

**Andy Lawton**

**Risk Based Monitoring, is the reality matching the model?**

A coordinated pharmaceutical industry response to the guidelines from the FDA, EMA and PDMA which have culminated in the forthcoming ICH E6 Integrated Addendum, has been via the TransCelerate RBM working group.

Individual company responses to the implementation model have varied, depending on infrastructure, systems, tactics and philosophy. Some of the early initiators are adapting their approaches as gaps are identified or to optimize the process.

The presentation will address some of the key differences in implementation between companies, the continued development of RBM and current gaps with regard to the ICH E6 Integrated Addendum.