

## 4<sup>th</sup> International Conference and Exhibition on **Pharmacovigilance & Clinical Trials** August 10-12, 2015 London, UK



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### **The EU-RMP - Planning risk management in a feasible fashion**

Since 2012, every new marketing authorization within the European Union (EEA) requires the inclusion of a risk management plan. With the introduction of the good pharmacovigilance practices, the template of the RMP has undergone major modifications. The current template can be found by consulting GVP module V. Depending on the type of application, certain modules can be omitted or require less information. If the RMP includes the implementation of additional PV or risk minimization measures, an implementation plan is necessary in order to be able to assess the adequate roll-out of the proposed measures and to facilitate the required assessment of effectiveness of the included measures. In this workshop, we will touch upon writing and implementation of the EU-RMP, best practices and upcoming changes and improvements.

### **Biography**

Angela van der Salm specialises in providing tailor made pharmacovigilance support, including QPPV provision and responsibility for the clients' pharmacovigilance systems. She creates safety data exchange agreements on behalf of her clients, database management of patient reports on adverse events related to medicinal product use, give training on basic and advanced pharmacovigilance, write periodic reports on the risk-benefit balance of pharmaceutical products by evaluating literature, case reports and all other relevant sources. She monitors the department for quality and compliance. Her research interests lie with benefit/risk evaluation and risk management, off label use and medication errors.

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### **Notes:**