Drug Safety and Pharmacovigilance Workshop

Course Description

Product safety makes headlines every day -- and the impact on a company's image, consumer confidence, and Wall Street's opinion is profound. Are you confident your current pharmacovigilance operations will meet the latest US and EU expectations for compliance and keep your products on the market? Do you understand the processes needed to perform adequate risk assessment?

Not knowing which systems and processes you must have in place for your own safety reporting could mean you miss an important issue with significant consequences for your product. You must be sure you have the understanding you need to avoid product recall, are able to work to international standards and have implemented regulatory requirements for signaling and risk management.

This training course is designed to give pharmaceutical and biologic companies operating an introduction to the fundamentals of product safety and regulatory compliance. The course will include case studies of adverse events to illustrate the decision-making process and reasoning needed behind when and how to properly report incidents to regulatory authorities.

Learning Objectives

- Gain an understanding of regulatory requirements for drug safety
- Describe how to collect, assess, report, and analyze adverse events
- Explain how to create signaling analyses based on FDA and EU requirements
- Describe the basic elements required for performing adequate risk assessment

Sild Conferencing Pharmacovigilance / Drug Safety

Who Should Attend

Almost everyone involved in drug development and marketing needs to understand drug safety. Staff who will benefit include:

- Drug safety and pharmacovigilance
- Regulatory affairs
- Clinical research and development
- Marketing approval
- Post marketing activities
- Medical affairs
- Quality assurance/compliance
- Executives (including C-Level) with any legal responsibility for drug safety

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Interactive Activities

- Case assessment: seriousness, severity and causality
- Signaling Exercises: Analysis of AE data by MedDRA System Organ Class, Preferred Term, Age Range, Sex, Country, Time to Onset, and Concomitant Medications

Presented by Steve Jolley

About Your Instructor

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 with FDA, EMA and MHRA on the topics of auditing and signaling. Steve has 30 years' experience in drug safety & pharmacovigilance and has worked with over 100 life science companies and regulators in North America, Europe, Japan, India and China. He holds degrees in mathematics and computer science from Cambridge University, England. He is an Adjunct Professor at Rutgers University and teaches part of their Master's degree in Drug Safety and Pharmacovigilance.

Steve was elected chairperson of the Drug Information Association Clinical Safety and Pharmacovigilance Steering Committee for North America in 2010. He is a member of DIA's training faculty and is an instructor for DIA's Clinical Safety and Pharmacovigilance Certificate Program.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Overview of Pharmacovigilance: Thalidomide and History of Pharmacovigilance; Limitations of Pre-approval Clinical Trials; Post-Marketed AEs; Pharmacovigilance Definitions; Assessing Adverse Events; Serious vs. Severe; Causality; Expectedness; SUSAR; Minimum Criteria for Reporting; Reporting Format; Expedited and Aggregate Reports; Reporting to IRB/ECs; Minimum Criteria for Reporting; Managing Blinded Therapy Cases; Adverse Reaction Types; Safety Signal Generation; Quiz

Global Regulatory Requirements: Matrix of Safety Regulations; FDA Regulations; International Conference on Harmonisation (ICH); CIOMS; Key EU Components; EU Member States; Eudravigilance; EU Clinical Trial Directive; Volume 10; Volume 9A; European Signaling Regulations; New EU PV Legislation; Quiz

Day Two: 8:30 a.m. – 5:00 p.m.

PV Audits: Preparing for a Pharmacovigilance Audit; Achieving Best Practices; Scope; PV Checklist; Case Studies; Eight Domains of PV; Key Inspection Findings by FDA &MHRA; Quiz

Signaling & Risk Assessment: Need for Signal Detection; the Cost of Failure; Regulatory Requirements for Signaling; EMA Signaling Legislation; MHRA & Signal Detection; Approach to Signal Detection; Sample Signaling Analyses; Methodologies: MGPS, BCPNN, PRR; Signaling Process; Quiz

Communicating Safety Issues: Pharmacovigilance process; Product Safety Profile; Risk Management Planning; EU RMP vs FDA REMS, EU RMP format, FDA REMS Elements

Registration Form

Please write in BLOCK CAPITALS

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KAWIMBE

Drug Safety and Pharmacovigilance Workshop

15th - 16th March 2018

FNB Conference Centre in Sandton- Johannesburg

Book & Pay Before 31 January 2018 and get a R1000.00 Discount

COMPANY AND DELEGATE DETAILS

Organization: .....

VAT Registration Number: .....

Nature of Business: .....

Address: .....

City: ..... **Post Code:** .....

Phone: ..... **Fax:** .....

Delegate Details:

1. Full Names: .....

Position: .....

Email: .....

2. Full Names: .....

Position: .....

Email: .....

3. Full Names: .....

Position: .....

Email: .....

4. Full Names: .....

Position: .....

Email: .....

5. Full Names: .....

Position: .....

Email: .....

FEES

(Please indicate your choice and complete the authorization)

Payment is required within 5 days.

☐ **Price per Delegate = R10,990.00**

Group Discount (per Delegate)

☐ **4 Delegates Less 10%**

Fees Include refreshments, luncheons and supplementary Documentation.

METHODS OF PAYMENT

Please indicate your choice of payment method

☐ **Cheque:**

Made Payable to SILD Conferencing & Training (Pty) Ltd

☐ **Bank Transfer:**

Bank Name: FIRST NATIONAL BANK(FNB)

Account Name: SILD Conferencing & Training (Pty) Ltd

Branch Name: Randburg

Branch Number: 261750

Account Number: 62480974651 | Swift Code: FIRNZAJJ

Quoting Delegate Name and Invoice number as reference

AUTHORISTATION

Signatory must be authorized to sign on behalf of the contracting Organization

Name: .....

Position: .....

Email: .....

Signature: .....

Date: .....

THIS BOOKING FORM IS INVALID WITHOUT THE SIGNATURE

Full payment is required within 5 working days. Payment must be received prior to the event date. **Sild Conferencing & Training** reserves the right to refuse entry into the event should full payment not have been received prior to this date. Cancellation will be charged under the term set out below. **2. Cancellations, No shows & Substitutions:** Cancellations received in writing more than 21 days prior to the event being held carry a 50% cancellation fee. Should cancellations be received between 21 days and the date of the event, the full event fee is payable and non – refundable. Non- payment or non-attendance does not constitute cancellation. No show will be charged the full registration fee. Cash alternatives will not be offered, however, substitutes at no extra charge are welcome. **3. Alterations to advertised package: Sild Conferencing & Training** reserves the right to alter this programme without notice or penalty and in such situations no refunds or part – refunds or alternative offer will be made. Should **Sild Conferencing & Training** permanently cancel an event, for any reason whatsoever, the Client shall be provided a credit of the equivalent amount paid towards the cancelled event. In the case of a postponed or cancelled event, **Sild Conferencing & Training** will not be responsible for covering airfare, accommodation, or other travel cost incurred by Clients. **4. Copyright:** All intellectual property rights in the materials distributed by **Sild Conferencing & Training** in connection with this event are expressly reserved and any unauthorized duplication, publication or distribution is prohibited.

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