

Monitoring and Reporting Adverse Drug Reactions

✓ Interactive Exercises

✓ Expert Trainers

✓ Practical Education

Improve your ability to:

- Ensure compliance when reporting drug safety data to FDA
- Implement methods for capturing and processing suspected adverse events
- Effectively manage your MedDRA program
- Comply with current requirements for safety surveillance and reporting
- Analyze the needs and focus of ADR monitoring and reporting programs
- Use web-based pharmacovigilance
- Formulate a systematic approach for reporting ADRs to allow appropriate analysis and intervention
- Implement a pharmaceutical risk monitoring system

Research Triangle Park, NC
July 12-13, 2004

St Louis, MO
July 26-27, 2004

Baltimore, MD
August 11-12, 2004

San Francisco, CA
September 29-30, 2004



PTi international is
accredited by the
Accreditation Council
for Pharmacy Education as a
provider of continuing
pharmaceutical education.

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Course Description

A competent adverse drug reaction monitoring system is essential to ensure compliance when reporting drug safety data to FDA. Providing a step-by-step foundation for understanding the regulatory guidelines governing adverse events, the course begins by reviewing the fundamentals of adverse drug reactions. Participants will learn to formulate a systematic approach for reporting ADRs, which allows for analysis to help identify common trends. The course provides

additional focus on implementing electronic submissions of adverse events. Techniques will be discussed for managing your MedDRA program and for validating your safety data system. Finally, crisis management strategies will be addressed. In addition to lecture, this course provides interactive exercises, case studies and group projects to strengthen your practices for managing effective and efficient adverse reporting systems and reports.

Impact Your Organization's Bottom Line

- Comply with FDA reporting requirements
- Avoid or manage crises
- Avoid a liability lawsuit
- Protect patient safety

Your PTi Instructor

Dr. Stanley Garbus has more than two decades of Pharmaceutical industry experience across all phases of clinical research and pharmacovigilance, including development and implementation of AE safety systems. He is Co-founder and Chief Medical Officer of Sentrax, a company that supports the Pharmaceutical industry in monitoring clinical and post-marketing adverse events, improving drug safety and assisting with risk

management. Previously, Dr. Garbus held senior clinical research management positions in several international pharmaceutical companies and CROs. He received his medical degree from the University of Geneva, Switzerland, completed specialty training in Internal Medicine and Nephrology and received an MPH in Epidemiology from the Yale University School of Medicine.

Who Should Attend

This course is designed for those responsible for the development, communication and facilitation of a product's safety profile within the Pharmaceutical, Biotechnology and Medical Device industries. Personnel who have some experience with adverse event reporting should attend this course; specifically, the following professionals would most benefit from the course:

- Drug Safety Associates/Specialists
- Safety Surveillance Professionals
- Clinical/Medical Affairs Directors
- Clinical Research Associates/Managers
- Clinical Safety Specialists
- Project Managers
- Complaint Management Professionals
- QC and Clinical Scientists
- Regulatory Affairs Professionals
- Adverse Event Information Specialists
- Pharmacovigilance Professionals

Interactive Elements

Adults and professionals learn better when the classroom is a vibrant, stimulating place. That's why we incorporate discussions, exercises and quizzes into all of our courses. These activities reinforce training and foster a practical, hands-on educational experience.

In this course, for example, we:

- Critique sample ADR reports and distinguish the differences between significant and insignificant reports
- Share best practices for MedDRA usage
- Organize patient safety information to explore potential causes of adverse drug reactions

Participant Testimonials

"Very thorough, interesting, helpful class. I found the material insightful and extremely useful."

- COLLEEN SELIGER, DSMI, BIOGEN

"Good course and content."

- LINNEA OLSSON, SENIOR CLINICAL RESEARCH ASSOCIATE, NPS PHARMACEUTICALS

Agenda: Day I

I. Outline the Fundamentals of Adverse Drug Reactions

- Define an Adverse Drug Reaction (ADR)
- Examine the history of ADRs and the progress of preventative measures
- Determine the differences between drug reactions, adverse events and serious adverse events
- Analyze the needs and focus of ADR monitoring and reporting programs

Discussion: *Compare and Review Participants' Experiences with ADR Programs*

II. Examine the Current Regulatory Guidelines Governing Adverse Event Reporting

- Clarify the regulatory framework for drug safety
- Determine how to ensure compliance when reporting drug safety data to the FDA
- Determine requirements for NDA reporting
- Define scope of new changes in regulations, guidances and procedures at FDA
- Explore CDER's perspective on adverse event reporting

III. Implement Current Requirements for Safety Surveillance and Reporting

- Examine the historical background of pharmacovigilance
- Determine the impact of ICH standards on drug safety reporting
- Comply with the expectations for capturing and reporting safety information
- Explore FDA's new proposed rule to improve safety reporting for human drugs and biologics (The TOME)
- Identify methods for capturing, processing and reporting suspected adverse events to FDA

IV. Explore the Best Ways to Implement and Manage the MedDRA Program

- Critique MedDRA and how it impacts drug safety
- Examine current FDA expectations for MedDRA usage in mandatory safety reporting
- Analyze the role of MSSO
- Explore FDA's recommendations for implementing MedDRA
- Examine best ways to output MedDRA data for meaningful results

Exercise: *Share Best Practices for MedDRA Usage*

V. Identify and Respond to Drug Reactions

- Determine the differences between intended and un-intended drug reactions
- Define what constitutes a reportable ADR
- Decide what criteria determines a preventable ADR
- Identify the severity of an ADR

VI. Implement a Pharmaceutical Risk Monitoring System

- Determine high-risk patients
- Analyze high-risk drugs
- Monitor targeted drugs
- Formulate a reaction plan

Exercise: *Organize Patient Information to Explore Potential Causes of ADRs*

VII. Identify and Ensure Proper Data Collection

- Determine critical data elements
- Analyze methods of gathering all crucial information
- Maintain a comprehensive audit trail
- Highlight unclear factors and triggering data
- Determine best ways to capture and exchange safety data

VIII. Ensure Effective Reporting Systems

- Determine what to document and how to best report findings to the Drug Information Service
- Address HIPAA reporting issues
- Gather patient specific information using an ADR Report and the Preventability and Causality Data Collection Form

Exercise: Critique Sample ADR Reports and Distinguish the Differences Between Significant and Insignificant Reports

IX. Validate Your Safety Data Systems

- Determine the key elements of a validation plan as it relates to safety
- Clarify the scope of what is to be validated
- Ensure the proper resources and personnel for validating a safety data system
- Incorporate documenting change control

X. Implement Electronic Submissions of Adverse Events

- Outline FDA's expectations for electronic submissions
- Explore the ICH's current set of guidelines that determine common data elements
- Implement E2B files according to guidelines
- Determine the benefits of electronic case safety reports
- Identify how best to use web-based pharmacovigilance

XI. Formulate a Systematic Approach for Reporting ADRs to Allow Appropriate Analysis and Intervention

- Maintain a patient specific database of ADR information
- Analyze ADR statistics to identify common trends
- Use the FDA's MedWatch program

XII. Implement Proven Techniques for Crisis Management

- Identify potential conflicts and reactions
- Determine how to build a more effective detection program
- Implement training and literature to promote awareness and consequences
- Initiate changes in drug use policies, procedures and SOPs

Exercise: Assess the Crisis and Identify Course of Action

About PTi international

SPEEDING PRODUCT DEVELOPMENT THROUGH PERFORMANCE SOLUTIONS

PTi international provides performance improvement solutions for FDA-regulated businesses. Every year, we train thousands of Pharmaceutical, Biotechnology and Medical Device professionals on a variety of subjects related to R&D and manufacturing. Through regular contact with our client base, we identify the essential skills required in today's environment. Next we design and deliver highly informative, interactive educational experiences, enabling you to **speed new products to market** and **avoid regulatory enforcement actions**. Focus is one of our greatest strengths. All we do is training, and we do it right.

"Good Training Practices"

- Exercises and quizzes to facilitate interaction and reinforce learning
- Courses well-organized into discrete modules with clearly defined objectives
- Classes limited to 25 participants*

Our **Public Classes** are offered at multiple dates and locations throughout the U.S., Canada and Puerto Rico.

PTi also delivers **On-Site Training** tailored to your organization's specific requirements. We can bring one of our Public Classes to your facility, or we can customize a solution just for you. Either way, our On-Site Training provides you the following advantages:

- **Convenience.** Get training when you need it, where you need it.
- **Confidentiality.** Discuss confidential company information comfortably.
- **Metrics.** Measure the impact of performance improvement interventions.
- **Strategy.** Align initiatives with your corporate and/or departmental strategy.

Simply contact the Client Solutions Manager at (800) 303 8194 or OnSiteSolutions@pti-international.com to discuss a solution that fits your organization's needs, objectives, schedule and budget.

* Class size flexible for On-Site Training

Professionals Who Benefited from this Course Also Profited from:

- Writing Reports for Failure Investigations and Process Deviations
- Preparing for an FDA Systems-Based Inspection
- Corrective and Preventive Action (CAPA)
- Change Control
- Conducting Batch Record Reviews and Investigations

Registration and General Information

Monitoring and Reporting Adverse Drug Reactions



PTi international is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmaceutical education. Participants will receive a maximum of 14 hours (1.4 CEUs) of continuing education credit for full participation in the two-day training. ACPE # 326-000-03-017-L04. Initial release: 04/2003.

Register Now and Save \$200: Registrations postmarked and paid one month prior to each course will receive a \$200 discount. Your early registration amount will be \$1695. Registrations postmarked within one month of each course date will be \$1895. All participants will receive a Participant Workbook, a permanent on-the-job reference of content and materials covered in the course.

Payments are due one week prior to the training course. You may pay by check, Visa, MasterCard, Diners Club or American Express. Please make checks payable to "PTi international" and write the name of the participant(s) and the training program code on the face of the check. If payment has not been received prior to registration, a credit card hold will be required and will be processed two weeks following the training course. Please indicate at the time of registration if you are eligible for a discount. No two discounts can be combined.

LOCATION/DATE:	PROGRAM CODE:
Research Triangle Park, NC July 12-13, 2004	AV614
St Louis, MO July 26-27, 2004	AV615
Baltimore, MD August 11-12, 2004	AV616
San Francisco, CA September 29-30, 2004	AV617

Confirmation Letters: Registration confirmation with venue information and a list of conveniently located hotels will be sent to all participants.

Certificates: Provided on-site for participants who register at least 10 business days in advance. All others who send a written request to Customer Service will receive their certificates by mail within 30 days following the course.

Substitutions/Cancellations: Substitutions of enrolled participants may be made at any time, by notifying Customer Service in writing. For cancellation notices received prior to 10 business days before the course date, you will receive a credit voucher for use toward a future training course, valid for one year from the date of issue. Cancellations made within 10 business days of the training course will not be issued a credit voucher. Please note that PTi does not refund your registration fee. All information is confirmed as of press time. Program content and instructor are subject to change without notice. Should PTi cancel this training course for any reason, we are not responsible for covering airfare, hotel or other costs incurred by registrants.



If you have any special requirements, please contact Customer Service at least 3 weeks prior to the training course.