

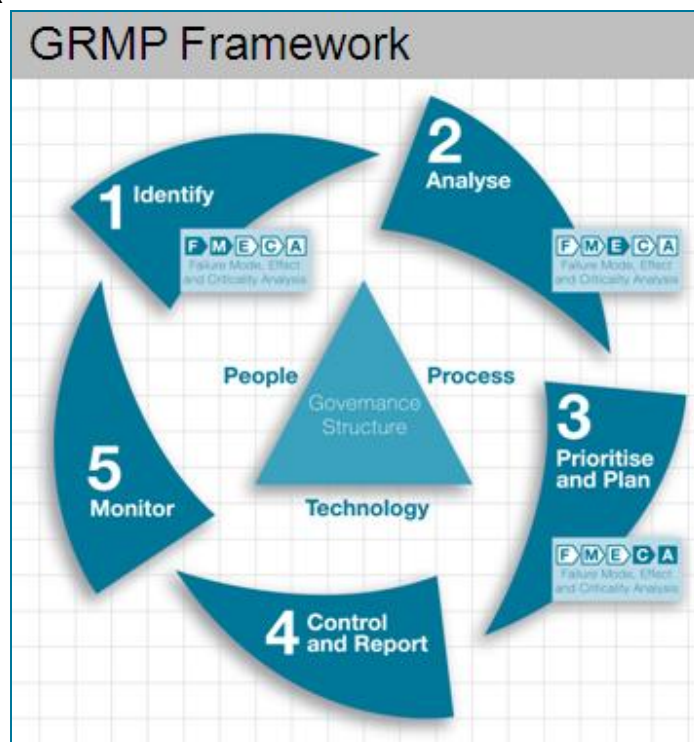
GRMP: Good Risk Management Practice

What is GRMP?

GRMP is WCI's approach to maximising the benefits of risk management across the business and ensuring satisfaction of the emergent requirements of regulators. This is achieved through the application of a closed-loop framework; ensuring the full cycle of risk is managed through to completion of actions and monitoring of effectiveness. The need to consider risks across a range of business activities is addressed by taking a holistic view of risk management throughout the product lifecycle, and applying this consistent best practice approach and methodology wherever risk management activities are being performed. The approach is based on the following key principles:

- For risk management to deliver business value, there must be a focus on root causes and monitoring the effectiveness of actions to address risk
- Risk management processes across the business should be consistent and supported by a single governance structure
- Risk management is of value throughout the product lifecycle, with a need to shift focus on categories of risk over time

The GRMP Framework



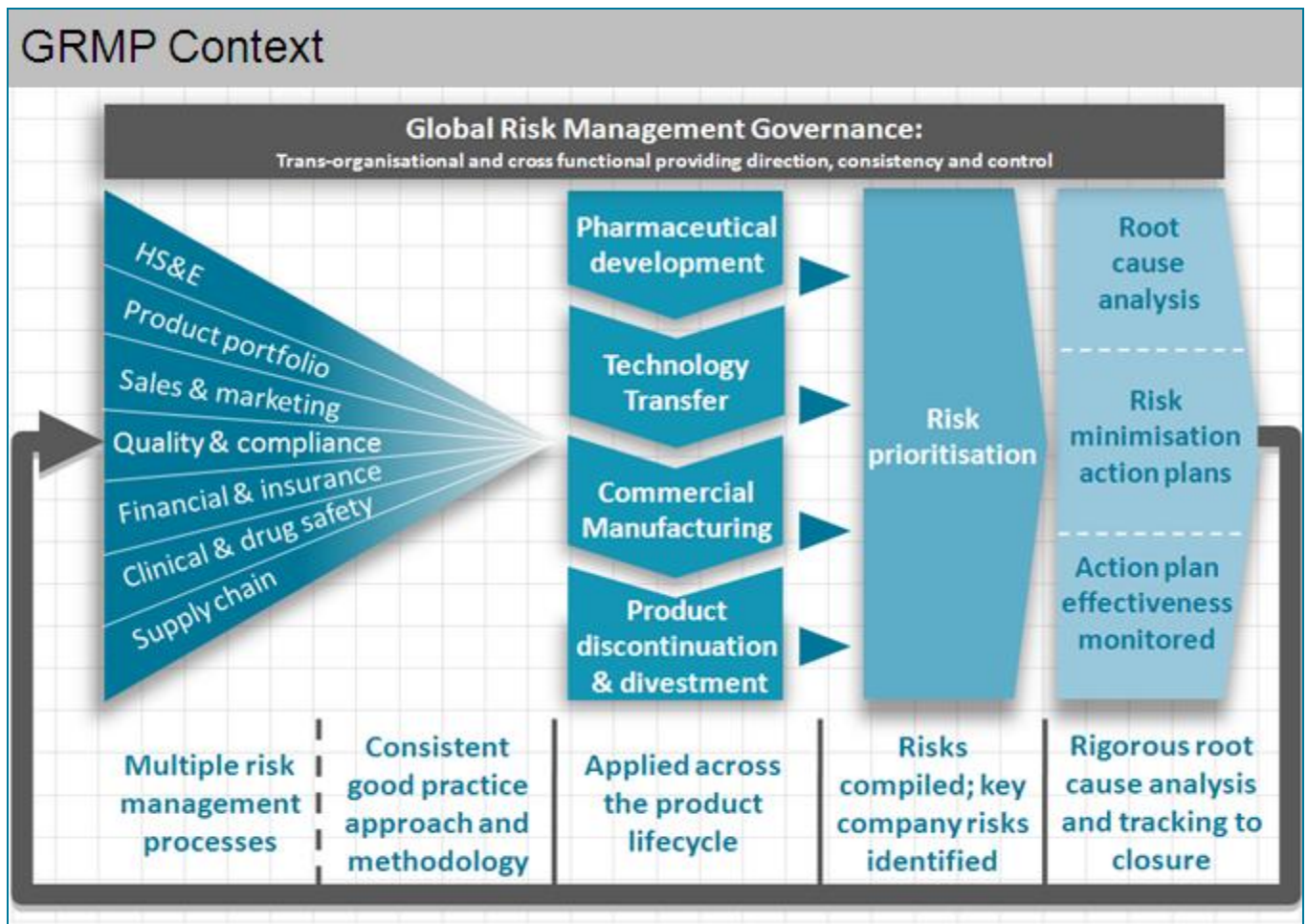
The benefits of GRMP

- Risks across the business are assessed consistently
- The avoidance of culpability with respect to known and documented risks
- Cost savings are made as there is a clear set of risk priorities for the business, enabling effective management of risk minimisation and avoidance of duplication of effort and/or non value adding activity
- Improved regulatory compliance through harmonisation of processes
- Improved product safety, quality and robustness of supply chain through early identification and minimisation of potential risks

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GRMP Context

The GRMP framework can be effectively applied to a specific activity, function, or category of risk. Ultimately, GRMP will be applied across the business, and through this approach, all risks will be assessed and managed consistently.



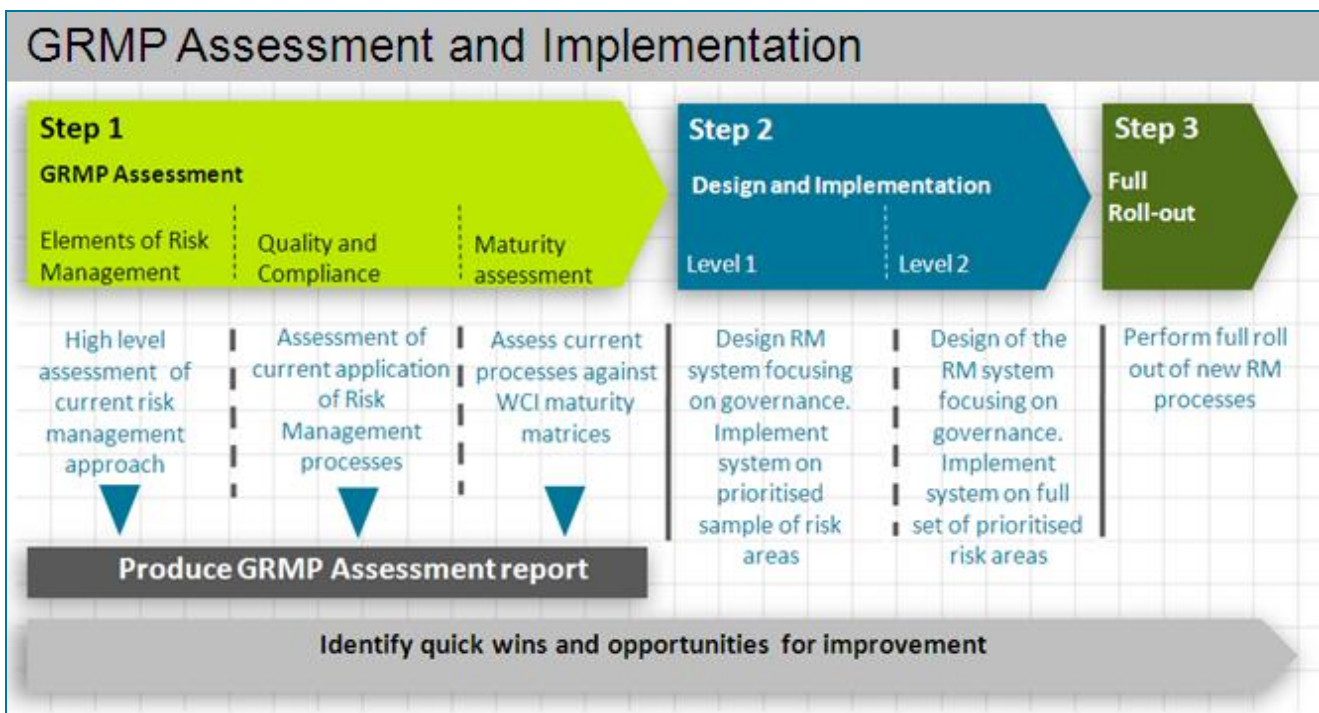
- The governance structure is the key to success and ensures oversight across all risk management systems
- Ability to manage multiple risk management processes across the business
- Consistency in application of risk management methodology allows the comparison of risks from different systems
- Applying risk management throughout the full product lifecycle ensures that processes are improved and strengthened to minimise systemic risk as well as product risk
- Compiling risks from different systems will enable the identification of overall risk priorities for the business. All other risks continue to be managed in the individual systems
- Rigorous root cause analysis, tracking to closure, and effectiveness monitoring ensure that risks are resolved in a single intervention

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GRMP Assessment and Implementation

WCI has a proven three step approach to implementing GRMP.

The first step is concerned with the assessment of what is already in place, and also identifies areas where risk management should be usefully employed, but isn't currently. Assessment is performed in alignment with recognised industry best practice and the latest understanding of regulatory requirements. The assessment also challenges the current application and methodology of risk management processes; Are they fit for purpose? Is there compliance exposure? Is governance effective? Are processes being followed, and are they consistent? Processes will then be assessed for their level of maturity. Deliverables of the assessment include opportunities for improvement, quick wins, and clearly identified gaps that need to be addressed in order to establish GRMP.



Implementation of the newly designed GRMP system would initially be in areas with the highest perceived business risk, before a complete implementation across a broader scope. At all stages, the governance structure is implemented prior to any of the new processes going live.

WCI has applied the GRMP principles and risk management framework in a variety of contexts, including drug safety, development, manufacturing, and supply. We know how to make risk management work in your business to satisfy regulatory demands and your business needs.

For further information about GRMP and WCI's GRMP Assessment, please contact us at info@wcigroup.com or call +44 (0) 2392 268133.