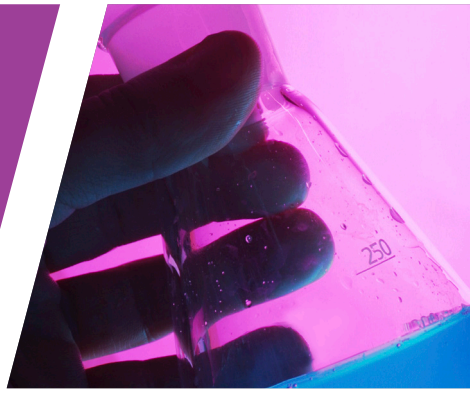
Global AE Reporting: Drug Safety Requirements in the US and EU

November 12 | Bethesda, MD



PROGRAM COMMITTEE:

Jean-Pierre Clement, MD
Vice President
Drug Safety and Pharmacovigilance
Onyx Pharmaceuticals, Inc

Andre Daniels, MD,MS
Executive Director
Global Regulatory Affairs and Safety
Amgen, Inc

Steve Jolley, MA
Chief Executive Officer
SJ Pharma Consulting

Sylvie Tomczyk, MD, PhD
Senior Medical Director
EMD Serono

OVERVIEW:

This one day conference will cover intermediate-level content around the topics of collection, assessment, reporting and analysis of adverse events to meet global requirements.

FEATURE TOPICS:

- Overview of Premarketing Safety Reporting Obligations in the US and EU
- Postmarketing Safety Requirements in the US and EU
- The Pharmacovigilance Audit
- Avoiding Mistakes in Pharmacovigilance Inspections
- Signal Detection/Data Mining/Risk Assessment/Risk Management

LEARNING OBJECTIVES:

At the conclusion of this conference, participants should be able to:

- Describe how to collect, assess, report and analyze adverse events
- Discuss US and EU regulatory requirements for drug safety and describe this impact on safety reporting
- Explain signaling analyses based on FDA and EMA requirements
- Discuss the objectives and components of a pharmacovigilance audit
- Describe the top ten findings from regulatory inspections for product safety

Register at
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DIA WORLDWIDE HEADQUARTERS
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

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Type of Activity: Knowledge

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PHARMACY CREDIT ALLOCATION
- Session 2: Post Marketing Safety Requirements: US and EU: 1.5 contact hours or .15 CEUs; 0286-0000-13-095-L04-P
- Session 4: Signal Detection/Data Mining/Risk Assessment/Risk Management/Risk Minimization: 1.5 contact hours or .15 CEUs; 0286-0000-13-096-L04-P

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- Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units
- Regulatory Affairs Certificate Program: 4 Elective Units

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MONDAY, NOVEMBER 11

6:00-8:00 PM REGISTRATION

TUESDAY, NOVEMBER 12

7:15-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM WELCOME AND OPENING REMARKS

Sylvie Tomczyk, MD
Senior Medical Director
EMD Serono

8:30-10:00 AM SESSION 1

Premarketing Reporting Obligations in EU and US

SESSION CHAIR:

Sylvie Tomczyk, MD
Senior Medical Director
EMD Serono

This session will describe the safety reporting requirements for drugs prior to market approval in the US and the EU region. This session will discuss the key obligations and differences between US and EU regions on individual and aggregate reporting to Health Authorities, IRB or investigators, clinical trial registration, signal detection and special reporting situations for development drugs.

SPEAKERS:

Overview of Premarketing Safety Reporting Obligations in the US

Michael Keatley
Director, Local Safety Officer
Janssen Scientific Affairs, LLC

Overview of Premarketing Safety Reporting Obligations in Europe

Vicki Edwards, BPharm
QPPV and Head of Affiliate Vigilance Excellence
Abbvie, Ltd

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 2

Postmarketing Safety Requirements: US and EU

SESSION CHAIR

Sylvie Tomczyk, MD
Senior Medical Director
EMD Serono

This session will describe the reporting requirements for marketed drugs in the US and the EU region, for individual and aggregate safety reports. Topics discussed during this session will provide a better understanding of the key obligations and differences between these two regions, as well as, the common goal towards updated and accurate safety information.

SPEAKERS:

Postmarketing Safety Requirements in the USA

Heidi Marchand, PharmD
Assistant Commissioner
Office of Health and Constituent Affairs
FDA

Postmarketing EU Safety Requiems for Individual Case Safety Reports

Sylvie Tomczyk, MD
Senior Medical Director
EMD Serono

Signal Management and Aggregate Safety Information Reporting with CoBRA(R), Best Practices According to EU/GVP Regulations

Susanne Ramm, Dr.Med
Medical Director
Dr. Ebeling & Assoc. GmbH, Germany

12:00-1:30 PM LUNCHEON

1:30-3:00 PM SESSION 3

The Pharmacovigilance Audit

SESSION CHAIR:

Steve Jolley, MA
Chief Executive Officer
SJ Pharma Consulting LLC

This session will give you a jump-start on how to prevent common problems that are found during regulatory inspections for drug safety and pharmacovigilance. It will include examples based on findings by the FDA and MHRA's pharmacovigilance inspectors. You will be able to use this information immediately to make the changes you need to address these common failings and avoid the findings.

SPEAKER:

Avoiding the Top Ten Mistakes Companies Make in a Pharmacovigilance Inspection

Steve Jolley, MA
Chief Executive Officer
SJ Pharma Consulting LLC

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM SESSION 4

Signal Detection/Data Mining/Risk Assessment/ Risk Management/Risk Minimization

SESSION CHAIR:

Andre Daniels, MD,MS
Executive Director
Global Regulatory Affairs and Safety
Amgen, Inc

This session will describe methods for the detection and prioritization of signals from multiple data sources and the use of data mining in association with case by case evaluation for signal confirmation. Evidence available for risk assessment associated with the prescribing of medications will be discussed. Methods and challenges in evaluating risk management and risk minimization programs including REMS will be considered.

SPEAKERS:

Detection, Evaluation, Mitigation and Reporting of Safety Issues through the Product Life Cycle

Joanna Faith Haas, MD, MSc, FISPE, FACPM
Founding Partner
Haas and Partners LLC

The Growing Use of Observational Studies in Risk Management Strategy

J. Michael Sprafka
Executive Director
Center for Observational Research
Amgen, Inc

Methods and Challenges in Evaluating Risk Management and Risk Minimization Programs

Paul J. Seligman, MD, MPH
Global Regulatory Policy Lead
Global Regulatory Affairs and Safety
Amgen, Inc

5:00-5:15 PM CLOSING REMARKS

Andre Daniels, MD, MS
Executive Director
Global Regulatory Affairs and Safety
Amgen, Inc

5:15 PM CONFERENCE ADJOURNED