Product safety makes headlines every day and the impact on a company’s image, consumer confidence, and Wall Street’s opinion are profound. While good safety data has historically been a prerequisite for product approval, recent media attention has intensified public and congressional scrutiny and resulted in regulations such as the CFDA Act and its strengthened requirements for monitoring post-marketing safety. Not knowing which approaches, systems and processes you must have in place for your own safety monitoring and reporting could mean you miss an important issue with significant consequences for your product. You must be sure it is your responsibilities to prevent the safety risk from consumers, to avoid product recall, are able to work to international standards and have implemented regulatory requirements for signaling and risk management. This training course will review approaches to the implementation of signal detection and data mining as part of your clinical data and safety monitoring operations as well as pharmacovigilance practice. The requirement for companies to perform pharmacovigilance globally is mandatory in Europe and highly recommended in the US. Many simple techniques can be applied to the generation and review of potential signals, which can also be augmented by the application of sophisticated data mining algorithms. Topics discussed will include general pharmacovigilance practice, signal assessment, use of signal triage algorithms in compliance with FDA guidance as specified in “Guidance for Industry Oversight of Clinical Investigations – A Risk-based Approach to Monitoring” and “Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment”, and the timing and frequency of signal detection, triage, and data mining runs.

SESSION TOPICS
- Signal Assessment Process
- Pharmacovigilance Overview
- FDA & EU Regulatory Requirements
- Data Mining Methodologies
- Signaling and Risk Assessment
- Series of Interactive Case Studies

LEARNING OBJECTIVES
At the end of the training course, participants will be able to:
- Understand regulatory requirements for drug safety and pharmacovigilance practice
- Learn how to collect, assess, report and analyze adverse event
- Understand the basic concepts and principles of signal detection for accumulating clinical data
- Describe how to apply these techniques within the company
- Apply data mining techniques to analyze large volumes of adverse event report data
- Conduct signaling analyses on real-life data

WHO SHOULD ATTEND
Professionals with background in the following areas:
- Clinical Research & Development
- Clinical Data Management
- Clinical Safety/Pharmacovigilance
- Risk Management
- Epidemiology
- Clinical Management and Operation
- Clinical IT Professionals and Supporters
- Clinical Informatics
- Technique Supports Related to Computer Systems in Clinical Studies

PROGRAM CHAIR
Xue TANG, PhD
Country Safety Lead for China, Global Pharmacovigilance Office, WSRO, Pfizer, China

PROGRAM COMMITTEE
Xiaojun GUO, PhD
Head of Clinical Safety and Pharmacovigilance, R&D China GlaxoSmithKline, China
Vera LIANG, MD
Director and Global Safety Risk Lead, Safety Surveillance and Risk Management, Pfizer (China) R&D Co. Ltd., China
Daniel LIU, PhD
Director, China Development Medidata Solutions Worldwide, China
Xiaoyao(Conny) MO
Director, head of Pharmacovigilance and Product Information (PPI), China R&D and Scientific Affairs, Janssen, Johnson&Johnson, China

SPEAKER
Steve JOLLEY
Principal
SJ Pharma Consulting, USA

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DAY ONE | TUESDAY, OCTOBER 22

07:30 – 08:30  REGISTRATION

08:30 – 08:35  INTRODUCTION

08:35 – 09:30  PART I - PHARMACOVIGILANCE OVERVIEW

PHARMACOVIGILANCE OVERVIEW
• History
• Regulatory requirement
  - FDA
  - EU
  - PV System Master File (PSMF)
• Definition
• Similarity and difference between pre- and post-marketing AEs
• Process and assessment
• ICH topic codes and reports
• CIOMS
• PV checklist
• Pharmacovigilance risk profile

09:30 – 10:30  PART II - GLOBAL REGulatory REQUIREMENT
• Definition of AE/ADR/SAE/SUSAR
• What expedite reporting and non-reporting
• Expectedness
  - Assessing expectedness/Labeledness/Listedness
  - Labeled vs. Listed
• Aggregate reports – common types
• Managing blinded therapy cases
• Special cases
• ADR reporting
  - During the transition period
  - Final arrangements
• Periodic safety update reports
  - Periodic benefit-risk evaluation report
  - PSUR periodicity, ex-EU
  - PSUR periodicity, EU
  - PSUR (PBRER) new features
  - PSUR sections: detailed requirements

10:30 – 10:45  COFFEE BREAK

10:45 - 12:00  PART III - BACKGROUND OF SIGNAL DETECTION
• Safety signal generation and/or detection
  - Regulatory requirements
  - Definition
  - Approach to signal detection
  - Premise for signal detection
  - Signaling overview
• Regulatory requirements
  - FDA
  - European signaling regulations
  - Characteristics of small versus large companies
  - Importance of astute clinical perspective
  - Danger of over-reliance on technology
  - Signal detection hierarchy
    - Layered approach to signaling
    - Incidence, numerator, and denominator
  - Statistical versus medical significance
  - Signaling analyses specified by good pharmacovigilance practices
  - Detailed characteristics
  - Elements of case series analysis
  - Recommended approach
  - Components of suggested analyses
  - How to characterize a suspected signal
    - Signal management
    - Additional monitoring
    - Risk management

12:00 – 13:30  LUNCH

13:30 – 15:00  PART III - BACKGROUND OF SIGNAL DETECTION (CONT.)

15:00 –15:15  COFFEE BREAK

15:15 – 17:00  PART IV - SIGNALING EXAMPLES
• Signaling overview
• Regulatory requirements
• Signal detection flow
• Recommended data elements to be obtained prior to analysis
• Typical PSUR data elements
• Analysis of signal and risk
  - Source data from PSUR
  - Sector maps
  - By MedDRA system organ class and preferred term
  - By age range
  - By sex
  - By country
  - By time to onset
  - By treatment duration
  - By AE duration
  - By concomitant medications
  - By dechallenge/rechallenge
• Describe signal and relate to prior signaling exercises
• Define correlations found via prior signaling exercises
• Analysis of clinical trial data:
  - Safety parameters
  - Efficacy parameters
  - Quality and integrity of clinical trial data
  - Patient compliance monitoring
### DAY TWO | WEDNESDAY, OCTOBER 23

#### 08:30 – 09:30 PART IV – SIGNALING EXAMPLES (CONT.)
- 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
  - Bayesian Confidence Propagation Neural Network (BCPNN)
  - Multi-- item Gamma Poisson Shrinker (MGPS)
  - Proportional Reporting Ratio (PRR)
  - Which data mining algorithm?
  - Comparison of methods
  - Relative timing

#### 09:30 - 10:15 PART V - DATA MINING
- 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
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  - Which data mining algorithm?
  - Comparison of methods
  - Relative timing

#### 10:15 – 10:30 COFFEE BREAK

#### 10:30 - 12:00 PART V - DATA MINING (CONT.)

#### 12:00 – 13:30 LUNCH

#### 13:30 – 15:00 PART VI – RISK MANAGEMENT
- Pharmacovigilance process
- Signal detection operational questions
- Signal detection sources
- Signaling process
- Signal evaluation steps
- Signal repository and safety profiles
- Product safety profile
- Sample PSP information
- Sample PSP index
- Introduction to risk management planning
  - RMP Vs REMS
  - EU-RMP Format
  - RU-RMP-Risk Minimization
  - REMS Elements
- Final conclusion

#### 15:00 – 15:15 COFFEE BREAK

#### 15:15 - 16:15 PART VI – RISK MANAGEMENT (CONT.)

#### 16:15 END OF DAY TWO
ABOUT THE SPEAKER

Steve Jolley
Principal
SJ Pharma Consulting, USA

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.

Steve has 27 years’ experience in drug safety & pharmacovigilance and has worked with over 100 clients in North America, Europe, Japan, India and China. He holds degrees in mathematics and computer science from Cambridge University, England. Steve is a featured speaker with FDA and MHRA at conferences and webinars on auditing, signaling and data mining. He is a member of DIA’s training faculty and is an instructor for DIA’s Clinical Safety and Pharmacovigilance Certificate Program. In 2010 Steve was elected as chairman of the DIA’s Clinical Safety and Pharmacovigilance steering committee for North America.

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.

PROGRAM CHAIR

Xue TANG, PhD
Country Safety Lead for China, Global Pharmacovigilance Office, WSRO, Pfizer, China

As Cluster Safety Lead, Xue Tang currently leads the China/Hong Kong/Taiwan Drug Safety Unit (DSU) and is responsible for the oversight of all cluster activities relevant to the pharmacovigilance system to ensure monitoring of the safety profile of Pfizer’s products and to meet regulatory requirements.

Xue currently represents Pfizer at China RDPAC (R&D based Pharmaceutical Association Committee) in the Pharmacovigilance work stream as a Core Member.

Xue has over 15 years experiences in Pfizer China covering Clinical Trial and Pharmacovigilance as well as Quality Assurance areas, with in-depth knowledge of Chinese GCP, Chinese laws/regulations and international guidelines that is relevant to these fields.

Before joining Pfizer, Xue obtained her Master Degree on endocrinology with 7 years clinical practice in the 2nd Affiliated Hospital of Dalian Medical University.

PROGRAM COMMITTEE

Xiaojun GUO, PhD
Director, Head of Pharmacovigilance and Product Information (PPI), China R&D and Scientific Affairs, Janssen, Johnson&Johnson, China

Xiaojun GUO holds Doctor Degree of Internal Medicine. She now is working in R&D China, GlaxoSmithKline as Head of Clinical Safety and Pharmacovigilance. Before joining GSK, she had worked in AstraZeneca China for more than 6 years, 6 years in Patient Safety as function head and half year in Medical Affairs as Research Alliance Leader. She also had working experience in clinical research as CRA and later as Project Manager in CROs, and as Physicians in the Second Hospital of Harbin Medical University before joining Pharmaceutical Industry.
Vera LIANG, MD
Director, Safety Surveillance and Risk Management Department (SSRM), Pfizer China R&D Center
Global Safety Risk Lead – Lipitor and Caduet, Worldwide Safety and Regulatory (WSR), Pfizer

Vera is a pharmaceutical physician with 17 years experience in the pharmaceutical industry in different roles (clinical development, medical affairs, and safety). She joined industry after receiving her Medical Degree from the Medical School of Fudan University in China. Vera currently works for Pfizer, heading up the department of Surveillance and Risk Management Department (SSRM) at Pfizer China R&D Center. She’s also a global Safety Risk Lead, responsible for overseeing and performing proactive pharmacovigilance and risk management activities to effect product safety signal detection and evaluation, and risk assessment and minimization for Lipitor and Caduet. Vera is a reputable drug safety expert as well as a talented leader who have developed a highly functioned global safety organization in China from scratch since she joined Pfizer in 2006. Also, she has been active in partnering with China FDA, academia, and varied organizations in past 7 years to grow the PV expertise in China. Prior to joining Pfizer, she was the Head of Medical Affairs in GlaxoSmithKline China and earlier on the Medical Affairs professional in Merck China, with increased responsibilities in medical affairs and drug safety in the areas of infectious diseases, diabetes, mental health, and hepatic diseases. During her GSK and Merck tenure, she played a pivotal role in a number of clinical trials leading to a successful product registration in China, and in maximizing the performance of various products.

C. Daniel LIU, PhD
Director, China Development
Medidata Solutions Worldwide, China

C. Daniel LIU received his B.Sc. in pharmacy and M. Sc in pharmaceutical chemistry from China Pharmaceutical University, Nanjing, P. R. China and his PhD degree in pharmacology from University of Illinois, USA. Prior to joining pharmaceutical industry, he had more than 10 years of researching experiences in academic environment for drug research and development. He had hands-on experiences in the designing, management and execution of global clinical trials, pharmacovigilance and assembly of regulatory files for the FDA NDA/IND submissions at Novartis, Pfizer, Sanofi-Synthelabo, Schering-Plough and Johnson&Johnson, respectively. Currently, he works as Director of China Development at Medidata Solutions Worldwide. He was the member of the Advisory Council of China DIA and co-Chair of Training Committee of ACC DIA China, the member of global training committee of DIA. He has more than 20 researching papers published in professional journals related to pharmaceutical area. Moreover, he is the one of co-authors for several global GCP guidance books “Good Clinical Practice: A question and answer reference guide” in 2008 – 2012, and “New Drug Approval Process (5th edition), 2009” and so on. He participated to develop the new global GCP guidance “Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts” published in 2011. His monographic works “Clinical Trial Methodology of Medicinal Products” was published 2011.

Xiaoyao (Conny) Mo
Director, Head of Pharmacovigilance and Product Information (PPI), China R&D and Scientific Affairs, Janssen, Johnson&Johnson, China

Director, Head of Pharmacovigilance and Product Information (PPI), China R&D and Scientific Affairs, Janssen, J&J. Xiaoyao MO has 14 years of experience in international pharmaceutical companies including AZ, Merck, Pfizer China R&D. Prior to join pharmaceutical companies, Xiaoyao Conny had been working as a respiratory physician in Beijing Xuan Wu hospital since 1994. Her professional industry experience and achievements focus on the field of clinical research operation, medical information and clinical safety as well as pharmacovigilance in both medical and R&D. Xiaoyao Conny has been the elected head of RDPAC Pharmacovigilance working group since 2005.
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Drug Safety Signal Detection and Data Mining
Event I.D. # 13985 – October 22-24, 2013
Beijing, CHINA


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