. Today Wendy leads the Strategy Realization Office for Merck's Global Vaccines & Sterile Manufacturing network. With responsibility for driving strategy execution and organizational effectiveness, she leads an integrated approach to operational transformation that includes building capability, applying lean/six sigma principles, engaging the work force, listening and leading change. With a strong record of accomplishment in all facets of organizational effectiveness, Wendy has significant experience in mergers and acquisitions, reputation and issues management, Lean/Six Sigma, process improvement principles and measurement. She is passionate about developing teams, advancing talent, and creating growth and learning opportunities for all colleagues. Wendy has led global functions and teams at several Fortune 500 companies, including Johnson & Johnson, JPMorgan Chase, Pharmacia and Lockheed Martin. Early in her career, she spent more than eight years at AlliedSignal, where she was the first public affairs leader to work in every business sector of the company, with assignments in the United States and Europe. Wendy graduated from the University of Massachusetts at Amherst with a degree in journalism and psychology, and completed the Executive Development Program at the University of Pennsylvania's Wharton School of Business. She also is a certified Lean/Six Sigma Green Belt and has been trained and tested as a Black Belt. A widely recognized thought leader, Wendy writes and speaks frequently on operational excellence, employee engagement and capability building, and the criticality of integrating these disciplines to sustain operational change. In 2008, she was named Communicator of the Year by IABC/New Jersey. In 2002, Wendy won the Gold Quill of Excellence Award, the highest honor given to practitioners by IABC, for her work entitled "Validating Bottom-line Impact of Strategic Communications." A passionate advocate of children's causes, Wendy serves on the board of the National Adoption Center in Philadelphia where she is leading a task force focused on branding and reputation management. Wendy has served as a Member of the Board of Trustees for The Children's Center for Therapy & Learning in New Jersey. She taught English as a Second Language in Spain, is an active literacy volunteer and a member of the Advisory Council at Baruch College in Manhattan. Wendy and her husband, Richard Heward, an executive with Hertz, reside in Berwyn, Pennsylvania with their two daughters.

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Bobbi Laver

Merck and Company, Inc.

Mrs. Laver has been with Merck for 11 years with seven years supporting the Training and Development Department at West Point. As a Sr. Learning Specialist, she is responsible for designing and delivering training in various areas including New Employee Onboarding, Aseptic Techniques, Aseptic Gowning and GMP Regulations. Mrs. Laver holds a BS degree in Medical Technology and is currently completing her Master's Degree in Instructional Technology Management at LaSalle University.



Elaine Lehecka Pratt

Lehecka Pratt Associates, Inc. and Stevens Institute of Technology

Elaine Lehecka Pratt is an Industry Professor at Stevens Institute of Technology, Hoboken, NJ where she teaches in the Pharmaceutical Manufacturing and Pharmaceutical Management graduate programs. She also serves as the Faculty Advisor to the Women in Pharma Club.



Elaine is also the president of Lehecka Pratt Associates, Inc., a consultancy with over 20 years of experience in regulatory compliance, technical training and consulting to the pharmaceutical, device and biotech industries. Before founding the company, she worked in the pharmaceutical industry for 10 years in supervisory and management positions in pharmaceutical line production and technical training. She holds a B.S. degree (biology) from Ursinus College, and a M.B.A. degree (management) from Fairleigh Dickinson University.

She is a past president of the GMP Training and Education Association and a past co-chair of the ASTD Pharmaceutical Industry Group. Elaine is a frequent speaker at international meetings of ASQ, ASTD, PMA, PDA, APhS, ISPI, PharmTech and Interphex. She has published articles in *Pharmaceutical Technology*, *Pharm Tech Japan*, and *Drug Development and Industrial Pharmacy* and is one of the authors of **Virtual Teamwork** (Wiley, 2010).

She is a member of ASTD, ASQ and PDA, and the planning committee of the PDA Biannual Training Conference.

David Mayorga

DAM Good Consulting, Inc.

David is the president of DAM Good Consulting, Inc. He has over 26 years of pharmaceutical and biotechnology experience working in manufacturing, validation, quality assurance, and training and has been working as a consultant for the past eleven (11) years. David holds a BA in Biology; a Trainer's Certification and is working on a Master of Information and Learning Technologies with emphasis on eLearning Design and Implementation.



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Ann McGee

McGee Pharma International

Ann McGee B.Sc.(Pharm), M.Sc., MPSI is the Managing Director and Principal Consultant with McGee Pharma International, providing quality, regulatory compliance and training services and products to the pharmaceutical industry worldwide. Ann is a member of the Committee of the Irish Chapter of the Parenteral Drug Association (PDA) and of the European QP Association Expert Panel on GDP.



Consultancy was a natural progression for Ann with 22 years' experience working within the pharmaceutical industry and as a Regulator. One of Ann's previous roles has been as a Senior Inspector with the Irish Medicines Board. In this role Ann inspected in the USA on behalf of the European Medicines Evaluation Agency (EMA) and the centralised procedure for the approval of medicines for European markets. Ann has also held the position of Registrar (CEO) with the Pharmaceutical Society of Ireland. In her career as a Regulator, Ann was actively involved in the development of legislation and best practice standards and guidelines for the broad pharmaceutical industry.

Between 1983 and 1993, Ann worked as a pharmacist and held various positions in the Pharmaceutical Industry in the areas of Product Development, Clinical Trials, Regulatory Affairs, Technical Management, Quality and Compliance.

McGee Pharma International received a Highly Commended Award in the Services Category of the Small Firms Association National Business Awards 2012. Previous awards include Highly Commended Outstanding Small Business at the Small Firms Association National Business Awards 2011, Best Small Business 2011 at the Fingal Chamber Awards and winner of the Fingal County Enterprise Board Entrepreneur Award 2009.

Kery Mortenson

Baxter Healthcare Corporation

Kery has 25 years leading performance improvement and learning strategies for global health care employees and organizations.

He is a Certified Performance Technologist (CPT). In 2006, He was president of ISPI Chicago Chapter. Kery is an adjunct professor of organizational leadership at Trinity International University in Deerfield, Illinois.



In his current role at Baxter, he develops customized learning curriculums and interventions for corporate quality initiatives. Kery successfully developed and implemented global training evaluation standards and guidelines. He has a mastery level of knowledge and experience in adult learning principles and facilitation techniques.

Kery has presented at domestic and international training and performance improvement conferences utilizing highly interactive presentation style with simple and effective tools and methods. Prior to his current role in Baxter, Kery was the Learning and Development Consultant for the Global Pharmaceutical Research and Discovery organization at Abbott Laboratories.

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Dean Pratt

Deloitte Consulting

Dean Pratt is a Manager with Deloitte Consulting, specializing in process improvements for the pharmaceutical industry. He has managed many training and systems integration projects across the drug development life cycle and specializes in portfolio/program/project management, regulatory compliance, drug safety, supply chain, and discovery. With over 20 years of experience consulting for Fortune 100 pharmaceutical companies, he has managed dozens of training projects with authoring tools and Learning Management Systems.

Dean has taught courses at New Jersey Institute of Technology and Stevens Institute of Technology on a part time basis. He has his own curriculum for project management and MS Project. He has been selected as speaker for many conferences.

Dean earned his BS in Computer Science and his M.B.A. in Finance at Rutgers University and is 80% complete with his MS in MIS at Stevens Institute of Technology. He has earned his Project Management Professional certification from the Project Management Institute and a Graduate Certificate in Project Management from, Stevens Institute of Technology.

Malcolm Pratt

Grifols Therapeutics Incorporated

Malcolm Pratt is a Performance Development OJT Specialist at Grifols. He recently joined the Performance Development Department in May of this year, but has considerable experience developing and delivering presentations to a wide variety of audiences. He has 14 years of tenure at Grifols. He has 10+ years of supervisory/managerial work experience obtained while working in Quality Operations and Supply Chain departments at Grifols as well as QA/QC department while working at Air Products and Chemicals. He has Bachelor degree in Chemistry from North Carolina State University and a Master degree in Business Administration (MBA) from University of Phoenix. He is a member of the Parenteral Drug Association and a Senior Member of the American Society for Quality (ASQ). Malcolm is certified by ASQ as both a Quality Auditor and Manager of Quality/Organizational Excellence.



Rick Rogers

Genzyme Pharmaceuticals

Rick Rogers is Training Manager for Genzyme Pharmaceuticals in Allston, Massachusetts. He is the author and coauthor of numerous and award winning training sessions. He is called on to speak at numerous conferences, including the ASTD International Conference, and the PDA Biennial Training Conference. He has served in leadership positions with numerous industry training organizations, including as a past President of the New England area's cGMP Trainers' group. He is the founding member of the PDA's Biennial Training Conference Committee. He holds both Undergraduate and Graduate degrees in Management from the University of Texas at Arlington, and served as a Captain in the US Army.

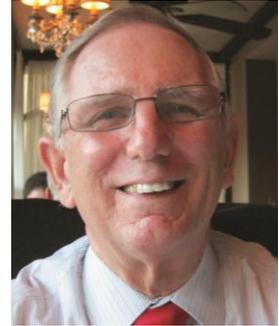


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Richard Sands

RTS Training Services

Dick Sands has over forty years' experience in the pharmaceutical industry. He retired from Merck & Co., Inc. in 1999 after almost 39 years. During that time, Dick held a variety of line and staff positions within Merck's Manufacturing Division. Prior to his retirement, Dick was charged with establishing a divisional level group to provide regulatory and job skills training for over 13,000 employees worldwide through internal partnering, external joint venture initiatives and leveraging existing resources.



Prior to his worldwide assignment, Dick was the Manager of Performance Improvement, a training and motivation department, responsible with supporting the development activities of over 2500 employees at Merck's largest manufacturing facility.

Dick is currently a consultant for the industry, specializing in regulatory and job skills training and assessments, working with a number of major pharmaceutical and chemical manufacturers.

He holds a B.S. degree in Industrial Management from La Salle University in Philadelphia and a Masters in Education degree in Instructional Technology from the Pennsylvania State University.

Erin Sorrell

Grifols Therapeutics Incorporated

Erin Sorrell has been a member of the Performance Development Team at Grifols Therapeutics for five years. In this role she works with various functional areas to assess, design, deliver, and evaluate the training programs. She has worked at Grifols for more than 12 years in various rolls which include validation and sterile manufacturing. Erin obtained her BS in Animal Science for North Carolina State University and is also an ASQ Certified Quality Auditor and ASQ Certified Manager of Quality and Organizational Excellence.



Donna Steele

Grifols Therapeutics Incorporated

Donna Steele is the Performance Development Manager at Grifols Therapeutics. This group provides technical training for the organization at five different sites. For the last 17 years she has managed and developed employee training programs, 9 years at Grifols (formerly Talecris) and 11 years at Wyeth. Donna has a Masters in Adult Education from Virginia Commonwealth University. She is also an ASQ certified Engineer, Auditor, and Manager.



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Tina Tocco

Merck and Company, Inc.

Tina Tocco has been with Merck and Co. since 1988. She worked in the Quality Control Laboratory for 12 years as a supervisor and analytical scientist supporting various testing assays for cell culture, potency and identity. She has spent the last 11 years working in West Point Training and Development responsible for designing and delivering training for operations, quality and technology groups within Merck. Today Mrs. Tocco manages the site training team responsible for New Hire Onboarding, GMP Education-Regulations, Aseptic Gowning and Aseptic Technique Training Programs. She holds a B.S. degree from Gwynedd Mercy College in Medical Technology.



Barbara van der Schalie

SAIC- Frederick, Inc.

Barbara van der Schalie has over twenty-five years of experience in education, with the last sixteen focused on outcomes-based adult professional training. She is currently the Clinical Training Manager in the Clinical Research Monitoring Program of SAIC-Frederick, serving the National Institute of Allergic and Infectious Diseases (NIAID). Prior to switching to the clinical side, Barbara was a Senior Manager in QA Compliance, Corporate Training at MedImmune, Inc, responsible for the design, implementation, evaluation and maintenance of the global Technical and Compliance Training Programs, the QA Training Manager at Human Genome Sciences, the Technical Training Manager at Celera Genomics and the Technical Training Manager at Life Technologies.



Ms. Van der Schalie has an undergraduate degree in Biology-Chemistry with a minor in secondary education, as well as a Master of Science degree in Biomedical Sciences with a focus on Cell Biology. She has taught Human Anatomy and Physiology 1 & 2 at Frederick Community College in the Allied Health Program for over 15 years. Her specialty is adult learning theory and its application in workplace training.

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James Vesper

Learning Plus, Inc.

James Vesper established and is president LearningPlus, Inc., and has had more than 30 years' experience in the pharmaceutical industry.

Mr. Vesper worked eleven years at Eli Lilly and Company, Indianapolis. His last assignment was as Project Leader of GMP Education and Instruction, establishing the department and its mission.



Since 1991, he and his firm have worked with pharma/biopharma, device, and blood products organizations around the world consulting on performance solutions and custom learning events; Mr. Vesper is frequently asked to present training courses and workshops on GMPs, Quality Risk Management, Investigation Report Writing, and Learning & Performance solutions.

Mr. Vesper has written five books, including *Risk Assessment and Risk Management: Clear and Simple*, *GMP in Practice (4th Edition)*, and multiple technical articles. He received the PDA's Agallico Award for Teaching Excellence and has been an invited speaker at meetings around the world.

Currently, Mr. Vesper is a consultant to World Health Organization's (WHO) Vaccine Quality Network – Global Learning Opportunities, working in China, Turkey, and Switzerland. He has a BS in biology (Wheaton College) and an MPH (University of Michigan School of Public Health). He is completing a Ph.D. in Education from Murdoch University in Perth, Australia.

Laurie Witte

Gallus Biopharmaceuticals

Laurie has over 10 years of experience leading and developing training programs for global Pharmaceutical organizations.

In her current role at Gallus Biopharmaceuticals, she manages the Quality Services department which includes the control, issuance, and reconciliation of all cGMP documentation, the support and administration of the GMP Quality Systems, and the GMP Training function.

Prior to her current role at Gallus, Laurie was the Manager of Learning and Development at KV Pharmaceuticals. She has also held similar positions at Centocor (a division of Johnson & Johnson), as well as Wyeth Biopharmaceuticals.

Specialties

- ✓ Design and Implementation of cGMP Training Systems
- ✓ Implementing Trainer Qualification Programs
- ✓ Developing On-Boarding Training Programs for New Employees and Re-integration Efforts
- ✓ Right-Sizing Curricula
- ✓ Implementing Training Effectiveness Audits

Education

B.S. in Biology (emphasis in Microbiology), Missouri State University

