

2012 PDA Biennial Training Conference
From Training to Learning - Improving Performance in a Regulated Environment
October 8-9, 2012 | Hyatt Regency | Bethesda, Maryland

Program Agenda

Sunday, October 7, 2012

3:00 p.m. - 6:00 p.m.
Registration Open

Ballroom Foyer

5:00 p.m. - 6:00 p.m.

Meet and Greet Reception - Pick up your registration materials a day early and enjoy light refreshments and the opportunity to network with other conference attendees

Ballroom Foyer

Monday, October 8, 2012

7:30 a.m. - 5:00 p.m.
Registration Open

Ballroom Foyer

7:30 a.m. - 8:30 a.m.
Continental Breakfast

Ballroom Foyer

8:30 a.m. - 8:45 a.m.
Welcome and Opening Remarks

Haverford/Baccarat Suite

Tim Gillum, PhD, Senior Manager, Training, *Baxter Healthcare*, Co-chair, 2012 Biennial Training Conference Program Planning Committee

8:30 a.m. - 10:00 a.m.

Haverford/Baccarat Suite

Opening Plenary Session

Moderator: Joyce S. Winters, Owner, *J Winters Consulting, LLC*, Co-chair, 2012 Biennial Training Conference Program Planning Committee

Hear about how a company's Vaccine Sterile Manufacturing division is leveraging learning to build capability and become a high performance organization - one where the hearts and minds of their people are fully aligned with, and seamlessly executing on, their goal: to increase production, decrease cost per dose and provide life-saving vaccines to patients who need them globally. This presentation will walk participants down the path that this company took - from needs assessment to curriculum design and execution - that are directly enabling this company to build the capability of its people, improve operational performance and meet its business objectives.

8:30 a.m. - 9:30 a.m.

Vaccine Academy Training

Wendy A. Kouba, Executive Director, Strategy Realization Office, *Merck Vaccines and Sterile Manufacturing*

Doug Gnutti, Senior Director, Sales and Account Development, *Performance Development Group*

Patty Jurgensen, Learning Manager, *Merck*

9:30 a.m. - 10:00 a.m.

Q&A

9:45 a.m. - 6:30 p.m.
Exhibit Area Open

Ballroom Foyer

10:00 a.m. - 10:45 a.m.

Refreshment Break in Exhibit Area

Ballroom Foyer

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<p><i>Waterford Suite</i> C1 - Instructional Design for Non - Dummies</p>	<p><i>Lalique Suite</i> C2 - Whose Learning Is It Anyway? - Evaluating Training Effectiveness</p>	<p><i>Cartier/Tiffany Salon</i> C3 - Learning Management Systems</p>
<p>Moderator: Joanna Gallant, Owner/President, <i>Joanna Gallant Training Associates, LLC</i></p>	<p>Moderator: Richard T. Sands, Project Manager, <i>RTS Training Services</i></p>	<p>Moderator: Joyce S. Winters, Owner, <i>J Winters Consulting, LLC</i></p>
<p>After attending this hands-on instructional design session, participants will be able to:</p> <ul style="list-style-type: none"> • Define and use a list of questions to ascertain training needs, gaps, and goals • Identify various options for training delivery based on the defined needs • Use defined needs to develop appropriate training interactions • Identify appropriate assessment types for the defined training 	<p>Employee training is such an essential part of life in the pharma industry, that we often lose sight of the actual "customer" involved. From a regulatory perspective, Quality departments are interested in being able to adequately demonstrate that personnel were trained before undertaking assigned tasks. From a Training and Development perspective, trainers are interested in being able to deliver meaningful training which will impact and affect behaviors on the job. However, what is the learner looking to gain? When shifting the focus from compliance and training objectives to a learner centered objective, you will find that the other two conditions will be more easily met in the process. This presentation will explore learning from the learner's perspective and help trainers and managers identify the real objectives behind the activities we call "training". Active learning principles will be shared and are utilized to increase the trainee's motivation and understanding. However, the true measure of any training initiative is the impact on the learner and the organization as a whole. This session will introduce a four level model of training effectiveness evaluation and provide insight into which level is appropriate for various initiatives. Finally, training is only really useful if it can be applied at the appropriate time. The session will identify opportunities for ongoing learning support to ensure the training investment yields expected returns.</p>	<p>Is the majority of your training read and understand? How do you prepare a workforce for commercial production when there has been a significant downtime in commercial production? How do you ensure employees are competent and qualified to perform a GMP activity? How do you maintain the skills and competencies of your workforce? This session will focus on these questions through the presentation of a case study and a discussion on the simple tools used to address said questions. Join us as we share the challenges and successes of an experience that most GMP training professionals will go through at least once during their career.</p>
<p>Joanna Gallant, Owner/President, <i>Joanna Gallant Training Associates, LLC</i></p>	<p>Kristina Barkhouser, President, <i>Excelen Performance, Inc.</i></p>	<p>Paul Corbin, Manager, Quality Training cGMP, <i>Cardinal Health, Inc.</i></p>

11:45 a.m. - 1:00 p.m.
Networking Luncheon

Concours Terrace

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<p><i>Waterford Suite</i> C4 - Make S.U.R.E. of your Training: The Basics of Instructional Design</p>	<p><i>Lalique Suite</i> C5 - Employee Qualification and Re-qualification Process</p>	<p><i>Potomac/Patuxent/Embassy</i> C6 - What to Do When Training is Not the Solution (Round Table)</p>
<p>Moderator: Joanne Cochran, Principal, <i>JWC Associates</i></p>	<p>Moderator: James Vesper, President, <i>LearningPlus</i></p>	<p>Organizations are often quick to use training as the corrective action for issues better addressed with non-instructional solutions. This facilitated round table session will provide participants with the opportunity to share their experiences, methods, tools and challenges with other learning professionals. The session will center on five key topics:</p>
<p>This highly interactive lecture/discussion will provide the participant with the basics of adult learning theory and present a proven model for the training design. The overall objective of the topic is to make the participant's training sessions more effective and valuable. The session will draw on the accumulated experience of the facilitator and the participants to illustrate the model. Individual and small group exercises will be used to apply the model presented to a training session of the participants' own design. The participants will leave the session with a step by step model for how to design an effective training session.</p>	<p>Both the U.S. and E.U. place the utmost importance in the establishment and maintenance of quality systems within pharmaceutical manufacturing facilities. The regulations state that there must be comprehensively designed and correctly implemented systems of quality assurance incorporating GMP and skills training. To help ensure that a firm is resourced with competent personnel, two major elements must be integrated within a firm's quality system. They are clear, well-written procedures and formalized training that includes testing of knowledge and skills to assure employee competence, both initially (qualification) and on a continuing basis (re-qualification).</p> <p>This session will discuss one approach of qualification/re-qualification that will ensure both employees with critical job functions that have a direct product impact or those who can indirectly influence product characteristics are qualified to consistently perform in a manner that assures the safety, identity, strength/potency, purity and quality of the product and/or the integrity of the service.</p>	<ul style="list-style-type: none"> • 1- If it is not training, what is it? • 2- Identifying the need for instructional and non-instructional solutions • 3- Linking real learning to the business through appropriate assessments • 4- Best methods and tools to ensure success in communicating when training is not the solution • 5- Gaining management buy-in on when training is the answer and when it is not <p>Participants will have the opportunity to rotate through the topics in this extremely interactive session.</p>
<p>Rick Rogers, Training Manager/Lead, <i>Genzyme Corporation</i></p>	<p>Richard T. Sands, Project Manager, <i>RTS Training Services</i></p>	<p>Facilitators: Joanna Gallant, Owner/President, <i>Joanna Gallant Training Associates, LLC</i> Tim Gillum, PhD, Senior Manager, Training, <i>Baxter Healthcare</i> Kery Mortenson, Training Effectiveness Manager, <i>Baxter Healthcare</i> Robin O. Wachter, Consultant - Global MQ Learning and Development, <i>Eli Lilly and Company</i> Joyce S. Winters, Owner, <i>J Winters Consulting, LLC</i></p>

2:10 p.m. - 3:10 p.m.

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<i>Waterford Suite</i> C7 - Training and Troubleshooting - How Current SOP Training Covers Only Half of What Trainees Need to Know	<i>Cartier/Tiffany Salon</i> C8 - Sound Bites, Sight Bites, and Write Bites...Positive Effects for Training	<i>Lalique Suite</i> C9 - Human Error
Moderator: Kristina Barkhouser , President, Excelen Performance, Inc.	Moderator: Rick Rogers , Training Manager/Lead, Genzyme Corporation	Moderator: Bob Dana , Senior Vice President, Regulatory Affairs and TRI, PDA
The pharmaceutical industry invests a great deal of time and resources training employees how to perform tasks correctly in order to ensure high quality products. But we often miss the critical “flip side” – training personnel how to respond to problems. Come hear and discuss ideas on how to train employees what to do when things go wrong!	What are sound bites, sight bites, and write bites? How can we use them effectively in our GMP training? Learn how to: <ul style="list-style-type: none"> • Deliver more impact with less • Hold your audiences’ attention • Use the “bites” appropriately • Leave a GMP message that lasts Put the “Bite” in GMP Training today!!!	Attendees will gain an insight into the common causes of human error in the area of pharmaceutical manufacturing and will leave with a defined approach to investigating risk influencing factors and root cause, reducing human error and sustaining error reduction within their own company.
Elaine Lehecka Pratt , President, <i>Lehecka Pratt Associates</i> and Industry Professor, <i>Stevens Institute of Technology</i>	Joanne Cochran , Principal, <i>JWC Associates</i>	Ann McGee , Managing Director and Principal Consultant, <i>McGee Pharma International</i>

3:10 p.m. - 3:55 p.m.

Refreshment Break in Exhibit Area

Ballroom Foyer

3:55 p.m. - 4:55 p.m.

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<i>Waterford Suite</i> C10 - Engaging Learners without Coming Across Like Big Bird of Sesame Street	<i>Lalique Suite</i> C11 - How to Meet FDA Expectations for Training in the Pharmaceutical Industry	<i>Cartier/Tiffany Salon</i> C12 - Focal Points for a Training Process
Moderator: Robin O. Wachter , Consultant - Global MQ Learning and Development, <i>Eli Lilly and Company</i>	Moderator: Richard T. Sands , Project Manager, <i>RTS Training Services</i>	Moderator: Tim Gillum, PhD , Senior Manager, Training, <i>Baxter Healthcare</i>
How do you get and keep a learner’s interest in training? We’ve all struggled with this question, and resorting to things like interpretive dance makes us look like we’re trying to entertain children. In this session, we’ll explore what contributes to capturing the interest of our learners (as well as things to avoid whenever possible!), and identify ways that learner engagement can be improved – and we’ll have the group share some of their most effective activities.	What are the FDA’s expectations on training? Take a different perspective: know what the requirements for training are in the CFR, develop a plan to ensure your employees are properly trained to do their job and have a system that provides documented evidence your employees meet the requirements. By doing this, you will meet the expectations on training of most, if not all, regulatory agencies. This session will go over the “qualification” requirements specified in the CFR. We will discuss ways in which you can meet those requirements and	Whether you working through the challenges associated with resolving compliance gaps while under regulatory action or simply preparing for an upcoming inspection, your organization will benefit by ensuring its training system is sound. This session will focus on some recent lessons learned on the following: <ul style="list-style-type: none"> • Developing a learning strategy • The role of Job Descriptions • Curricula Development • Quality System Linkages (ie doc mgmt) • Role of Management

Session C10 continued	Session C11 continued demonstrate your personnel are properly trained to do their job to ensure your company's product(s) are safe, pure and effective.	Session C12 continued So if you are interested in helping your organization resolve existing enforcement actions or avoid any enforcement actions, please join us for this session.
Joanna Gallant , Owner/President, <i>Joanna Gallant Training Associates, LLC</i>	David Mayorga , President and Senior Consultant, <i>DAM Good Consulting</i>	Laurie Witte , Quality Services Team Lead, <i>Gallus BioPharma</i>

4:55 p.m. - 6:30 p.m.

Ballroom Foyer

Networking Reception in Exhibit Hall

6:30 p.m. - 7:15 p.m.

PDA/Training Research Institute Open House - attendees are encouraged to take a short 2 block walk to PDA Headquarters and tour the TRI facility. Please meet in the ballroom foyer at 6:20 and PDA staff will be available to direct attendees to TRI.

Tuesday, October 9, 2012

7:30 a.m. - 5:15 p.m.

Ballroom Foyer

Registration Open

7:30 a.m. - 8:30 a.m.

Ballroom Foyer

Continental Breakfast

8:30 a.m. - 9:30 a.m.

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<i>Waterford Suite</i> C13 - Basic and Foundation Training for Personnel Working in an Aseptic Environment	<i>Lalique Suite</i> C14 - Training Effectiveness: Thinking Outside the Molecule	<i>Cartier/Tiffany Salon</i> C15 - The Globalization of Quality Training: Identifying, Assigning, Tracking and Reporting
Moderator: Elaine Lehecka Pratt , President, <i>Lehecka Pratt Associates and Industry Professor, Stevens Institute of Technology</i>	Moderator: Kristina Barkhouser , President, <i>Excelen Performance, Inc.</i>	Moderator: Joyce S. Winters , Owner, <i>J Winters Consulting</i>
This program will walk you through a two week program for new hired personnel preparing to work in aseptic environments. The core content of the presentation includes a discussion around the challenges the pharmaceutical industry faces when trying to onboard new hires on basic GMPs, safety concepts and aseptic skills and cleanroom conduct principles.	Increasing the impact, effectiveness, and measurement of training is the focus of this session. The core content will highlight the <i>High Impact Learning Methodology</i> and how it has been used in leading organizations to maximize training application and results. Also, the <i>Success Case Method</i> will also be highlighted and will show a practical and credible ROI methodology that can be applied to training initiatives.	The training organizations in many regulated companies are leveraging a variety of Learning Management Systems (LMS) to help in the identification and management and reporting of training data. These systems each experience the unique challenge of meeting regulatory validation requirements while ensuring all personnel data complies with privacy requirements. This session will provide real life experience in implementing and managing an LMS for a global organization. If you would like to gain more perspective on establishing the an optimal balance of standardization and flexibility within your LMS or how regional requirements potentially impact your LMS, then this session is a definite value add for you.
Roberta Laver , Senior Learning Specialist, <i>Merck</i> Tina Tocco , Learning Lead, <i>Merck</i>	Eric Flasck , Partner, <i>Advantage Performance Group</i>	Tim Gillum, PhD , Senior Manager, Training, <i>Baxter Healthcare</i>

9:15 a.m. - 4:30 p.m.

Exhibit Area Open

Ballroom Foyer

9:30 a.m. - 10:15 a.m.

Refreshment Break in Exhibit Area

Ballroom Foyer

10:15 a.m. - 11:15 a.m.

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<i>Waterford Suite</i>	<i>Lalique Suite</i>	<i>Cartier/Tiffany Salon</i>
C16 - Evidence-Based Competency: More Than an Observation!	C17 - Training Effectiveness - What's a Good Approach Look Like	C18 - Blended Distance Learning: What, Why, When, Who, & How
Moderator: Joyce S. Winters , Owner, J Winters Consulting, LLC	Moderator: Rick Rogers , Training Manager/Lead, Genzyme Corporation	Moderator: Robin O. Wachter , Consultant - Global MQ Learning and Development, <i>Eli Lilly and Company</i>
Do you want to get past “just observations” to verify ongoing staff competency? We would like to share a new process for ongoing competency assessment that we have implemented, one that is outcome-focused and accountability-based. This type of Evidence-based Competency Assessment provides managers with multiple methods to verify an employee's competency while focusing not only on technical skill assessment but also critical thinking and interactive skills as well. From an employee's viewpoint, the Evidence-based Competency Assessment provides them with opportunities to choose various methods to demonstrate their competencies and complete those methods in a timeframe that fits their work schedule. So, if you are interested in dumping your checklists and learning more about this new approach, please join us for this session and we will walk you through what we did to implement it in our company	The session will target the challenges that human performance improvement functions face in regulated organizations. In this interactive session, participants will review key principles and tools to achieve greater compliance and productivity by using unconventional methods and tools. Specific tools to rapidly identify instructional and non-instructional solutions, align key knowledge, skills and behaviors to desired goals, and lastly implement predictive measures for organization impact.	Do any of these issues sound familiar? Reductions in training/travel budgets... Technology tools everywhere... Improving access to learning... Learners taking more control of their learning... Less "instruction"/more "facilitation"... Blended distance learning can be a viable solution for all of these issues. Learn about what's being blended; why it works; when to consider it; who can benefit, and how to decide which programs to deliver this way.
Jill Drummond , Director, Training and Education, <i>Blood Systems</i> Jan Gray , Instructional Design Manager, <i>Blood Systems</i>	Kery Mortenson , Training Effectiveness Manager, <i>Baxter Healthcare</i>	Paula Fritsch , Consultant, Learning/Development Strategy, <i>Eli Lilly and Company</i>

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<p><i>Waterford Suite</i> C19 - Project Management for Trainers - First Steps</p>	<p><i>Potomac/Patuxent/Embassy</i> C20 - What to Do When an Employee Passes their Initial Assessment, but Does not Apply the Knowledge/Skills on the Job – (Round Table)</p>	<p><i>Lalique Suite</i> C21 - Why Should Supervisory Training be Different?</p>
<p>Moderator: Robin O. Wachter, Consultant - Global MQ Learning and Development, <i>Eli Lilly and Company</i></p>	<p>Training organizations are increasing their investment of time and energy on ensuring successful knowledge/skill transfer occurs as part of their training courses. These level two assessments provide evidence that the learner met the learning objectives of the course. What happens when they do not apply this knowledge/skill on the job? This facilitated round table session will provide participants with the opportunity to share their experiences, methods, tools and challenges with other learning professionals. The session will center on five key topics:</p>	<p>Moderator: Richard T. Sands, Project Manager, <i>RTS Training Services</i></p>
<p>Trainers often have to manage many project planning scenarios including multiple vendors, technologies, content providers, and delivery schedules. How can you plan for all of these everchanging and interrelated activities and still keep your sanity? This session will explain concepts and tools for trainers to successfully manage complex training projects.</p>	<ul style="list-style-type: none"> • 1-How do you know if employees are applying new knowledge/skills on the job? • 2-What is the best use of requalification? • 3-What is the appropriate level of assessments? • 4-What are the best methods and tools to ensure success in communicating the gaps in application? • 5-How do we gain management understanding and support? <p>Participants will have the opportunity to rotate through the topics in this extremely interactive session.</p>	<p>At a trainer's conference more than 20 years ago, a national drug expert from FDA said that "it is more important to train management than anyone else" in a pharmaceutical manufacturing facility. In this session, we will examine what supervisors and managers do, how these roles and responsibilities define the content of the training and ways it can best be presented, and how tacit knowledge or "know how" can be shared within the organization. We will discuss ideas for both initial and on-going learning events to help develop the GMP knowledge, skills, and expertise of supervisors, managers, and executives.</p>
<p>Dean Pratt, Manager Strategy and Operations, Life Sciences, <i>Deloitte Consulting LLP</i></p>	<p>Facilitators: Kristina Barkhouser, President, <i>Excelen Performance, Inc.</i> Joanne Cochran, Principal, <i>JWC Associates</i> Tim Gillum, PhD, Senior Manager, Training, <i>Baxter Healthcare</i> Kery Mortenson, Training Effectiveness Manager, <i>Baxter Healthcare</i> Joyce S. Winters, Owner, <i>J Winters Consulting, LLC</i></p>	<p>James Vesper, President, <i>LearningPlus</i></p>

1:40 p.m. - 2:40 p.m.

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<i>Cartier/Tiffany Salon</i> C22 - The Open Courseware Initiative at Johns Hopkins University	<i>Lalique Suite</i> C23 - What's Your Yield? Increasing the Training Effectiveness of your Training System	<i>Waterford Suite</i> C24 - Curricula Blitz: From Job Description to Learning Plan to Measurement
Moderator: James Vesper , President, <i>LearningPlus</i>	Moderator: Paul Corbin , Manager, Quality Training cGMP, <i>Cardinal Health, Inc.</i>	Moderator: Joyce S. Winters , Owner, <i>J Winters Consulting, LLC</i>
This presentation will introduce OpenCourseWare (OCW) at Johns Hopkins Bloomberg School of Public Health (JHSPH) as well as the OpenCourseWare Consortium (OCWC), an organization that supports the development of open educational resources (OER) around the world. It will also provide some examples of how OERs are being used by educators, public health professionals, and independent learners. Visitors to JHSPH OCW and other OER sites will find high-quality materials covering a wide array of topics. These materials may be adopted and even adapted because OERs use Creative Commons licensing to encourage sharing and reuse. OCW helps JHSPH fulfill its educational mission for teachers and learners who are unable to formally enroll in the School's academic programs.	Come follow the life cycle of measuring the training effectiveness of a robust training system. Learn how the measurements evolved with the business needs over time. The life cycle of the transformation will be told through the eyes of practicing professionals who are continually searching for a balanced implementation of Best Practices in the real world of Technical Training.	Organizations often feel that the training processes are slow and do not add sufficient value for the time commitment they require. This session will provide participants with an effective and efficient process of curricula development in a regulated environment. Participants will review key principles and process steps of the Blitz Methodology. The session will also provide tools and templates to aid in change management, communication, process facilitation and demonstrated business results for participants who will want to apply this methodology within their organizations. This session is ideal for participants looking to increase their value proposition within their organization and for those looking to streamline their approach to the learning value stream.
Sukon Kanchanaraksa, PhD , Director, Center for Teaching and Learning, <i>Johns Hopkins Bloomberg School of Public Health</i>	Donna Steele , Performance Development Manager, <i>Grifols, Inc</i> Malcolm Pratt , Performance Development OJT Specialist, <i>Grifols, Inc.</i> Erin Sorrell , Performance Development OJT Specialist, <i>Grifols, Inc.</i>	Tim Gillum, PhD , Senior Manager, Training, <i>Baxter Healthcare</i>

2:50 p.m. - 3:50 p.m.

Concurrent Sessions

From Training Programs to Learning Programs

Training System Effectiveness

From Theory to Practice

<i>Lalique Suite</i> C25 - To Test or Not to Test? And if So, How?	<i>Waterford Suite</i> C26 - Training in a Regulated Environment	<i>Potomac/Patuxent/Embassy</i> C27 - Use of Job Aids (Paper and Electronic) - Roundtable
Moderator: Rick Rogers , Training Manager/Lead, <i>Genzyme Corporation</i>	Moderator: Paul Corbin , Manager, Quality Training cGMP, <i>Cardinal Health, Inc.</i>	Training organizations are experiencing the need to balance the validity of knowledge Management with the evolution of social learning within their businesses. This "need now, learn now" requirement is placing an increased level of attention on the effective use job aids. This facilitated round table session will provide participants with the opportunity to share their experiences,
As FDA scrutiny of the qualifications of professionals in the regulated environment increases, the need for a documented, demonstrated knowledge and skill set is becoming more important. In addition, the need to demonstrate effectiveness of training,	Before making a decision, it is wise to assess the risks involved with it! Attending this session will assist attendees define techniques for risk-based decision making and how to apply them in a training environment.	

<p>Session C25 continued especially as part of a corrective and preventive action (CAPA) plan , is also increasing. This session will provide an overview of the selection, construction, and implementation of appropriate assessment tools in the regulated workplace. This presentation will provide a “decision tree” to determine if an assessment is warranted, and, if so, which tools are available for specific applications. It will also include a brief overview of the construction, implementation, and evaluation of tests</p>	<p>Session C26 continued</p>	<p>Session C27 continued methods, tools and challenges with other learning professionals. The session will center on five key topics:</p> <ul style="list-style-type: none"> • 1-What is the risk of using job aids? • 2- How do organizations leverage mobile technology for job aids? • 3- Where do job aids currently reside within your Quality System? • 4- What are the best methods and tools to ensure success in utilizing job aids? • 5- How do we gain management understanding and support? <p>Participants will have the opportunity to rotate through the topics in this extremely interactive session.</p>
<p>Barbara Van der Schalie, Clinical Training Manager, <i>SIAC-Frederick, Inc.</i></p>	<p>Troy Fugate, Vice President, <i>Compliance Insight</i></p>	<p>Facilitators: Joanna Gallant, Owner/President, <i>Joanna Gallant Training</i> Tim Gillum, PhD, Senior Manager, Training, <i>Baxter Healthcare</i> Richard T. Sands, Project Manager, <i>RTS Training Services</i> James Vesper, President, <i>LearningPlus</i> Joyce S. Winters, Owner, <i>J Winters Consulting, LLC</i></p>

3:50 p.m. - 4:30 p.m.

Refreshment Break in Exhibit Area

Ballroom Foyer

4:30 p.m. - 5:30 p.m.

Closing Plenary Session: Regulatory Training Expectations

Moderator: Tim Gillum, PhD, Senior Manager, Training, *Baxter Healthcare*

It is not only what regulators expect from pharmaceutical training or what the industry would like regulators to see during audits. It is also about getting ready and about confidence. From the pages of regulations enforcing manufacturing, storage and distribution of pharmaceutical products, we move to a unique learning example of a WHO-PDA initiative where all players, public and private including regulators get together for an experiential learning event: Pharmaceutical Cold Chain Management on Wheels: Video presentation.

4:30 p.m. - 5:15 p.m.

WHO Perspective on Pharmaceutical Training

Ümit Kartoğlu, MD, Scientist, *World Health Organization (WHO)*

5:15 p.m. - 5:30 p.m.

Q&A

Haverford/Baccarat Suite

5:30 p.m.

Closing Remarks and Adjournment

Tim Gillum, PhD, Senior Manager, Training, *Baxter Healthcare*

Haverford/Baccarat Suite