

Quality Management System of the Future

WCI Consulting Limited

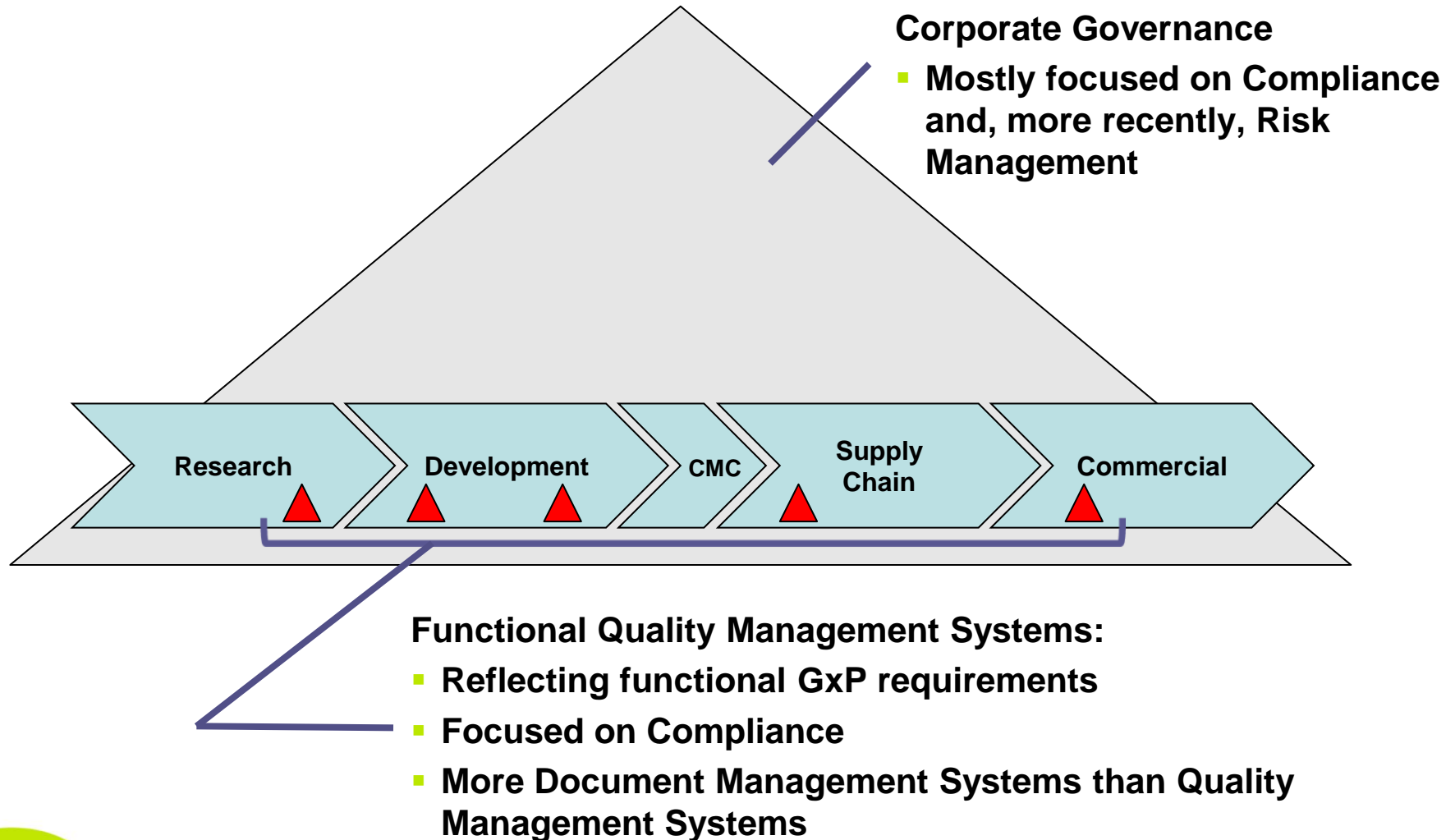


Simplify what you do

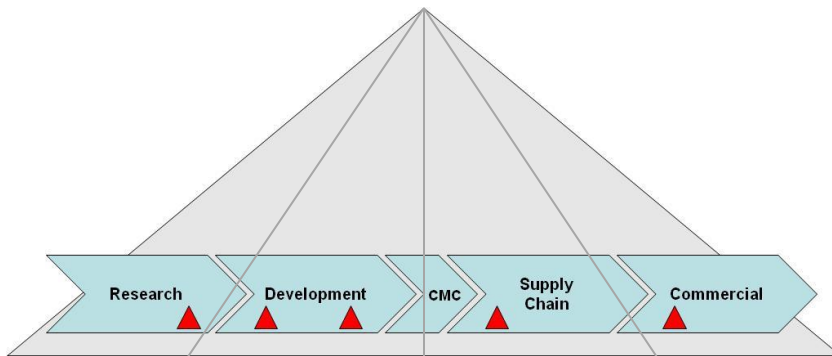
Objectives

- To explain how traditional Quality Management Systems (QMS) impede business improvement
- To clarify that Performance, Quality and Compliance are inseparable
- To show how a different approach to QMS can enable a business to improve performance, create a total quality culture and enhance compliance

Traditional QMSs are more Compliance than *Quality* Management Systems

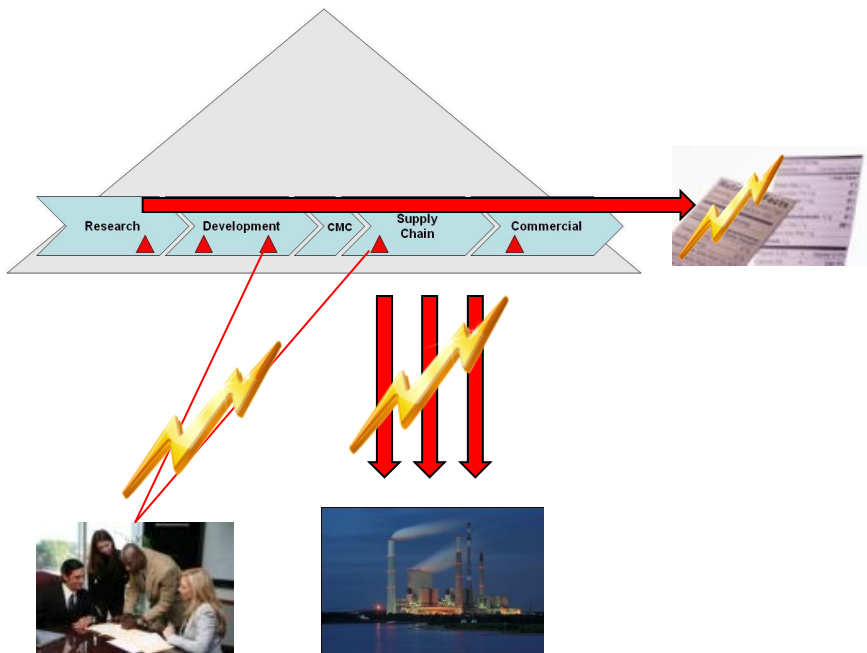


The compliance focus is mostly driven by a reactive culture in the functional groups



- Pharma/Biotech are generally change and risk averse
- Development of the QMS is a reaction to:
 - Regulatory changes
 - Inspection findings
 - Product / Market changes
 - Maturity of the functional areas
- Total Quality Management not considered

The functional focus has led to the fact that issues are build into the QMSs

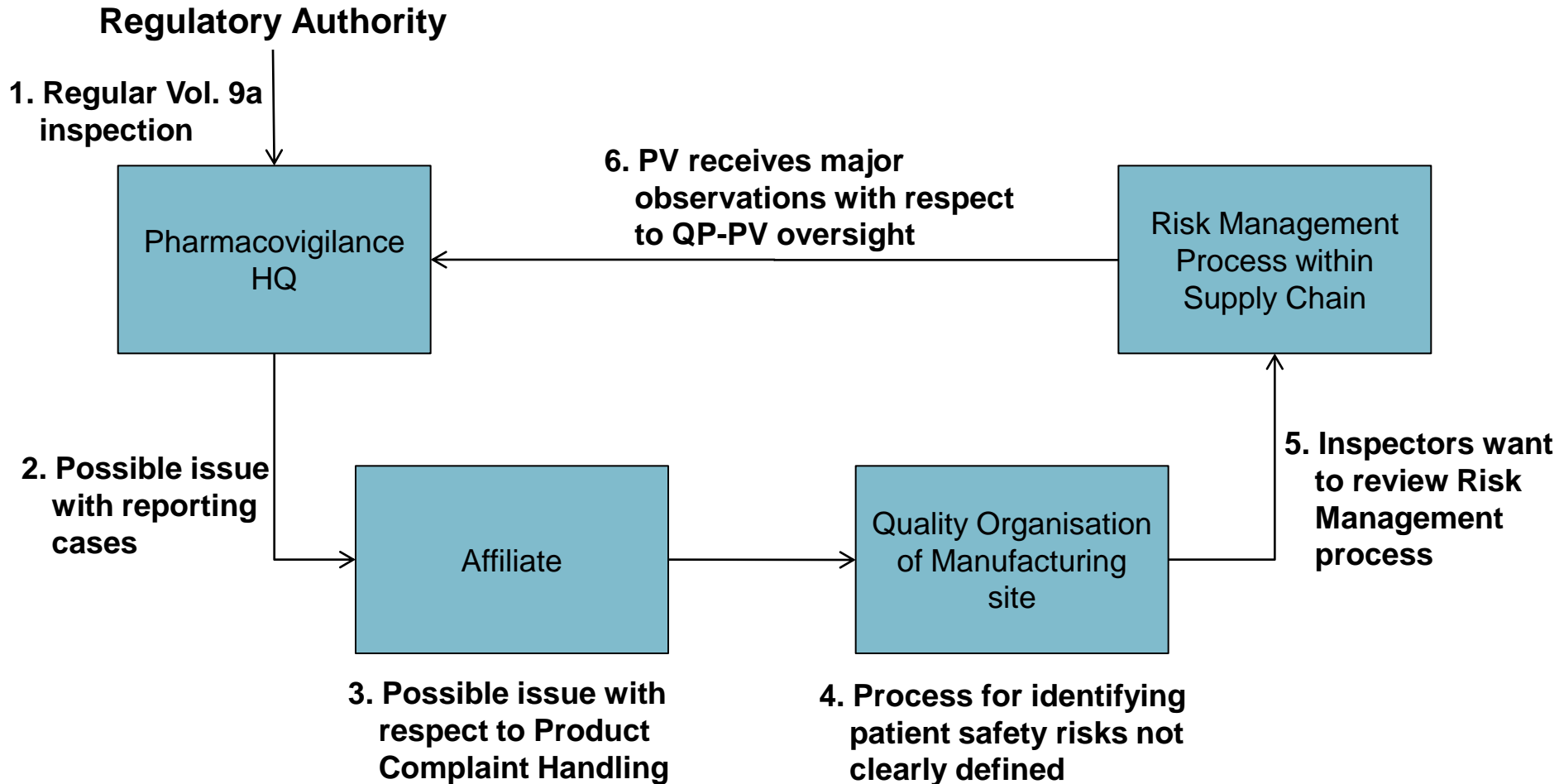


- Cross-functional processes
- Lack of clarity for those who are governed by more than one functional QMS
- Conflicting objectives with respect to Performance, Quality and Compliance

The impact of these build in issues is significant

Issue	Example	Impact on		
		Performance	Quality	Compliance
Cross-functional processes require high coordination efforts	Label Change Management	<ul style="list-style-type: none"> ▪ Excessive lead times ▪ High costs for coordination ▪ More waste than necessary 	<ul style="list-style-type: none"> ▪ Rework in the form of re-packing or re-labelling ▪ Patient Safety risks 	<ul style="list-style-type: none"> ▪ Late implementation ▪ Lack of clarity of current labelling situation
Lack of clarity for those who are governed by more than one functional QMS	Resources in Local Operating Countries	<ul style="list-style-type: none"> ▪ Potentially duplication of effort 	<ul style="list-style-type: none"> ▪ Potentially activities are not performed 	<ul style="list-style-type: none"> ▪ Non-compliance to internal regulations
Conflicting objectives with respect to Performance, Quality and Compliance	Supplier Management; lower price versus Quality Assurance/Control requirements	<ul style="list-style-type: none"> ▪ Total acquisition cost higher than necessary 	<ul style="list-style-type: none"> ▪ Increased risks when tier 1 suppliers pass price reductions to tier 2 suppliers 	<ul style="list-style-type: none"> ▪ Gaps in Quality Oversight

Regulatory Authorities understand these issues too and are changing the Inspections



The Authorities and the Pharma industry are catching up in more than one way!



- Late 19th century
- Lillian and Frank Gilbreth
- Motion efficiency



- 1950s
- Toyota & Ohno
- Toyota Production System (TPS)



- Early 20th century
- Frederic Taylor
- Scientific management



- 1950s
- Shigeo Shingo
- TPS, SMED, Zero Quality, Stockless Production



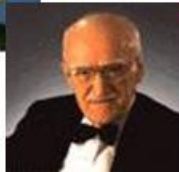
- Early 20th century
- Henry Ford
- Standardisation



- 1980s
- Richard Schonberger
- World Class Manufacturing



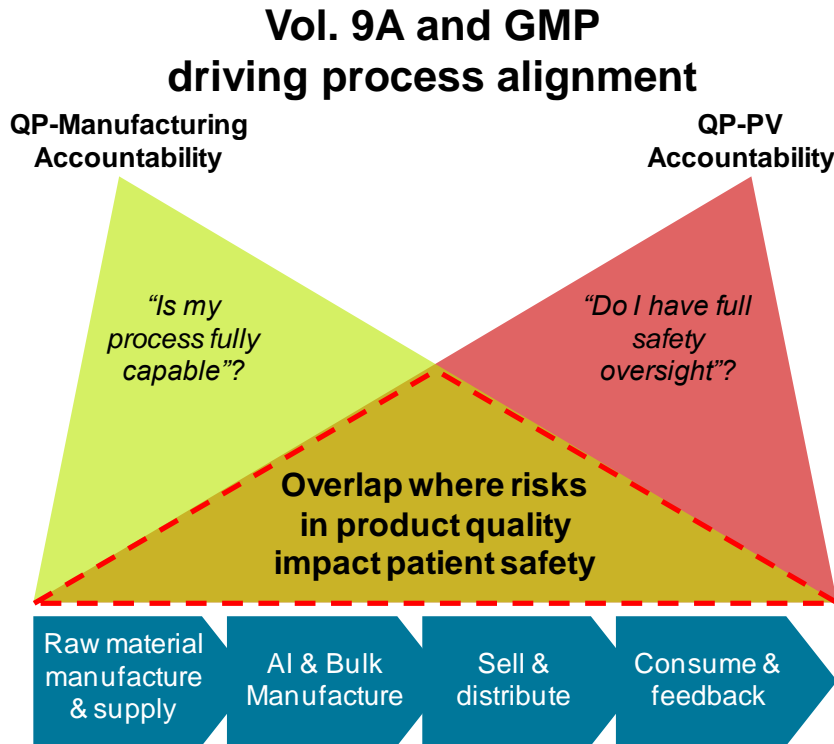
- 1940s
- Deming & Juran
- Statistics & quality



- 1990s
- Jones & Womack
- 'The Machine that Changed the World' and 'Lean Thinking'

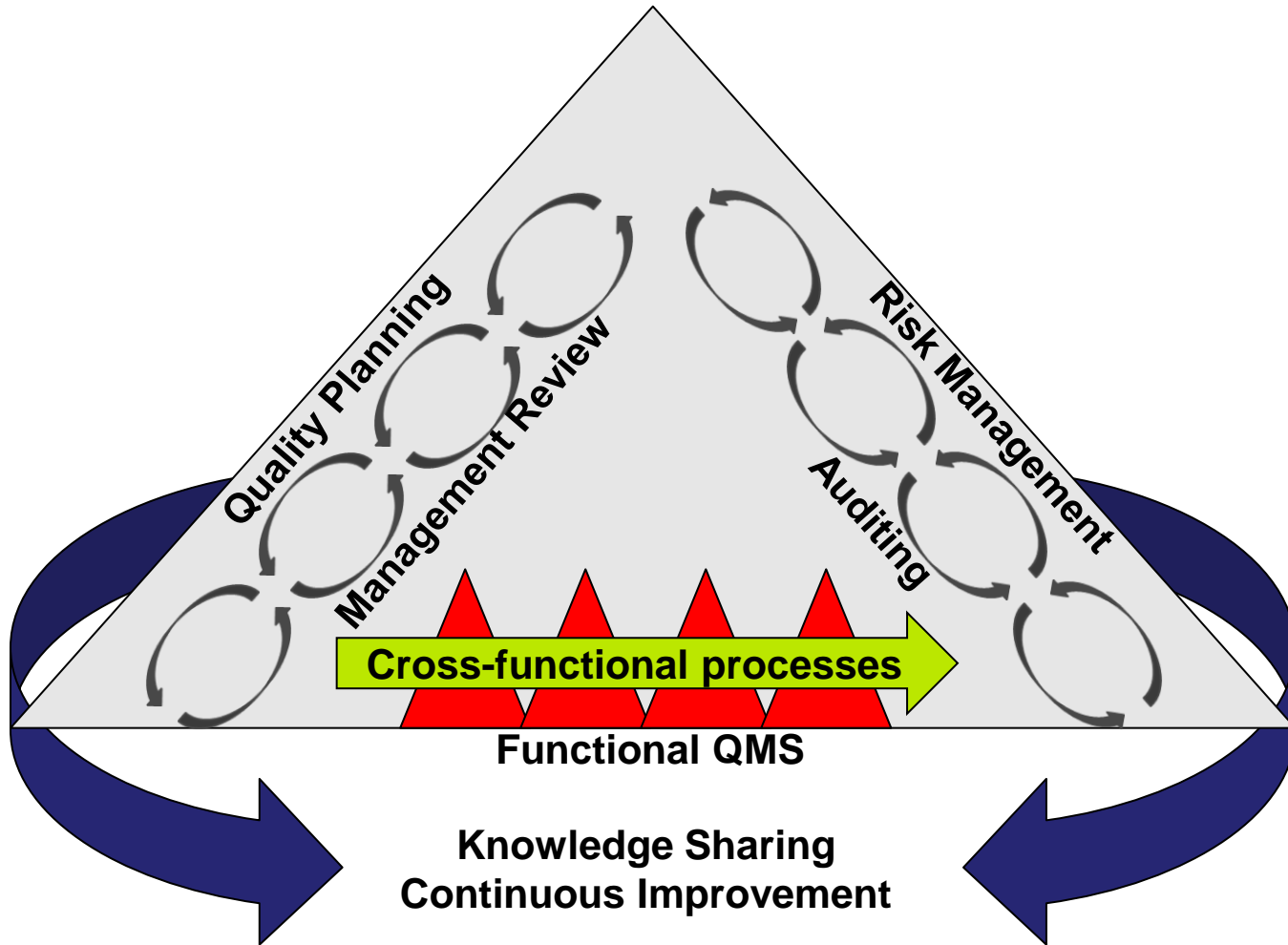


The real complicating factor in Pharma; Lack of processes thinking



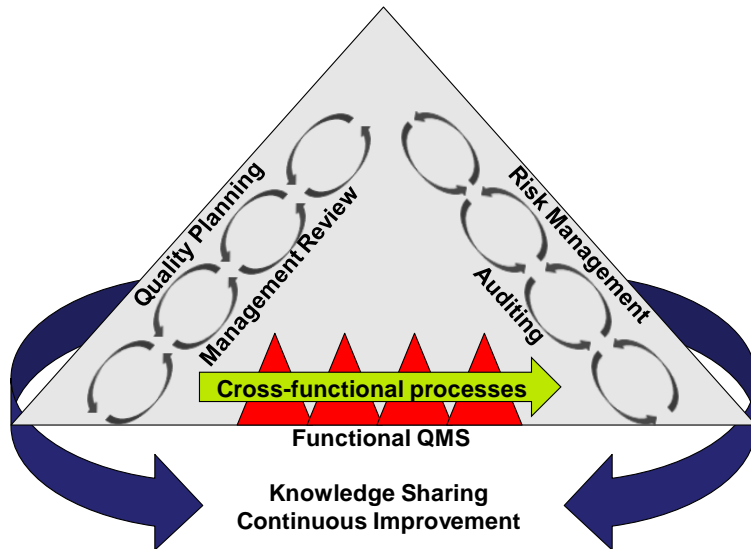
- Pharma is functionally and not process aligned
- Problem areas are always those processes that are cross-functional e.g.
 - Change Management
 - CMC
- Regulations (e.g. Vol. 9a) and Guidance (e.g. ICH Q10) require process thinking and process alignment

The QMS of the Future



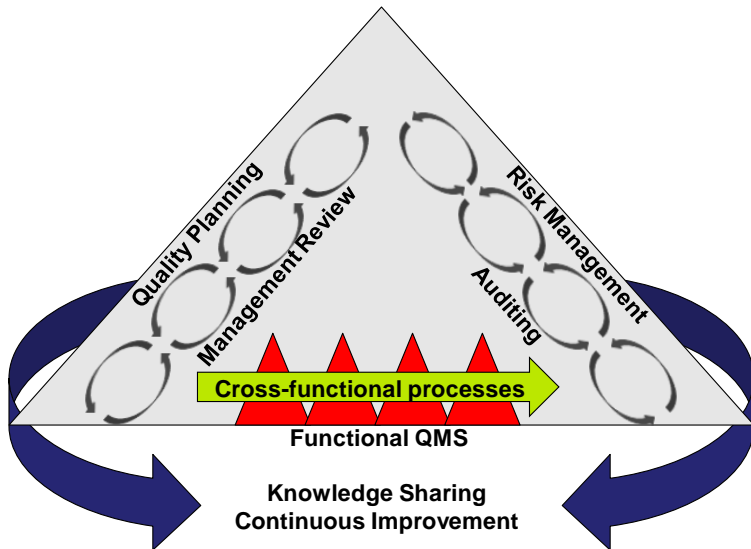
Simplify what you do

The QMS of the Future is a Total Quality Management System



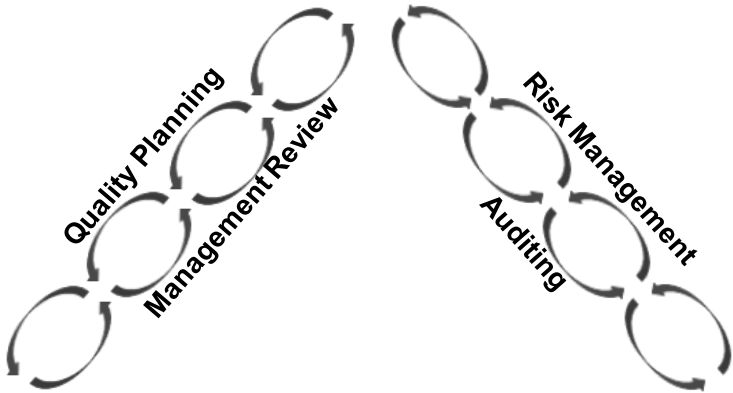
- 4 controlling processes
 - Quality Planning
 - Management Review
 - Auditing
 - Risk Management
- Key cross-functional processes governed centrally
- Balance central governance and functional requirements
- Knowledge Management and Continuous Improvement are key enablers

The QMS encompasses the entire business and respects functional requirements



- The QMS needs to balance central Governance against specific regulatory requirements for the different functions or divisions
 - How much functional freedom is needed or acceptable?
- Functional QMSs are of a lower level and are an integral part of the overall QMS
 - They're not perfectly isolated islands

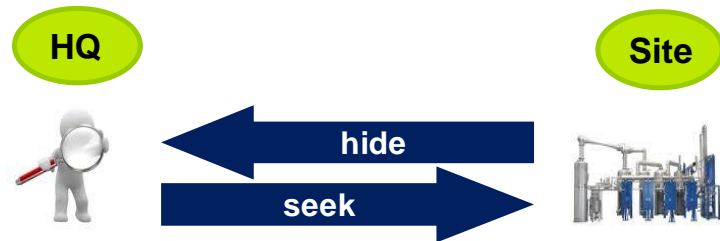
4 processes control Performance, Quality and Compliance



- Quality Planning
 - Cascade of Quality related objectives and targets to operational levels
- Management Review
 - Regular review of Performance, Quality and Compliance from operational level upwards
- Auditing
 - Enables knowledge sharing and risk reduction - more than just the internal police
- Risk Management
 - Enables pro-activeness and prioritisation

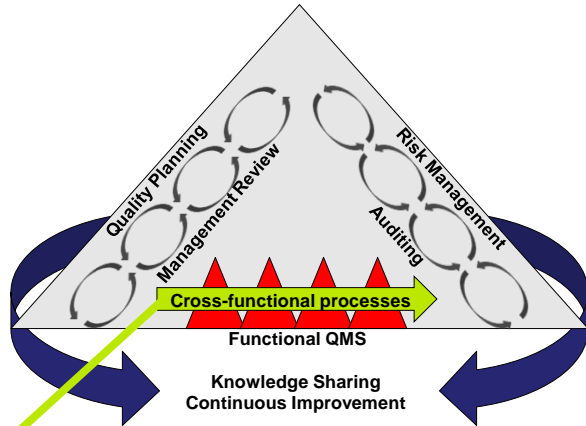
Open Disclosure is essential to making the 4 core processes work effectively

Non-disclosure vs. Open Disclosure



- A state where senior management are aware of the companies key quality and compliance risks and issues
- Achieved by:
 - Trust and support
 - Effective communication
 - Empowered teams
 - Reward openness, decision making, problem solving and sharing information
 - Enforce and monitor through re-designed audit process

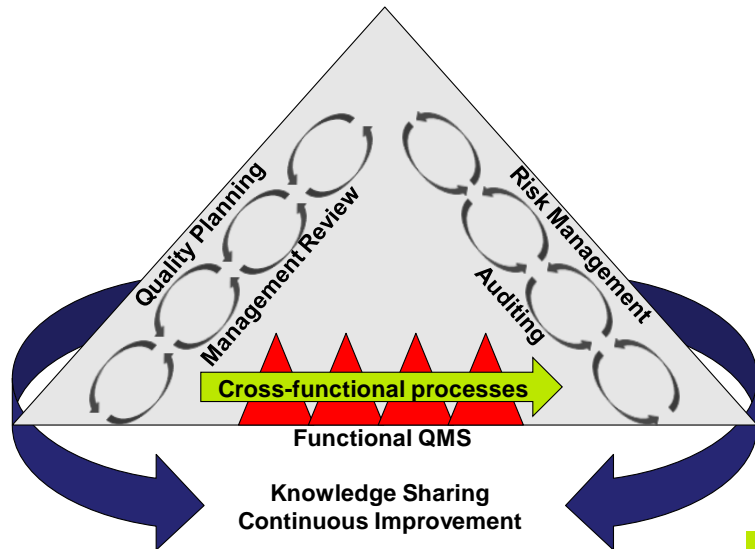
Key cross-functional processes will be governed centrally



- Regulatory Change Control
- CAPA/Deviation Management
- Issue Management
- Traceability
- Supplier Management
- ...

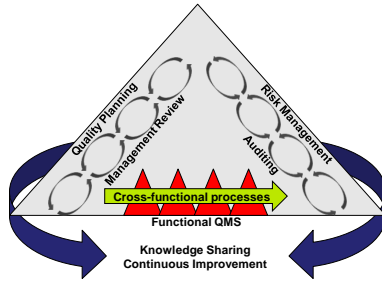
- Decide which processes will be governed centrally based on a set of criteria
 - Performance improvement
 - Assure compliance
- Central Governance means definition of
 - Process Owner
 - Key process steps
 - Accountability per process step
 - KPIs / Management Review activities

The QMS of the Future drives Continuous Improvement through Knowledge Sharing



- Enable Knowledge Sharing across the business
 - Support with infra-structure
 - Organise Knowledge Communities e.g.
 - Product Life-cycle community
 - Auditing Community
 - Drive Best in Class performance through the development of Best Practices
- Use a structured approach to improving Performance, Quality and Compliance e.g. PDCA or DMAIC

How do we get there?



- Get buy-in to the concept
 - The functional groups will fight this!
 - Understand & agree the problems and the impact cross-functional processes are causing
- Develop criteria for deciding if a process requires central governance
- Define cross-functional processes at highest level
 - Owner, Activities, Accountabilities & KPIs
- Re-design the 4 core processes