

# IT Infrastructure Qualification Planning

**IQPC – IT Infrastructure  
Compliance, Security & Risk Management, 16Nov2009**

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# Welcome and Introductions

- Introduction
- A short poll...
  - What's the mix of engineers vs. managers, quality assurance?
  - Has your organization qualified their infrastructure?
  - What did the activity include?
  - What do you hope to get out of this presentation?



“The validated status of GXP applications that are dependent upon underlying IT Infrastructure is compromised if the IT Infrastructure is not maintained in a demonstrable state of control and regulatory compliance.”

*GAMP Good Practice Guide: IT Infrastructure Control and Compliance, ISPE, 2005*

# Overview

- Some Basics
- Typical System Development Lifecycle (SDLC)
- Applicability to Infrastructure Qualification
- What is Infrastructure?
- What is Infrastructure Qualification?
- Why Qualify Your Infrastructure?
- Infrastructure Qualification Planning
- Qualification by Platform (An Approach)
- Maintaining the Qualified State



# Some Basics

- Qualification

- **qualification, installation.** (FDA) Establishing confidence that process equipment and ancillary systems are compliant with appropriate codes and approved design intentions, and that manufacturer's recommendations are suitably considered.
- **qualification, operational.** (FDA) Establishing confidence that process equipment and sub-systems are capable of consistently operating within established limits and tolerances.
- POINT IN TIME

- Validation

- Establishing **documented evidence** which provides a **high degree of assurance** that a specific process [system] will **consistently** produce a product meeting its **predetermined specifications** and **quality** characteristics (FDA)
- FROM CONCEPT TO DECOMMISSION

**GOOD SYSTEM DEVELOPMENT PRACTICE**



# Typical SDLC vs.. Validation Lifecycle

## Waterfall SDLC

Software Concept  
Development

Requirements Analysis

Architectural Design

Detailed Design

Coding and Debugging

System Testing

Implementation

## Validation Methodology

Plan System and Validation  
Approach

Define Requirements

Select a Vendor

Design the System

Construct the System

Integrate and Install the  
System

Qualify the System

Evaluate the System

Governing Process and  
Procedures

# Typical SDLC vs.. Validation Lifecycle

## Waterfall SDLC

Software Concept  
Development

Requirements Analysis

Architectural Design  
Detailed Design

Coding and Debugging  
System Testing

Implementation

## Validation Documentation

*Project and Validation Plan(s)*  
*User Requirements*  
*Risk Analysis*

*Requirements*  
*Specification/Documentation*  
*Traceability Matrix*  
*Vendor Audit*

*Technical Design/Hardware*  
*Specification(s)*  
*Design Review(s)*

*Code Review(s)*  
*System Test Plan(s) and Scripts*

*Installation Verification*  
*Operational Verification*  
*Performance Verification*



# Applicability to Infrastructure Qualification

- Prospective Validation/Qualification
  - Either model, and others, are worthwhile and recommended
- Retrospective Validation/Qualification
  - Less Applicability
  - Requires more customization and ingenuity
    - Infrastructure is already in place, can't pre-define
    - Changes tend to be more frequent and driven by management of the infrastructure
    - Dynamic operational needs.

# So What is Infrastructure Qualification?

- First, what is 'Infrastructure'?
  - Depends on whom you are talking to...
  - Depends on the services offered by IT...
  - *What do you think 'Infrastructure' is?*
  - There's no *absolute* right answer
- Typical to consider 'Infrastructure' analogous to 'Network'
- This idea could result in gaps in your approach, i.e.
  - Database Services
  - Backup and Restore Services
  - Storage Area Networks
  - Security (authentication and authorization)

# Then What is 'Infrastructure'?

## On the Technical Side...

- All of the computer systems with their associated hardware, operating software (other than software applications), and networks used to run the business

## On the Regulated Side...

- An aggregation of platforms and services including their associated processes, procedures and

personnel . *GAMP Good Practice Guide: IT Infrastructure Control and Compliance, ISPE, 2005*

# What is 'Infrastructure'?

- Most will typically include the basics...
  - Network (LAN/WAN)
    - Cabling, Switches, Routers, Firewalls, Protocols, VPNs, etc.
  - Data Center/Computer Rooms
- Must also include...
  - Operating Systems
  - Software Tools
  - Service Management and Associated Procedures
    - Incident Management
    - B&R
    - Security
    - Performance
    - Problem Reporting and Resolution
  - People
  - Governing Processes and Procedures, i.e.
    - Change Control
    - Maintenance, Administration, Support
    - Documentation and Document Management

# What is 'Infrastructure'?

- May include:
  - Servers and Desktops
  - Database Infrastructures
  - Storage Devices (SANs)
  - File Servers
  - SLAs and OLAs
- What else?



# So what is 'Infrastructure Qualification'?

- **Infrastructure Qualification** - Establishing confidence that infrastructure process equipment, ancillary systems and sub-systems are compliant with appropriate codes and approved design intentions, are capable of consistently operating within established limits and tolerances.
- Basically verifying the 'Infrastructure' as scoped from above slides, does what you said it was going to do and will continue to do so.
- Ensuring you include:
  - Documented Evidence
  - High Degree of Assurance
  - Quality Attributes

# Why Qualify the Infrastructure?

- “The validated status of GXP applications that are dependent upon underlying IT Infrastructure is compromised if the IT Infrastructure is not maintained in a demonstrable state of control and regulatory compliance.”
- In theory, an application can not be considered validated unless it sits on a qualified infrastructure
- Ensures you have good control over your baseline configuration and any changes to that baseline.
- Ensures change impact is more accurately assessed prior to implementation
- The business and business applications (regulated and non-regulated) are dependant on the infrastructure and need assurance of it’s stability.
- Ensures a positive cultural shift in understanding regulatory expectations within an IT organization.

## REMINDER:

**GOOD SYSTEM DEVELOPMENT PRACTICE/GOOD BUSINESS PRACTICE**

# Infrastructure Qualification Planning

- Things to consider when planning...
  - Most likely Retrospective in nature
  - Is typically an extensive effort (can last 2-3 yrs. depending on scope and resources)
  - Breaking the effort into manageable pieces is key
  - Be aware, it will result in additional documentation and possible re-design
  - It will involved the development and execution of multiple protocols

# Infrastructure Qualification Planning

- To Start...
  - Need to understand your organization
    - What does your organization look like?
    - How do IT, IS, Application Development fit in?
    - Are all the infrastructure pieces centralized in one group?
    - Is application development centralized in one group?
    - Who and what depends on your infrastructure?
    - Is there a Quality Group that must be involved
    - Who are the key stakeholders?

# Infrastructure Qualification Planning

- Be sure...
  - To Identify the Sponsor and...
  - To Identify a preliminary cross-functional team
    - System Engineers/Architect(s)
    - Service Manager(s)
    - Security Manager(s)
    - Quality Assurance/Compliance
    - Impacted System Owners
    - Impacted User Representatives
    - Impacted Business Representatives, as applicable

# Infrastructure Qualification Planning

- Perform an initial assessment of the current infrastructure, and document
  - Immediately create high level “as-built” diagrams to help determine scope including:
    - Servers, routers, switches, hubs, firewalls, protocols, and locations (IDF, MDF, Data Centers etc.)
    - WANs relationships with LANs
  - Establish a master list of significant infrastructure components
  - Review any existing procedures and process to ensure usability and modifications, as needed
  - Conduct risk analysis of entire infrastructure including a graded identification of potential points of failure and gaps
- Map out an approach...in manageable pieces!

# Qualification by Platform – One Approach

- Break out the effort into ‘Platforms’ and specific ‘Platform’ qualifications efforts.
- Where Platform = “The underlying architecture of hardware and software configurations constituting the computing environment hosting specific services, components, and applications”
- May include:
  - Network and Data Communications
  - Data Center
  - Desktops and Servers
  - Authentication and Authorization Services
  - Backup and Restoration
  - Storage Area Network

# Qualification by Platform

- Create one 'Infrastructure Qualification Plan' that...
  - Describes the overall effort (all platforms)
  - Includes the High-Level Diagram(s)
  - Identifies the Platforms and Scope of Each Platform Qualification
  - Prioritizes the Platforms in terms of criticality and dependencies
    - s/b based on Risk Assessments and Gap Assessments
  - Includes references to and conclusions made from any assessments performed
    - note: if you didn't do them, DO THEM
  - Identifies Platform Specific PMs and Teams

# Qualification by Platform

- Ensure it defines the standard methodology that will be used for each Platform Qualification, i.e.
  - Each will have a Qualification Plan (QP)
    - Platform Description
    - Scope
    - Platform Impact and Risk Assessment
    - Defined Qualification Activities
    - Defined Roles/Responsibilities, etc.
  - Each QP will include consistent steps such as:
    - Plan
    - Design
    - Installation
    - Qualification
      - IQ/OQ/PQ
    - Ongoing Monitoring and Maintenance
    - Procedure Development
    - Training
  - Each Platform Qualification will be summarized in a Platform Qualification final Summary Report

# Qualification by Platform

- In addition the Infrastructure Qualification Plan should...
  - Define consistency in:
    - Having identified documented inputs and outputs (*note: documents may vary, but should be called out in the QP*)
    - Defined, applicable reviews and approvals
    - Project Timelines, Milestones, Deliverables
  - Ensure regular reporting to Sponsors and Stakeholders on the status of each Platform Qualification
  - Define Standard Procedures that run across all platforms
    - Protocol development and execution methods
    - Document Management
    - Change Control
    - Training
    - Procedure Development Processes
  - Identify Consistent Approval Expectations for each Plan and associated documents (i.e. PM, Business, QA, Tech.Rep.)

# Time check and segue options...

- Change Management, Administration and Maintenance of your Infrastructure
- Continue with Platform Planning
- Discussion

# Platform Qualification Planning and Execution

- Documented Requirements
  - No matter what the platform, high level requirements should be documented to help in planning the effort and scope.
  - These may include:
    - High Level Diagrams
    - User Requirement Specifications
    - RFPs, Business Cases
    - SLAs, OLAs
    - Maintenance Agreements
  - May be one document, may be many
  - These should be created/verified before performing any next steps.

# Platform Qualification Planning and Execution

- Risk Assessments
  - Should always be performed as they:
    - Provide the documentation back-up for risk-based decisions (i.e. reduction in effort/scope)
  - Are key in..
    - Defining the approach and scope
    - Identifying potential design/process gaps
    - Identifying critical mitigation activities
    - Assisting in risk and time management activities
- Note: Will show an example with case study

# Platform Qualification Planning and Execution

- Design Documents
  - Design Documents should exist for all Platform Qualifications
  - May include:
    - Design Reviews
    - Development/Update of Specifications, Configuration Records
    - Additional next level diagrams
    - CMDB Data
  - Mechanisms for ensuring they are maintained in a current state is critical

# Platform Qualification Planning and Execution

- Installation Activities:
  - Installation changes may need to occur as a result of your design reviews and Risk Analysis.
  - It is best to have a stable configuration baseline for your platform once you begin protocol executions.
  - Any changes should be made following formal change control procedures.
  - Some changes may also be incorporated into the Installation Qualification activities
  - Design and Requirements Documentation should be modified in accordance with any changes made

# Platform Qualification Planning and Execution

- Qualification Activities
  - Protocols should be developed in order to ensure expedited execution wherever possible
    - Templatize where possible (repeatable execution)
    - Pre-Approved templates for ongoing execution
    - Perform subset executions and perform configuration compares instead
  - Identify early, what changes can be considered administrative
    - Allows changes to move into Admin. SOPs
    - Removes them from requiring protocol execution in the future

# Platform Qualification Planning and Execution

- Qualification Activities
  - Execution
    - Protocols should be followed as written, changes documented per procedure
    - Execution most likely will not be in test environment so
      - Mitigate any potential impact
  - Evidence and Results
    - Can't really get away from the need for evidence
    - Be smart
      - Automated scripts
      - Reports vs. screen shorts
      - Cumulative activities evidenced 1 time
    - Take advantage of your Prioritized Requirements and Risk Analysis
      - Some failures may be O.K.

# Platform Qualification Planning and Execution

- Qualification Activities
  - Summarize Results in Protocol Summary Reports
  - Will later be summarized in the Platform Qualification Summary Report

# Maintaining the Qualified State

- Most Important – Control Changes Made to the Infrastructure
  - Change Control Procedures
  - Administrative and Maintenance Procedure
  - Auditing Tools
  - Using a Configuration Management Database or Master System Inventory
- Develop Platform Specific Process/Procedures for:
  - Administration and Maintenance
  - Operation
  - Performance Monitoring
- Other Non-Platform Specific Process/Procedures
  - Training
  - Internal Auditing
  - Incident Management
  - Problem Reporting and Resolution
  - Performance Monitoring

# Q&A

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