

is risk
management
operating
effectively in
your business?

why



**“we have
implemented
effective Risk
Management
ahead of the
regulatory
imperative”**

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

Why this is important

Life science companies have public responsibilities beyond those of ordinary business ethics. Public safety is paramount and, as such, understanding and managing risk is a must within any life science organisation. What you don't know is going to hurt you. A proactive approach to Risk Management is essential; as workload increases a solution that enables you to do 'more with less' is needed. Prevention is better than cure and is a far better investment than being masters at handling repeating problems. Now the regulators are demanding it. How right they are. WCI has already put Risk Management into action, taking into account current and future regulations and the benefits are showing.

“we configure our Risk Management framework to align with the objectives of the business”

Model for Success

An effective Risk Management strategy ensures the ability to both anticipate and mitigate risk. It has a formalised and transparent evaluation and communication process, accountability for all functions involved in decision making, clear decision escalation criteria and a crisis management policy for high impact issues requiring fast track action.

WCI's Risk Management approach is aligned with that adopted by the FDA. Our proven approach and methodology and the way in which we apply cross industry best practice ensure that we understand the application of Risk Management across all functional areas.

“we apply our experiences in aerospace and defence to the life science context”

Benefits

WCI's practical approach to Risk Management delivers many benefits including:

- reducing the impact of potential product and process risks
- driving synchronised actions across organisational boundaries to mitigate risk
- effective management of regulatory enquiries
- an optimised and proactive approach for Quality Risk Management
- permanent problem elimination through root cause isolation
- a defensible Risk Management regime aligned with new regulatory approach (FDA, EMEA, MHRA)
- a means to measure and monitor quality
- the creation of a 'risk alert culture'

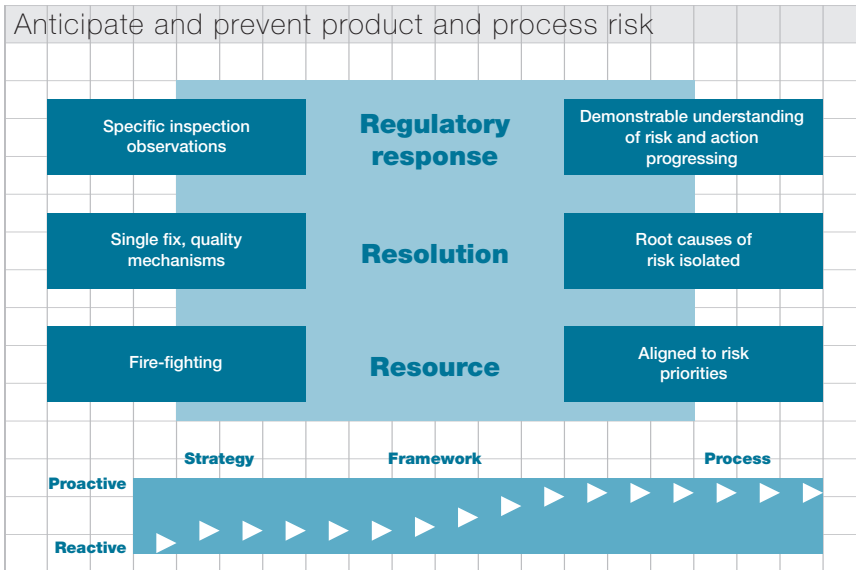
Proof of Solution

“The combination of WCI and Sidley Austin LLP's depth of experience provides not only a thorough understanding of compliance risks, but also a systems based perspective on how to manage these risks with a view to both current and future regulations.”

Scott Bass, Partner and Head of International Food and Drug Practice, Sidley Austin LLP

“WCI has helped Wyeth set up a world class process for Risk Management planning and implementation. As a result, Wyeth is able to conduct all aspects of Risk Management throughout a products life cycle in a way that ensures achievement of high quality, consistency and clear definition of roles and responsibilities.”

Mary Ellen Turner, Vice President Global Safety Surveillance and Epidemiology, Wyeth



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