

# RoseTECH Consulting, Inc.

## GLP Training Workshops

*Attendance will be limited.*

October 4, 5, 6, 2010 – Cleveland, Ohio

Presented by – Celeste Rose, RQAP-GLP

# GLP Training

October 4, 2010

**Brass Tacks of GLPs** - *Practical Understanding of the Fundamentals as Never Before Explained*

October 5, 2010

**Amendments, Deviations & Unforeseen Circumstances** - *The Good, the Bad, & the Ugly*

October 6, 2010

**Beyond the GLPs** – *Keys to A Successful Study*

# GLP Boot Camp

*Attend all three workshops above for the Ultimate GLP Training Experience  
A Savings of \$300!*

### These Workshops Are Designed For:

- Study Directors
- Principal Investigators/Contributing Scientists
- Study Personnel
- GLP Supervisors and Management
- QA Professionals
- Study Monitors

Interactive, application exercises and "real-life" GLP scenarios are integrated throughout the workshops. FDA Warning Letters and 483 findings are incorporated for emphasis. Participants are challenged to develop skills to reinforce their newly acquired knowledge, tools & techniques through immediate, direct, practical application and develop their "GLP tool kit" to gain confidence and competence in handling GLP studies.

***Celeste approaches training in an innovative exciting fashion, which stimulates the interest of the participant along with meeting their informational needs.***

***See next page for just some of the testimonials from prior workshop attendees.***

# About RoseTECH Consulting, Inc.



**Celeste A. Rose, RQAP-GLP**, has 25 years GLP experience and 10 years experience as a Study Director. She is certified by the Society of Quality Assurance (SQA) as a GLP Registered Quality Assurance Professional (RQAP-GLP). She has a broad base of expertise in EPA, FDA and OECD Good Laboratory Practice, including study direction/study conduct; protocol/report writing and documentation; technical writing; SOP writing and review; archiving procedures; data, in-study and facility audits; and GLP and technical training.

**RoseTECH Consulting, Inc.** provides services in the areas of GLP and technical training, and QA audits and inspections (protocol review, in-study inspections, data and report audits, third-party independent audits, test facility inspections, GLP gap analysis inspections). RoseTECH also provides services for development and implementation of quality systems, (e.g., SOPs, archives, master schedule, documentation, training) and assists facilities in the transition from Research to GLP. For more information, visit [www.rosetechconsulting.com](http://www.rosetechconsulting.com).

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## **Below are just some of the testimonials from prior training sessions:**

*"Celeste is a very knowledgeable and experienced Subject Matter Expert."*

*"Very knowledgeable instructor. She was able to give specific examples relating to her subjects. I enjoyed her presentations."*

*"Celeste Rose, GLP Subject Matter Expert, effectively communicated her knowledge through her approach of referencing "real-life" examples and group application exercises."*

*"Well-informed about the material. Well-organized slides mixed with interesting examples based on her experience."*

*"Very informative ... makes you really think and remember the rules."*

*"Great fun ... good discussions ... a lot of content with a variety of fun."*

**Attendees overwhelmingly recommend Celeste's training workshops.**

# RoseTECH Consulting, Inc.

October 4, 2010

## Brass Tacks of GLPs

*Practical Understanding of the Fundamentals as Never Before Explained*

### **What Participants Will Learn**

- Good business practices of GLPs
- GLPs really are "good laboratory practices"
- GLPs are needed to support good science
- Purpose behind all those "stupid" requirements

This workshop will provide participants with a heightened respect and deeper understanding of the fundamental principles of GLP. Awareness of the underlying meaning and rationale for GLP will allow the attendees to assimilate a fresh GLP mind-set and apply their knowledge to enhance the integrity, quality and compliance of GLP studies in which they are involved. Six GLP fundamentals are covered:

### **CONTROL & ACCOUNTABILITY**

Without effective direction, management and organization, GLP compliance and data integrity are at jeopardy and left to chance. Comprehensive regulatory roles and responsibilities are covered.

### **CLEAR STUDY DESIGN & OBJECTIVES**

Study protocol and procedures set the platform for study quality and reconstructibility. This session covers how a well-designed study plan and clearly written procedures are pivotal to study execution and critical to the success of the GLP study.

### **PREVENTION OF CONTAMINATION, MIX-UP OR DETERIORATION**

The integrity of test materials and test system sets the bar for study integrity. This session delves into what can go wrong and where, and how to raise awareness for prevention of common culprits.

### **DATA QUALITY & STUDY INTEGRITY**

Study integrity is clearly dependent upon recordkeeping and data quality entry. Other factors that have an impact are also discussed in this session.  
QUALITY CANNOT BE AUDITED INTO A STUDY!

### **ACCURATE RESULTS/STUDY SUMMARY/CONCLUSIONS**

Without proper study file documentation, generation of a high quality study report is impossible. Without accurate results, study integrity is jeopardized. Valid data and results do not guarantee a quality report.

### **ULTIMATELY RECONSTRUCTIBILITY**

This wrap-up session covers the gamut of the GLP study life-cycle and summarizes approaches to improved study reconstructibility.

# RoseTECH Consulting, Inc.

October 5, 2010

## Amendments, Deviations & Unforeseen Circumstances

### *The Good, the Bad, and the Ugly*

#### **What Participants Will Learn**

- GLP requirements and effective documentation of amendments, deviations, unusual events
- Prevent, minimize and handle excursions
- Identify and raise awareness when excursions occur
- Objectively address excursions and remove the stigma barriers

#### **GLP Studies - Welcome To The Real World!**

“Real life” plays a part in all Life Science studies; thus errors, deviations, and unforeseen circumstances occur. Many go undetected and improperly addressed. One must first be able to recognize that a “situation” has occurred. “Real life” examples are presented to sharpen awareness of how to promptly recognize deviations and circumstances.

#### **Amendment, Deviation, OR Unforeseen Circumstance – That Is The Question!**

This session defines amendment, deviation and circumstances, distinguishes between intentional/unintentional excursions, and covers types of deviations and circumstances that may affect study integrity, and when a protocol amendment should be written.

#### **“How Did It Happen, and What Are We Going To Do About It?”**

Participants partake in interactive real-life scenarios to trace and identify potential root causes, and formulate resolutions to prevent and/or minimize the chance of occurrence.

#### **Plan for the Best, Prepare for the Worse**

This session demonstrates typical “real life” trials and tribulations that can occur during a GLP study in an engaging group format that turns a mundane topic into a lively, interactive, learning experience.

#### **When All Else Fails – Document!**

Documentation is crucial to GLP study reconstructibility, quality, and compliance. Protocol and SOP deviations and unexpected events can be problematic and impact study integrity. This session provides insight into the “how to” of reconstructible documentation.

#### **Avoiding GLP Study Pitfalls**

Many amendments, deviations and unforeseen circumstances can be prevented. This session presents strategies to prevent “avoidable” pitfalls, minimize the “potential” for excursions, enhance readiness for the “inevitable unknown” and reduce the stigma so as to foster good communication between study director and personnel when events do occur.

# RoseTECH Consulting, Inc.

October 6, 2010

## Beyond the GLPs – Keys to A Successful Study

### **What Participants Will Learn:**

- Improve technical writing skills
- Generate quality study documentation
- Accurately, clearly and completely capture study conduct activities, results, conclusions
- Enhance integrity, quality, and compliance of GLP studies in which they are involved

### **Elements of Technical Writing**

Fundamental elements of good technical writing include important principles of organization; format; sentence, paragraph, and section structure; verb tense and person. Guidelines, models and "writing for the reader" are covered, as well as tips for selecting the presentation style to best convey the data and information.

### **Writing Effective GLP Documents**

Clear, concise writing is key to study reconstructibility. This session covers protocol, amendment, and report writing; report organization skills to produce well-written documents; how to write reports with clear, concise, and accurate results and conclusions; and how to tactfully and truthfully deal with problematic results. "Real" examples of poor wording are shown for illustration.

### **Study File Organization**

Good Science is one thing, but study file organization is another key to study success. This session is a hands-on activity in effective study file organization working with study binders and materials. Participants will then use these materials for other activities through-out the day and will have the examples to "take back to the lab."

### **Good Documentation Practices & Recordkeeping Challenges**

This session covers general good recordkeeping practices, documentation of raw data, manual and electronic data recording rules, complying with 21 CFR 11 requirements, proper error corrections, and recordkeeping Dos and Don'ts. Practical application exercises challenge the participant to tackle errors and problematic documentation and apply effective corrective measures.

### **GLP Study Audits & Inspections**

QA and regulatory audits and inspections are a "real-life" part of GLP studies. This session covers aspects of audit and inspection activities, expectations and how to be prepared for successful audits and inspections, as well as reaping the benefits from them.

# GLP Training Workshop Registration Form

*RoseTECH Consulting, Inc.*

<input type="checkbox"/> <b>\$600</b> October 4, 2010 <b><i>Brass Tacks of GLP</i></b>	<input type="checkbox"/> <b>\$600</b> October 5, 2010 <b><i>Amendments, Deviations &amp; Unforeseen Circumstances</i></b>	<input type="checkbox"/> <b>\$600</b> October 6, 2010 <b><i>Beyond the GLPs – Keys to A Successful Study</i></b>
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***Or sign up for all three days October 4-6, 2010 for a savings of \$300.***

**\$1500 GLP Boot Camp**  
includes Brass Tacks of GLP; Amendments, Deviations & Unforeseen Circumstances; and Beyond the GLPs

**Participant's Name:**

**Job Title:** \_\_\_\_\_ **Dept:** \_\_\_\_\_

**Company:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**City/State/Zip:** \_\_\_\_\_

**Phone:** \_\_\_\_\_ **Email:** \_\_\_\_\_

**My Current job function is:**

- Study Director
- New Study Director (<1 year)
- To Be** Study Director

- Principal Investigator/Contributing Scientist
- Management
- QA
- Other \_\_\_\_\_

**How did you hear about this workshop?** \_\_\_\_\_

***Registration includes continental breakfast, lunch, snacks, and workshop materials.***

*Send form by mail with check made payable to:*      **RoseTECH Consulting, Inc.**  
**1185 Waterfront Place,**  
**Painesville, Ohio 44077**

*OR e-mail (crose@rosetechconsulting.com) or fax (440-392-9466) form with the following information.*

<b>Bill To Name:</b>	<b>Purchase Order #</b>
<b>Job Title:</b>	<b>Dept:</b>
<b>Company:</b>	
<b>Address:</b>	
<b>City/State/Zip:</b>	
<b>Phone:</b>	<b>Email:</b>

**Location:** Corporate College East, 4400 Richmond Rd, Warrensville Heights, Ohio 44128  
*(Approximately 26 min from Cleveland Hopkins Airport)*

**Hotels:** *(\$149-\$159. Ask for Corporate College rate. \* Transportation available between hotel and workshop)*  
 Embassy Suites\*      3775 Park East Drive, Beachwood, OH      phone: 216.765.8066  
 Solon Hampton Inn\*      6035 Enterprise Parkway, Solon, OH      phone: 440.542.0400  
 Marriot East      26300 Harvard Rd, Warrensville Heights, OH      phone: 216.378.9191

**Ground Transportation:** from Cleveland Hopkins Airport [www.clevelandairport.com/site/514/default.aspx](http://www.clevelandairport.com/site/514/default.aspx)