GLP Training Workshops

Two Locations!
March 9-10, 2010 - Doubletree Hotel San Diego Downtown
March 11-12, 2010 - Doubletree Hotel San Francisco Airport

The Brass Tacks of GLP:
Practical Understanding of the Fundamentals
As Never Before Explained

&

Writing Effective GLP Documents

Presented by enKap

ENGAGED KNOWLEDGE APPLICATION

These Training Workshops Feature “Hands On” Application Exercises

Publisher of FDA Compliance Digest
The Brass Tacks of GLP - Fundamentals

7:30 a.m.
Registration/Continental Breakfast

8:30 a.m. - 9:15 a.m.
Control & Accountability - GLP Roles and Responsibilities

Without effective direction, management and organization of a GLP study, compliance and data integrity are at jeopardy and left to chance. This session goes beyond the Personnel and Organization sections in the FDA, EPA, and OECD Good Laboratory Practice regulations and standards. We clearly define and expound on the comprehensive regulatory roles and responsibilities for GLP personnel. Topics covered in this session include:

- Control, responsibility & authority
- Study Director responsibility – it’s not just 58.33
- Single point of study control – what does that really mean?
- Test facility management – it’s not just a figurehead job
- QA – monitoring for conformance with GLP
- Principal Investigator – multi-site studies
- Compliance – responsibility of Study Director and management
- Study personnel – GLP responsibilities
- Other skills important for effective study conduct

9:15 a.m. - 9:45 a.m.
Clear Study Design & Objectives

Study protocol and procedures set the platform for study quality and reconstructability. A well-designed study, well-defined plan, and clearly written procedures are pivotal to the execution of the study and critical to the success of the GLP study. Topics covered in this session include:

- Importance of the protocol – study plan
- How to prevent “avoidable” pitfalls
- How to minimize “potential” excursions
- How to prepare for the “inevitable unknown”

9:45 a.m. - 10:15 a.m.
Prevention of Contamination, Mix-up and Deterioration

The quality and integrity of data and results are dependent upon the quality and integrity of the materials and systems used for the study. The integrity of test materials and test system sets the bar for study integrity. The chemistry and analytics of test materials can be an intimidating aspect of study conduct. This session demystifies the topic and focuses on providing an understanding and respect for the importance of these critical fundamentals:

- Test, control (and many times overlooked) reference materials
- Handling and Chain-of Custody – Do you know where that material has been?
- Characterization & stability
- Dose formulation analysis
- Key reagents
- Equipment
- Specimens & samples
- Factors critical to specimen integrity & data results

10:15 a.m. - 10:30 a.m.
Morning Break
10:30 a.m. - 11:30 a.m.

APPLICATION EXERCISE

Real-Life GLP Scenarios
This hands-on session is conducted in a group format. Interactive exercises provide the participant with the opportunity to apply the material covered in the first three modules. “Real-life” GLP scenarios will be presented from varying perspectives – Study Director, PI, study personnel, management, QA, and challenge the participant to develop skills for prevention and effective handling of issues which may arise during GLP studies.

These exercises are designed to encourage the participant to broaden their perspective of typical, as well as unexpected events, that may occur during GLP studies. This broadened perspective allows the participant to develop their “resource tool bag” to gain confidence and competence in handling GLP studies and dealing with pitfalls, excursions and inevitable obstacles that can occur during GLP studies.

11:30 a.m. - 12:30 p.m.

Lunch

12:30 p.m. - 1:00 p.m.

Data Quality/Study Integrity
Study integrity and data quality are clearly dependent upon the quality of recordkeeping and data entry. Other factors that have an impact on study data quality and integrity are also discussed in this session. Quality CANNOT be audited into a study.

1:00 p.m. - 2:15 p.m.

APPLICATION EXERCISE

Study Data Activities
Data quality exercises will be interspersed throughout this session in combination with questions posed to the class in a lively format to encourage input from the group and prevent the “after lunch nod off.” Topics will include:

- Good documentation practices
- Manually-recorded vs. electronic records
- Equipment – obvious and unobvious sources of error
- Study phases and multi-site trials and tribulations
- Study file organization

2:15 p.m. - 2:30 p.m.

Afternoon Break

2:30 p.m. - 3:00 p.m.

Accurate Results/Study Summary/Conclusions
A final report must be prepared for each GLP study. Without proper study file documentation, generation of a good quality study report is difficult. Without accurate results, study integrity is jeopardized. Valid data and results do not guarantee a quality report. Effectively committing the study summary to written media is a skill in itself.

Examples will demonstrate how to write quality factual conclusions even when study results may be problematic. This session addresses effective and factual report writing and covers the following key points:

- Organization and structure of reports
- Getting to the point
- How to address deviations and unforeseen circumstances
- Clear and concise conclusions
- Dealing with inconclusive results
What Attendees Will Learn in This Training Workshop

This workshop will provide participants with a heightened respect and profound 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 mindset and apply their knowledge to enhance the integrity, quality and compliance of GLP studies in which they are involved.

Who Should Attend

This workshop is ideal for those individuals in your organization involved in the following functions:

- Study Director
- Principal Investigators/Contributing Scientists
- Study Personnel
- Test Facility Management/Test Site Management
- Quality Assurance
- Sponsor Monitors

General Information

Training Workshop registration fee includes continental breakfast, breaks, lunch and all conference materials.

Application Exercise

Reporting Results and Conclusion Activities

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This session addresses effective and factual report writing and covers the following key points:

- Organization and structure of reports
- Getting to the point
- How to address deviations and unforeseen circumstances
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- Good documentation practices
- Manually-recorded vs. electronic records
- Equipment – obvious and unobvious sources of error
- Study phases and multi-site trials and tribulations
- Study file organization

3:45 p.m. - 4:30 p.m.

Study Reconstructibility and Q&A

This session covers the gamut of the GLP study lifecycle and summarizes approaches to improved study reconstructibility. Group discussions will recap the key points covered during the day. Attendees will have the opportunity to ask the instructor questions. This time can also be used to expand on any topic discussed earlier in the day which may be of particular interest to attendees.
### Elements of Effective Technical Writing

The workshop begins with coverage of fundamental elements of good technical writing. These elements include important principles of organization; format; sentence, paragraph, and section structure; verb tense and person. Guidelines and models for writing instructions versus descriptions and ‘writing for the reader’ are covered. Tips for selecting the presentation style (e.g., text, tables, figures, flow-charts, graphs) to best convey data and information are also covered.

### Protocols, Amendments, Deviations and Reports

Study protocols and procedures set the platform for GLP studies. This module covers protocol, protocol amendments, and effective documentation of deviations and unexpected circumstances. The importance of writing detailed, yet flexible protocols is emphasized, as well as how to avoid “protocol pitfalls” that lead to unnecessary deviations and amendments.

Development and generation of a compliant report that accurately reflects the study is a GLP requirement. Study reconstructibility is more than just “good recordkeeping practices.” Reconstructibility is analogous to a puzzle. The pieces of a study file must fit together completely and clearly to create the whole picture.

### Good Recordkeeping Practices

This session covers general good recordkeeping practices, documentation of raw data, manual and electronic data recording rules, proper error corrections, and recordkeeping Dos and Don’ts. Examples are presented of techniques to simplify data capture and ensure good documentation, as well as how to avoid poor documentation “pitfalls.” Examples of effective uses of forms, checklists and templates are included.

### Recordkeeping Challenge Exercises

To prevent the “after lunch nod off,” participants will be challenged with recordkeeping and data exercises posed to encourage group interaction and work to develop GLP study checklists and forms. “Real-life” examples which demonstrate day-to-day recordkeeping struggles and human “mistakes” will be incorporated. “An error doesn’t become a mistake until you refuse to correct it.” — Orlando A. Battista (b. 1917) Canadian-American chemist

### Protocol Exercises

This session will be devoted to a hands-on review of example protocols to identify missing information or potential pitfalls in the examples. Participants will learn how to check their protocol drafts to assure all required GLP elements are addressed before finalization. Participants will then get a chance to use their newly learned knowledge and skills to “redraft” the protocol document and critique its
effectiveness. Effective documentation of protocol excursions will also be covered.

**WHAT ATTENDEES WILL LEARN IN THIS TRAINING WORKSHOP**

This workshop is designed to improve the technical writing skills of the participant. It is designed to provide a sound understanding of how to generate study documentation that is written to accurately, clearly and completely capture study conduct activities, results and conclusions. Participants will be able to apply their knowledge to enhance the integrity, quality, and compliance of GLP studies in which they are involved.

**WHO SHOULD ATTEND**

This workshop is ideal for those individuals in your organization involved in the following functions:

- Study Director
- Principal Investigators/Contributing Scientists
- Report Writers
- Study Personnel
- Test Facility Management/Test Site Management
- Quality Assurance
- Sponsor Monitors

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**APPLICATION EXERCISE**

**Report Writing Activities**

This session covers essential components of GLP study reports and demonstrates good writing skills to produce reports which reconstructively summarize the study and convey results and conclusions clearly and accurately. Participants have the opportunity to use their newly learned knowledge and skills to write, review and edit GLP documents. Examples of how to tactfully and truthfully handle inconclusive and problematic results and conclusions are presented.

**APPLICATION EXERCISE**

**Standard Operating Procedures**

This session covers SOP format, content, and writing instructional procedures. The session will also include a practical exercise of writing and reviewing SOPs.

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**Q&A**

Attendees will have the opportunity to ask the instructor questions. This time can also be used to expand on any topic discussed earlier in the day which may be of particular interest to attendees.
Mission Statement:
enKap provides an exclusive learning community for professionals in FDA-regulated industry to continuously strengthen and apply their foundation of knowledge related to Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP). Our training workshops are based on the principle of engaging learners through a variety of active learning and instructional activities.

FDA COMPLIANCE DIGEST
To view our November 2009 Sample Issue or November 2009 Premier Issue article excerpts click on links below
FDA Compliance Digest November 2009 Sample Issue
FDA Compliance Digest November 2009 Premier Issue article excerpts
### Registration Form

Please check off which seminars you will be attending

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### Four easy ways to register:
1. Call: 561-795-2785
2. Online: [http://www.enkap.com](http://www.enkap.com)
3. Fax this completed form: 561-798-8138
4. Mail this completed form: enkap, 1480 Royal Palm Beach Boulevard, Suite A, Royal Palm Beach, FL 33411

### Contact Information

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### Payment

- Enclosed find my payment of________
- Early Registration Discount: Register for any training workshop by February 1, 2010 and save 10%

#### Credit Card

- American Express
- Master Card
- Visa
- Discover
- PayPal

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### Check

- Forward together with completed registration form payable to enKap (checks must be in U.S. dollars and drawn on a U.S. bank). No personal checks will be accepted.

### Invoice

- Please mark here to request an invoice from enKap. You are not considered registered until payment is received and a confirmation has been sent from enKap.

### Refunds

- Refund requests must be made in writing and received by February 25, 2010. You will receive a full refund, less a $200 processing fee. After the above-mentioned date, no refunds will be approved. enKap’s liability is limited to refund of the training workshop registration fee only.
- Substitutions: If you are unable to attend, substitutions can be made anytime.
- Group Discounts: Available for three or more individuals from the same facility. Call the enKap community desk toll-free at 1-877-823-4GXP for more details.