This training course will review approaches to the implementation of signal detection and data mining as part of your pharmacovigilance operations. The requirement for companies to perform signal detection 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.

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
- Clinical Safety/Pharmacovigilance
- Public Policy/Law/Compliance
- Regulatory Affairs
- Research & Development
- Risk Management

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DAY ONE | TUESDAY, OCTOBER 22

07:30 – 08:15  REGISTRATION

08:30 – 08:35  INTRODUCTION

08:35 – 09:15  PART 1 - 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

09:15 – 10:00  PHARMACOVIGILANCE REPORTING REQUIREMENTS
- 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

10:00 – 10:15  COFFEE BREAK

10:15 – 12:00  PART II - BACKGROUND OF SAFETY 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
- Company characterization
  - 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

12:00 – 13:30  LUNCH

13:30 – 15:00  PART III - SIGNALING AND RISK ASSESSMENT
- 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:
  - By safety parameters
  - Efficacy parameters
  - Quality and integrity of clinical trial data
  - Patient compliance monitoring

15:00 – 15:15  COFFEE BREAK

15:15 – 17:00  PART IV - 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
- 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

17:00  END OF DAY ONE
DAY TWO | WEDNESDAY, OCTOBER 23

08:30 – 10:00  PART V – SIGNAL DETECTION PROCESS
- Pharmacovigilance process
- Signal detection operational questions
- Signal detection sources
- Signaling process
- Signal evaluation steps
- Signal repository and safety profiles
- Product safety profile
- Introduction to risk management planning
- Factors to consider in signaling optimization
- Signal detection triage example
- Triage algorithms used
- Comprehensive signaling process elements
- Final conclusion

10:00 – 10:15  COFFEE BREAK

10:15 - 12:00  PART V – SIGNAL DETECTION PROCESS (CONT.)

12:00 – 13:30  LUNCH

13:30 – 17:00  PART VI - SERIES OF INTERACTIVE CASE STUDIES
- Signaling and data mining analyses based on company and FDA data
- Analysis of both safety and efficacy parameters to assess the quality and integrity of clinical trial data

17:00  END OF DAY TWO

DAY THREE | THURSDAY, OCTOBER 24

08:30 – 10:00  CASE STUDY

10:00 – 10:15  COFFEE BREAK

10:15 - 12:00  CASE STUDY (CONT.)

12:00  END OF THE TRAINING
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.