

Regulatory compliance made simple

Risk assessment is a relatively new concept for the pharmaceutical industry, but there are lessons to be learnt from risk management techniques in other compliance areas.

There are some terms that compliance and quality assurance (QA) people in the pharmaceutical industry have been hearing constantly of late. One of the loudest has been 'risk assessment', or 'risk management'. This has created an air of nervousness in the industry, fuelled perhaps by QA professionals' fear that they must work towards zero risk on product quality issues. They also worry that risk assessment is just the latest suit of emperor's clothes that expensive consultants are selling.

However, risk assessment does have a role to play in product quality and efficacy of pharmaceutical products, and there are lessons to be learnt from risk management techniques in other compliance areas.

Background

The term 'risk assessment' was first used specifically to determine the scope and extent of validation in Annex 15 of the EU Guide to Good Manufacturing Practice, Qualification and Validation. This document also defined 'risk analysis' as 'a method to assess and characterise the critical parameters in the functionality of an equipment or process'. More recently, the US Food and Drug Administration (FDA) has issued high-level guidance stating its intention to work towards the initiative – 'a science- and risk-based approach to product quality regulation incorporating an integrated quality systems approach'.

There have been several updated guidance notes from the FDA, including the revised Part 11 (electronic records/electronic signatures – scope and application). The International Conference on Harmonisation is also actively involved, establishing a steering committee considering 'a better definition of the principles by which risk management is integrated into decisions regarding quality including GMP [good manufacturing practice] compliance both by the regulators and industry'.

So, how do we use risk assessment to our benefit in the arena of facility, equipment and process validation? And

how do we justify the decisions that are made when the comfort zone of many QA professionals is to take a zero risk option?

Towards common compliance

Risk assessment has been used in many industries for a considerable time, but the pharmaceutical industry has been only gradually introduced to the concept through engineering colleagues. The International Society for Pharmaceutical Engineering's Baseline Guide for Commissioning and Validation has introduced us to the concept of impact assessment, teaching us to identify objectively direct impact equipment or components that require validation documentation in addition to the commissioning records dictated by good engineering practice.

With a little luck, good consultancies will be working to provide a 'common compliance' risk assessment service

In safety and environmental hazard evaluation, there are standard risk assessment techniques that, through a disciplined procedure, guide us to risk criteria deemed acceptable by society and – perhaps more importantly – by the law courts. Most risk assessment processes involve some risk ranking, following consideration of the likelihood and the severity of the consequence of failure. The results can be shown in a matrix or graphical presentation (see Figure 1). This structured approach then provides a defensible assessment.

So, a range of methodologies is available and, with a little luck, good consultancies will be working to provide a 'common compliance' risk assessment service to cover safety, environmental and product quality aspects – thereby meeting all regulatory requirements in an efficient and cost-effective manner. ■

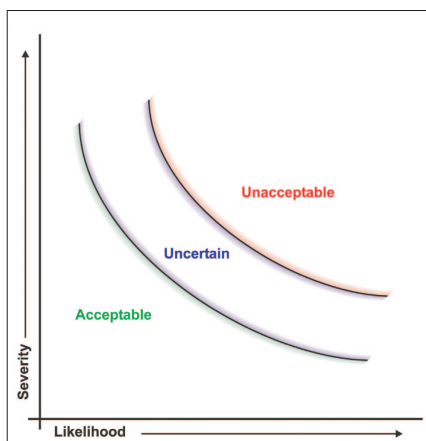


Figure 1. A structured approach to risk ranking provides a defensible assessment

AUTHOR/COMPANY PROFILE

Phil Thomas is validation manager for UK-based AK pharmaceuticals, which delivers total project solutions to leading pharmaceutical and biopharmaceutical companies. AK pharmaceuticals is the dedicated European pharmaceutical business of the Aker Kvaerner Group.