



No Risk Management or Poor Risk Management?

Nostrapharmus calls for Good Risk Management Practice in order to satisfy both regulatory demands and business needs

'At least we tried' is a phrase unlikely to receive any sympathy when you are held to account for knowing about a risk, but not addressing it appropriately. Especially in an industry where public responsibilities are beyond those of ordinary business ethics, safety is paramount and, what you don't know is going to hurt you.

As Nostrapharmus says, 'the minimum requirement has to be an explanation of the actions taken, or not, as the case may be. This, alongside evidence to support the decisions made, is a start to exercising the principles of Good Risk Management Practice (GRMP). Such principles must maximise the benefits of risk management across the business whilst also ensuring the satisfaction of emergent requirements from the regulators. It is imperative when implementing risk management, to put mechanisms in place to manage the required actions before getting too excited about where the greatest risks exist in the business.

Recent events in the financial markets represent, only too well, the perils of inappropriate risk strategy, poor governance in respect of the strategy, and a lack of process to continually review and resolve risks. Much has been written and said about the limited understanding of financial products by those charged with managing the risks. Whilst the general public can do little about this, the regulatory bodies are there to protect us; but what happens when they too lack the risk management components essential to operate effectively?

Post economic meltdown, there is little chance that any regulatory body will ever be left so exposed again. Even less chance that it would be those that regulate our pharmaceutical industry. So, as the regulations continue to evolve in the 'prevention is better than cure' context, we had better make sure that we know what we are doing. This is only right. Lives may be ruined by poor financial risk management, but lives are lost through poor clinical risk management. So, is no risk management better than poor risk management? Well, that really depends on whether you are a patient, a shareholder, or a litigator.

Objectively informing risk/benefit decisions is very much the primary return on operating good risk management in business, but it is not just about being well prepared when things go wrong. We must remember that one of the primary aims of the pharma industry, and those who work within it, is to help people. GRMP can, and will, give more people access to more products, and sooner.

It is no secret that high profile lawsuits are commonplace in the world of pharma. The cost to individual patients and their families is not one which can be measured financially. The full commercial costs are also difficult to ascertain with accuracy. Awards to plaintiffs are typically well publicised, but represent only a fraction of the total commercial impact, when lost revenues, damaged reputation, share price impact, to name but three, are taken into account.

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Just some of the payouts in recent years¹:

Fenphen 2005	Wyeth \$21bn
Zyprexa 2007	Eli Lilly \$500m (in addition to \$700m in 2005)
Premarin 2007	Wyeth \$134m
Vioxx 2007	Merck \$4.85bn
Celebrex and Bextra 2008	Pfizer \$894m
Risperdal 2009	Johnson and Johnson \$3.95m
Phenegen 2009	Wyeth \$6.7m

Who knows what the total commercial cost was in each case. It is likely that the impact is still being felt in many of these instances. So, how could risk management have made a difference in these, and other, cases?

Complete risk avoidance would be an unlikely scenario, but should be considered the 'ultimate goal' as we learn from our history as an industry. Better, in risk management terms, to consider how the following could have reduced the impact commercially, and for patients...

- Earlier identification and escalation of a potential problem
- Greater visibility of risk to a broader range of senior executives
- Ongoing integrated review of risk throughout the product lifecycle
- Faster implementation of actions to minimise and mitigate risk
- Assurance that risk minimisation was effective

Clearly, Risk Management Plans (RMPs) and Risk Evaluation Mitigation Strategies (REMS) go some of the way to reducing the likelihood and impact of product risks. But these can only operate to good effect in the right context. That is a context where risk management is well understood across the business and is an integral part of day-to-day practices. These examples, from a patient safety perspective, are an easy way to highlight the need and the opportunity in good risk management. The same approach also applies to the whole gamut of risks in the business, from research portfolio management, through supply interruption, to fulfilling regulatory compliance.

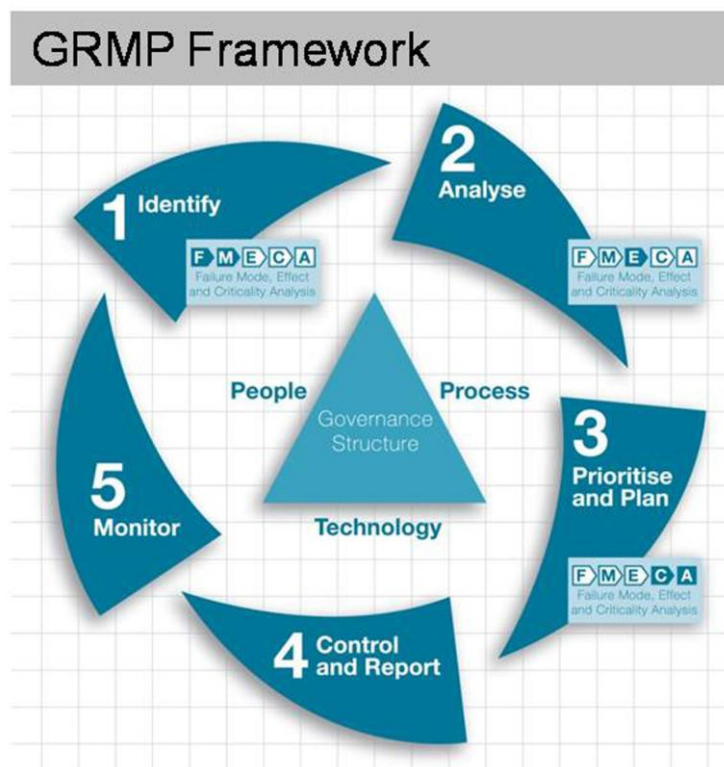
Whilst good risk management is common-sense, its application and operation in a business context require clarity, definition, discipline, management commitment, and engagement of a broad population. Even a business that believes this is all working well needs to take stock of how easy it would, or wouldn't, be to demonstrate to a third party. Good intent is a great starting point, but is just that, a starting point. Understanding the need and the approach is also a good place to begin, but again, it is not enough.

It is no surprise that most of the industry is not yet able to demonstrate Good Risk Management practice. Good intent, yes. Good understanding, yes. Good practice, no.

¹ Information provided by Datamonitor

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However, the good news is that it is not so difficult to get GRMP operating in your function or business. It does, however, require commitment, and a level of effort to get going and maintain. Beware: it is easy to fall into the trap of creating a new and separate process and organisation – this is neither effective nor efficient. It is far better to integrate risk management into existing business processes, functions, and governance.



The approach to implementing GRMP needs careful consideration. It is essential to avoid making a list of risks without having a robust process to identify root causes and execute effective actions to their conclusion, to ensure resolution. Think also about the sequence in which GRMP is implemented, it would be ironic to get it working in the lower risk areas first!

GRMP is not only the management of risks, but also a key to opportunity; through better informing the risk/benefit decisions that have become part of your daily business life. GRMP protects the patient and the business, but also gives opportunity to focus efforts on where the patient and the business can benefit most.

Nostrapharmus predicts 'the Safety Risk Management system will become a regulatory obligation for proactively identifying and communicating information. This will ensure appropriate use by end user, unknown safety issues are found early and, to non-issues to avoid becoming issues. Effective implementation of the plan is key, it is essential to have 'closed loop' on actions and this requires cross-functional working both centrally and across local operating companies.'

Email: nostrapharmus@wcigroup.com