

Up Coming LSAM Training Events

To register call: Norma at
(204) 272-5095

September 16, 2009
Qualities of an Effective Leader

September 18, 2009
Qualities of an Effective Supervisor

September 23, 2009
Emotionally Intelligent Leader

September 25, 2009
Introduction to Effective Communication

September 30, 2009
GMP-Quality Systems Management Controls & the Missing "M" System.

September 30, 2009
Priority Setting

October 2, 2009
Decision Making

October 7, 2009
How to Delegate Effectively

October 9, 2009
Facilitating Teamwork

October 14, 2009
ACRP Recruitment & Informed Consent: Motivations Challenges and Special Consideration Researchers & Participants Perspective

October 14, 2009
Performance Management

October 16, 2009
Coaching Workers to Peak Performance

October 23, 2009
Problem Solving

October 28, 2009
Employee Engagement

November 2 & 3, 2009
UV/VIS Spectrophotometers Course

November 3 & 4, 2009
UV/VIS Spectrophotometers Course



Regulations, Roles and Requirements: An Interactive Monitoring Workshop

PLACE: 1000 Waverley Street, Winnipeg MB

DATE & TIME: November 9 & 10, 2009, 8:00 am – 4:30 pm

INSTRUCTORS: ASKA Research, Val Willett & Hannelore Vannetta

FEE: \$477.00 LSAM members; \$954.00 non-members

Day One

Welcoming Remarks, Goal and Objectives

Clinical Trial Process Overview

- Phases I-IV

Regulations

- GCP Global Comparison
- Activity: Fill-in-the-blank ICH/GCP Quiz

Ethics and Privacy in Clinical Research

- Ethics Composition and Submission Requirements
- Privacy Laws
- Activity: Discussion of selected news article

Sponsor Compliance - ICH/GCP Requirements

Investigator Compliance - ICH/GCP Requirements

- Activity: Safety Management

Fraud and Misconduct

- Definitions
- Detection and Prevention – How to develop CAPA
- Activity: Fraud vs. Misconduct
- Activity: Review of FDA Warning Letter

Monitoring Study Procedures and Documentation Overview

- Pre-Study Qualification
- Site Initiation
- Site Closure
- Activity: Case Study
 - SIV: Challenges and Conclusions

Review, analysis and discussion

Day Two

Informed Consent Requirements and Process

- Study Participant Rights
- Ethical Principles
- Information Disclosure
- Withdrawal/Early Termination
- Impact of changes to the Declaration of Helsinki
- Activity: Analysis & ICF Review

Monitoring Study Procedures and Documentation Overview

- Site Monitoring

Up Coming Training Events

December 1 & 2, 2009
FT-IR Workshop

December 3 & 4, 2009
FT-IR Workshop



Monitoring Techniques and Tools

Conduct a Virtual Visit & using documentation samples

- Where do you start?
- Site Relations Management
- Confirm site status – workload, recruitment and retention
- Confirm ICFs and process
- Assess Safety – SAEs and AEs
- Verify Compliance – protocol, regulations, REB
- Verify Integrity of the data
- Source Document Verification
 - Complete and Correct?
 - Review of Lab Processes
 - Assess lab reports for clinical significance – AE's
 - verify sample storage and shipments
- Investigational Product Reconciliation: Looking at the record
- Assess Investigator Site Files

Write the MVR & Follow Up Letter

- CAPA
- What's important and what's not
- Writing the MVR: Form, context and language

Questions and Answers, Summary, Certificates and Evaluations