Risk Management: How Not To Do It

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CASE #1 THE COPY / PASTE SOP It is not uncommon to find that a company's Standard Operating Procedure (SOP) on risk management is an almost one to one copy / paste of the ICH Q9 guideline already mentioned. What could be wrong with that one might ask. In fact, a lot. First of all, it shows a lack of understanding for the difference between what one should find in a guidance document and what should be written in a SOP. The SOP n