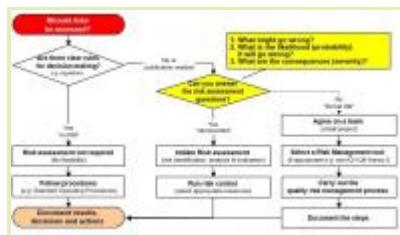


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Understanding the Concept of Formality In Quality Risk Management

By **Kevin O'Donnell, Deidre Tobin, Stephanie Butler, Ghada Haddad, and Donal Kelleher** Jun 25, 2020 7:00 am EDT



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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