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CTI Clinical Trial and Consulting Services

**CTI Clinical Trial and Consulting Services named "Best Places to Work" in Greater Cincinnati for Second Consecutive Year**

# Utilization of Failure Model and Effect Analysis for REMS Programs

Risk Evaluation and Mitigation Strategies (REMS) is a program of evaluation initiated by the FDA (FDAAA, 2007) to "tip the risk-benefit balance" by maximizing the possible benefits of a drug or biological product while mitigating known or potential serious risk(s). REMS are plans used to ensure that the benefits of a prescription drug outweigh the drug's risk of harm to the patient. Once on the market, risk/benefit evaluation has to be continued in order to determine whether the risk far outweighs the benefit. But these plans are often evaluated and modified after the fact; that is, once an error has taken place, which could have serious consequences e.g., the unintended use of a **teratogenic** drug.

Failure Mode and Effect Analysis (FMEA) is a systematic process that identifies areas where potential failures are likely to occur, quantifies their potential effects and provides ways in which the failures may be mitigated before an error actually takes place. Most error-reduction efforts begin in response to a serious problem, and REMS is no exception. Individuals and practice sites are accustomed to reacting to an error once it has occurred. Unfortunately, it is only then that they consider how to prevent the same error from being repeated.

CTI believes it would be more beneficial to be able to predict the types of errors that could occur and ***proactively*** institute preventive measures. FMEA should be done early in the drug development process with all representative stakeholders involved. This technique can be used to develop REMS in a more systematic and comprehensive manner for new products as well as review and improve existing plans to achieve greater levels of program effectiveness. Although FMEA is a well-established technique used in risk management outside the pharmaceutical industry, it has not been adapted to date in the development of REMS for pharmaceuticals.

To learn more about FMEA, please contact:

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## Upcoming Medical Meetings CTI will be Attending …

CTI will have a significant presence at upcoming medical meetings over the next few months.

**The Transplantation Society Meeting**
Vancouver Canada
August 13th

**StemCells USA, Regenerative Medicine Congress**
Philadelphia
September 13th-15th

**BioPharm America 2010**
Boston
September 15th-17th

**European Society of Transplantation Meeting**
Nice, France
October 1st-3rd

If you are interested in scheduling a meeting with CTI at one of these events, please contact Nick Schatzman at 513-598-9290 or via email at nschatzman@ctifacts.com