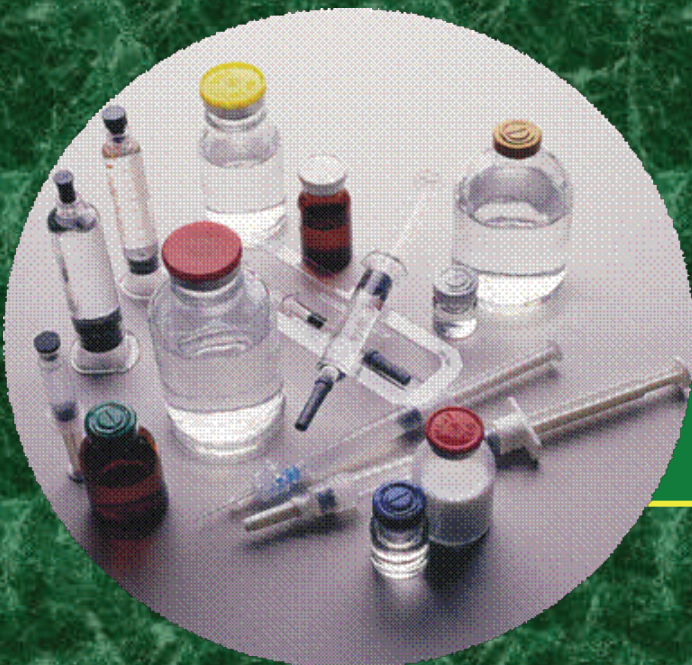




# 2009 GMP TEA Biennial Conference

**“MISSION POSSIBLE: GMP TRAINING”**

**NOVEMBER 1 - 5, 2009  
ORLANDO, FLORIDA**



★ *Register before June 30,  
2009 for discount*

**Walt Disney World  
Contemporary Resort**

[www.gmptea.org](http://www.gmptea.org)



## About the GMP TEA Inc.

The GMP TEA Inc. is a not for profit organization, consisting of compliance trainers from Life Science companies and their affiliates and/or subsidiaries. Our mission is to unite Life Science Training and Behavioral Education individuals in an effort to educate, collaborate and share best practices as we develop and prepare the workforce of the future. More information including membership requirements and application can be found at our web site [www.gmptea.org](http://www.gmptea.org).

## About the Conference

This year's event will be the 12th GMP TEA biennial conference and promises to be the best yet. The conference is divided into a healthy mix of general sessions and an abundance of concurrent sessions for participants to select targeted topics. We're currently working to attract training vendors, so that attendees will also have the opportunity to see the latest in goods and services available to enhance their in-house programs . . . And as always (the basis on which the organization was founded and our continuing mission) networking, networking, and more networking - opportunities at breakfast, lunch, break, after hours . . . Not to even mention the special events we've arranged.

### From the 2007 Conference

*In my 16 year association with the TEA, I'd say that was definitely one of the best, if not the best: great plenary sessions, good breakouts, timing of the day right mix of business and networking /social, and outstanding venue. □ My people all commented on the value they received and like myself can't wait for the next one in two years! □ Everyone I talked to loved it!*

*- Longtime GMPTEA Member*

### Topics for Concurrent Sessions

#### GMP Training

Refreshers, Good Doc Practices, New Hire Orientation, GMPs for Management, etc.

#### Evaluations / Qualification

Knowledge Checks, Knowledge Transfer, Participant Assessments, Writing Tests, Effectiveness, etc.

#### Training Content/Design

Instructional Design, Curricula Development, Needs Assessments, Creative ideas, Using Humor, etc.

#### Training Delivery

Interactive solutions, Ice breakers, Games, Simulations, etc.

#### Job Specific Training

Procedural, OJT, Competency Based, etc.

#### Regulatory Currency

System Based Inspections, Quality Systems, Training Audits, EU regulations, ICH Guidelines, Risk Management, Investigations, etc.

#### E Training Tools

Learning Management Systems, E Doc and Trackwise Systems, E Learning, Helpful Software packages, etc.

#### Business of Training

Managing Training Resources, Management Support, ROI metrics and Reporting, Continuous Improvement, Changing Behavior, Successful Roll Outs, Gap Analysis, Reactive Training

## Who Should Attend

Anyone charged with designing, developing, delivering or coordinating any GXP training or anyone with supervisory/ managerial responsibilities for the training function. The "C" in CGMP is the foundation for complying with the spirit of the regulations – what better way to measure your currency than to benchmark and share best practices with your peers across the industry.

## Registration Fees

★ Register before June 30, 2009 for discount

	Feb 1 – Apr 30	May 1- Jun 30	Jul 1-Sep 30 *
Member	<del>\$1249</del>	\$1249	\$1349
Non-Member	\$1249	\$1349	\$1449

Registration includes Networking reception, 4 continental breakfasts, 4 lunches, 1 theme dinner, 6 breaks, 4 Day Session Attendance, gifts, prizes and giveaways.

•Registration will close on September 30.

•Registration does not include hotel accommodations

# Conference Schedule

**Sunday**

Afternoon Registration - Evening Welcome Reception/Networking Activity (Contemporary)

Monday	Grand Republic B	Grand Republic C	Grand Republic D	Grand Republic A	Ballroom of America B
7:00 - 8:00 AM	Breakfast				Vendor Exhibition
	General Session (Grand Republic B) 8 - 9 Opening: GMPTEA 2009! 9 - 10 "The Great Pin Escapade" - Bernice Marshall				
8:00 - 10:00 AM	Break				
10:00 - 10:15 AM	Break				
10:15 - 11:00 AM	How to make SURE of Your Training - Rick Rogers	How to Train Your Organization - Reg Inspections - Tela Engdahl	Training Isn't Always the Answer - Joanna Gallant	Best Practices for Designing E Learning Content - Rick Bennett	
11:00 - 11:45 AM	Reinventing Yourself for the New GxP Environment - Vivian Bringslimark & Katie Anschutz	Justifying your existence - How to show ROI from training - John Hunt & Frank Zukowsky	Implementing a Successful Learning Strategy - Trina Lima & Michael Parrish	Get Beyond SOP Training to Skill Training - Patty Bowers	
11:45 AM - 12:45 PM	Lunch				
12:45 - 1:00 PM	Networking Function				
1:00 PM - 1:45 PM	Who's GMP Line is it Anyway? - Bill O'Connor	Case Study: Implementing SAP in a global GMP environment - Jennifer Lapioli	Capital is Capital - Barbara Litsenberger	Teaching Old Dogs New Tricks - Kristina Spitzer	
1:45 - 2:30 PM	Reserved	Reserved	Reserved	Reserved	Vendor Reception 1:45 - 3:45 PM

Monday Evening: Dinner On Your Own - Enjoy the Parks!

Tuesday	Grand Republic B	Grand Republic C	Grand Republic D	Grand Republic A	Ballroom of America B
7:00 - 8:00 AM	Breakfast				Vendor Exhibition
	General Session (Grand Republic B) Producing In-House Training Videos - Garth Mussey				
8:00 - 10:00 AM	Break				
10:00 - 10:15 AM	Break				
10:15 - 11:00 AM	Tricks for New Trainers - Patty Bowers	283s - 483's - David Gallup	Management Support for Training - V. Bringslimark	E Training Tips - Tom Leise	
11:00 - 11:45 AM	The Holistic Training Approach - Katie Anschutz	Opertor Certification - Reinventing the Wheel - John Hunt & Frank Zukowsky	Implementation of Procedural Document Training Program - Alex Armendariz & Susan Lara	Poka Yoke - Donna Butchko	
11:45 AM - 1:00 PM	Lunch				
1:00 - 1:15 PM	Networking Function				
1:15 - 2:00 PM	Starting From Scratch: Development of an OJT Guidance Document - Joanna Gallant, Patrick Spain, Susan Adamzack	Quality Control - New Hire Training Program - Training System - Amanda Glover	Implementing an OJT program from the ground up - Cheryl Boll & Jason Packard	Center of Excellence for Content & Delivery - Trina Lima	
2:00 - 2:15 PM	Break				
2:15 - 3:00 PM	Brewing Up Some GMP Training - Bill O'Connor	Having a Successful On-Boarding Program in a Regulated Environment - Michelle Parker & Maria Rolo	Reduce Operator Errors Using Needs Assessments - Patrick Kelly	Do it Yourself - Michele Nonatelli	

Tuesday Evening: Themed Dinner - Dress for the Roaring 20's (Atlantic Dance Club at Disney's Boardwalk Resort)

Wednesday	Grand Republic B	Grand Republic C	Grand Republic D	Grand Republic A
7:00 - 8:00 AM	Breakfast			
	General Session (Grand Republic B) FDA Speaker (Invited)			
8:00 - 10:00 AM	Break			
10:00 - 10:15 AM	Break			
10:15 - 11:00 AM	Performing in Compliance: the FISH! Philosophy - Patty Bowers	What is a Quality System? - Barbara Litsenberger	Risk Assessment for Training - Elaine Lehecka Pratt	How to Develop E Learning Using Limited Resources - Rick Bennett
11:00 - 11:45 AM	Site Readiness Training - Preparing a Site for a Regulatory Inspection - Tom McKelvey	So Why Didn't the Job Skills Transfer? - Joanne Cochran	Integrating Video into GMP Technical Training - Geoff Kapke	Self-Service to Training in a Regulated Environment - Michelle Parker & Maria Rolo
11:45 AM - 1:00 PM	Lunch			
1:00 - 1:15 PM	Networking Function			
1:15 - 2:00 PM	Auditory and Regulatory Inspections - Michele Nonatelli	Accelerated Learning to Recognize Change - Garth Mussey	WIP IT! - Marie Donat	No Assembly Required - Nancy Giard
2:00 - 2:15 PM	Break			
2:15 - 3:00 PM	Last Chance GMP Q & A - Rick Bennett	Beg Borrow and Steal - Patrick Spain	Business Jeopardy - Donna Butchko	Mission Possible: Setting Up An Aseptic Training Facility - Sandy Wilson

Wednesday Evening: Optional Event - Dessert Party at EPCOT and Reserved Viewing for Illuminations

Thursday	
7-8 AM	Breakfast
	GMPTEA Committee Poster Fair Recruitment for Current Committees and Chartering the New Committees
8-10 AM	Break
10-10:15	Chapter Business Meetings
10:15-12	Lunch
12:00-1:00	General Session: The Business of TEA GMPTEA Conference 2009 Wrap Up GMPTEA 2010 "To Infinity and Beyond"
1:00-3:00	

Business of Training	Evaluations/Qualifications	E Tools	Job Specific Training	GMP Training
Keeping Current	Training Content and Design	Training Delivery	Other	

Registration includes Networking reception, 4 continental breakfasts, 4 lunches, 1 theme dinner

Optional Dessert/Character(s) Fireworks Event at EPCOT

\$35 Per Adult; \$20 per child 4-11; Children 3 & under -Free  
Wednesday, November 4, 2009, 7:45 pm - Epcot ...  
Open to family, friends, guest, etc.

Stay Extra Days Before or After the Conference  
Room rate is available 3 days before and 3 days after event, based on availability.

**\*\*Times are approximate and subject to change.**

GMP TEA reserves the right to substitute presenters and re-schedule programs due to unforeseen events.



## Session Descriptions

### 283- 483s! - David Gallup

In 2007, Leiner Health Products—with 5 manufacturing facilities-- was audited by the FDA as a result of complaint by a whistleblower. The result was a massive 283, Form-483 citations. As a result, the company hired the requisite 3rd party and began the remediation process—then stopped, closed all of their manufacturing facilities and went bankrupt. The purpose of this session is to explain to attendees how this situation occurred and how to prevent such an occurrence from happening in their facility.

This session will present an overview of the FDA's Observational Inspection Program. Then participants will walk through the Inspection Program following an actual case that resulted in a Consent Decree and bankruptcy.

### Accelerated Learning to Recognize Change - Garth Mussey

Change Control is one of the top quality systems cited by the FDA. Before initiating a formal change control approval process, one must be able to recognize what kind of change, alteration or modification is being considered. Attendees will learn and practice how to make these distinctions. The concept of "functional equivalence" is introduced.

Centered around a baseball theme, this program demonstrates the use of many accelerated techniques described in Dave Meier's handbook including color, music, and an interactive baseball game.

### Auditory and Regulatory Inspections— Michele Nonatelli

Having a common industry approach of training auditors for self inspection will help to assess all aspects of product quality and compliance risks. Identify strengths and opportunities for improvement within the organization.

This session will facilitate the sharing of best practices for training auditors. Provide participants with what are the essential elements of auditing. Provide examples and material for participants that need to implement or improve a training on "Self inspection"

### Beg Borrow and Steal - Pat Spain

All trainers struggle to make their trainings as effective and engaging as possible. Story telling is a unique tool for trainers to help reach a wider variety of learners, increase information retention, break up a long session or topic, invigorate an old training, and engage participants in a way that costs them nothing. The stories shared in this session have been accrued over many years, but participants will have them to add to their trainings after only 1 hour.

This session will include the benefits of story-telling as a tool in classroom trainings, it's success in assisting with information retention, and some favorite stories. The session's stories will primarily focus on the topics of cGMP and safety and all participants will be invited to "borrow or steal" these stories, which can then begin "I know this guy who told me about..."

### Best Practices for Designing E Learning Content - Rick Bennett

Designing training content for online delivery is not the same as other training. This session will provide a person new to E-learning with the basic knowledge for creating e-learning quickly and efficiently. The session will also address best practices (tips and design concepts) that are different from regular training. Attendees can return to work after this session and begin creating E-learning within days.

This session will provide a person new to E-learning, and those with limited resources, with the basic knowledge for designing effective, affordable E-learning content. The session will address best practices and useful tips for creating E-learning content.

### Brewing Up Some GMP Training - Bill O'Connor

The presenter seeks to separate from the rigors of the CGMP environment into a relaxing hobby but in the long run, the same concepts carry over to anything we become passionate about. The participants will learn that a little creativity and humor can turn an otherwise dull topic into something fun and meaningful, and they'll actually learn how to brew beer along the way. The participant will leave the session energized with several ideas for "livening-up" their GMP training sessions.

This session will challenge the notion that training in CGMP concepts has to be the same old boring stuff by replacing the drug manufacturing process with one's passion for a hobby and drawing comparisons; in this case: Home-brewing Beer.

### Business Jeopardy - Donna Butchko

Trainers need to be able to speak the language of business in order to have credibility with their clients. Also, many trainers do not have the benefit of formal education on training. This game addresses both of those gaps, enabling trainers to hold their own in a conversation with other training or business professionals.

Not everyone who we work with today went to business school, got an MBA or even a training degree. However, everyone in business should have certain core knowledge about the leading thinkers in business and training. This core knowledge gives credibility when speaking with internal customers, stakeholders and peers in other companies. This Jeopardy-like game uses fun and friendly competition to present leading thinkers in five topic areas: General Business Knowledge; Human Performance Improvement; Quality Control and Improvement Tools; and Training. The game can be expanded to include Double Jeopardy and Final Jeopardy as time permits.

### Capital is Capital - Why Keep Training? - Barbara Litsenberger

Traditionally in times of economic stress, money and other resources designated for training programs are quickly redirected to other areas of the organization. To maintain those resources, it is critical that individuals who direct and manage training programs are able to explain, defend, and promote the important role of train-

ing within the organization. The design of this session is to help those individuals with that challenge.

Participants will collaboratively develop a model that can be used to help their organizational leaders and others understand the importance personnel training.

1. Discuss the perception of training in organizations
2. Review statistics associated with organizational training
3. Create an analogy that explains the critical role of training

### Do it Yourself Training - Trina Lima

Participants will be provided tools that can be used for the design, development, and delivery of learning projects. The project management tools will frame out the learning project so that Level III (Change) and Level IV (Results) evaluations can be completed.

This session will provide an overview of the implementation of a center of excellence for Training Content and Delivery

- ◆ Describe the purpose of a Center of Excellence for Content & Delivery
- ◆ Describe the Trainer's Toolkit
- ◆ Identify tools that can be used for learning projects

### Do it Yourself Training - Michele Nonatelli

The use of templates based on learning principles and training structure will reduce efforts:

The Standard Format will help participants to build their own training package for different contents. The format can be applied to a company quality system (policy-guidelines) to develop standard training packages to be disseminated all over the organization.

More than one policy-SOP-guideline can be covered in one package, which means, for a training organization: Good use of time and Ownership of training standards

This session will provide participants with a template to use to build up a training package based on the 5 steps to structure a session.

### Having a Successful On-Boarding Program in a Regulated Environment - Michelle Parker and Maria Rolo

Building and maintaining a successful orientation program in a regulated environment brings its own set of challenges. Explore the major components of having a successful program and understand the key questions that you will need to answer along the way. Learn about the do's and don'ts associated with designing a successful program.

Participants who attend this presentation will learn essential information on planning, designing and implementing a successful on-boarding program. Attendees will obtain knowledge around blended learning strategies as well as gain insight into some of the potential traps and pitfalls that they need to avoid.



## Session Descriptions

### E Training Tips - Tom Leise

Participants who are considering using E Training or who are just getting started will have the most benefit from this training. They will be able to take the tips provided and apply them directly to their E-Training programs at their companies.

Tips learned from experience with more than 300 web-based training modules used in a GMP manufacturing setting at Pfizer will be shared.

### The Holistic Training Approach – Building the Perfect Employee - Katie Anshutz

Businesses now require their employees to have advanced skills in many areas ranging from their technical expertise to communicating with FDA auditors. Today, there are unmet needs with regard to building training around a competency model for these quality organizations as well as developing the training level of expertise in those desired competencies. This holistic model allows companies to retain their exceptional talent and meet the ever-changing business requirements.

This session is a combination of lecture, facilitated group discussions and activities and contains three main components necessary for developing a Holistic Training Approach.

Key Session Takeaways:

1. A competency model that can be applied to our industry
2. Working knowledge of all three components of the holistic training model
3. A core list of the necessary competencies for the Ideal Employee

### How to Develop E Learning Using Limited Resources - Rick Bennett

This session will provide a person new to E-learning with the basic knowledge for creating e-learning quickly and efficiently. A user can return to work after this session and begin creating E-learning within days.

In this session we will look at low-cost software that:

- ◆ is easy-to-use
- ◆ is easy to learn
- ◆ maximizes efficiency during training development
- ◆ is designed for people without an e-learning background, and
- ◆ can stand up to regulatory scrutiny.

We will also identify success techniques for delivering e-learning modules to the end user, with or without an LMS.

### How to make S.U.R.E. of your Training: A Design Model that Works - Rick Rogers

One of the most important skills that any trainer must have is the ability to design a piece of training that successfully accomplishes its objectives. The success of the training activity and thus its value to the organization is proportional to how well the training activity both conveys and transfers its target knowledge or skills to the participant. To the extent that a trainer can improve their ability to design training that truly works then the value

of their training efforts to the organization can be greatly enhanced. The participant of this session will leave with a model in hand and a plan on how to use it to improve their own training designs.

This interactive lecture/discussion will provide the participant with the basics of adult learning theory and present a proven model for the design of a training session which will 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 models presented to a training session of the participants' own design.

### How to Train Your Organization for Regulatory Inspections - Tela Engdahl

The participant and their organization will gain insight on how to successfully host and manage a Regulatory Inspection. Attendees will learn how to prepare for a Regulatory Inspection and how to manage a Regulatory Inspection. Although this presentation is focused on Regulatory Inspections, these elements could be applied to Contract Manufacturers that host client audits.

The pharmaceutical industry is highly regulated; therefore being adequately prepared for an inspection is critical to the success of the inspection. This session will describe the elements of successfully hosting a Regulatory Inspection from room logistics to document control and interaction with an FDA Investigator or other Regulatory Inspector. In addition, participants will learn which personnel from their organization should be included in the inspection and what is expected of the Inspection host.

### Implementation of Procedural Document Training Program - Cheryl Boll and Jason Packard

Attendees will see how a company has developed and implemented a procedural document training program. This includes the use of ExpressTrain® to write procedural documents and automatically generate training materials. Additionally, they will review a philosophy on developing and implementing role based curriculum.

Overview of the Procedural Document Training program:

- ◆ Review of the workflow for developing the procedural document training materials including the use of ExpressTrain®
- ◆ Implementation of the training program which includes on- the-job training and lessons learned
- ◆ Establishing role based curricula to manage training and lessons learned

### Implementing a Successful Learning Strategy - Michael Parrish & Trina Lima

Participants will be provided an overview of two successful blended learning training programs; specific to Investigations and Change Management System Training. A discussion of lessons learned will help the participants implement a blended learning strategy.

The session will:

- ◆ Describe decision points, including tradeoffs, for optimum approach
- ◆ Identify considerations for phased strategy (e.g. launch versus long-term)
- ◆ Discuss tailored approaches based on specific roles
- ◆ Identify opportunities for migration from classroom-based sessions to online courses.

### Implementing an OJT Program From The Ground Up - Alex Armendariz and Susan Lara

This presentation will discuss how a small training department sourced, developed, and implemented a successful OJT program for a facility of 800 employees.

Attendees will:

- ◆ Establish a business case for an OJT program
- ◆ Review the process for implementing and managing an OJT program
- ◆ Examine the OJT model and its key components

### Implementing SAP in a global GMP environment: A Case Study - Jennifer Lapioli

In this session, you will hear how a team of people through collaboration, communication, driving change, and ultimately meeting the business need were able to plan, build, and implement training that resulted in a successful SAP implementation in a global environment. The presenter will share the plan, execution strategy, and eventual delivery best practices with you as well as lessons learned. If you are considering a large training rollout – be it SAP or other system - this is a session you don't want to miss!

Have you implemented an ERP/SAP system? How would you handle large scale training across multiple sites? How do you measure the change impact in the organization? How do you create training for a large audience set that is relevant and achieves the desired behavior in a time when change is constant?

### Integrating Video into GMP Technical Training - Geoff Kapke

Case study on the use of video for technical training in a pilot plant Awareness of considerations for filming, editing, and post-production.

This session is a demonstration on in-house development of training videos. Videos introduce employees to new apparatus' and behaviors for working in a bioproduct pilot plant. The session will explain the constraints and considerations for filming in a GMP environment.



## Session Descriptions

### **Justifying your existence: How to show ROI from training - Jonathan Hunt, Frank Zukowsky**

With cutbacks facing every part of every industry, non-revenue producing factions face a bleak and difficult future. If trainers cannot show how an investment of time or money in a training program can help contribute to shareholder value, they can easily find themselves facing severe budget cuts. By examining certain metrics that are more than likely already being tracked in your organization, you can show how investing a little in training can help make a lot in the end.

Attendees will learn how to implement a successful evaluation program with the ultimate goal of successfully determining ROI.

### **Management Support for Training - Vivian Bringslimark**

If "People are our greatest asset" then why are today's Trainers lamenting about lack of management support for training; even required training? The answer may be found by examining today's training model. It lacks the ability to produce the kind of results that Management is now seeking. However, Performance Consultants are having success at getting those results.

The session covers:

- ◆ Evolution of Today's Training Model
- ◆ Two Types of Training Decisions
- ◆ Training Transfer Research Study
- ◆ Performance Consultant Model
- ◆ Building Performance Partnerships
- ◆ And two activities:
  1. Create your Own Credibility Campaign
  2. Performance Data Patrol

### **"Mission Possible! Setting up an Aseptic Training Facility" - Sandy Wilson**

Participants will benefit from this session by gaining an understanding of what is involved in putting in an Aseptic Training Facility at their company, so that the correct decision can be agreed upon. Also, participants will leave with an outline of project stages to work through to achieve a successful implementation.

This session outlines the steps taken with a team in managing the project of launching an aseptic training area at our site, and includes the pitfalls and the benefits.

### **No Assembly Required - Nancy Giard**

Effective OJT Checklists provide documented evidence of operator's qualifications to perform their job. Properly constructed checklists document proficiency and knowledge. They can be used to qualify new operators and to cross-train or re-qualify existing operators. Companies who implement effective On-The-Job Training Checklists in cGMP areas are meeting regulatory expectations for demonstrating and documenting training effectiveness. Participants will leave with a complete OJT Writing course AND a best-in-class, comprehensive template for OJT Checklists. All of this will be ready to implement immediately with minimal effort.

This session will provide you with the complete train-

ing package needed to implement this best-in-class course on writing effective OJT Checklists. The session will cover 3 main areas:

- ◆ A quick overview of the slides and exercises to familiarize you with the course content
- ◆ Review of Templates and Tools including: OJT Checklist Template and several examples of effective OJT Checklists
- ◆ Closing discussion time to share lessons learned and benchmark

### **Operator Certification - Reinventing the Wheel - John Hunt and Frank Zukowsky**

Training individuals in a regulated industry faces very unique challenges. Not only do employees need to follow agency rules and regulations, but they also need to be prolific on the technical aspects of their jobs. Our Company has developed a unique training method that meets all of our employees learning needs. Participants will learn how to train our way, either we do it right or we won't do it at all.

This session will describe a successful operator certification program that has been implemented and shown to generate a return on investment for the organization.

### **Performing in Compliance: the FISH! Philosophy - Patty Bowers**

This course offers a new twist in GMP (and GLP) training. The participants are surveyed as to why compliance may be difficult to adhere to and then realize that training is not the only answer. Using a 20 minute video to demonstrate how to get customers and colleagues engaged in the process leaves participants in a GMP/GLP training session energized to make changes they are empowered to make.

This course assesses the problems colleagues address when trying to meet compliance demands. Using the video, The FISH! Philosophy, the audience is engaged in activity that fosters their participation in making change within an organization.

### **Poka Yoke - Donna Butchko**

Trainers are often in an ideal place to identify when a training solution has been selected to solve a non-training related performance problem. Knowledge of Poka Yoke will give them an alternative solution to suggest, which can be implemented with minimal cost and effective outcomes, increasing the trainer's credibility within the organization.

Poka Yoke, or Mistake Proofing, is the ideal corrective action because it ensures that the mistake cannot recur. However it is frequently underutilized. This class gives students an overview of Poka Yoke: what it is and how to use it. They will be presented with real world examples, then challenged to identify other examples. Finally, each group will identify a situation and work to find a Poka Yoke solution that will prevent it.

### **Quality Control – New Hire Training Program – Training System -Amanda Glover**

This session will provide the audience with 2 tools. The first is Role Mapping. This will help in defining what training is needed, what exactly will be assigned to the employee, and will give the employee a more defined idea of what is expected in their new job function. This tool can also help with curricula assigning and maintenance of curricula. The second tool is Training Compliance Assessment Check Sheet. This tool will give a trainer a way to audit their group with positive feedback. It will identify gaps that might not usually be seen by just running a report. This session will also give a brief overview of the comprehensive detail that goes into new hire training. The audience will have a chance to use the role mapping tool and get a brief overview of how the Training Compliance Assessment Check Sheet can be used.

This session is an overview a QC Training System. It will provide people a quick look at a new hire coming into a QC Lab environment. Topics covered:

- ◆ What goes into QC training
- ◆ How a department stays compliant with training
- ◆ What keeps employee's complete and on target
- ◆ Activity: Complete a Role Map for department/group and Training Compliance Assessment Check Sheet

### **Reduce Operator Errors Using Needs Assessments - Patrick Kelley**

Operator errors continue to be a trend for deviations occurring in our industry. By attending this course, you will be able to: Identify several ways to conduct a needs assessment and determine which methods should be used. Determine multiple issues contributing to operator error deviations. Prioritize action items identified from the needs assessment. Reduce operator errors at your facility.

What would you do if you were assigned a CAPA that stated you needed to significantly reduce the amount of operator errors in your function? Where would you start? In order to determine the root cause of multiple operator errors, you will need to conduct a needs assessment of individuals as well as management. In this session, you will be able to identify different ways to conduct needs assessments to determine causes of operator errors. The next steps will be to create and prioritize action items from the needs identified ultimately reducing operator errors in your function. The methods learned in this session can also be applied to conduct needs analyses for other issues or improvements in your company as well as to increase professional development of your employees.



## Session Descriptions

### Reinventing Yourself for New GxP Environment - Vivian Bringslimark & Katie Anschutz

The old paradigm of the GMP Trainer for commercial manufacturing is disappearing since technology is abundant and the manufacturing jobs they once supported have been scaled back, eliminated or off-shored. Today, the rules are about providing unmet needs whether internally or externally. Inside organizations, we are starting to see a market mindset. Leaders are deciding between building core competencies or outsourcing component parts. So, anyone seeking to work for an organization (internally or as a vendor) will need to view the organization as a marketplace or lose the business to someone else who does.

Participants leave the session with strategies and tools to stay employed / rapidly find new employment in today's ever changing business environment.

Key Session Takeaways:

1. List of current Industry Changes and possible Unmet Needs DATA Tool with an examination of current abilities
2. Individual skills gap analysis and how to determine what development to pursue

### Risk Assessment for Training - Elaine Lehecka Pratt

This session will benefit the participant by teaching a risk analysis tool, and demonstrating some training applications for risk analysis. This provides professional development for the trainee. The organization will benefit by having trainers who can link risk management to training, as well as teach the tool to employees.

Risk analysis is used for many business applications, but what about training? Learn a simple risk analysis tool, review a case study of how it was applied to a FDA training requirement, and then apply to other common training situations to make training a more value-added activity! This interactive session will feature a Learn It – Do It – Take It Back to the Job methodology.

### Self-Service to Training in a Regulated Environment - Michelle Parker and Maria Rolo

Building a Self Service Training system in a regulated environment brings its own set of unique challenges. Explore the major components of the system and understand the key questions that you will need to answer along the way. The identification of key data elements, the establishment of position and job specific curricula, and the elimination of labor intensive paper-based business processes all will be discussed as part of the journey taken to deliver a fully validated, technology-driven training solution. Learn about the do's and don'ts associated with designing a self service training system and take away invaluable information about how to keep system flexibility without increasing maintenance time and costs.

Session takeaways

- ◆ Benefits of a self-service training and management system

- ◆ How to define the scope of your project for your specific training needs
- ◆ Different delivery methods and training strategies
- ◆ Data collection activities required to implement a self-service training and management system
- ◆ Tradeoffs between flexibility and data maintenance
- ◆ Resources that are required as part of the development of a self-service training and management system

### Site Readiness Training: Preparing a Site for A Regulatory Inspection - Tom McKelvey

Participants will be introduced to tools that are linked to conducting an effective Regulatory Inspection. Participants will be introduced to how to evaluate the needs of their facilities and then how to appropriately match the tools to those needs.

Learn ideas for preparing Subject Matter Experts, Plant Personnel and your core team during an investigation on how to prepare and manage an inspection.

Questions to be explored:

- ◆ Do the people in your facility know what is expected of them during a Regulatory Inspection?
- ◆ Do you have a trained team ready to support a Regulatory Inspection with multiple inspectors?
- ◆ Do your Subject Matter Experts (SME's) understand your expectations for them during an interview and how they should conduct themselves during a Regulatory interview?

### So Why Didn't the Job Skills Transfer? - Joanne Cochran

During this session the participant will find out what prevents training, both knowledge and skills, from being transferred effectively into the work environment. This session will identify factors that can enhance or sabotage transfer. Some factors that will be analyzed are motivation, the trainee's and other personnel involved in the training process, the physical environment, organization. During the session participants will have the opportunity to assess their training process and system to identify areas of improvement for their organization.

This training session will identify barriers that prevent or influence transfer of competency based operator job skills training to the workplace. Specific strategies to enhance transfer will be discussed. Finally a production skill transfer and assessment model will be introduced.

### Starting From Scratch: Development of an OJT Guidance Document - Joanna Gallant, Susan Adamzack and Patrick Spain

Discussion of a case study demonstrating the successful formation of a collaborative team from volunteers that overcame inter-site differences to produce an OJT guidance document that will benefit the whole corporation.

This session will focus on the process of pulling together a group of multifunctional training people and producing a guidance document on OJT through all of their efforts. It will further demonstrate that it is possible to form a collaborative team from volunteers and over-

come inter-site differences to produce something of benefit to the whole corporation, through describing the process of building and facilitating an internal team of people who had issues & questions about OJT.

### Teaching Old Dogs New Tricks - Kristina Spittler

Many GMP / Pharma trainers are transplants into the training world due to their subject matter expertise in a process area. However, knowing a lot about a subject, does not qualify one to transfer that knowledge to others. A lot of poor training is the result of delivering training in a way that's not suited to adult learning. Identifying adult learning principles and applying them to training design and delivery will yield more effective training in less time! Employing active training principles, suited for the adult learner, will ensure that training is no longer a dreaded task, but an exciting opportunity!

Training adults is a completely different science (some say art!) from teaching children. If you've never explored the differences between pedagogy and andragogy, but you've witnessed eyes glazed over, this course is for you! Session covers:

- ◆ Identifying the key differences between pedagogy and andragogy.
- ◆ Describing learning style preferences and how each translates to adult learning.
- ◆ Discussing methods for capturing adults' attention and engaging them in active training.

### Training Isn't Always the Root Cause - Joanna Gallant

Root cause identification is an expectation of FDA, yet many companies do not have a good grasp of the process. Take home benefits from this session will include:

- ◆ learning how to use basic root cause analysis tools that can transfer to any company
- ◆ understanding the major cause categories that can affect our processes
- ◆ being able to identify the true cause of an issue, and as a result, identify and implement more effective CAPAs, including appropriate training
- ◆ tips for implementing a root cause training program at their facility

Have you ever retrained people on a topic or a procedure because of a deviation, had a similar deviation occur, and corrected it by yet another round of retraining on the same procedure? There is a better way. You can identify and implement better corrective actions if you identify the root cause and understand what it takes to truly fix what allowed the problem to occur in the first place – and it isn't always training. This session will demonstrate very simple tools that help to identify what really caused an issue and identify and implement more robust corrective actions. By doing so, you'll cut down the number of retraining sessions you do – and the training you need to do will be more effective.



## Session Descriptions

### Tricks for New Trainers -Patty Bowers

This session will provide helpful tools for the new trainer such as presentation techniques, where to find useful material for courses and building a system to maintain training information which may be under scrutiny in an audit. This course is aimed at those who are building systems for their company and who are new to the training function.

Participants will gain tips on where to find material for training, tricks for the trainer to present comfortably, how and where to document training.

### What is a Quality System?

#### - Barbara Litsenberger

Structuring an organization's quality management requirements into a system of related policies, processes and procedures provides a framework to implement and consistently apply the quality and regulatory requirements throughout the organization. Understanding the organization of the quality management system also provides a framework for the development of personnel training.

The purpose is to provide a general overview of a quality management system\* and the overarching concepts within each essential element of the system. \*A quality management system used in Health Care will provide the model for this session.

Attendees will be able to:

1. Collaboratively define the essential elements that needed to be incorporated into a quality system.
2. Review the concepts and general content of the Quality System Elements (QSE)
3. Discuss the value of organizing quality management into a defined system

### Who's GMP Line Is It Anyway!

#### - Bill O'Connor

The Game Show host will kick-off the session, but quickly engage the audience by inviting members to take common objects found in the room and not so common objects and rapid fire turn them into props to be used to illustrate a training concept. At the conclusion of the session, participants will feel empowered as they'll have practiced creating memorable training on a shoestring budget.

This session is a take-off on the Drew Carey show and designed to tap into the creativity of the participants in the room to generate hundreds of ideas/teaching points. The session will be fast-paced, high energy, high entertainment. Participants will leave, energized and full of creative ideas.

### WIP it! - Marie Donat

Participants will benefit from this session, as it provides an approach to control their work in order to:

- ◆ Ensure they are continually focused on high-priority business needs
- ◆ Allow time for high impact, performance improvement projects that we often do not have time to devote to because of high volume of day-to-day operations work. Improve employee satisfaction

due to clear work plan expectations and elimination of constantly changing priorities and assignments

- ◆ Provide a mechanism to plan work and appropriate resource allocation. There will be a continual challenge to not only keep up with work in resource-constrained environments, but also to continually prove our value and contribution to the organization. The WIP Cap process allows for both to be achieved.

As Performance Improvement professionals, we often see a high volume and continual churn of procedure - and associated training - changes impacting our workload.

Frequently, the drivers for these changes do not yield high business value or impact, and can keep us from focusing our attention on more value-added work. This session will offer details about a Work In Process (WIP) Cap strategy and tactical approach to put control around:

- ◆ How work comes into the system / prioritization
- ◆ The amount of work in process at any given time
- ◆ Cycle time expectations and accountability to meet timelines.

Therefore, this session offers the WIP Cap process as an approach to plan work and resource allocation in order to become more productive and effective in resource-constrained environments.



## Speaker Bio's

**Alex Armendariz** is manufacturing trainer for Teva Parenteral Medicines. For the last 11 years he has worked in various quality and manufacturing capacities. Mr. Armendariz has a Masters in Instructional Design and Technology and a Bachelor of Arts in Communication.

**Amanda Glover** is the Quality Control Training Specialist in the Quality Control Department at Bayer Corporation. This department provides the testing services for the manufacturing and clinical groups on site. She has been with Bayer Corporation since 1999. She has supported the training for the QC Testing laboratories since 2005 before that she worked in the QC Sample Office

**Barbara Litsenberger** is the Quality Unit Education Coordinator for the Department of Laboratory Medicine and Pathology (DLMP) at the Mayo Clinic in Rochester, Minnesota. The Quality Unit provides functional oversight of the quality management system in the clinical laboratories and service lines. Barbara's undergraduate degree is in clinical laboratory science. She spent an additional year in the study of transfusion medicine and is a board certified specialist in blood banding technology. Barbara has a master's degree in education with an emphasis in adult education. She also holds a certificate in human resource development.

**Bill O'Connor** is currently the Associate Director of Training at Genzyme's Allston, MA manufacturing facility. Over a span of 32 years, Bill has worked in most of the functional areas of the plants, including Quality, Manufacturing, R&D, and Employee Development. Actively involved for the past 17 years and currently a board member of the GMPTEA, he is passionate about discovering and designing creative approaches to delivering CGMP training. He's a longstanding member and past president of the BETA chapter and former chair for PDA training conferences and Trainer's Choice Awards. Bill has provided consultative services to a wide variety of audiences across industry and academia, and still continues to teach CGMP's and regulatory affairs courses at several universities in the Boston Area.

**Cheryl Boll** is the Operations Business Systems Lead within the Process Research and Development Division of Bristol-Myers Squibb, New Brunswick, NJ. Some of the group's responsibilities include procedural document management and training. She has been with BMS for over 28 years and has developed and implemented GMP and On-the-Job training programs for Technical Operations and R&D groups. She has been a member of the GMP TEA since 1992 and worked on a GMP TEA/FDA focus group to develop Pre-Approval Inspection training programs. Cheryl has a MBA in Pharmaceutical Studies and a B.S. degree in microbiology

**David Gallup** is a frequent speaker at both regional and national GMPTEA and PDA conferences. Dr. Gallup has 20+ years experience conducting training audits and designing, developing and implementing compliance training plans and programs. Projects include working with pharmaceutical manufacturers cited by federal or

international regulatory agencies to audit training, develop compliance training plans, and support the implementation of compliance training strategies. Dr. Gallup is a faculty member of Pennsylvania State University and PDA-TRI. He is on the Advisory Board for the Bioprocessing Curriculum at East Carolina University.

**Donna Butchko** has done training and development within pharmaceutical corporations for over 20 years before going independent in 2007. She's worked for Merck, Hoffmann-LaRoche, and a company that has since been acquired by Pfizer. She has presented across the US (from Albany, NY to Albany, Ga) and in Canada, Puerto Rico, London, and Hong Kong. She has her BA in Chemistry from Rutgers University and her MS in Organizational Dynamics from the University of Pennsylvania. She's both a Certified Quality Auditor (from the American Society of Quality) and a Certified Leadership Development Facilitator (from the Rutgers University Leadership Development Program).

**Elaine Lehecka Pratt** is president of Lehecka Pratt Associates, Inc. and Industry Professor at Stevens Institute's Graduate Schools of Engineering and Management, teaching Pharmaceutical Manufacturing and Management. She holds a B.S. degree (biology), and a M.B.A. degree. Before founding Lehecka Pratt Associates in 1986, she worked at Schering-Plough in production supervision and as training manager, and was one of the first presidents of GMP TEA. She is published in Pharmaceutical Technology, Pharm Tech Japan, Performance in Practice, and Drug Development and Industrial Pharmacy. Elaine has spoken at ASQ, ASTD, PDA, PMA, GMP TEA, APhS, SME, ISPI, Pharm Tech and Interphex.

**Frank Zukowsky** is the Senior Compressing Training Specialist for Mylan Pharmaceuticals. Frank conducts all technical training in the tablet press department. Frank has over 12 years experience in the pharmaceutical industry. Frank graduated from Fairmont State with a degree in criminal justice and he is an army veteran of the first Gulf War.

**Garth Mussey** is Manager of Quality Training at Ben Venue Laboratories. His department is responsible for the design, implementation, delivery and management of QA related training. GMPs, auditing, SOPs including appropriate effectiveness checks, and train the trainer programs are included in the department's charge. A Certified Training Manager/Director; he is a 25 year veteran of the pharmaceutical industry with experience in the regulated fields of quality, safety, manufacturing, research and compliance. Garth holds degrees in Microbiology and Latin American Studies from the University of Pittsburgh.

**Geoff Kapke** has worked at Lilly since June 2002 as a training associate in Product Research & Development, supporting areas and activities that operate under GMP regulation. He has a Master's degree in Instructional Systems Technologies from Indiana University.

**Jason Packard** is the Operations Business Systems Manager within the Process Research and Development Division of Bristol-Myers Squibb at the New Brunswick, NJ. He has spent 15 years within pharma R&D Pilot Plants and has been involved in their design, construction, start-up, qualification and operation. Jason transitioned in 2008 to the Operations Business Systems group and brings his energy and enthusiasm to the team. Jason has a B.S. degree in Chemical Engineering.

**Jennifer Lapioli** is a Learning Manager in the Learning & Behavior Realization Organization at Merck & Co., Inc. Over the last 18 months she assumed Lead responsibility for the Merck Manufacturing US implementation of COMET - Merck's name for their large scale SAP implementation. Jennifer has over 20 years experience in project management, training & education, and information technology. Before Merck, she worked for PricewaterhouseCoopers as a Management Consultant, and GE Aerospace as a Computer Engineer. She has a BS in Computer Engineering from Bucknell University and a MS in Systems Engineering from Virginia Tech.

**Joanna Gallant** is the Unit Manager of the Quality Training Group at Genzyme Corporation, where she is responsible for training in support of the Framingham, MA biopharmaceutical, pharmaceutical and medical device operational sites. Joanna's current and past responsibilities have included designing and delivering classroom and computer-based training on the GMP and medical device regulations, along with new hire orientation, technical skill development and organizational development training. She was the 2007 President of BETA, and is a longtime member of both the GMP TEA and PDA.

**Joanne Cochran** has been involved in GMP, aseptic, quality, and organizational training for over 25 years. At Merck and Co., Inc. she had the opportunity to work with all levels of personnel on many different types of training programs, ranging from competency based training for operators to Quality and GMP training programs for executives. She received her Masters of Education from Penn State in 2003. She currently consults in the areas of training system design, aseptic processing, and regulatory training for pharmaceutical and biopharmaceutical companies.

**John D. Hunt** is the Senior Fluid Bed Training Specialist for Mylan Pharmaceuticals. John is responsible for the technical training dealing with fluidized beds. He brings over 12 years of pharmaceutical expertise to his position. John graduated from Fairmont State University in 2008 with a degree in Applied Science.



## Speaker Bio's

**Katie Anschutz** has used her education and over 19 years of experience in training and human performance to leverage her skills in the Life Sciences industry. Currently, she partners with the Quality Assurance and Manufacturing areas providing training solutions to improve performance and compliance. Certified in many practical tools, she brings a wealth of experience in designing competencies and training that align with Corporate Business strategies. Katie earned her B.S. emphasizing in Industrial Psychology from Central Michigan University. This discipline allows Katie to see training from a unique perspective that takes into account the human performance model. Her holistic view of development is considered a refreshing change to her current business partners.

**Kristina Spitzer** is Training Manager at Almac Clinical Services, Durham, NC, a global packager and distributor of clinical supplies for the pharmaceutical industry. For the last six years Kristina has been managing the site's training system and providing GMP training that employees actually want to attend! She has 19 years of experience in training with a background in Human Resources, Quality Assurance, Education, and Instructional Design. She specializes in designing training to for a variety of educational levels and learning styles. Kristina has a talent for designing interactive learning experiences to improve employee effectiveness and increase organizational compliance.

**Maria Rolo** is Associate Director of QA, GMP Training at Purdue Pharma with 20 years experience in the pharmaceutical industry. Maria holds a B.S. Degree in Biology, with a minor in Chemistry and a Masters Degree in Public Administration, concentration in health-care. Maria is currently pursuing a Masters Degree in Pharmaceutical Management Certification at Stevens Institute of Technology, NJ. Prior to joining Purdue in 2002, Maria worked for Novartis (former CIBA), Pfizer (former Warner-Lambert) and Elan Pharmaceuticals as a chemist and managing the technical and regulatory training functions respectively.

**Marie Donat** is a Team Leader for the Product Research & Development Operations Performance Improvement Team within Eli Lilly & Co. This team provides training support for product development work as well as clinical trials management and manufacturing. For the last eight years, she has worked in the pharmaceutical industry. Marie has a Masters Degree in Educational Technology with an emphasis in instructional design and has a Bachelors Degree in Communication with an emphasis in public relations.

**Michelle Parker** is Sr. Manager of Quality Assurance - Training with Purdue Pharmaceuticals, LP where she joined Purdue in September of 2005. She holds a Bachelors degree in Science from Barton College and has 19 years of Quality Assurance /Regulatory Compliance experience. Prior to joining Purdue, Michele worked with Phoenix Imperative a consulting firm in Raleigh NC; Leiner Health Products a OTC manufacture in Wilson NC and Abbott Laboratories a sterile manufacturing facility in Rocky Mount NC.

**Michael Parrish** is the Associate Director of Training for the Pharmaceutical Sciences organization within Schering-Plough. Since August 2006, he has led the restructuring and reengineering of the training group including centralization of core activities and implementation of structured processes and systems. Prior to that he led the creation and implementation of a central documentation group. He has also held positions in manufacturing and quality assurance. Mr. Parrish has an MBA in finance and marketing from New York University and a bachelor of science in Biochemical Engineering from Rutgers University.

**Michele Nonatelli** is a Training Expert within GSK biologicals. In charge of cGMP training within the organization from year 2000-08 he developed a trainer's network and implemented GMP training programs. His 23 years experience within the industry comes from Production area for the production of Hepatitis B vaccine to Quality Assurance Department for compliance purposes. Speaker for the 2006 PDA biennial training conference and 2007 GMP TEA conference. Michele has started-up on his own consulting business. Michele has a Bachelor in Industrial Chemistry from Naples, Italy and was a Scholarship recipient from the R&D center, Experimental Station for the Industry of Hides, Skins, and Tanning Materials, Naples, Italy, 1984-1985.

**Nancy Giard** is a Principal Training Specialist at Genzyme Corporation's biotech manufacturing facility in Allston, MA. As an internal training constant at this innovative, cutting-edge biotech company, Nancy has assessed, designed, developed, delivered, implemented and evaluated a multitude of training solutions in areas such as cGMP, Information Technology, Root Cause Analysis, Train the Trainer, Time Management, and Project Management. Now Nancy applies her sixteen years of training experience as she works with departments in her facility to develop and implement robust On -The-Job training programs, including delivery of an OJT Writing course she co-developed.

**Patrick Kelley** has worked in the regulated industry for over 10 years in both medical devices and pharmaceuticals. He is currently attending Suffolk University to obtain his Masters of Science in Organizational and Learning Development. In his most recent role, he has created a training department for a site that had been established and for two sites that were to be opened. Patrick has spearheaded many programs for his division including a Deviation Reduction Program, Qualified Trainer Program, and Audit Awareness Training. Patrick is currently on the Advisory Board of the BETA organization.

**Pat Spain** is a Senior Training Specialist at Genzyme Corporation's manufacturing facility in Allston, MA. Pat began his career in biotech in the QC labs spending over 5 years in chemistry and micro before making the switch to training and development. As a full time trainer, Pat is able to relate the other facets of his life to his new career; these include his stint on Animal Planet and his side-project as a nature show host for the web-based program "Nature Calls". While designing and presenting topics

such as OJT Writing, cGMP Annual Refreshers, and Train the Trainer, Pat has found story-telling an invaluable resource in getting his message through to participants.

**Patricia Bowers** has been employed by Boehringer Ingelheim Pharmaceuticals, Inc since 1996. She currently holds the position of Associate Director, Regulatory Compliance and Training in the Quality Assurance and Records Management Department. She has been responsible for the design and delivery of courses for multiple regulatory agency requirements including the FDA, USDA, and DEA. Her primary focus has been on GLP, GMP, animal care and use, and controlled substance topics. She has been a co-chair on the company SOP Consolidation Committee for multiple years and advises on laboratory notebook documentation. Patty has a BA in Social Sciences and Justice and Law Administration and a MBA in Human Resources Management

**Rick Bennett** is Manager of Training and Development for Immucor, Inc. Rick has been in the education field for 16 years, with the last 8 years working in the Medical Device industry. He has built Immucor's Training Department from the ground-up including implementing a LMS and transitioning his company to an e-learning format. During this time, Rick has researched and utilized inexpensive and effective methods for creation and delivery of E-Learning that can stand up to regulatory scrutiny. Rick has an Educational Specialist (EdS) degree in Instructional Design and Technology with a focus on E-Learning. He also has a Masters and a Bachelors degree in Education.

**Rick H. Rogers** is currently the GMP Training Manager for a parenteral manufacturer in Massachusetts. His business experience includes two decades in the pharmaceutical industry, and has spanned the oil & gas, banking, and computer industries. He is Past President of B.E.T.A., a past officer of the GMP TEA, and Past Chair of the PDA's national interest group on training activities. Rick has both a Bachelor's and a Master's Degree in Management from the University of Texas at Arlington, and served as a Captain in the US Army.

**Sandy Wilson** is a Learning Lead in the Learning & Behavior Realization Department at Merck & Co., in West Point, PA. Her team of Learning Specialists are responsible for managing the learning strategy for Operator Learning in the Bulk Viral Vaccine Business Units. Sandy has been a Learning Professional for the past 17 years, 13 of which have been with Merck & Co. Inc.. Sandy has a M.Ed. in Instructional Systems - Training Design & Development and a B.S. in Education - dual degree in Elementary Education and Special Education.

**Susan Lara** is Training Manager for Teva Parenteral Medicines. For the last 11 years she has worked in various academic and corporate capacities. Ms. Lara has a Masters In Education and a Bachelors of Arts in Linguistics.



## Speaker Bio's

**Suzanne Adamczak** is a Senior Training Specialist at Genzyme Biosurgery in Cambridge, MA, where she provides training and development support within a cell culture manufacturing facility. Her main responsibilities focus on regulatory compliance and system enhancement, and include classroom training development and delivery, identifying performance improvement solutions and strengthening on-the-job training procedures. Suzanne previously worked in the non-profit sector where she honed her training and facilitation skills as a community educator, a consultant and by running leadership programs for college interns. In 2008, she completed a Master's degree in Adult and Organizational Learning with a concentration in Organizational Development at Suffolk University.

**Tela Engdahl** has worked for Hollister-Stier Laboratories for 27 years in the Quality department. She has hosted and participated in numerous FDA inspections and other regulatory inspections with the EMEA, ANVISA, and PMDA. She also has been a host and participant in client audits with many different customers ranging from large Pharmaceutical Companies to small Biotech Companies. Ms. Engdahl has a Bachelor of Arts in Education

**Trina Lima** is Manager of the Training Content & Delivery group within the Pharmaceutical Sciences (PharmSci) training department. This group owns and provides the foundational training programs (i.e. NEO, TTT, Systems training) for PharmSci. For 18 years she has worked in the Pharmaceutical industry with extensive experience in quality, documentation and training. Ms. Lima has a BS from Rutgers University.

**Tom McKelvey** is the Document Control Supervisor within the Perrigo Company. Tom's previous roles at Perrigo have been the lead cGMP Trainer, FDA Readiness Trainer and Leadership Development Trainer. Tom has a Bachelor of Business Administration from Spring Arbor College and his M.B.A. from Western Michigan University.

**Tom Leise** is a Senior Principle Scientist in the Global Quality Operations Training and Program Development group at Pfizer, Inc. Tom has more than 30 years experience in GMP manufacturing and more than 10 years experience in E Training. Tom has a degree in Chemical Engineering from Penn State.

**Vivian Bringslimark** has a unique mixture of education, Life Sciences industry experience and consulting practice enabling her to provide human performance consulting services for improving people strategies. In her current role, she partners with clients to analyze root causes of human performance gaps and implement appropriate solutions that align with stated business outcomes to bring about more long term and predictable performance resulting in yearly goal achievement and operational excellence. She is on the Board of Directors for GMP Training, Education Association, Inc. as Chief Communications Officer. Vivian received her M.A. in Adult Education from Teachers College Columbia University in New York, her M.S. in Educational Computing from

IONA College in New Rochelle, New York, and holds a dual B.S. in Secondary Math Education and Liberal Arts Mathematics from SUNY @ Oneonta in New York



## Accommodations

Rooms have been set aside for the 2009 GMP TEA Biennial Conference at the Walt Disney World's Contemporary Resort, Lake Buena Vista, Florida. To make your room reservations, *please contact the Group Reservations Office at 407-824-3869.*

Let the resort know that you are making your reservation for the *GMP TEA* to take advantage of the \$185 room rate.

Rate is available 3 days before and 3 days after event, *based on availability.*

Disney's Magical Express Service is complimentary transportation to and from airport and hotel for registered guests. Reservations should be made by contacting 407-827-6777. Please contact this number once you have received your hotel and airline confirmation numbers.



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Registration is by credit card or company check.

### Member Credit Card Registration:

Contact [gmptea@yahoo.com](mailto:gmptea@yahoo.com) for member registration link.

### Non- Member Credit Card Registration:

Press CTRL and click on link [http://www.amplifyllc.com/in-tel/Regform.cfm?](http://www.amplifyllc.com/in-tel/Regform.cfm?D=hVc$5x0bm2ET.b)

[D=hVc\\$5x0bm2ET.b](http://www.amplifyllc.com/in-tel/Regform.cfm?D=hVc$5x0bm2ET.b)



### If Paying by Check:

Complete the Registration Form at the back of this brochure

**Check must be payable to: GMP TEA 2009 Biennial Conference.** Payment in full must be received before attendance at the conference and must be received by discount deadline in order to receive discounted pricing. If you require special accommodations to fully participate, please call 609-454-9363 with a description of your needs. **Registration does not include hotel accommodations.** Space is limited.

Send check or money order with completed form to: GMP TEA 2009 Biennial Conference, P.O. Box 7471, Freehold, NJ 07728

**Cancellation Policy:** There are no refunds allowed. Individuals registered can send a substitute representative. Notice must be given at least 5 days prior to the event. GMP TEA assumes no liability for non-refundable transportation costs, hotel accommodations or additional costs incurred by registrants. GMP TEA reserves the right to substitute presenters and re-schedule programs due to unforeseen events.



Good Manufacturing Practices Training & Education Association  
2009 Biennial Conference Registration  
November 1-5, 2009  
**Disney's Contemporary Resort at the Walt Disney World  
Resort, Orlando, FL.**



**CONFERENCE REGISTRATION**

Name: \_\_\_\_\_ Street: \_\_\_\_\_  
 Title: \_\_\_\_\_ City: \_\_\_\_\_  
 Company: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_  
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	February 1 – April 30	May 1- June 30	July 1-September 30 *
Member	<input type="checkbox"/> \$1149	<input type="checkbox"/> \$1249	<input type="checkbox"/> \$1349
Non-Member	<input type="checkbox"/> \$1449	<input type="checkbox"/> \$1349	<input type="checkbox"/> \$1449
	Registration subtotal:		

Registration includes Networking reception, 4 continental breakfasts, 4 lunches, 1 theme dinner, 6 breaks, 4 Day Session Attendance, gifts, prizes and giveaways. \* **Registration will close on September 30.**

**Optional Dessert/Character(s) Fireworks Event at EPCOT**

\$35 Per Adult; \$20 per child 4-11; Children 3 & under -Free

Wednesday, November 4, 2009, 7:45 pm – Epcot ... Open to family, friends, guest, etc.

Name: \_\_\_\_\_ Age: \_\_\_\_\_ Fee: \_\_\_\_\_ Name: \_\_\_\_\_ Age: \_\_\_\_\_ Fee: \_\_\_\_\_  
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Total Number Guests (including Member) \_\_\_\_\_ Total Optional Party Remittance: \_\_\_\_\_  
 Remittance must be received prior to arrival at conference.

**Payment Information:**

**Registration subtotal** \$ \_\_\_\_\_  
**Registration Fee:** \$ **25.00**  
**Dessert Party:** \$ \_\_\_\_\_  
**Total amount enclosed:** \$ \_\_\_\_\_

Registration is by credit card or company check.

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Press CTRL and click on link [http://www.amplifyllc.com/in-tel/Regform.cfm?D=hVc\\$5x0bm2ET.b](http://www.amplifyllc.com/in-tel/Regform.cfm?D=hVc$5x0bm2ET.b)

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