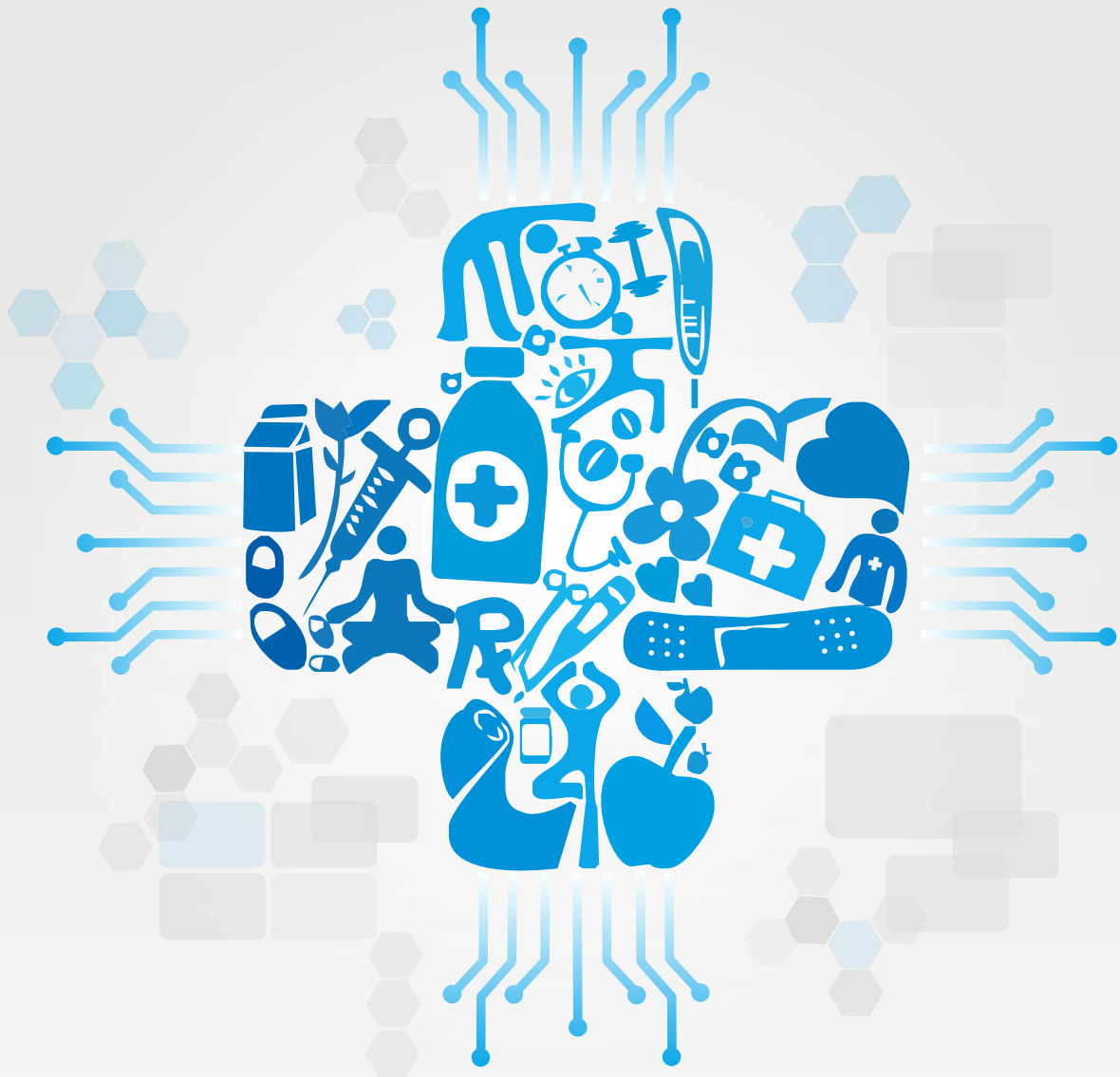


FEASIBILITY OF ITIL ON CLOUD IN EMERGING PHARMA IT LANDSCAPE



The current Application Management landscape

Application support and maintenance account for approximately three-fourths of the overall cost involved in SDLC. This provides IT service providers an enormous opportunity to deliver value added benefits, lower total cost of ownership and demonstrate greater return on investment, thereby adding to bottom lines. Today's enterprises are adopting transformational ideas and solutions that can bring higher efficiency to SDLC management. The IT support in pharma and life sciences industry is no exception. The regulatory nature of 'Application Support and Maintenance' makes this service all the more challenging. Combined with the industry trend of moving service delivery towards Cloud and Virtualization, the pharma and life sciences industry is witnessing tectonic change in technology – one that can empower it to efficiently deliver breakthroughs in clinical development at lowered costs.

Overview of Service Management framework

Service Management, or the routine management of operational activities, support and maintenance against specific SLAs by either internal or external service providers, is based on a variety of frameworks. The IT industry has popularized the concepts of Six Sigma, COBIT, ISO, ITIL etc, which have become widely accepted approaches to Service Management. Over the last two decades, ITIL has synthesized ideas drawn from different business and operational models, helping IT executives answer questions such as, "What services should be offered? To whom? How do we ensure continuous alignment between IT and business? How can we reduce IT service maintenance costs? How can we standardize services? Which IT services deliver the best value? How can we improve customer satisfaction? How can

ITIL has become the most popular and the most widely adopted Service Management framework because it addresses an entire gamut of services required for IT related service delivery. Although adoption has flattened marginally this year, major IT organizations continue to embrace ITIL, endorsing its efficacy. Research firm Computer Economics released a study in August 2011 that said 39% of organizations were utilizing ITIL, about the same as the 40% that were embracing ITIL in 2010.

New collaborative technologies and virtualization of services is giving fresh direction to traditional methods of IT service delivery. These are also giving fresh impetus to ITIL in its continued evolution as the world's most widely adopted methodology for Service Management and operational excellence. For the pharma industry ITIL holds special value as the framework is an acknowledged model for regulatory compliance vis-à-vis FDA requirements. Using ITIL in combination with special augmentations, cost-effective FDA-related compliance for approval levels, risk management etc can be enabled. In an increasingly complex risk landscape and growing regulatory scrutiny, ITIL can effectively assist with risk mitigation.

The Information Technology Infrastructure Library (ITIL) is an Information Technology (IT) management framework that provides practices for Information Technology Services Management (ITSM), IT development and IT operations.

Cloud computing and relevance of ITIL for pharma

One of the primary challenges that ITIL faces is related to cloud computing. Can ITIL remain relevant in a flexible cloud environment? As an example, ITIL-approved Change Management is difficult when IT has little or no influence over cloud computing environments. Critics have suggested that cloud violates the policies that control ITIL processes. However, cloud computing in the pharma industry is already being leveraged for new drug development, clinical trials and HIEs as vast amounts of data from next generation sequencing are being stored, analyzed and manipulated in cloud environments. The additional ability to collaborate with teams across geographies while meeting regulatory requirements using cloud is also making the investment in the cloud attractive. Pharma companies that have moved towards cloud are experiencing liberation from their own IT infrastructure to become more agile and responsive to business needs. In such an environment, ITIL needs to get rid of its burdensome processes of seeking "bureaucratic" approvals in complex IT environments and instead focus on increasing the efficiency and benefit delivered by cloud.

We believe that ITIL can continue to deliver benefits as a Service Management tool, regardless of the platform, when two central issues are addressed:

- Controls for strict adherence to governance policies
- Framework for operational management and support plan in place with stringent adherence

The combined benefits of ITIL and cloud computing are not in doubt. The stumbling block for ITIL, before the benefits can be translated into reality, remains some process and technology tweaks. Besides, cloud computing will require additional control mechanisms to ensure smooth service delivery. Neither are insurmountable obstacles.

How does ITIL map to a cloud environment?	
ITIL service category	Applicability to cloud based framework
Documentation and Configuration	Documentation in an ITIL environment is a crucial activity especially where GxP complaint systems are concerned in industries like pharma and life sciences. Cloud based services would provide an ideal platform for configuration requirements where stringent documentation process is mandated. Closely evaluating the strategy generation processes, documentation, and verifying its alignment with the needs of pharma and life sciences is critical.
Incident, Problem, Change Management, and Release Management	A cloud based platform/ service coupled with mobility will move the Level 2 and Level 3 support to a more efficient and prompt service delivery. It would also address some of the gaps in the current service delivery method.
Overall Service Management	Overall Service Management can be tweaked to customer's satisfaction due to the flexibility in SaaS model that can be integrated and coupled with 'Infrastructure As A Service' model.
Information Security and Data Privacy	Information Security and Data Privacy remain a grey area. Customization is required based on local regulations. Nonetheless emerging technologies and processes provide a way where this can be addressed.
Disaster Management	Cloud based platforms provide flexibility for Disaster Recovery
Service Continuity Management	and Business Continuity. There is considerable scope for data archival in alternate locations.

Journey to cloud based application management

A mix of public and private cloud applications and infrastructure is quickly replacing the current cumbersome physical infrastructure owned by an enterprise. The approach for the pharma industry should be to unify on-premise application management with public and private cloud services, to reduce costs and ensure flexible access to high compute resources.

This would entail a plethora of challenges including complex integration as well as data disparity issues due to incongruent systems. The IT service provider will have to plan for a slow and arduous journey if future business and compliance needs have to be met. Web 3.0 systems would be the need of the hour in this cloud based support environment.

The biggest challenge for service providers continues to remain the evolving nature of cloud technology. The answer lies in creating customized solutions that can maximize benefits.

What is required?

Cloud based application management solutions have the dual challenge of meeting the standards of traditional models and providing the added benefit of proactive problem management. The solutions should be able to address issues related to security, real time delivery and short term/ long term cost benefits for:

- Private cloud management
- Public cloud management
- HelpDesk Support in a cloud

There are several factors that help as well as hinder application management solutions. The first is the exponential rate of technological change and the emergence of collaborative Web 3.0 technologies that are being tweaked for IT HelpDesk support services. For example the need for security and data privacy is paramount now a days. Web 3.0 technology enables enhanced security features which can be used for critical help desk support services especially in the context of Pharma environment. Also the recent growth in mobile adoption and mobile-based solutions is adding a new dimension to the evolution of IT management and support. Web 3.0 can be leveraged on mobile devices to enable state of art and instant help desk services. Innovations around mobile technologies are delivering anytime, anywhere and can be leveraged for 24*7 kind of support environment.

Emergence of Web 3.0

Web 2.0 technologies facilitate the intelligent collection and analysis of data. They also allow data sharing and collaboration through various platforms. Users can interact in real time using blogs, wikis, networking sites like Google+, Facebook etc that are all driven by Web 2.0.

There is however a shift to Web 3.0 which is a step ahead of Web 2.0 as an intelligent system that analyzes the available information and makes intelligent deductions.

Web 3.0 integrates different systems including software and infrastructure and is able to derive artificial intelligence out of the collaboration. Information flow is easy, real time and actionable data is extracted quickly. The future service desk and support using Web 3.0 technologies hold the promise of delivering far superior outcomes. A check on the major differences and features of Web 2.0 and Web 3.0 makes this apparent:

Features	Web 2.0	Web 3.0
Visibility	Widely read and accessed, billion+ global users	Individualized, personalized web
Content privacy and security	Sharing content	Semantic web
Technology/ Tools	Web applications	iGoogle, NetVibes
Usage	Interactive	Individual

Managed services is the practice of transferring day-to-day related management responsibility as a strategic method for improved effective and efficient operations inclusive of production support and lifecycle build/maintenance activities.

For ITIL services, the overall objective should be to focus on the requirement of the services. It could be anything, from a simple website to a service which requires complex web applications. Their application operational plan should include application rollout, change management, database management, application monitoring, performance management and optimization and compliance management.

Managed services on cloud

Cloud based solution models are still in an evolutionary phase. Service providers have the scope to explore and experiment with new ideas and delivery methodologies. For example, currently there are no vendors providing managed application services on cloud. The right infrastructure, service strategy, architecture and service design is needed for customized and scalable cloud based service delivery that can be achieved by managed services on cloud.

One of the biggest benefits of the cloud environment in ITIL processes can be leveraged during release and change management. Testing can be done in real time on cloud by replicating the production environment and hence release in production can be quicker. This mitigates risk and lowers cost enormously. A look at the various dimensions of Managed Services is presented below to provide a deeper perspective and appreciation of the potential of Managed Services.

One of the biggest benefits of the cloud environment in ITIL processes can be leveraged during release and change management. Testing can be done in real time on cloud by replicating the production environment and hence release in production can be quicker. This mitigates risk and lowers cost enormously. A look at the various dimensions of Managed Services is presented below to provide a deeper perspective and appreciation of the potential of Managed Services.

How Managed Services stack up		
Challenges	How managed services help	Benefits
High expectations on cost arbitrage	<ul style="list-style-type: none"> - Higher levels of support and availability -Fixed-fee basis with a SLA driven contract 	Predictable cost
High requirements volatility	<ul style="list-style-type: none"> - Complete decision making responsibilities in providing the agreed set of deliverables 	Increased operational agility
Lack of architectural guidelines and unclear engagement models	<ul style="list-style-type: none"> - Clearly marked SLAs for each deliverable and penalties applicable for non-delivery 	End-to-end responsibility of a set of deliverables
Infrastructure issues and lack of flexibility(In a multi-vendor scenario, where one vendor manages applications and the other manages infrastructure, blame games are common)	<ul style="list-style-type: none"> - Service can be performed onshore or offshore or a combination of both - Clearly defined Organization Level Agreements 	Clearly scoped out work with clearly marked out deliverables

The benefits of emerging platforms and technologies

There are several immediate and long-term benefits of the approach discussed thus far:

- Greater operational efficiency in the landscape of emerging technology and flexibility provided by the cloud platform
- Intelligent and advance detection of non-compliance that will be triggered by intelligent technical systems and documentation control
- Real time SLA adherence driven by mobility platforms and converging cloud platform with various facets of media and technology
- Speedy remediation will be the cornerstone of adhering to SLAs facilitated by new platforms and technologies. (Cloud, Mobility and Web 3.0)
- New model can give added tangible and intangible benefits, save cost in terms of compliance and virtual platforms within 2 to 3 years
- New approach would lead to proactive problem management and root cause analysis

The million dollar question: How to ensure success?

The success of adopting cloud computing in application maintenance and support would depend on sound strategy and a phase wise approach. Organizations should first measure the applicability of cloud service in their ITIL framework through a due diligence exercise which should measure the following:

- Is the service mature enough to go on cloud?
- What are the various service frameworks that are eligible to go on cloud?
- What would be the probable operational efficiency achieved?
- What would be the extrapolated cost benefit in next 3 years?
- How would security and scalability issues be addressed?

Adoption of cloud computing has to be designed and created around phase wise service delivery, keeping in mind that the game changers in the future would be emerging technologies like Web 3.0 and mobile computing.

Nevertheless, organizations should use their own priorities while availing ITIL services on cloud. ITIL in itself is a service framework and hence not a 'One Size Fits All' solution. Some thoughts on probable approaches and suggestions provided below can be useful:

Area of implication	Approach
Service strategy and design	An altogether new approach and directive should be in place by
Service delivery	managementbased on the evaluation to decide phase wise approach. Once the serviceportfolio is chartered for movement to cloud, effective tools and models can be selected for execution.
Service and security improvement	Moving to a vendor cloud increases the challenges on security and data privacy requirements. On the other hand it also provides data continuity assurance in case of any disaster, as the model has no location constraints. Automation tools that are validated can be used to ensure enhanced security and data privacy features. Apart from providing enhanced security mechanisms, it would also ensure operational efficiency.

Challenges and ISEC needs in pharma environment

The life sciences industry involves the scientific study of living organisms and their nature of research has a direct impact on human life. The life science R&D process is a long and expensive venture. The product development process follows these basic high level steps:

- Phase 1 – identification of the drug combination, initial testing, and toxicology studies
- Phase 2 – further development, formulation, human testing
- Phase 3 – full-scale double blind clinical trials to test efficacy, submission for FDA approval

The support framework in the IT environment of these companies has to adhere to stringent regulatory norms. An example is the FDA guidelines put forth in the Code for Federal Regulations 21 Part 11 – or CFR 21 Part 11, which defines how systems managing electronic records in life science firms must be validated and verified to ensure that the operation of and the information in these systems can be trusted. Many processes in the pharma value chain e.g. Laboratory

Information Management System, Clinical Trials and Data Management, Drug Manufacturing processes, Supply Chain, Labeling etc are supplemented by an IT support framework that is regulated and needs constant upgrade due to emerging regulations.

Organizations manage the environment separately for the life science applications and with due controls in place. Keeping these factors and long-term benefits in view, the new cloud environment supplemented by upcoming technologies can bring vast benefits in terms of process and compliance adherence, collaboration and production test environments. Cloud computing can improve and speed up this process by reducing IT complexity and cost while allowing life science organizations to focus on the 'what' of the process instead of the 'how'.

10. References

<http://www.computereconomics.com/article.cfm?id=1666>

<http://www.intrasphere.com/category.asp?categoryid=10000859>

<http://www.manageengine.com/news/helpdesk-software-mobile-interface-news.html>

<http://www.zensar.com/software-service/support-maintenance#ixzz1UQ19B67i>

Some inputs and views are based on real time project experience and client interaction

Conclusion

All this is easier said than done. The main challenge lies with the public cloud where security is an area of concern and calls for improvement. The advantage of a private cloud is obvious as the owner has control over all resources (hardware and software).

As of now the public cloud model would not provide an exact requirement fit unless it evolves over time and finds apt solutions. However the private cloud environment could be leveraged to provide life science companies with a short cut to completing overall system validation process and hence regulated ITIL support.

Glossary

SDLC: Software Development and Lifecycle

SLA: Service Level Agreement

COBIT: Control Objectives for Information and Related Technology

ITIL: IT Infrastructure Library

FDA: Food and Drug Administration

HIE: Health Information Exchange

21 CFR: 21 Code of Federal Regulation

OQ: Operational Qualification

IQ: Installation Qualification

PQ: Process Qualification

RCA: Root Cause Analysis

SaaS: Software As A Service model

ISEC: Information Security

About Wipro Technologies

Wipro Technologies, the global IT business of Wipro Limited (NYSE:WIT) is a leading Information Technology, Consulting and Outsourcing company, that delivers solutions to enable its clients do business better. Wipro Technologies delivers winning business outcomes through its deep industry experience and a 360° view of "Business through Technology" – helping clients create successful and adaptive businesses. A company recognised globally for its comprehensive portfolio of services, a practitioner's approach to delivering innovation and an organization wide commitment to sustainability, Wipro Technologies has 120,000 employees and clients across 54 countries. For information visit www.wipro.com or mail info@wipro.com



DO BUSINESS BETTER

WWW.WIPRO.COM

N Y S E : W I T | OVER 131,000 EMPLOYEES | 54 COUNTRIES | CONSULTING | SYSTEM INTEGRATION | OUTSOURCING

WIPRO TECHNOLOGIES, DODDAKANNELLI, SARJAPUR ROAD, BANGALORE - 560 035, INDIA TEL : +91 (80) 2844 0011, FAX : +91 (80) 2844 0256, email : info@wipro.com

© Copyright 2011. Wipro Technologies. All rights reserved. No part of this document may be reproduced, stored in a retrieval system, transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without express written permission from Wipro Technologies. Specifications subject to change without notice. All other trademarks mentioned herein are the property of their respective owners. Specifications subject to change without notice.

IND/TMPL/MAY2011-DEC2011