



Managing Risk Through Business Process Management

Dee Carri Feb 2010

Agenda

1. Foreword
2. A common process framework for Quality, Compliance and Operational Risk
3. Standardisation / reduction in variation in common processes
4. Outsource Contract Governance Management using process frameworks
5. Summary

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Foreword

- a **business process** is

A repeatable series of activities that produces value for one or more stakeholders (BPTrends)

- **Risk** is

The effect of uncertainty on objectives (ISO 31000)

- **Fact**

Risks screw up good processes (me)

Managing Risk Through Process

- Process-centric organisations are realising significant benefits by leveraging their process maps, particularly through tight integration of quality, risk and compliance activities. These benefits are available to everyone...
- In this talk I will discuss three key trends:
 - A common process framework for Quality, Compliance and Operational Risk
 - Standardisation/ reduction in variation in common processes
 - Outsource Contract Governance Management using process frameworks

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Wouldn't it be good if ...

... you could connect your enterprise around your processes ...

giving employees a personalised, consistent place to look to understand the processes relevant to their role ...

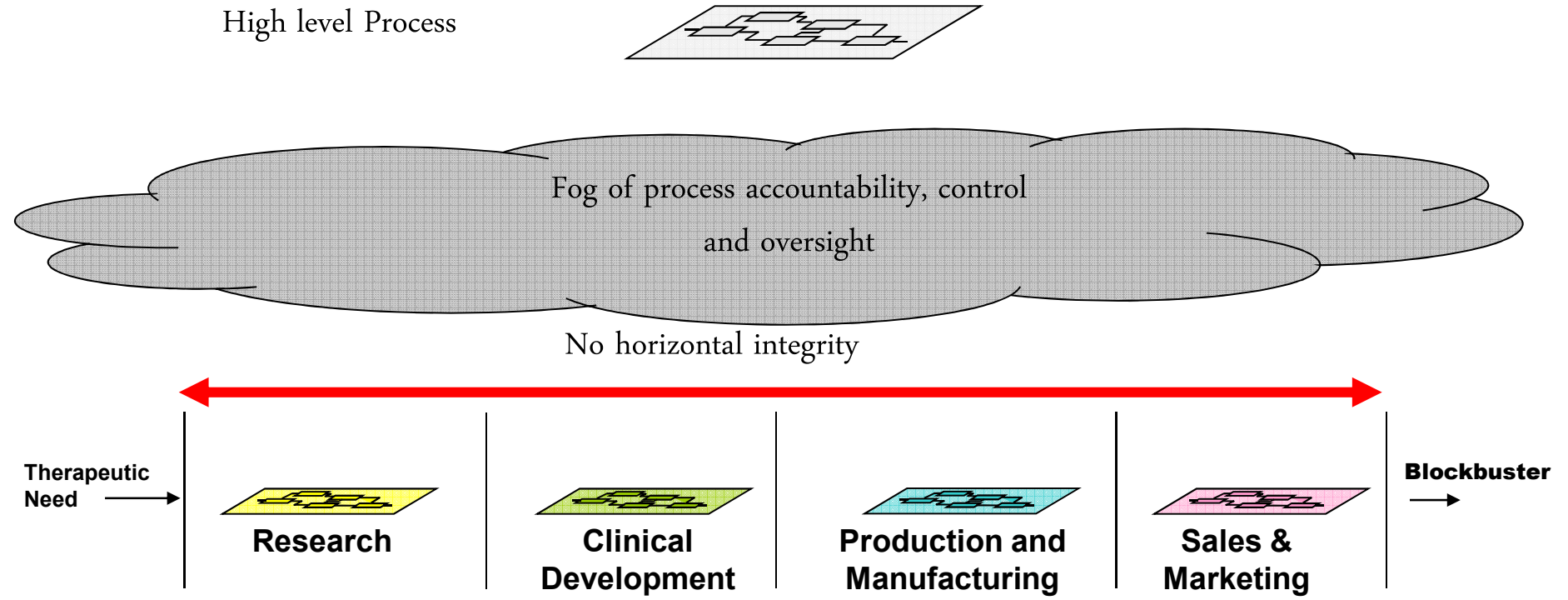
one consistent easy to understand language ...

the ability for readers to collaborate with process owners and authors

to enhance the knowledge keep it up to date ...

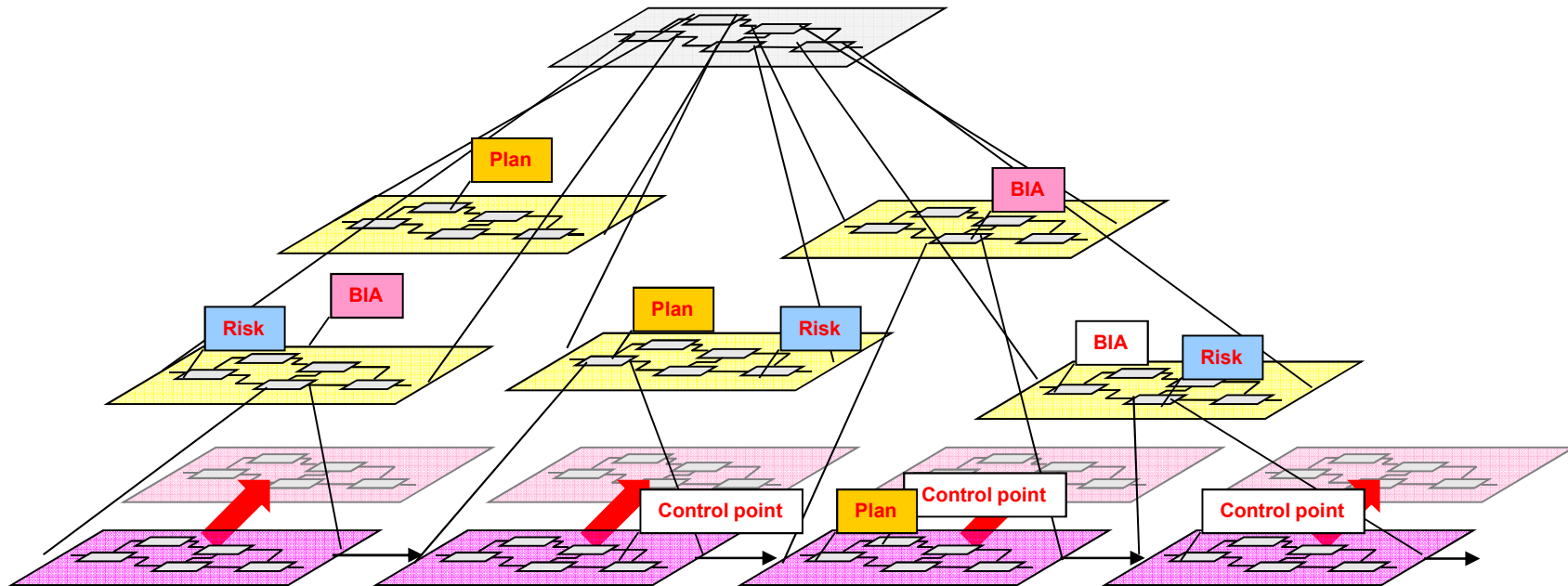


An Integrated Process Framework: The challenge



Regulatory Affairs, Risk Management, Compliance Management, Quality Management
Internal Audit, External Audit, Customers, Suppliers, Operational Management

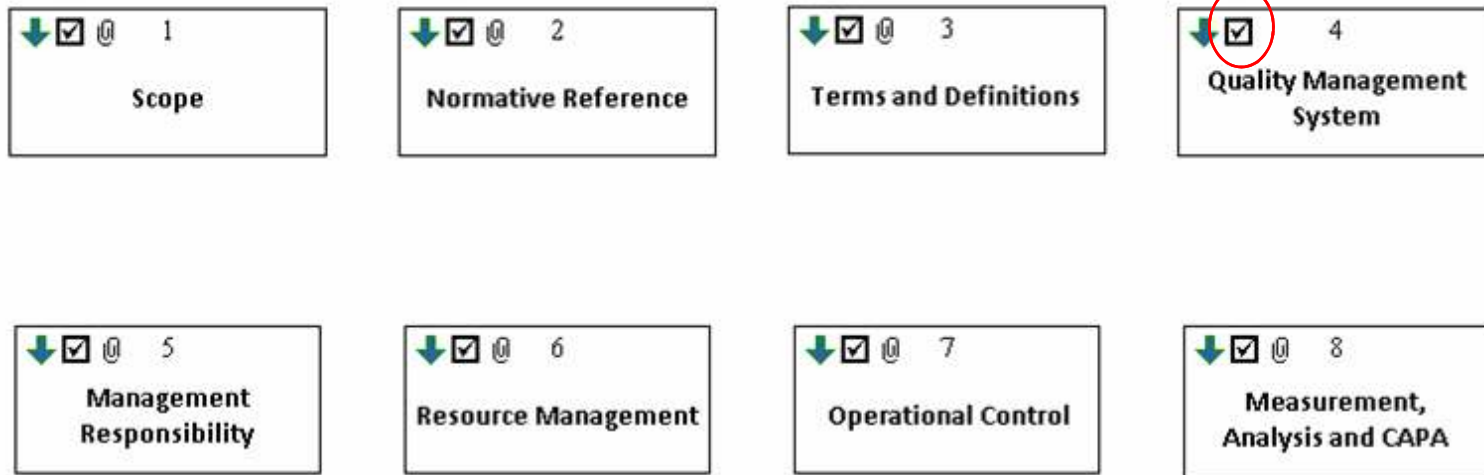
A Common Process Framework: Quality, Compliance and Operational Risk



The requirements...

- One, integrated set of managed data for Operations, Quality, Compliance and Risk:
 - Quality and Compliance Statements (multiple if required)
 - Linked to control points on process maps
 - Process artefacts (Policies, Guidelines, Standards, Docs, SOPs, Storyboards for training, etc)
 - RACI
 - Measures, Control Points
 - Enterprise-wide CAPA
 - Integration with other systems e.g. Intranet, SharePoint etc.
 - Capable of compliance to security standards e.g. FDA 21 CFR part 11
 - Audit/Assurance schedules and outcomes
 - Personalised view of process maps, actions, measures, risks
 - Full change control, version management and workflow

Example: Integrated Management System



Compliance Statement section 4.0 Gen Reqmnts

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Statement Link Details

Statement Link

Statement Set Name:	ISO 9001
Title:	4.1. General requirements
Description:	<p>The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.</p> <p>The organization shall</p> <ul style="list-style-type: none">a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),b) determine the sequence and interaction of these processes,c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,e) monitor, measure and analyse these processes, andf) implement actions necessary to achieve planned results and continual improvement of these processes. <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard.</p> <p>Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.</p> <p>NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.</p>

Linked Activity

 torque management

Company Response to ISO requirement

COMPANY NAME		
Quality Manual	4.0 GENERAL REQUIREMENTS	

4.0 QUALITY MANAGEMENT SYSTEM

The quality assurance system operated by the company is based upon the requirements of ISO 9001:2000. This addresses the following aspects: pre-qualification, Tendering, Purchasing, Operations Health and Safety, Quality Management, Finance and Management Control, Client Management.

Company response to ISO requirement

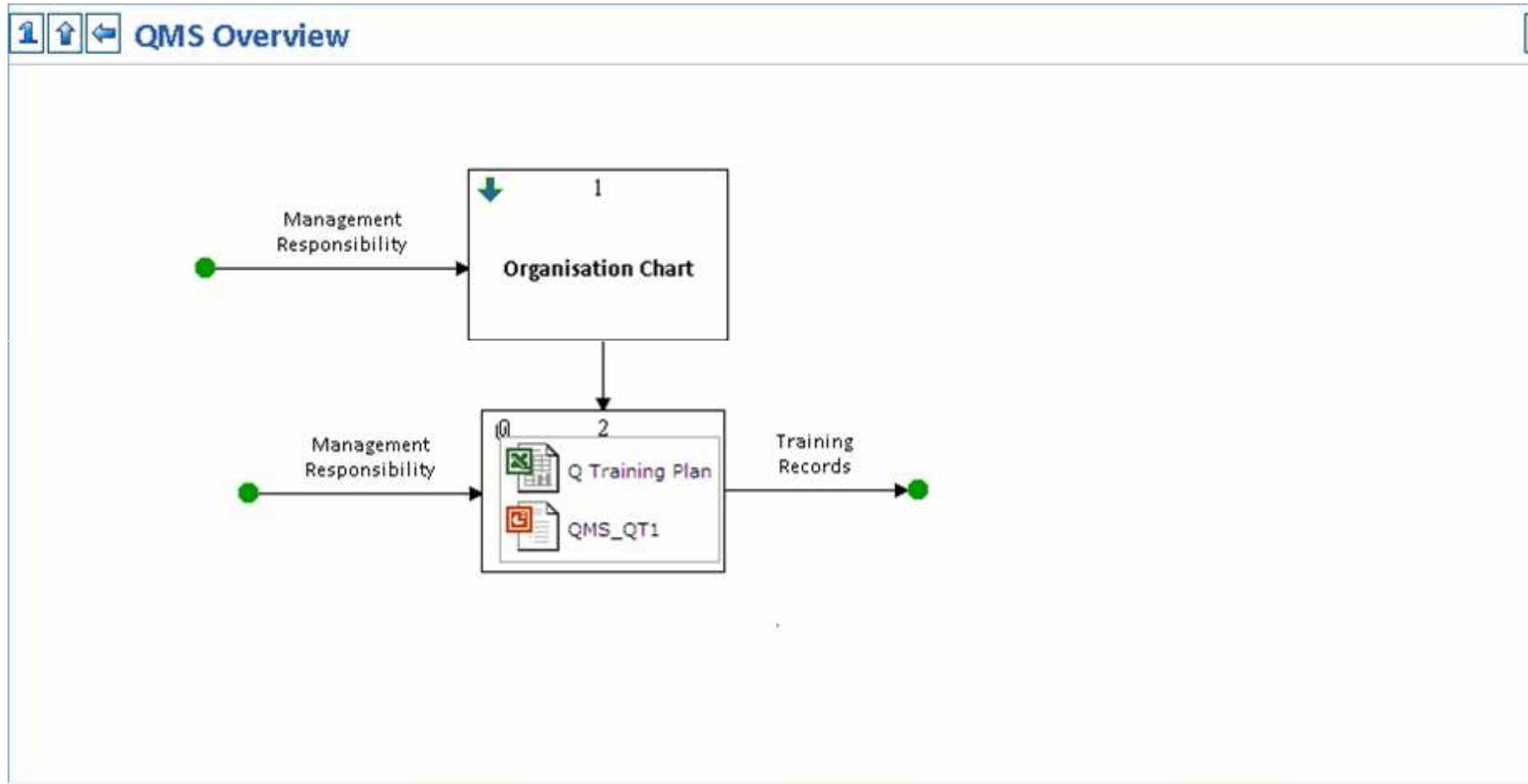
Note – same numbering system as ISO standard for ease of navigation

4.1 GENERAL REQUIREMENTS

Processes are in place that

- Identify the quality management processes and their application throughout the organization.

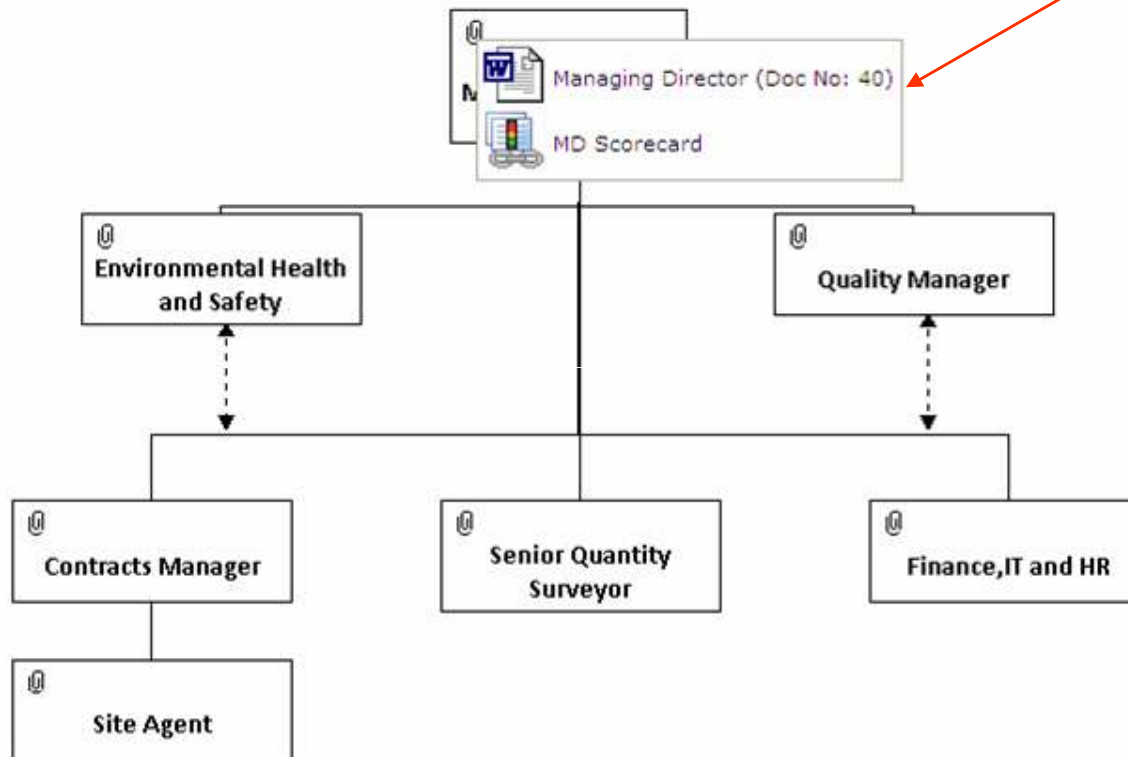
Organisation Chart, Training plan(s), Training Materials



Individual Job Spec and Job Scorecard

Organisation Chart

Job Spec & scorecard per role

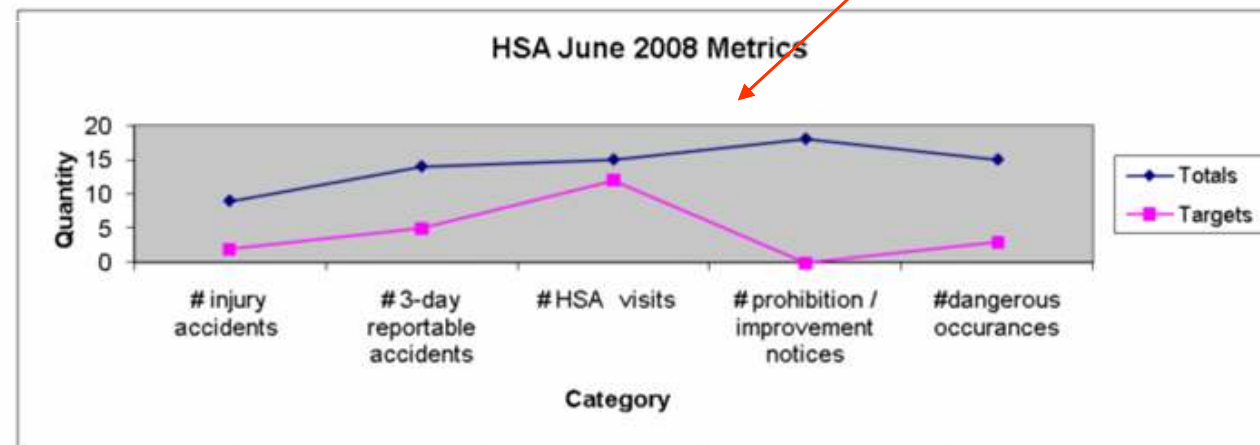


Example: Q, C, and Risk Measures

Scorecard: Health&Safety

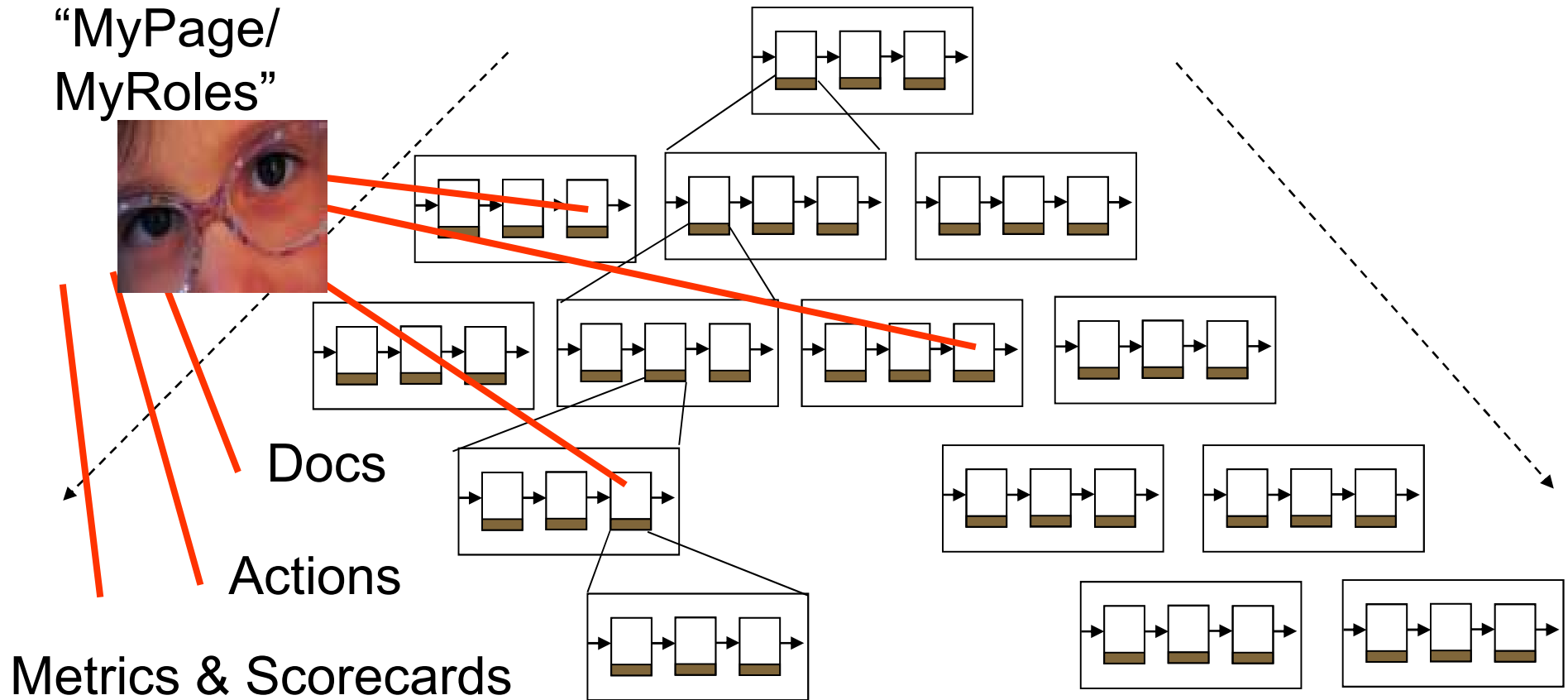
Owner: Dee Carri(Deleted)
Description:

Sample Quality and Compliance measures (fictitious)




« < > » Sheet1 Sheet2 Sheet3

Personalised View



Key Benefits

- One System, one set of data
- Easy to assess and integrate new requirements
- Easy to identify and manage risks
-  “Don’t mess with me button” protects control points / compliance steps from enthusiastic improvement specialists
- The Quality Management System documentation becomes dynamic – no longer “shelf ware”
- Removal of waste – parallel management systems eliminated
- Personalised view improves performance
- Storyboards greatly improves speed and adoption of new processes

Case Study: Lockheed Martin



Revenue \$31.9 Billion

Backlog \$76.9 Billion

R&D \$1 Billion

125,000 employees world-wide

Lockheed Martin : Issues

- Core process defined by US in 200 page MSWord document
- Called IEP (Integrated Engineering Process)
- Stored on intranet with supporting documents
- Not related to performance metrics or measures



Lockheed Martin: results

- \$21M in operational savings registered year to date
- Average days to close corrective actions reduced by 75%
- Operational metrics tied directly to process
- Greatly improved employee ownership of processes

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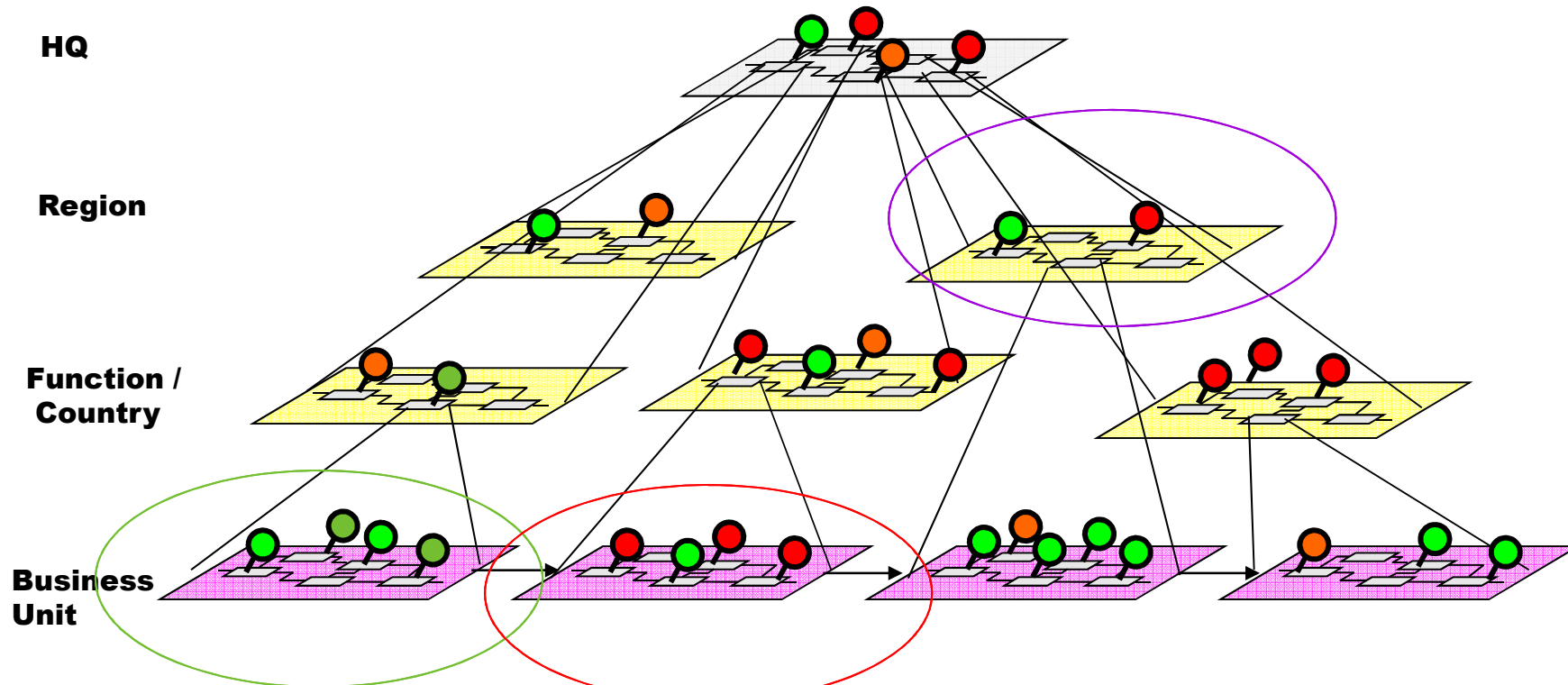
The Network effect

“Standards are characterized by a snowball effect: the greater the number of people using them, the more valuable they become, and therefore the greater the number of people motivated to use them.”

Blown to Bit – The Economics of Information

By Philip Evans, Thomas S. Wurster

Standardised Processes



- Easy to identify biggest overall risk
- Easy to identify deviation from the standard
- Easy to identify share best practices
- Enables early detection and notification of new risks
- New business start up can identify and adopt best available practice - lower risk

Case Studies



Strategy to reduce complexity, lower risk and increase efficiency - standardising a number of process in >30,000 business in a five year journey



SAP & Siebel rollout 36 - >18months
Quote process 14 days ->10 mins
... And SOX as a by product



Lean Operations Strategic Programme across Europe
....And White Collar productivity savings

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Outsource Reality: Most Organisations Outsource

- Outsourcing is inherently risky and can result in a loss of Intellectual capital, skill and know-how, and cause compliance exposures
- Documented processes provide a degree of protection against risks, ambiguity, gaps, overlaps
- Capture your processes prior to, and during, outsourcing, to protect your position
- **Embed processes in contract to manage risks associated with change and service levels**

Standards

- Many SPs (Service Providers), many standards. All know that theirs is best!
- Adherence to industry standards will provide a common vocabulary and reference point
- Embed *your* standards, *your* processes, *your* GQRC requirements and measures in the contract
- Document the process steps where standards apply
- Share the information with the SPs and collaborate for improvement

Life Sciences: Special considerations

- GxP training record required for all associated with service delivery
- SOP training required for GxP services
- Challenges:
 - Initial training
 - On-going management as personnel changes
 - Management and custodianship of training records
 - SOP change control management – “read, understood, accepted”

Critical Success Factors for Relationship Management

- Strategic Control
- End-to-end visibility
- Transparency and Accountability
- Governance, Risk, Quality and Compliance
- Customer Satisfaction / Performance Management

Example: Outsource Relationship Governance

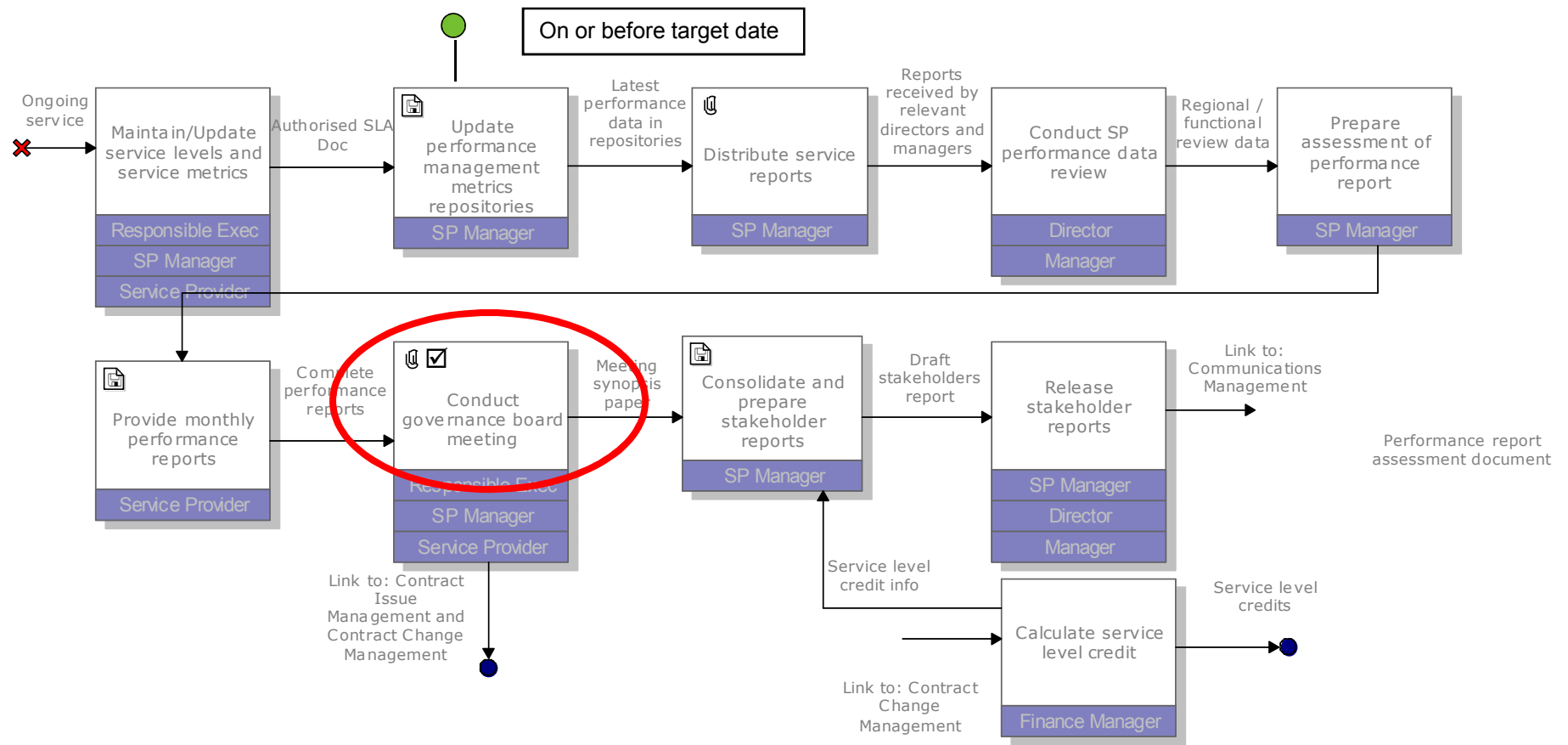


All our suppliers are required to comply with clearly defined control processes and procedures. Here you will find process descriptions and support information that describe all aspects of our governance model for our suppliers.

Governance Model by Supplier

Service Quality & Performance Management	Change Management	Contract & Compliance Management	Financial Management	Relationship Management
↓ @ Service Performance Management	Service Change Management	Contract Management	↓ @ Invoice Verification and Payments Management	↓ Stakeholder Communications Management
Service Level Management	↓ Project Initiation and Authorisation	↓ @ Contract Change Management	Service Cost Allocation Management	Stakeholder Relationship Management
Stakeholder Satisfaction Management	Program Management	@ External Compliance Management	Financial Benefits and Realisation Management	↓ Continuous Improvement & Innovation Management
Service Knowledge Management	Demand and Consumption Management	Internal Compliance Management	Financial Performance Reporting	Service Provider Relationship Management
↓ @ Issue Management	General Risk Management	Market Analysis and Benchmarking	Asset Management	

Service Performance Management



Governance



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Service Level Management	↓ Project Initiation and Authorisation	↓ @ Contract Change Management	Service Cost Allocation Management	Stakeholder Relationship Management
Stakeholder Satisfaction Management	Program Management	@ External Compliance Management	Financial Benefits and Realisation Management	↓ Continuous Improvement & Innovation Management
Service Knowledge Management	Demand and Consumption Management	Internal Compliance Management	Financial Performance Reporting	Service Provider Relationship Management
↓ @ Issue Management	General Risk Management	Market Analysis and Benchmarking	Asset Management	

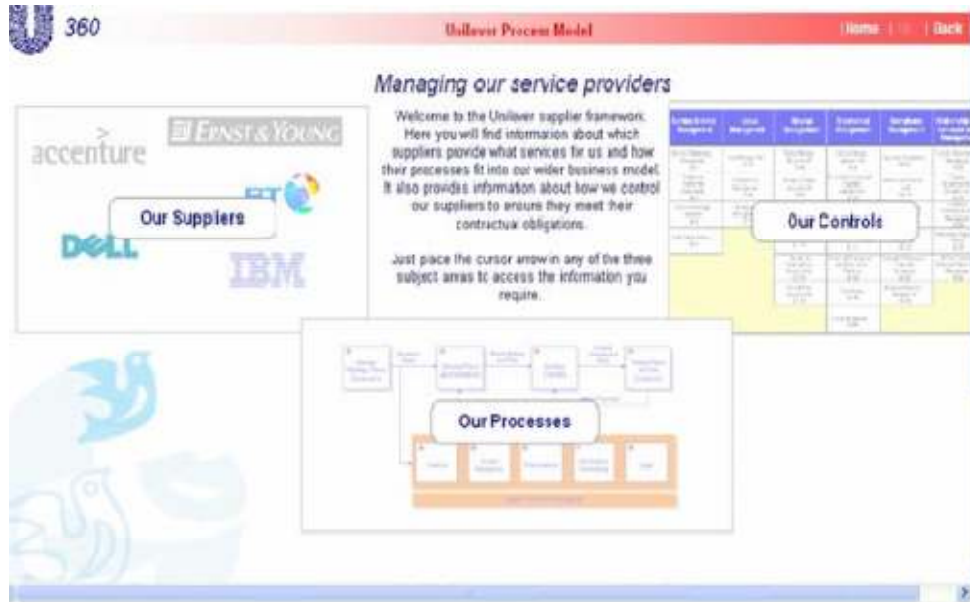
Drill Down to Attachments



Conclusions

- It is possible to outsource, maintain control and minimise risk, even in a multi-source environment
 - Map processes, performance criteria, Business Rules, Standards, Targets and Performance
 - Link processes to overall contract governance & document (SOPs) repository
 - Share process maps with SPs – only what they need to see
 - Rigidly manage the change control process

Case Study



- Global Implementations
 - Finance - 3 regional deals
 - NPI - 3 regional deals
 - IT - 3 major global deals

- Unilever 360 is a repository for all documentation associated with outsource contracts.
 - Processes and Work instructions
 - Training Material
 - Metrics
 - Audit Plans
 - Compliance Materials



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Summary

- Process maps are an important business asset that can be leveraged in many novel ways
- Leading organisations 'get this' and they use their process maps as enhanced integrated process management tools to integrate the critical functions of operational management, Risk Management and Quality / Compliance management. *They also have better business outcomes*
- There is no need for separate quality, compliance, risk and operational management systems,
- Scalable approach – from discreet project to enterprise level
- Benefits:
 - Transparency and accountability are enhanced
 - Risk are managed and reduced
 - Waste of duplicate systems is removed

About Dee Carri

- **Founder and Director, Torque Management Ltd**

- MSC Strategic Quality Systems: Lean/Sigma; Six Sigma MBB; Lean BB; Cert. In training and continuing education. BPTrends Associates accredited trainer
- Founded TM to pursue interest in quality and performance

- **Positions Held**

- CIO Elan Corporation plc. Member of Board Elan Pharma
- Consulting Director, Gartner UK
- eBusiness Director, PA Consulting Group

- **Strong Industry and policy links**

- Irish and European Telecommunications
- Irish Government Information Society Commission
- Women in Science and Technology
- Drug Information Association

Torquemanagement



Further information and contact details

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