

LIFE SCIENCES

Risk Management

Risk management
Compliance
Safety regulations
Product RM plans

do you have
oversight and
control of your
product and
process risks?

why



**“ we have
embraced
regulatory
guidelines and
requirements
in our approach
to Risk
Management ”**

“we have applied Risk Management in product safety”

“we have reduced compliance risk through implementing our Risk Management framework”

Why this is important

With public safety high on the agenda, life science companies need to be able to demonstrate responsible behaviour to any, and all, interested parties; from the regulator and management, to the patient, the customer, and staff. In addition, companies must also ensure that they make best use of available resources, whilst demonstrating a sound understanding of priority areas.

A risk-based approach to setting priorities is objective and robust, and not only does it align with emergent regulatory requirements, it also makes good business sense.

There is an ever growing requirement to invest improvement efforts into activities and entities with greatest need, those that present the greatest risk to compliance. This can, and will, avoid potentially and unnecessary increased risk to patients.

The era of ‘random’ inspections should soon be behind us. The future will require

us to demonstrate a thorough understanding of our business and to attract attention to the area of greatest concern. Whilst this will be somewhat alarming to many, it is ultimately logical and will be a key driver in the need for more partnership type relationships with regulators rather than their continuing the role of ‘policemen’.

Model for success

Fundamental to the success of Risk Management is the completeness of both the approach and the context. To succeed the approach must initially have objective prioritisation, supported by the reliable completion of key actions and, finally, must close the loop to re-assess the risk post-intervention.

There is a need for a structured approach to implementing and integrating with other business processes. This approach should be risk-based and needs to display a progressive approach to implementing Risk Management. This need not be as

overwhelming as it may sound. There is no need to ‘reinvent the wheel’ but rather, WCI Consulting Limited has developed a single Risk Management solution, the elements of which are all well proven. A number of Risk Management techniques and methodologies exist, and correctly implemented, a structured framework will ensure compliance to the regulations whilst, at the same time, improve the processes; thereby contributing to an increase in patient safety.

Benefits

Through the deployment of its holistic Risk Management framework, WCI delivers many benefits including:

- Complete oversight of potential risks
- Prioritisation of risks with regard to likelihood, impact and detectability
- Permanent problem elimination through root cause isolation
- Effective management of regulatory enquiries
- A defensible Risk Management regime aligned with new regulatory approach (FDA, EMEA and MHRA)
- The creation of a ‘risk alert culture’

Proof of solution

“Adopting this approach in GSK has enabled us to have a better understanding of risks within our pharmacovigilance activities worldwide, including identifying new risks and measuring the worldwide existence of risks that had already been identified in isolated instances through internal audits. As a result, we have been able to develop action plans to address the risks in a time frame determined by the priority of that risk. We believe that by utilising this risk management framework, we can ensure consistent high standards in our pharmacovigilance operations in both our global safety department and the local affiliates.”

Sue Gammons, Director of Pharmacovigilance Risk Assessment, GlaxoSmithKline

The Risk Management Framework

