S42-4 Risk Management Plan in the US and Europe

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Even before adoption of the ICH E2E Guideline on Pharmacovigilance Planning there was significant movement toward developing and requiring Risk Management Plans (RMP), and in some cases Risk Minimization Action Plans (RiskMAP) in the US or Europe in order to better define and control the risks of pharmaceutical products on the market. Since adoption of E2E it is now a regulatory requirement to submit an RMP with each marketing application for a new chemical entity in Europe and additional details have been added to the requirements outlined in the ICH guidance. The FDA has also adopted the ICH E2E guidance but does not necessarily require submission of an ICH-style RMP with new drug applications because there were already three additional guidance documents on risk evaluation, management and minimization. With the adoption of the FDAAA in 2007, Risk Evaluation and Mitigation Strategy (REMS) plans have replaced the concept of the RiskMAP and may be required by the FDA for marketed drugs. This presentation will describe the current status of risk management planning internationally and look specifically at the different expectations for the content of the RMP, how they are to be periodically evaluated or updated, what tools are available to assess the effectiveness of interventions to minimize risk and the range of practical problems created when trying to minimize risks to patients while maintaining access to important medications. Examples will be given of the scientific tools that are applied to risk reduction and its assessment when developing and implementing risk management strategies in the US and Europe.