Teleconference Course Materials
You may duplicate this for each person attending the conference.

Show Me Your Safety Data...
FDA & EU Pharmacovigilance Inspections

by Steve Jolley
SJ Pharma Consulting

Date:  Monday, January 30, 2012

Time:  1:00pm – 2:30pm Eastern Standard Time (GMT/UT 1800)
       12:00pm – 1:30pm Central Time
       11:00am – 12:30pm Mountain Time
       10:00am – 11:30am Pacific Time

Call-In:  Dial 1-888-848-0354 approximately 10-15 minutes prior to the start time.
         When prompted, enter the PIN code followed by the # key: 1941553#
         Outside the U.S. & Canada, you will receive special instructions by email.
         If you become disconnected and cannot reconnect through the number above,
         you can also call in on +1-801-853-0800.

At the conclusion of the conference, an audio file will be made available
for order. Attendees receive a special reduced price of $225.
To order go to www.foiservices.com/pvinsp1553 or call 301-975-9400.

Important Notice
The information provided in this course by the instructor is his/her personal opinion and does not necessarily
represent the opinions of FOI, Inc. or its staff. Companies relying on the information do so at their own risk
and assume the risk and any subsequent liability that results from relying on the information.
The information provided does not constitute legal advice.

Produced by:  FOI Services, Inc.
704 Quince Orchard Road • Suite 275
Gaithersburg MD 20878-1770 USA
Phone:  1-800-654-1147 or +1-301-975-9400
Fax:  301-975-0702
Email:  infofoi@foiservices.com
www.foiservices.com
Steve Jolley

- Principal, SJ Pharma Consulting
- 25 years of experience in drug safety & pharmacovigilance
- Specialist in global safety compliance, business process improvement and signal detection
- Worked with over 80 clients in the US, Europe and Japan
- Featured speaker with FDA and MHRA at DIA conferences and webinars on drug safety topics including auditing and signaling
- Chairperson of the DIA Clinical Safety and Pharmacovigilance Steering Committee for North America
- Degrees in mathematics and computer science from Cambridge University, England
Regulatory Background
U.S. Regulations

- Regulations – The Food, Drug & Cosmetic Act, enacted by Congress, empowers the Food and Drug Administration to create & issue regulations which have the force of law
  - The regulations do not have to be approved by Congress or signed by the President
  - A proposed new or amended regulation is announced in the Federal Register
    - A period is defined during which the public may submit written comments on the proposal to the FDA
    - After review of submitted comments, a final regulation is published in the Federal Register and compiled into the Code of Federal Regulations (CFR)
  - Often, a long period elapses between a draft announcement and the final regulation
    - The “Tome” rewriting many pharmacovigilance (PV) regulations was proposed in 2003, but most of this has yet to be finalized
    - Part of the Tome, the new IND reporting rule, was issued in 2010 and became effective in 2011
  - The draft regulation may be withdrawn
U.S. Guidances

Guidances – Documents issued by the FDA containing their current thinking on a particular subject.
- “They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both”
- May be issued as draft guidances for comment or directly as final guidances
- It is generally felt that following FDA guidances is a wise course of action
EU Legalities

- The EU situation is very different than the U.S.
  - EU is composed of 27 sovereign Member States
  - Other countries not in the EU may also follow EU laws
  - EU laws exist in all EU languages
  - National laws may only be available in the national language
EU Legalities – Regulations

- Directly applicable and binding in all EU member states without the need for any additional national implementation legislation
  - That is, the regulation as it is published, is word for word and immediately, the law in each of the member states
EU Directives

- Directives bind member states to the objectives of the legislation within a certain time period (e.g., 3 years)
  - Allow each member state to create its own version of the law
  - Each member state may modify the wording and requirements, provided the objectives are met
  - This often produces differences & inconsistencies in each member state
Matrix of Safety Regulations

<table>
<thead>
<tr>
<th></th>
<th>Clinical Development</th>
<th>Post Marketing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global</strong></td>
<td>ICH E2A (Clinical Safety)</td>
<td>ICH E2D (Expedited Reporting) ICH E2C (PSUR)</td>
</tr>
<tr>
<td><strong>European Union</strong></td>
<td>EU CTD Directive 2001/20/EC Volume 10</td>
<td>Volume 9A</td>
</tr>
<tr>
<td><strong>United States</strong></td>
<td>21 CFR 312 (IND)</td>
<td>21 CFR 314.80</td>
</tr>
</tbody>
</table>
Postmarketing Safety Reporting: CFR

- 21 CFR 310.305
  - Records & reports concerning ADEs on marketed drugs without NDAs
- 21 CFR 314.80
  - Postmarketing reporting of ADEs
- 21 CFR 600.80
  - Postmarketing reporting of biological AEs
- *U.S. Reports*: FDA MedWatch 3500A form
- *Non-U.S. Reports*: CIOMS I form or 3500A form
- Good Clinical Practices (GCPs)
- Good Pharmacovigilance Practices (GPVPs)
FDA Risk Management Guidances
March 2005

- Premarketing Risk Assessment

- Risk Management Programs
  - Risk Communication
  - Risk Intervention
  - Risk Management Evaluation

- Good Pharmacovigilance Practices & Pharmacoepidemiology
FDAAA – September 2007

- FDA Amendment Act (FDAAA) was signed into law in September 2007
- Requires Risk Evaluation and Mitigation Strategies (REMS)
- Requires increased activities for active post-market risk identification and analysis
New FDA Regulation: IND Safety Reporting

- FDA issued the new draft guidance “Safety Reporting Requirements for INDs and BA/BE Studies” in September 2010
  - Proposed implementation date was March 2011
  - Deferred until September 29, 2011

- Intended to reduce “noise”, enhance “message”

- FDA requests sponsors to evaluate data
  - Only submit to FDA what sponsor deems of interest

- Causality assessment:
  - Change from “cannot be excluded” to “reasonable possibility”
International Conference on Harmonisation (ICH)

- ICH: 1990
  - EMA, EFPIA, MHLW, JPMA, FDA, PhRMA (WHO, Health Canada)

- Principles
  - Develop scientific consensus regulatory/industry
  - Consult on draft consensus documents for final text
  - Commit by regulatory authorities to implement ICH harmonized texts

- Topics
  - Quality, safety, efficacy, multidisciplinary
    - For example, PV plan is topic E2E

- Steps (Five)
  - Technical discussion, consensus, outside consultation, final ICH guideline, implementation
ICH Topic Codes & Reports

- **Q = Quality**
  - Chemical and pharmaceutical quality assurance
    - Q1 = Stability
    - Q3 = Impurity Testing

- **S = Safety**
  - *In vitro* and *in vivo* pre-clinical studies
    - S1 = Carcinogenicity
    - S2 = Genotoxicity Testing

- **M = Multidisciplinary topics**
  - Cross-cutting topics that do not fit above categories
    - M1 = Medical Terminology
    - M2 = Electronic Standards for Transmission Regulatory Information (ESTRI)
    - M3 = Timing of Pre-clinical Studies
    - M4 = Common Technical Document
ICH Topic Codes

- **E = Efficacy – Clinical studies in human subjects**
  - E1 = Extent of Population Exposure Assess Clinical Safety
  - E2A = Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
  - E2B = Data Elements for Transmission of ADR Reports
  - E2B(M) = Data Elements for Transmission of Individual Case Safety Reports (ICRs)
  - E2C = Periodic Safety Update Reports
  - E2D = Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
  - E2E = Pharmacovigilance Planning
  - E2F = Development Safety Update Report
  - E3 = Structure and Content of Clinical Study Reports
  - E4 = Dose Response
  - E6 = Good Clinical Practices
Council of International Organizations of Medical Sciences (CIOMS)

- Established 1949 by UN: WHO, UNESCO
- Over 100 international scientific/national biomedical organizations
- Industry, regulators discuss/work for proposals
- **CIOMS Publications**
  - I – International Expedited Report ADR – “CIOMS” Form = E2A
  - IA – Data Field Standardization for Electronic Transfer = E2B
  - II – Periodic Drug Safety Update Summary (PSUR) = E2C
  - III/V – Company Core Clinical-Safety Information
  - IV – Benefit/Risk Evaluation/Balance – Marketed Drugs, Evaluating Safety Signals
  - V – Pragmatic Approaches to PV
  - VI – Managing Safety Info from Clinical Trials
  - VII – DSUR
  - VIII – Signal Detection
Key EU Components

- Eudravigilance
- Eudract
- EU Clinical Trial Directive
- Volume 10
- Volume 9A
- DSUR
- Signaling
- New pharmacovigilance legislation
EU Member States

- Austria
- Belgium
- Bulgaria
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom
Eudravigilance Database

- Eudravigilance is a central computer database created & maintained by the EMA containing AEs for products licensed in the EU
  - SUSARs from HAs in the EU & companies
Applicable to sponsors for all interventional clinical trials since 2004

All Suspected Unexpected Serious Adverse Reactions (SUSARs) are reportable electronically

Sponsors to report to

- Concerned Member State(s) (paper or electronically)
- Concerned Ethics Committees (on paper)
- EudraVigilance Clinical Trial Module (EVCTM) at the EMA
Eudravigilance:
Post-Marketing Requirements

- Mandatory e-reporting of ICSRs
  - Since 2005 for all medicinal products authorised in the EEA, independent of the authorisation procedure

- Fall-back procedures to maintain expedited reporting compliance should also be in place
EUDRA CT Database

- Registry of all clinical trials in EU
  - Identifies details of clinical trial and protocol
  - Identifies manufacture/import and QP
  - Includes other member state opinions
  - Records GCP/GMP inspections
EU Clinical Trial Directive 2001/20/EC

Volume 10

- Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use April 2006

Volume 9A


DSUR

- Harmonize EU & US clinical study periodic safety reporting requirements
  - Takes into account CIOMS VII recommendations
  - Constrained by existing EU and US regulations
- First meeting: October 2006 (Chicago)
- Step 2: June 2008
- Step 4: August 2010
- European launch: September 2011
  - EMA/CHMP/ICH/309348/2008
European Signaling Regulations

- Volume 9A, section 8.1 describes the MAH’s requirements for signal detection
- MHRA further states that “All MAHs are expected to have in place systems and procedures for systematic signal detection that are adequately documented in formalized procedures”

MHRA & Signal Detection

- MHRA’s “Good Pharmacovigilance Practice Guide” states:
  - Signaling should be performed more frequently than PSUR review
  - “The method used should be appropriate for the MAH’s dataset”
  - “The use of complex statistical tools may not be appropriate for MAH’s with a small dataset”
  - “MAHs should have systems in place to assure the quality of their signal detection processes”
  - “The MAH should take timely and appropriate actions and decisions based on the outputs from cumulative data review”
New European Pharmacovigilance Legislation

- The new legislation represents the biggest change to EU pharmacovigilance requirements for over a decade and will have a significant impact for regulators and industry.

- Directive 2010/84/EU amending, as regards pharmacovigilance, Directive 2001/83/EC, was published on 31st December 2010

- Regulation 1235/2010 amending, as regards pharmacovigilance, Regulation No 726/2004, was published on 31st December 2010
  - The Regulation shall apply from 2nd July 2012.
# New European Pharmacovigilance Legislation

<table>
<thead>
<tr>
<th>Impact on Risk Management Plans</th>
<th>Will be required for all new authorizations and for existing products on the basis of safety concerns. Greater emphasis on follow-up of commitments within RMP. Increased likelihood of post-authorization studies as part of RMP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation of Pharmacovigilance System Master File (PSMF)</td>
<td>Companies must maintain a detailed file on site. Living document that contains more information than DDPS. Includes audit findings. PSMF can be requested by agencies at any time. Replace DDPS.</td>
</tr>
<tr>
<td>Expedited reporting</td>
<td>Expedited reports sent only to the EMA. All serious with 15 days from any country. All non-serious reports must also be expedited to the EMA (within 90 days). Language strengthened on medical errors.</td>
</tr>
</tbody>
</table>
Penalties for Non-Compliance

- Regulators can impose penalties following an inspection
- In the US the possible sanctions are as follows:
  - FDA 483: A report of deficiencies following an FDA Inspection
  - Establishment Inspection Report (EIR)
  - Warning Letter
  - Seizure of product
  - Consent decree
    - Schering Plough was fined $500 million for manufacturing violations
  - Criminal prosecution
Penalties for Non–Compliance (2)

- FDA can also impose civil monetary penalties for violations of the REMS provisions in FDAAA
  - Penalties may not exceed $250,000 per violation, or $1 million for all violations adjudicated in a single proceeding
  - If a violation continues after the sponsor receives written notice, the penalty is:
    - $250,000 for the first 30–day period (or any portion thereof) that the violation continues
    - Not to exceed $1 million for any 30–day period
    - Not to exceed $10 million for all violations adjudicated in a single proceeding
Penalties for Non–Compliance (3)

- In Europe, financial penalties to MAHs were introduced in 2007
  - For infringements associated with non–compliance for centrally authorized products
  - Penalty of up to 5% of total EU annual turnover per annum
Audits vs. Inspections

- **Inspection:** An inquiry, examination and verification of processes, data, records, databases etc. by a government or official authority (e.g. FDA, MHRA, EMA, Health Canada etc.)

- **Audit:** The same but by a non-governmental entity such as a partner, vendor, supplier, client, etc. or an internal group within one’s own organization

*Note: These terms will be used interchangeably during this presentation unless otherwise specified in particular topics*
Why?

- Inspections
  - Protect the public health
    - Compliance: see if regulations & laws are being followed
    - Monitoring of industry
    - Part of normal business: e.g. pre-approval inspection
    - Investigation of a problem
    - Risk Management/Patient Protection

- Audits
  - Business reasons
    - Compliance: see if SOPs & regulations are being followed
    - Due diligence of a new vendor, client, supplier etc.
    - Investigation of a problem
    - Part of quality management system
Types of Audits & Inspections

- **Routine**
  - Periodic, global every 2–4 years
  - One drug or product
  - Specific function that an agency is looking at across the industry: alert reporting, IT systems, data privacy & security etc.
  - Scope usually broad

- **For Cause**
  - Specific issue that the HA (or partner, vendor etc.) is alerted to (e.g. late expedited reports), failure to report expedited reports that agency receives from another source, whistle blower, fraud, data issue
  - Scope may start limited but may expand during or after inspection
Who Can be Audited?

- **Company**
  - Central group (headquarters)
  - Regional or national offices
  - Data entry & call centers
- **Investigator sites**
- **Partners, distributors, co-developers**
- **Licensees and licensors**
- **Vendors, contractors & suppliers**
- **Data storage facilities**
- **CROs**
Approaches

- Inspections by health agencies
  - Adversarial often
  - Inspectors have governmental/legal authority
  - Agenda: protect the public health
  - Severe consequences for untruths
  - May or may not be highly skilled PV inspectors (general inspectors or dedicated PV inspectors)
Preparing for a Pharmacovigilance Inspection
Achieving Best Practices through the Pharmacovigilance Assessment

- Conduct a diagnostic overview of pharmacovigilance activities to gain a rapid understanding of the current position versus best practices and current regulations

- As a result, gaps and risks are identified, and priorities can be established for moving forward to ensure company compliance and brand protection
Value Derived

- Assessment of PhV Operations vs. Best Practices and Regulations
- Background and Education on Specific Regulations Pertaining to Findings
- Pharmacovigilance Risk Profile
- Prioritized Actions to Address Gaps
Scope

The assessment should include a review of:

- Pharmacovigilance strategy
- Results of FDA or other third party assessments
- Structure of the Company’s pharmacovigilance organization
- Skills and resource levels
- Interfaces, linkages and communication
- Pharmacovigilance processes and SOP’s
- Tools utilized in assessing, analyzing and reporting safety data
- Safety surveillance and signaling activities
- Quality assurance and quality control processes
- Performance monitoring and metrics
Pharmacovigilance Process Model

1. Collect Data
2. Assess Cases
3. Report for Regulatory Compliance
4. Analyze to Detect Signals
Audit Items – Collection

- Processing of safety information
  - Telephone, email, letter, website, partners
  - Transfer of information from subsidiaries, partners etc. to HQ safety department

- Sources of data
  - Adverse events
  - Product complaints
  - Medical information requests
  - Literature review

- Safety Data Exchange Agreements
  - Partners, distributors, licensees, licensors

- Outsourcing to CRO/CSO
  - Contracts, supervision, quality

- Follow-up data collection
  - Number and type of follow-up attempts
  - Skill level of person calling

- Clear definition of start date
  - Receipt by company/agent/partner
Audit Items – Assessment

- Who is assessing cases for serious/expected/causally related?
- Coding (MedDRA, drug names)
  - Consistency, level of coder, coding guidelines
Audit Items – Reporting

- All boxes checked on MedWatch Form
- Meet 7/15 day deadlines
- Meet periodic reporting deadlines
- Medical review for consistency
  - source documents
  - database information
  - final MedWatch/CIOMS form
Audit Items – Analysis

- Signaling & risk assessment
  - When is this done?
  - How is it done?
  - What is done with the results?

- Escalation of safety issues
  - Committees, responsibilities, actions taken
  - Communication to regulatory authorities, IRBs, etc.

- Crisis management plans
Additional Audit Items (1)

- Previous audit/inspection reports
  - Follow-up commitments from previous inspections, CAPA
  - Include affiliated contractors/locations that are involved in workflow

- SOPs & Work Instructions
  - Content, quality, completeness, deployment

- Personnel files
  - Job descriptions
  - CVs
  - Complete, chronological training records

- Metrics
  - Scope, frequency, monitoring
Additional Audit Items (2)

- Quality systems
  - Quality assurance
  - Quality control
- Vendors
  - Safety database vendor
  - Do all databases maintain an audit trail?
  - Signaling software
  - Off-site storage & business continuity suppliers
- Validation
  - 21 CFR Part 11
- Business continuity plans
Company Sources of Information to Examine

- Process/Workflow diagrams
- Organization charts
- Safety Data Exchange Agreements
- Current Safety SOPs
- Sampling of Cases
- Safety Specification and Risk Management Plans
PV Checklist

1. PHARMACOVIGILANCE STRATEGIC INTENT
2. STRUCTURE OF THE PHARMACOVIGILANCE ORGANIZATION
3. QUALITY MANAGEMENT
4. BUSINESS PROCESSES
   4.1. Overall Case Processing
   4.2. Receipt of Reports
   4.3. Clinical Trial AEs
   4.4. AE Assessment and Triage
   4.5. AE Coding and Code Review
   4.6. Data Entry into safety database
   4.7. Entry of Narratives
   4.8. Medical Review
   4.9. Case Reports
   4.10. Statistical Analysis/Signaling
   4.11. Reporting (Expedited Reports, PSURs, Annual INDs)
   4.12. Labeling
   4.13. Archiving
5. STANDARD OPERATING PROCEDURES
6. SYSTEMS
   6.1. Adverse Event Reporting System
   6.2. Electronic Reporting
   6.3. Signaling and Data Mining
7. SURVEILLANCE
   Appendix - Cross Reference of Regulations
As a result, the company can establish the Risk Profile, knowing which gaps to close.
## Report Table of Contents

- **Introduction** (background of company situation and relevant drug safety and pharmacovigilance operations)
- **Scope of Assessment**
- **Approach and Methodology** (tools utilized, collection of information from sources, evaluation and findings, basis for references)
- **Analysis**
  - Positive observations
  - Gaps identified with cross-reference to regulations, laws, guidances and best practices
- **Conclusion**
  - Overview (brief review of results)
  - Next Steps (approach to moving forward)
Limited Diagnostic Can Initiate The Assessment

- Operating Unit
- Geographic Site
- Product or Therapy
- New Product Introduction
- Identified Problem

- All regions, departments and products
- All partners
- Mapping to global best practices
- Produce detailed report and gap analysis to include findings, priorities, estimated resources, “as-is”/”to-be” models
- Corporate SOP development
- Training plan
Inspection Findings
Watch out for the Qualified Person (QP) role... according to the MHRA, most inspection findings relate to the QP. These include:

- No evidence that QP was in place prior to the inspection
- QP not “permanently and continuously” available in the EEA
  - QP role outsourced, but contract deficient
- QP has no access to medically qualified safety expert, if not medically qualified himself/herself
- QP does not have adequate experience in all aspects of PhV
- QPs contact details not communicated to authorities
MHRA Inspection Findings (2)

- QP has inadequate oversight of the PhV system, especially quality and timeliness of expedited reporting and PSURs
- QP does not ensure that information regarding suspected adverse reactions is collected and collated to be accessible in at least one point in the Community
- Lack of understanding of EU and national legislation, including QP roles and responsibilities
MHRA Inspection Findings (3)

- People have inadequate
  - Qualifications
  - Experience
  - Expertise
  - Knowledge
  - Training
MHRA Inspection Findings (4)

- Procedural Documents
  - Key processes not supported by procedural documents
  - Lack of sufficient detail in the procedure in order to ensure a consistent approach to the process
  - Procedures out of date vis-à-vis EU and UK legislation
MHRA Inspection Findings (5)

- Processing of ICSRs
  - Significant non-compliance with 15-day reporting timelines for expedited reports
  - Failure to submit all appropriate reports to competent authorities
MHRA Inspection Findings (6)

- Electronic Reporting
  - MAH unable to submit reports electronically to Eudravigilance (and ultimately, all competent authorities)
MHRA Inspection Findings (7)

- **PSURs**
  - Failure to produce PSURs that are ICH E2C compliant
  - Failure to product PSURs that are complete and accurate
    - Computer programming errors
  - Failure to prepare and submit PSURs at the correct time
    - Periodicity
    - Within 60 days of data lock point
MHRA Inspection Findings (8)

- Signal Detection
  - No formal procedures for signal detection/trend analysis
  - No formal, periodic review of information to identify new safety issues (except at time of PSUR production)
  - Documentation relating to performance of signal detection/trend analysis not retained
  - Failure to communicate new safety issues in a prompt manner to competent authorities
Addressing Inspection Findings

- Prepare for the inspection!
  - Create a Summary of Pharmacovigilance Systems
  - Review FDA Compliance Program Guidance Manual
  - Seek an independent, unbiased evaluation of your drug safety organization
Addressing Inspection Findings (2)

- Keep track of all prior audit and inspection findings
  - Implement a Corrective and Preventive Actions (CAPA) system
  - All findings should be monitored by the group responsible for quality
  - Show progress made to fix the problems
  - In the event of a subsequent inspection, if prior findings have not been corrected then the fact that they are being tracked in a CAPA will go some way to mitigate the failure to resolve the issue
Addressing Inspection Findings (4)

- Systematic failures in a PV system cannot be fixed overnight
- Companies must be prepared to invest time and effort to get things on track
- This is a worthwhile investment!
- Some regulators have an institutional memory, and once a company has committed a significant transgression it will continue to be regarded with suspicion
Conclusion

- In order to ensure compliance, companies should:
  - Establish and conform to industry best practices
  - Ensure awareness of all applicable regulatory standards
  - Perform ongoing self-monitoring and self-correction of pharmacovigilance
  - Provide corporate support to ensure resource allocation
  - Conduct audits
  - Ensure complete and timely response to any findings of non-compliance either by regulatory authorities or by an auditor
Thank You! Questions?

We welcome all questions!
The telecommunications provider will describe how you can ask a question. When it is time for your question, you will be announced only by the first name of the person reported to the operator when you first dialed in. Anyone in your group may actually ask the question.

If you think of a question or two later, or have concerns you would like to discuss privately, please do not hesitate to contact Steve Jolley at steve@sjpharmaco.com

Your feedback is valued.
Please complete and return the evaluation to be entered in a prize drawing for a $100 amazon.com gift card and/or to arrange to receive a Certificate of Attendance.
Training Evaluation Form

Show Me Your Safety Data...FDA & EU Pharmacovigilance Inspections
by Steve Jolley, Presenter – January 30, 2012

Win a $100 Amazon.com Gift Certificate from FOI!

Just complete this form and fax it to +1-301-975-0702 by February 6, 2011
and you will be entered in a drawing for an Amazon.com Gift Certificate.

Please indicate your primary job responsibility (circle one):

Regulatory Affairs  QA/QC  Statistics  Medical Writing  Electronic Submissions  General Management

Other (please specify):____________________________________

Please rate various aspects of this course
(1 = Poor; 2=Fair; 3=Good; 4=Very Good; 5=Excellent – please circle your answers)

What is your overall rating of the course? 1 2 3 4 5

How do you rate the content of the course? 1 2 3 4 5

Were course materials clear and understandable? 1 2 3 4 5

Was the length of the course adequate to cover the content? 1 2 3 4 5

Was the instructor knowledgeable about the subject matter? 1 2 3 4 5

How would you rate the instructor overall? 1 2 3 4 5

Other comments:
Please feel free to comment on any aspect of this course, including the instructor, content, and technical arrangements:

________________________________________________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

Check here to receive a Certification of Attendance verifying your 1.5 training contact hours for this educational session. Please provide your legibly printed name with your signature next to it, email address, and fax this form to the number below. Your certificate will be emailed to you.

By providing the information below and faxing this page to +1-301-975-0702 by Monday, February 6, 2011 you will be entered in a drawing for a $100 Amazon.com Gift Certificate from FOI.

Your Name:______________________________________________________________

Company Name:__________________________________________________________

Email Address:___________________________________________________________