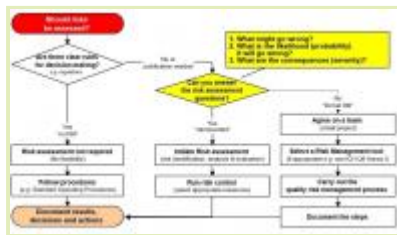


## Understanding the Concept of Formality In Quality Risk Management

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Flowchart from ICH Q9 Briefing Pack that refers to Formal and Informal Risk Management

**ABSTRACT** Formality in Quality Risk Management (QRM) is an interesting concept. What makes a QRM activity 'formal' and what makes one 'informal'? A simplistic viewpoint might be that formal is when a QRM tool is used to manage risks, and informal is when no such tool is used. But is it that simple? And are there different degrees of formality in QRM - is it a spectrum, or is it a binary concept? These questions are explored in this paper. Since the introduction of ICH Q9 in 2005, there have been discussions in the pharmaceutical industry and among regulators regarding...

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