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UNITING THE WORLD OF
SERVICE MANAGEMENT
09

**Implementing Change
Management in a Regulated
Environment: A Case Study**

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Session 237

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Testing and Transition Services Manager
Global Information Services (GIS)
Vertex Pharmaceuticals Incorporated

- The group's focus is to collaborate with GIS, Quality, and Business Partners to ensure services/service changes :
 - Meet requirements and defined standards for compliance
 - Are integrated into the GIS operating environment
 - Can be operated and managed throughout the life of the service
- Worked in technology focused areas for 10+ years
- ITIL v2 Service Manager certified



Valerie Arraj, Managing Director Compliance Process Partners, LLC

- CPP
 - IT compliance-focused consulting and training company
 - Uses service management good practice and control objectives with focus on:
 - Compliance to regulatory and governance guidelines
 - Efficient and effective IT process and automation.
- Assisting companies for 8 years with ITIL-based consulting and training
- ITIL Expert, ISO 20000 Certified Consultant



Content

- Background – Why we started this journey and the steps we took to get there
- Overview of the Process
- Benefits to Date – What’s worked well
- Lessons Learned – What we learned and need to improve on

Background – Vertex Pharmaceuticals

- Global biotechnology company
- Product pipeline focused on viral diseases, inflammation, autoimmune diseases, cancer, pain and cystic fibrosis
- Several drugs various stages of development
 - Telepravir, Phase 3 Clinical Trials
 - 8 Other Drugs in the pipeline
- Must adhere to multiple regulatory requirements
 - 21 CFR Part 11
 - Sarbanes Oxley
- Vertex is 20 years old moving towards commercialization

Why Vertex Chose ITIL

Vertex Goals



ITSM/ITIL Benefits

Transition to commercialization

Support rapidly expanding population

- Scalable systems
- Investment aligned with value (TCO)
- Compliance baked in
- Scalable processes

Support distributed operations with:

- Standards driven application/infrastructure management
- Utilize industry best practices

• Work as part of a virtual team

- Functional Experts
- Outside service providers
- Partners and suppliers

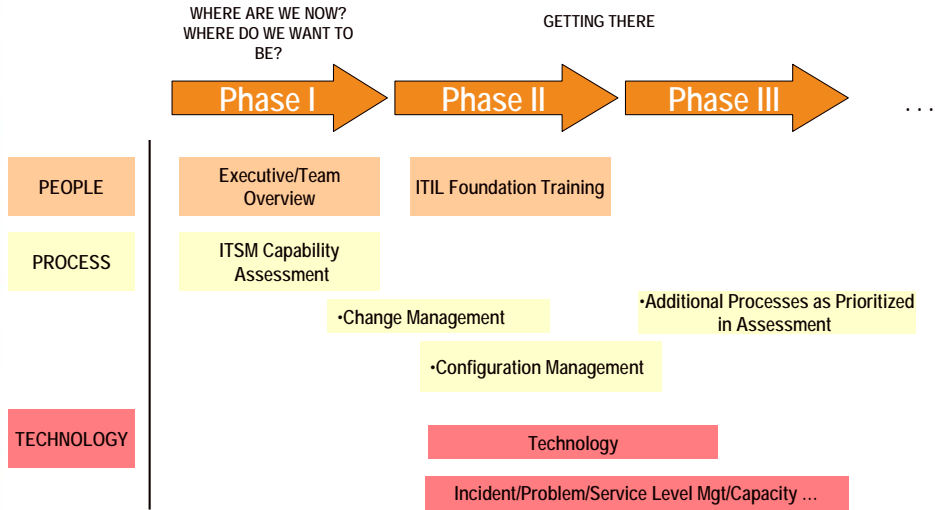
- Aligns business with technology
- Promotes effective use of technology
- Improves the quality and reliability of IT services offered
- Optimizes IT resource utilization
- Facilitates adherence to regulatory requirements
- Provides well-defined processes that support business scalability

- ISO Standard for IT Service Management based upon ITIL – a proven cross-industry good practice approach.

- Pharma Adoption: *Eli Lilly, Pfizer, Genzyme, Biogen Idec, Millennium, Sepracor, Cubist, Alkermes, Synta Pharmaceuticals*

- Cross functional processes foster teamwork.
- Standards-based process assure consistency within and outside of the immediate IS organization

Approach

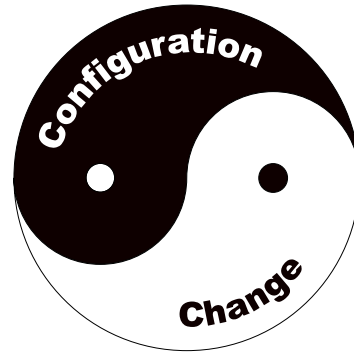


Change Management as a First Step

- Improve Consistent Operational Management and Efficiency
- Minimize Risk –Risk-Based Process
 - Reduce compliance deviations
 - Balancing “Slowing things down” versus deploying changes that don’t destabilize service operation
- Eliminate the distinction between “Regulated” and “Non-Regulated” services
 - Initial state included:
 - Regulated Change Management
 - SOX-driven Change Management
 - Informal Change Management
 - No Change Management
- Move From Paper Process to Automated Process

Configuration and Change Management

- The automation journey must address these two
- Central to everything
 - Every decision needs configuration information
 - Every decision results in a configuration change
- Implement:
 - a CMDB (CMS)
 - Strict change management



**... to ensure accurate decisions
(manual or automated)**

Taking this One Step Further....

- The CMDB can:
 - Assist in change categorization
 - Identify assessors and reviewers (CAB)
 - Guide workflow steps

Approach for Change & Configuration Management

- Agree on:
 - Change Definition
 - Scope
 - Change Models
 - Standard
 - Predefined
 - Normal
 - Emergency
 - Approvers
 - Level of detail for Configuration Items
 - Decide on Service Types (Business vs Technical)
 - Modeling techniques (accommodating virtualization)
 - RACI matrix
- Workshops with cross-functional stakeholder teams
 - Steering committee for guidelines and arbitration
 - Use case walkthroughs and prototyping

What is a change?

•For example...is a break/fix activity a change or is it just documented in the incident ticket? If so, under what circumstances?

What environments are managed under change?

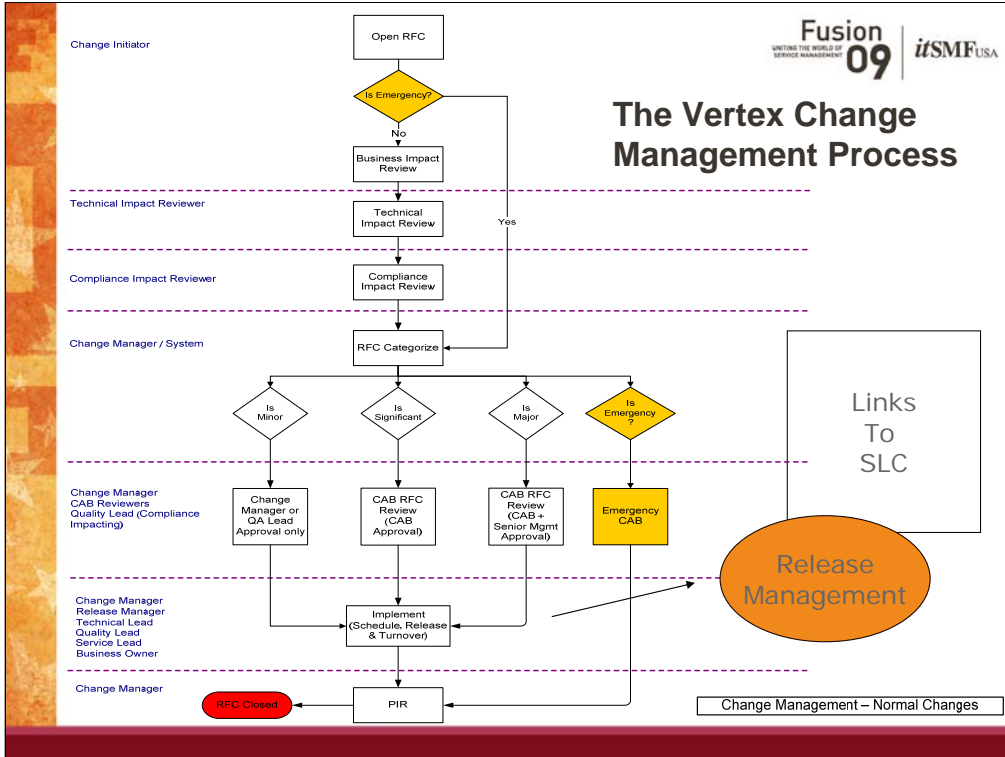
Standard, Normal, Emergency?

•Does an emergency include “high business urgency” changes?

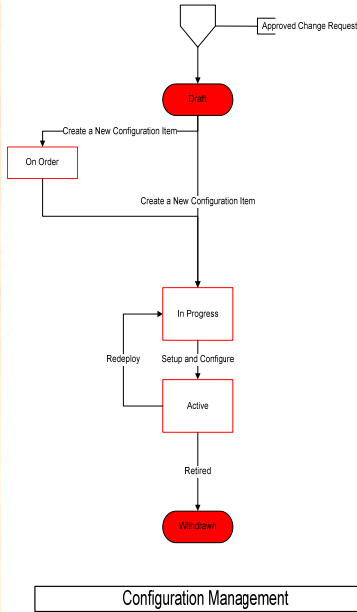
Change Models






Model	Category	Description/Characteristics	Approval
Standard		<ul style="list-style-type: none"> • Work which is part of routine, recurring maintenance and/or support; changes under applicable procedures. <ul style="list-style-type: none"> – Well understood; does not alter baseline business requirements/functionality of primary or related service(s) – Risk is well understood – May include repair (break/fix) activities or like-for-like swaps 	<ul style="list-style-type: none"> • Pre-Approved
Predefined		<ul style="list-style-type: none"> • Part of routine, common support changes under applicable procedures. <ul style="list-style-type: none"> – Well understood; does not alter baseline business requirements/functionality of primary or related service(s) – Follows a predefined set of steps in association with a procedure or work instruction 	<ul style="list-style-type: none"> • Requires approval from a specified individual(s) or role(s)
Normal Changes susceptible to some level of risk and that require assessment and approval	Minor	<ul style="list-style-type: none"> • Changes of additions to configurable elements without significantly altering the business requirements • Little or no impact to the validated state of the computerized system or software • Require very few resources and minimal time to complete • Risk of change to Service is generally assessed as low. 	<ul style="list-style-type: none"> • Change Manager (non-compliance impacting) • <i>Quality Lead (Compliance Impacting)</i>
	Significant	<ul style="list-style-type: none"> • Changes considerably alter a system's requirements or creating a considerable amount of new functionality or capability • A sizeable number or resources and amount of time are required to implement 	<ul style="list-style-type: none"> • Change Advisory Board (CAB)
	Major	<ul style="list-style-type: none"> • Changes will alter system requirements and create substantial new functionality or capability • Large number of resources and substantial amount of time required. • Substantial estimated cost to the organization, often large, capitalized projects 	<ul style="list-style-type: none"> • CAB and Senior Management
Emergency		<ul style="list-style-type: none"> • Unplanned changes requiring immediate action. <ul style="list-style-type: none"> – To restore a service or protect electronic records/data, product or IT hardware. – Urgent business needs such as modification necessary to meet an immediate regulatory requirement. 	<ul style="list-style-type: none"> • Emergency CAB (ECAB)

The Vertex Change Management Process



Moving a CI Through the Workflow



- **Draft:** 
 - Indicates CI has been entered.
- **On Order (Optional State):** 
 - CIs that are purchased.
- **In Progress:** 
 - CIs that are being set up & prepared for use in target environment (validation or production).
- **Active:** 
 - Represents CIs placed in target environment and are in production (live).
 - **Redeploying:**
 - Represents CIs being reconfigured for a new purpose.
 - Move CI from Active to “In Progress” state.
- **Withdrawn:** 
 - Represents CIs that are decommissioned or in retirement.

Configuration Item Types & Attributes: The Drivers to Change

Hardware Attributes

- Hardware Description
- Hardware Type
- Server Use
- Server SubType
- Network Subtype
- Storage Subtype
- Power Device Subtype
- Service Tag
- Asset Tag
- Manufacturer/Model
- OS
- IP Address(es)
- Hostname(s)
- # Processors
- # Cores
- # of Network Ports
- Memory
- Location
- Rack
- Other
- Administrator Primary
- Administrator Alternate

Software Attributes

- Software Description
- Software Type
- Manufacturer
- Version
- Build
- Number Of Licenses
- Notes
- Software Admin Primary
- Software Admin Alternate

Common Attributes

- CI Id
- CI Name
- Created Date
- Description
- CI Status
- Item Type
- Deployment

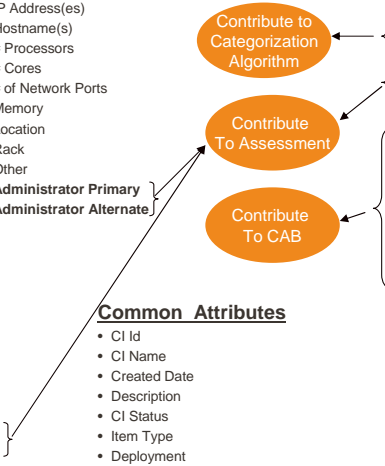
Service Attributes

- Service Description
- SLA Type
- Compliance Implications - None/GxP/SOX/HIPAA/Other
- Service Criticality
- Service Provider
- Service Consumer
- SLA Status
- Service Tech Lead Primary
- Service Tech Lead Alternate
- Service Business Owner
- Service Business Owner - Alternate
- Service IS Owner
- Service IS Owner - Alternate
- Service Business Admin Primary
- Service Business Admin Alternate
- Additional CAB Reviewers
- Additional Watchers

Contribute to Categorization Algorithm

Contribute To Assessment

Contribute To CAB



Configuration Management Roles / Contacts

Role	Description
Business Owners	Primary and alternate named to approve implementation of/changes to Service CIs
Business Lead	Primary business interface to IS for daily activities.
Service Owner	The IT Owner of the Service (Product Manager)
Service Lead	IS Business relationship manager
Technical Lead(s)	Primary and alternate individuals with technical responsibility for the service or underlying configuration item
Additional CAB Reviewers	Additional individuals to include in CAB vote for changes related to this service
Additional Watchers	Individuals notified of changes related to service
Implementers	Individuals assigned to a pre-defined change related to service

Assessing Risk

- The 3 dimensions of risk: Criticality, Complexity & Compliance
 - Criticality = Business impact
 - Complexity = Technical impact
 - Compliance = Compliance to Regulation & Internal Standards
- Applies to both New Services & Changes
- Service risk is pre-determined and populated into the CMDB
- Change risk is determined by Change Initiator and assessors

Categorization Algorithm

	A	B	C	D	E	F	G	H	I	J
1	Normal Change Categorization									
2										
3										
4	Category	Field	Choose the Appropriate Value From Dropdown		Category	Total Score	Factors		Fields	High Score
5	Business Assessment Values				Risk	40		Business Risk		13.3
6	Risk	Business Risk	Change will considerably alter system requirements, security/data integrity or create significant new functionality or capability	13.3				Technical Type		6.7
7	Cost	Business Cost	<\$25K	0.8				Technical Complexity		6.7
8	Value	Business Value	Sustaining operations	10.0	Criticality	30		Compliance Risk		13.3
9	Priority	Business Priority	Aligning to corporate/IT strategy					Service Criticality		30
10	Technical Assessment Values				Cost	10		Business Cost		3.3
11	Risk	Technical Type	New Service	6.7				Technical Time		1.7
12	Risk	Technical Complexity	External Facing	6.7				Technical Cost		1.7
13	Cost	Technical Time	<= 10 days	0.4				Compliance Time		1.7
14	Cost	Technical Cost	<\$25K	0.4				Compliance Cost		1.7
15					Value	10		Business Value		10
16					Priority	10				10
17	Compliance Assessment Values				SUM	100				100.0
18										
19	Risk	Compliance Risk	Change will considerably alter system requirements, security/data integrity or create significant new functionality or capability	13.3						
20	Cost	Compliance Time	>45 days	1.7						
21	Cost	Compliance Cost	<\$25K	0.4						
22										
23	Service Criticality									
24										
25	Risk	Service Criticality	High	30.0						
26										
27	TOTAL SCORE			84						
28										
29	Category			MAJOR						
30										
31										
32										
33	Category Legend									
34										
35										
36										
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43										

Spreadsheet Instructions

To use this spreadsheet choose a value from Column C, which is a drop down list box containing valid values for each field. By manipulating these values you will be able to see what type of a total score/category a given change will have and can run various scenarios through the model.

To change the scoring algorithm fields in BLUE in the column "Category" above may be modified in order to do "what-if" analysis against the scoring method. All other numbers and values in this spreadsheet are calculated. Please note that if you change the values you should do so such that the SUM at the bottom should always equal 100.

The Column Labeled "Choose the Appropriate Value from the Dropdown" derives its data from Sheet2. Do not manipulate anything in sheet 2 unless you want modify the text values of the of the dropdown.

Value Added

Configuration Management Metrics:

- Services
 - Business or Infrastructure
 - Impact of Change to underlying CI
 - Regulatory implications guidelines (GxP, HIPAA, SOX, etc)
 - Location
 - Subscribers
 - Consumers
- Servers
 - Physical or virtual
 - Application installed
 - Connections
- Contracts
 - For Service or any underlying CI
 - Expired or expiring contracts
 - Contracts by contract type (outsourcing, support or maintenance)
 - Software licenses
- People/Contacts
 - Primary and secondary support person for hardware or software
 - Business Owner of a given service
 - IS Owner of a given service

Change Management Metrics:

- Number of changes by device, service, application
- Date of changes by device, service, application, database
- Number of changes successful
- Number of changes needing to be backed out
- Change schedule
- Changes that have some regulatory/compliance impact (need QA involvement)
- Changes that have no regulatory/compliance impact (no QA involvement necessary).
- Number of changes by category
- Changes by requestor
- Changes that have been approved
- Changes that have been rejected
- Average time to approve a change
- Average time to approve a change by approver
- Average time to close a change by type of change

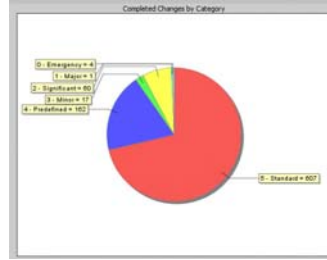
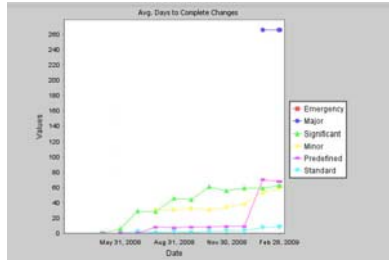
Benefits to Date

- In 2008 ~110 changes captured on paper (GxP services only) to 1500 as of 30 June of this year
- Deviations related to Change Control documentation issues eliminated
- Repository of system information that can be integrated for other processes and services

Benefits to Date

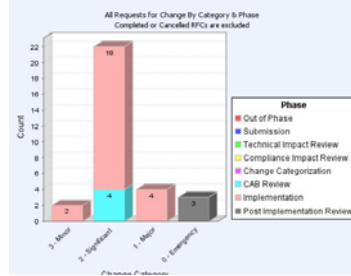
- More efficient and compliant process
 - Integration with CMDB provides enhanced visibility into the impact and risk of changes to focus work
 - Integration of Quality into process from beginning reduces rework and ensures that GxP services are maintained in a Validated state
- Forward Schedule of Changes
- All things automated
 - Trending
 - Reporting
 - Tracking
 - Personalized & Departmental Dashboards

Benefits to Date – Metrics Dashboard



All Completed Changes by Category by Month Trend Table

Date	Emergency	Major	Significant	Minor	Predefined	Standard	Total
Mar 2, 2008							0
Mar 31, 2008							0
Apr 30, 2008	0	0	1	0	41	182	224
May 31, 2008	0	0	2	0	43	206	251
Jun 30, 2008	0	0	6	0	45	228	279
Jul 31, 2008	0	0	17	1	53	310	381
Aug 31, 2008	1	0	27	1	59	390	438
Sep 30, 2008	1	0	33	3	63	398	498
Oct 31, 2008	1	0	50	5	67	440	563
Nov 30, 2008	1	0	60	11	88	492	652
Dec 31, 2008	2	0	65	14	91	519	691
Jan 31, 2009	2	1	109	21	127	578	838
Feb 28, 2009	5	1	114	24	160	656	960
Mar 2, 2009	5	1	114	24	160	659	963



Lessons Learned - CMDB

- Don't underestimate level of effort to maintain the repository
 - Integration with HR systems is vital in order to keep information up to date with organizational changes
 - Auto discovery tools are necessary for fast adoption and to keep the CMDB up to date and accurate
- Visualization is key!
 - Self-service auditing of CIs is difficult to do without visual cues for dependencies

CMDB

Need to distinguish changes to service versus changes to data regarding the service in the CMDB

Lessons Learned

- Successful implementation means more work
 - Plan to reevaluate resources and process to maintain proper efficiency & support
 - You may need to start with “Process Shepherds” but it is not scalable over time
- Include business customers during process definition and rollout
 - Individuals need to buy-in and understand the responsibilities associated with their role in the process

Lessons Learned

- Have a robust training and communications plan
 - Transparency to the process across the organization is key to keeping the organization engaged and on track
 - Training on Foundations and process needs to continue beyond initial implementation to keep everyone speaking the same language

Lessons Learned

- Integrate with Portfolio Management Office (PMO)
 - Coordination between Change Manager and PMO is needed to ensure proper scheduling & resources, RFCs need to be balanced with project portfolio support
 - Clear guidance must be provided to help teams tailor their work based on change categorization (one size does not fill all)

Final Comments

- ITIL implementations can meet compliance and efficiency requirements
- Configuration Management provides the platform for a robust Change Management process
- When implementing remember:
 - There will always be change
 - Organizational
 - Regulations
 - When in doubt, leave things flexible
 - Don't legislate behavior
 - Leave room for process to mature and related processes to be developed (e.g. Release Management, System Life Cycle)
 - Make sure any tool selected can grow and mature with the process

Thank you

- Implementing Change Management in a Regulated Environment: A Case Study
- Session 237

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