



A BEGINNER'S GUIDE TO QUALITY RISK MANAGEMENT (QRM)

by Pete Gough

Risk is a familiar concept. We take risks all the time. Even the act of driving to work carries some risk. It is important to understand that in life no activity can ever be totally risk free. Some individuals want to experience high risk (exhilaration?) so they take up pastimes such as rock-climbing, free-fall parachuting, or even bungee jumping. Whatever we do we are constantly assessing the risks associated with our activity and controlling them. If we deem them too high we take risk reduction measures to reduce the overall risk. For example, in free-fall parachuting we carry an emergency 'chute just in case the main one fails to open. So none of us are strangers to the process of risk management, we have done it from an early age and before that our parents did it for us. If we did not behave in this way, our lives could be considerably shorter!

The advent of the FDA's 21st century GMP and other initiatives have turned a spotlight on to how we manage quality risks in the pharmaceutical industry. Other industries, including closely related ones like the medical devices and food industries, have adopted a more structured approach to this subject than we have traditionally used. Our approaches to assessing and controlling quality risks have largely been empirical. This is often fine but in more complex or hazardous situations there are a number of very helpful tools and techniques that the pharmaceutical industry has mostly ignored.

ICH Q9 was needed to explain what quality risk management is, how it can be applied to pharmaceuticals and to provide a common language with an agreed process for the pharmaceutical industry and regulators. In many structured risk management models 'risk' is defined as "the combination of the probability of occurrence of harm and the severity of that harm" and this definition is used in Q9. Harm is further defined as "damage to health, including the damage that can occur from loss of product quality or availability".

The ICH Q9 model process for quality risk management is outlined in the diagram (Figure 1).

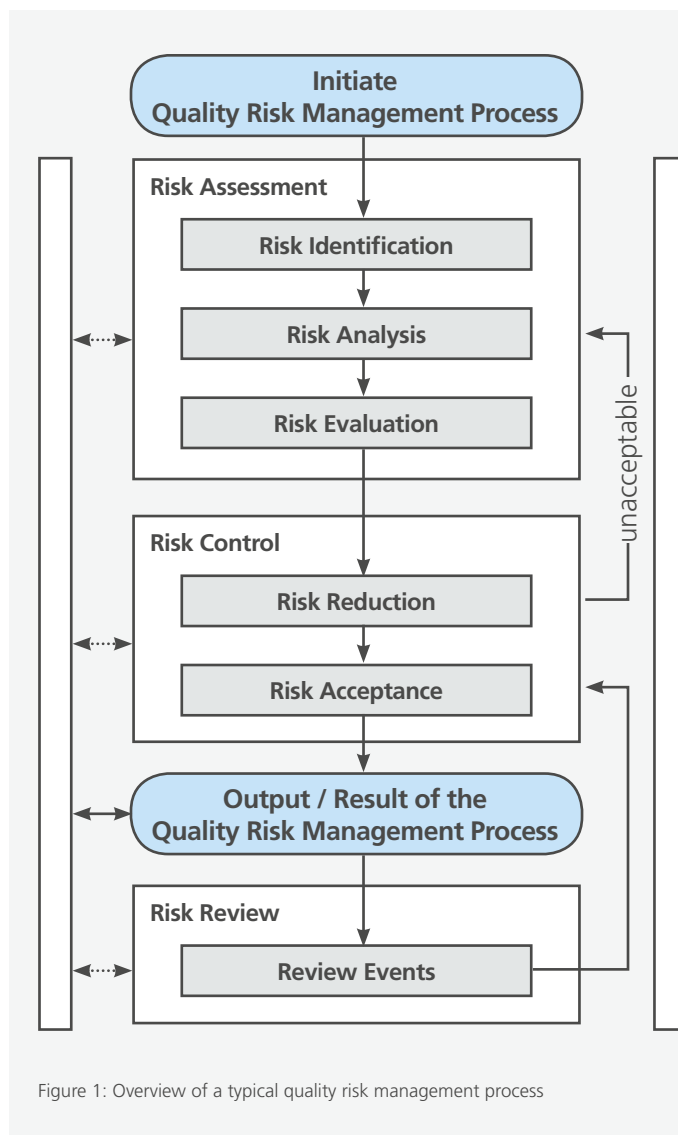


Figure 1: Overview of a typical quality risk management process

The first stage in risk management is Risk Assessment, which is sub-divided into three steps:

RISK IDENTIFICATION

- > identifying potential sources of harm (hazards)



RISK ANALYSIS

- > the estimation of the risk associated with the identified hazards; i.e. the severity and probability of occurrence

RISK EVALUATION

- > compares the estimated risk against your risk threshold to determine the significance of the risk. If the estimated risk is greater than your threshold then it will need to be reduced somehow

The next stage is Risk Control, which includes the identification of possible Risk Reduction measures and, eventually, Acceptance of the residual risk (which can never be zero). The final stage is Risk Review, which is the process of reviewing the risk assessment and risk control decisions in the light of experience to identify whether the risks are adequately controlled, and to take any consequent actions.

ICH Q9 provides some details of the tools and techniques commonly used in risk management in Annex 1. The most commonly used tool is Failure Modes and Effects Analysis (FMEA). This is a structured way of assessing the severity of risk and the probability

of its occurrence and, often also includes the likelihood of detection. FMEA and other risk management tools allow relative risks to be estimated so that you can prioritise your inevitably finite resources to address the higher ones first. It also allows us to determine those areas where no action is required because the residual risk is acceptable.

Now that we have ICH Q9 approved and being put into effect in the ICH regions it is important for industry to have a strategy for implementing structured QRM. Six important rules for this implementation are:

1. Make sure you have sufficient expert knowledge to be able to assess risks.
2. Ensure that your organisation is aware of ICH Q9 and the opportunity that it affords. A significant amount of education is required here, both in industry and regulatory agencies.
3. Encourage an open, risk aware culture.
4. Keep quality risk management SIMPLE (it is an essentially straightforward concept but as an industry we have a tendency to over-complicate).
5. Integrate QRM with your existing Quality Systems.
6. Be open to new ways of thinking.

ABOUT THE AUTHOR



A chemist with a master's degree in analytical chemistry, Peter Gough has nearly 40 years' experience of pharmaceutical manufacture, control and quality management, culminating in the role of Senior Quality Consultant in Eli Lilly's Global Quality Systems division. He has broad experience, particularly with quality control laboratories and the manufacture of solid dosage forms and active pharmaceutical ingredients.

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