

India Seminar 2012 at Mumbai

USFDA & EU ESSENTIALS OF DRUG SAFETY AND PHARMACOVIGILANCE

by **Steve Jolley**

On 5th, 6th and 7th March, 2012 at Mumbai at InterContinental The Lalit



About GlobalCompliancePanel:

GlobalCompliancePanel is an online training provider of Regulatory and Quality compliance. We deliver a broad range of high quality regulatory and compliance-related services.

At GlobalCompliancePanel, we offer extensive and high quality training for Risk Management, Regulatory Compliances, Corporate Governance and Quality Management. We have been serving our customers for the past three years, during which we have successfully completed over 350 training courses, from which more than 15,000 professionals have benefited. Many of these sessions have had over 100 participants. Over 100 well-versed Experts from various industries with several decades of collective experience are associated with us.

Our services benefit the Medical Devices, Pharmaceutical, Bio Technology, Food Safety, Financial Accounting Standards, and IT Control & PCI Industries. Our clients can choose from any of these mediums - online seminars that are live, recorded or for group viewing, workshops, live seminars and conferences, onsite trainings and consulting. Our clientele includes companies such as J&J, Pfizer, Sanofi Aventis, Pall Corp, Abbott, Merck, Bayer, and Roche, some of which are Fortune 500 companies.

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Steve Jolley

Principal, SJ Pharma Consulting

About Speaker:

Steve Jolley is a subject matter expert in all areas of global safety compliance and signal detection, and is a frequent speaker at leading industry events including DIA and MHRA.

He has 25 years' experience in drug safety & pharmacovigilance and has worked with over 50 clients in the US, Europe and Japan. He holds degrees in mathematics and computer science from Cambridge University, England. Steve is a featured speaker with FDA at DIA conferences and webinars on auditing, signaling and data mining.

Steve began his career in the pharmaceutical industry in 1985 when he founded DLB Systems, a supplier of computer systems for clinical trials and adverse event reporting to many of the leading life science companies worldwide. DLB was acquired by eResearch Technologies in 1997; since then Steve has worked as an independent consultant.

Past Seminars



Date and Venue:

March 5th, 6th and 7th, 2012
Intercontinental The LaLiT Mumbai
Sahar Airport Road
Mumbai – 400059 India

Seminar Content:

Day 1 - 5th March 2012

- ✓ **Lecture 1: Overview of Pharmacovigilance**
 - ▶ Learning Objectives for this Session
 - ▶ History of Pharmacovigilance
 - ▶ Pre-Marketed Aes
 - ▶ Post-Marketed Aes
 - ▶ Pre- and Post-marketing: Basic Differences
 - ▶ The Importance of Adverse Event Reporting
 - ▶ Pharmacovigilance Definitions
 - ▶ ICH Definition of Adverse Event
 - ▶ ICH Definition of Adverse Drug Reaction
 - ▶ Suspected Unexpected Serious Adverse Reaction
 - ▶ Sources of ADRs
 - ▶ Pharmacovigilance Process
- ✓ **Lecture 2: Assessing Adverse Event Cases**
 - ▶ Assessing Adverse Events
 - ▶ Regulatory Definition of a Serious Adverse Event
 - ▶ Severity/Intensity
 - ▶ Difficulty Assessing Relationship of AEs with Drug
 - ▶ Causality
 - ▶ Lack of Efficacy -- ICH
 - ▶ Expectedness
 - ▶ Assessing Expectedness/Labeledness/Listedness
 - ▶ Labeled vs. Listed
- ✓ **Lecture 3: Reporting Adverse Events**
 - ▶ General Types of Reports
 - ▶ Expedited Reporting – What to Report
 - ▶ Expedited Reporting – What not to report
 - ▶ Aggregate Reports – Common Types
 - ▶ Reporting Timeframes for ICSRs
 - ▶ Timelines for Follow-Up
 - ▶ Reporting to IRB/ECs
 - ▶ Investigator Notification
 - ▶ Minimum Criteria for Reporting
 - ▶ Minimum Data Set – Day “0”
 - ▶ Reporting Format
 - ▶ Key Data Elements for Inclusion in Expedited Reports
- ✓ **Lecture 4: Global Regulatory Requirements**
 - ▶ Matrix of Safety Regulations
 - ▶ New FDA Regulation for IND safety reporting
 - ▶ International Conference on Harmonisation (ICH)
 - ▶ ICH Topic Codes and Reports
 - ▶ Eudravigilance – Pre-Marketing Requirements
 - ▶ Eudravigilance – Post-Marketing Requirements
 - ▶ Annual Safety Report
 - ▶ IND Annual Report
 - ▶ Development Safety Update Report
 - ▶ New European Pharmacovigilance Legislation

Day 2 - 6th March 2012

- ✓ **Lecture 5: Inspections and Audits**
 - ▶ Audits vs Inspections
 - ▶ Why Conduct Them?
 - ▶ Types of Audits & Inspections
 - ▶ Who Can be Audited?
 - ▶ Approaches
 - ▶ Preparing for a Pharmacovigilance Inspection
- ✓ **Lecture 6: Pharmacovigilance Best Practices**
 - ▶ Achieving Best Practices through the Pharmacovigilance Audit
 - ▶ Value Derived
 - ▶ Scope
 - ▶ Pharmacovigilance Process Model
 - ▶ Audit Items - Collection
 - ▶ Audit Items - Assessment
 - ▶ Audit Items - Reporting
 - ▶ Audit Items - Analysis
 - ▶ Additional Audit Items (1)
 - ▶ Additional Audit Items (2)
 - ▶ Company Sources of Information to be Examined
 - ▶ PV Checklist
- ✓ **Lecture 7: Preparing for an Inspection**
 - ▶ Pharmacovigilance Risk Profile
 - ▶ Priority of Findings
 - ▶ Report Table of Contents
 - ▶ Limited Diagnostic Can Initiate The Assessment
 - ▶ Assessment Approach
 - ▶ Workflow/Processes-Global
 - ▶ Processes-CRO
 - ▶ Data Assessment
 - ▶ Personnel Qualifications & Training
- ✓ **Lecture 8: Case Studies with Real-Life Inspection Findings**
 - ▶ Representative Findings from Case Study
 - ▶ Four Case Studies
 - ▶ Critical Issues Observed
 - ▶ Major Issues Observed
 - ▶ Tips for the Pharmacovigilance Audit
 - ▶ Eight Domains of PhV
 - ▶ Inspection Findings
 - ▶ How to Address Inspection Findings?

Conference timings: 9:00 am - 6:00 pm

Day 3 - 7th March 2012

- ✓ **Lecture 9: Background to Signal Detection**
 - ▶ The need for signal detection
 - ▶ Regulatory Requirements
 - ▶ Approach to Signal Detection
 - ▶ Company Characterization
 - ▶ Characteristics of small versus large companies
 - ▶ Premise for Signal Detection
 - ▶ Importance of astute clinical perspective
 - ▶ Danger of over-reliance on technology
 - ▶ Detailed characteristics
 - ▶ Elements of case series analysis
- ✓ **Lecture 10: Signalling Exercises**
 - ▶ Signaling Case Study
 - ▶ Data Flow
 - ▶ Recommended data elements to be obtained prior to analysis
 - ▶ Typical PSUR data elements
 - ▶ Analysis by MedDRA System Organ Class
 - ▶ Analysis by MedDRA Preferred Term
 - ▶ Analysis by Age Range
 - ▶ Analysis by Sex
 - ▶ Analysis by Country
 - ▶ Analysis by Time to Onset
 - ▶ Analysis by Treatment Duration
 - ▶ Analysis by AE Duration
 - ▶ Analysis by Concomitant Medications
- ✓ **Lecture 11: Data Mining Exercises**
 - ▶ What is Data Mining?
 - ▶ Principles of Safety Data Mining
 - ▶ Challenges in Adverse Event Databases
 - ▶ Recommended Approach: Large Company
 - ▶ Components of suggested analyses
 - ▶ Discussion of external data sources
 - ▶ Pros and cons of different external data sources
 - ▶ Data Flow Elements
 - ▶ Data Mining Fundamentals
 - ▶ Description of recommended data mining methodologies
- ✓ **Lecture 12: Pharmacovigilance and Risk Management Process**
 - ▶ Pharmacovigilance Process
 - ▶ Signal Detection Operational Questions
 - ▶ Signal Detection Sources
 - ▶ Signaling Process
 - ▶ Signal Evaluation Steps
 - ▶ Signal Repository and Safety Profiles
 - ▶ Product Safety Profile (PSP)*
 - ▶ Risk Management Planning
 - ▶ Factors to Consider in Signaling Optimization
 - ▶ Signal Detection Triage Example
 - ▶ Triage Algorithms Used
 - ▶ Comprehensive Signaling Process Elements

What you get:

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
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7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals



Companies that will benefit:

- Drug Companies
- Biologic Companies
- CROs

Pricing List:

1. Price for One Delegate pass – INR 20000 + 10.3% tax
(Between February 19th to March 4th)

2. Early bird price for one Delegate pass – INR 18000 + 10.3% tax
(Between January 30th to February 18th)

3. Group Delegate pass (5 & above) – 10% discount on total amount.

Professionals who will benefit:

- Drug safety and pharmacovigilance
- Regulatory affairs
- Clinical development
- Executives (including C-Level) with any legal responsibility for drug safety
- Clinical safety staff
- Pharmacovigilance specialists
- Regulatory affairs professionals
- Quality management specialists
- Management involved in clinical oversight
- Pharmacovigilance
- Pharmacoepidemiology
- Regulatory affairs

How to Register:

- Step 1: Download the registration form from GlobalCompliancePanel website.
- Step 2: Fill in the requested information and fax us or email a scanned copy of the same.
- Step 3: Send us the cheque with the purchase document which comes with the registration form.
- Step 4: We will send you a confirmation letter within 1 week after we receive the check.
- Step 5: Bring the confirmation letter with you on the 1st day of the seminar and submit it at the registration counter to receive your seminar kit and join the seminar.

Contact Information:

Event Coordinator

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**Kindly get in touch with us for any help or information.
Look forward to meeting you at the seminar
Team GlobalCompliancePanel**