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IT Auditing for GxP systems and How to Integrate into a Company's IT Continuous Improvement Program

ASQ PRESENTATION

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RCM Technologies

• Providing business and technology solutions since 1971
• Over 30 locations throughout North America and Puerto Rico (four offices in California)
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• Vertical focus on Life Sciences, Healthcare, Banking & Finance, Insurance, Telecom, Utility, Technology, Manufacturing & Distribution, & Government Sectors
• 1,000 national, regional & international clients
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• Three primary divisions: Engineering, IT (Life Sciences) and Commercial

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Introduction

- Understand ***why*** auditing IT vendors is important
- Become familiar with the ***terminology*** and ***principles*** of effective IT auditing and integration into an IT continuous improvement program
- Learn ***how*** to perform audits based on risk
- Determine ***which*** audit techniques best suit your needs

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Why Audit Vendors of GxP IT Systems

- Computerized systems which ***impact*** the manufacture, distribution, holding, or testing of drug product, substance, or medical device must be validated.
- A determination of the maturity of the product based on results from the audit on a vendor is required to ***classify*** the level of testing required.

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Why Audit Vendors of GxP IT Systems

- For example, if you have a GAMP Category 4 (configurable) application and the vendor did not fare well on the audit the validation strategy would be to treat the system as a Category 5 requiring ***additional testing***.

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Why Audit Vendors of GxP IT Systems

- Criteria for determining the ***testing strategy*** to ensure, that in addition to the system performing as specified, that mitigation plans have been implemented to reduce identified risk……

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Why Audit Vendors of GxP IT Systems

- **LOW** – This is where the code/ configuration is mature as this is standard OOB functionality. The required functionality can be addressed via another system process or through backup procedures without impacting business objectives. For formal testing, positive testing is sufficient; no specifications for challenge testing are needed.

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Why Audit Vendors of GxP IT Systems

- **MEDIUM** – This is for configuration made in accordance to the design specification as specified to the business using standard functionality and there is medium maturity. Failure could result in business impact, but a failure is detectable and can be overridden or corrected manually. Formal testing will include positive and challenge testing; just positive testing is insufficient and there needs to be challenge scenarios included.

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Why Audit Vendors of GxP IT Systems

- **HIGH** – This is for custom code where the code has low maturity. The function has direct impact on critical business processes and is necessary for the proper operation of the system. Manual backup procedures will impact business objectives. Formal testing will include positive and challenge testing; just positive testing is insufficient and there needs to be challenge scenarios included.

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Types of Audits

- Technological innovation process audit - e.g. impact of incorporation of SOA
- Innovative comparison audit - J2EE vs .NET
- Technological position audit
- IT Compliance against FDA regulations
- Risk

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How to Audit Vendors Based on Risk

- Low risk system – questionnaire
- Medium risk system – virtual audit
- High risk system – on-site thorough audit

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How to Audit Vendors Based on Risk

- High risk system audit topics
  - **General Business**
  - **Quality System**
  - **Project Management**
  - **Methodology**
  - **Testing**
  - **Regulatory Compliance**
  - **Configuration Management**
  - **Manufacturing**
  - **Documentation / Records Management**
  - **Security**
  - **Training / Education**
  - **Maintenance**

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How to Audit Vendors Based on Risk

- High risk system audit topics
  - **Quality System**
    - **Quality System Framework**
    - Written Quality Commitment
    - Organizational Structure (Roles and Responsibilities)
    - Procedures
    - Procedure Management
    - Internal Audits and Inspections
    - Continuous Improvement Process
    - **Supplier/Subcontract Management**
    - **Quality Assurance**
    - **Quality Control**

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How to Audit Vendors Based on Risk

- High risk system audit topics
  - **Methodology**
    - **Software Methodology**
    - **Re-Usable Software Products**
    - **Purchased Software Products and Services**
    - **Source Code**
    - **Hardware Methodology**
    - **Purchased Hardware Products and Services**
    - **Product Line Practices**

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Continuous Improvement for IT Systems

- Continuous Monitoring
  - Performance Monitoring
  - System up/down
- Analysis of Incidents
- Analysis of Change Management
- Periodic Reviews
- Process/System Optimization

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Continuous Improvement for IT Systems

- CMMI 5 – optimized
  - CMMI 1 – ad hoc
  - CMMI 2 – repeatable
  - CMMI 3 – defined
  - CMMI 4 – managed
- Organizational Innovation and Deployment
- Casual Analysis and Resolution
- CMMI / Six Sigma DFSS

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Utilizing IT Audits within an IT Continuous Improvement Program

- Periodic Internal Audits
- Periodic Vendor Audits
- These audits provide the input to the process optimization effort assuring continuous improvement.

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Discussion

- What do you do in your firm?