



Adverse Event Workshop

MEASURING PATIENT SAFETY

About the instructor:

Joy Frestedt, PhD, RAC, CCTI is President and CEO of Frestedt, Inc., a virtual CRO providing clinical, regulatory and quality services to drug, device and food companies. She has more than 30 years experience designing and conducting clinical trials for institutions like the UofMN and Mayo Clinical Trials Services and for companies like Medtronic, Johnson and Johnson, Astra Zeneca and the Minnesota Applied Research Center. Dr. Frestedt is a frequent speaker at research conferences and she actively mentors, coaches and trains individuals and teams in the industry. She currently serves as the chair of the Ethics Committee for the Regulatory Affairs Professionals Society (RAPS) and has just completed service on the Editorial Advisory board for the Association of Clinical Research Professionals (ACRP) where she still serves as a mentor for aspiring authors.

Who Should Attend:

- Directors & Managers of Regulatory, Safety, QA & Post Market Surveillance
- Biostatisticians
- CRA/Cs & Site Managers

Certificates of attendance offered at all seminars and programs may be used towards Contact hours and CEUs.

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This workshop is designed for those who understand the FDA definition for an adverse event:

*"An adverse event is any undesirable experience associated with the use of a medical product in a patient."*¹

and who sift through countless adverse events to identify safety signals. The instructor will offer an overview of several current tools for grouping adverse events with consistent dictionary definitions (MEDRA, COSTART, WHO Drug Dictionary) and for grading toxicity with common toxicity grading scales (CTCAE v 4.0, WHO Toxicity Grading Scale). The goal of the workshop will be to share best practices and to approach an increased awareness of safety vigilance through appropriate review and trending of adverse events. Simply collecting adverse event information is not enough; sponsors need to understand the global trends in their safety signals.

¹<http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm>

What Will Be Covered:

- Do we have the correct definition for groups of adverse events?
- Do we have the correct toxicity grade for groups of adverse events?
- What do we do with conflicting information within our grouped adverse events?
- What process do we use to identify safety signals and to act on the information?

Tuesday, October 19, 2010 1:00 p.m. – 5:00 p.m.

Fee: MA members only \$199 per person. Non-MA members \$299 per person
(Fee includes materials and refreshments)
Receive a 10% discount if you register 10 days prior to the event

Location: Omni-Tract Surgical
4849 White Bear Parkway
St. Paul, MN 55110
(For directions and map go to www.mfrall.com)

Reservations: For instant confirmation reserve on-line at www.mfrall.com, click on **Training & Education** then **All Events/ Medical Device** by October 15, 2010.
Your satisfaction is guaranteed.

Cancellation Policy: **No refunds** for cancellations after 5:00 p.m. Friday October 15, 2010, or for no-shows at workshop. (Substitutions accepted)

Pre-registration required!