

Supplier Auditing and Quality Agreements: Ensuring Compliance and Efficiency

Presented by:

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For Discussion Purposes Only

Agenda

- About Kneat
- Leveraging Vendor Documentation
 - GAMP 5 Overview
 - Actions for Leveraging Vendor Documentation
 - How to Assess Supplier Capabilities
 - Support and Maintenance
- Supplier Quality Agreements
- Closing Points & Key Take Aways
- Q&A



Validation, digitized.

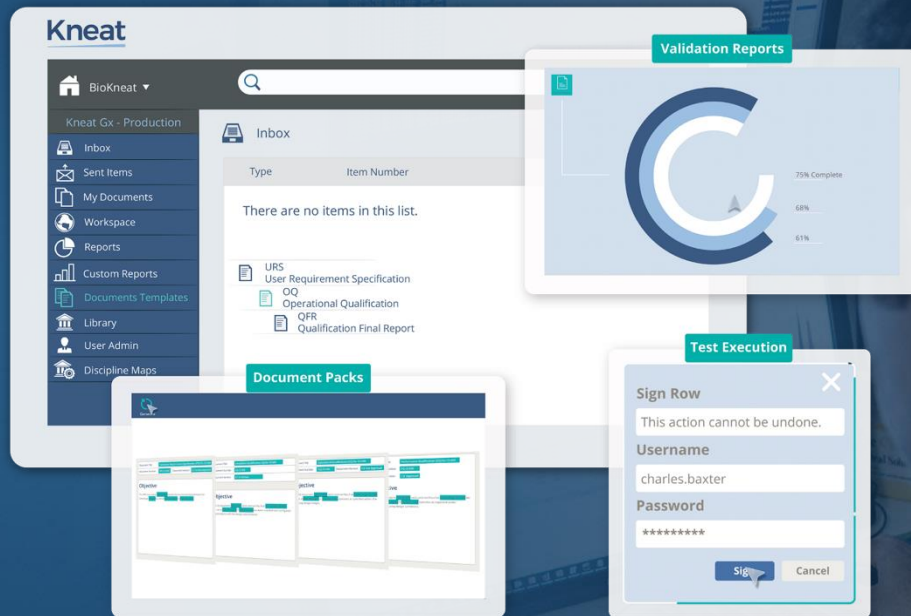
About Kneat

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What Is Kneat Gx?

Kneat Gx is a SaaS Validation Life Cycle Management Platform that digitalizes validation from end to end, enabling regulated companies to make validation easier, faster, and smarter.



Delivering Digital Validation Value Worldwide

- Global organization with operations in **Ireland, USA, France, Germany, Switzerland, Denmark, and Canada**
- Public company, listed on the Toronto Stock Exchange (TSX), **held to high governance standards**
- Validation platform to **eight of the top 10 life sciences companies and three of four COVID-19 vaccine manufacturers**
- **40,000+ users** in the Kneat SaaS platform
- **50+** global partner network
- All in-house development, no outsourcing for maximum quality
- **ISO 9001:2015, ISO 27001 certified**



40,000+

Users globally

8/10

of the world's top 10
pharma companies

1st

To fully digitalize facility, utility,
and equipment C&Q for a new
large facility build

**Leverage Vendor Documentation to
Streamline Validation Processes Using
GAMP 5**

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GAMP 5 Overview

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What is GAMP 5?

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

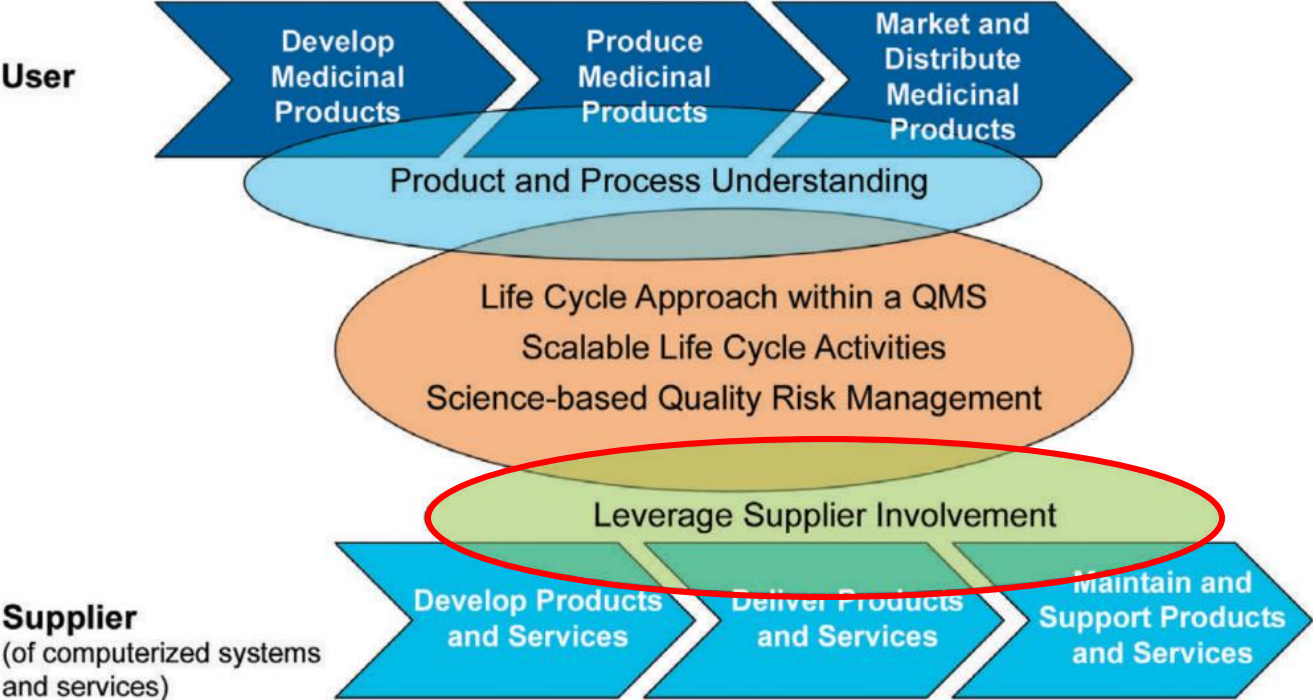
“1. GAMP guidance aims to safeguard patient safety, product quality, and data integrity in the use of GxP computerized systems. It aims to achieve computerized systems that are fit for intended use and meet current regulatory requirements by building upon existing industry good practice in an efficient and effective manner.”

What is the Importance of GAMP 5 Second Edition?

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“1.1 ...technical content of the Guide has been updated to reflect the increased importance of IT service providers including cloud service providers, evolving approaches to software development, and increased use of software tools and automation to achieve greater control, higher quality, and lower risks throughout the life cycle.”

From “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems (Section 2.1)”:

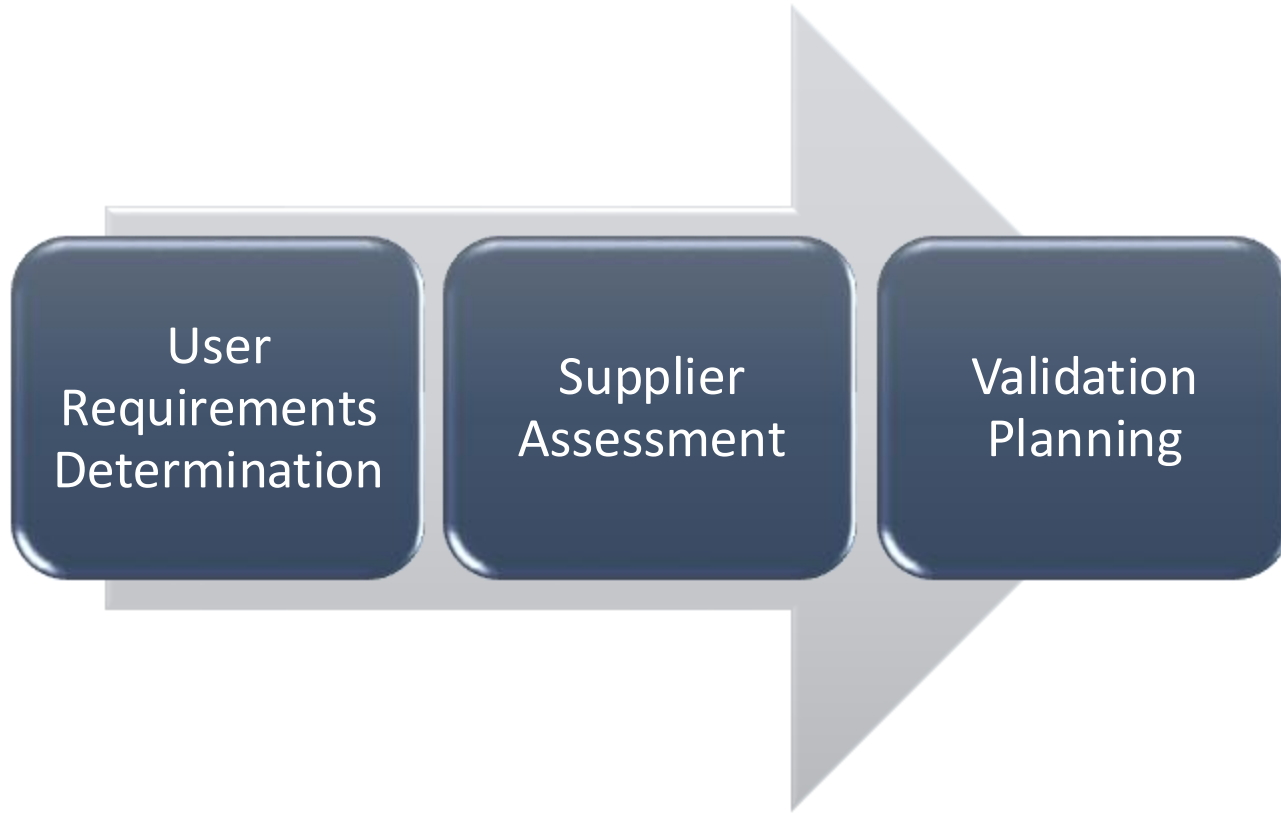


Required Actions for Leveraging Vendor Documentation

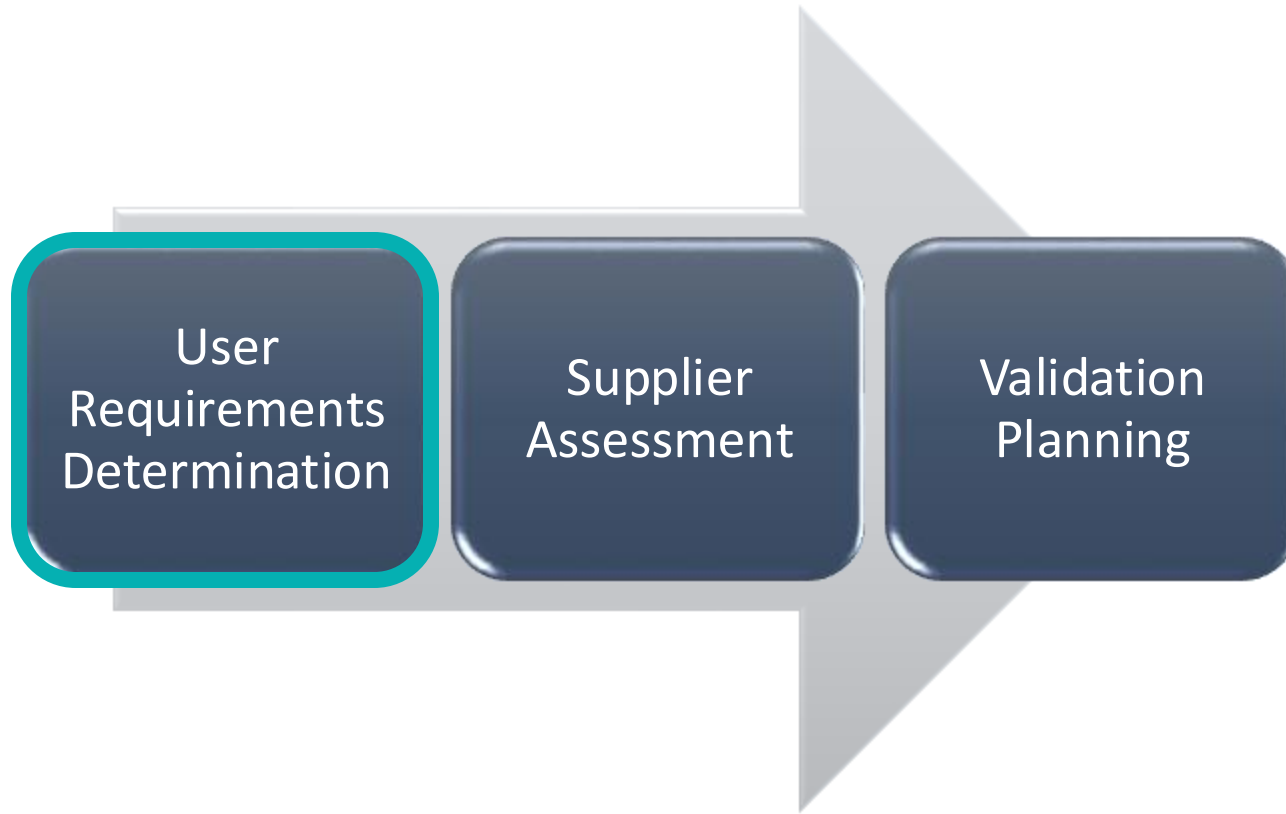
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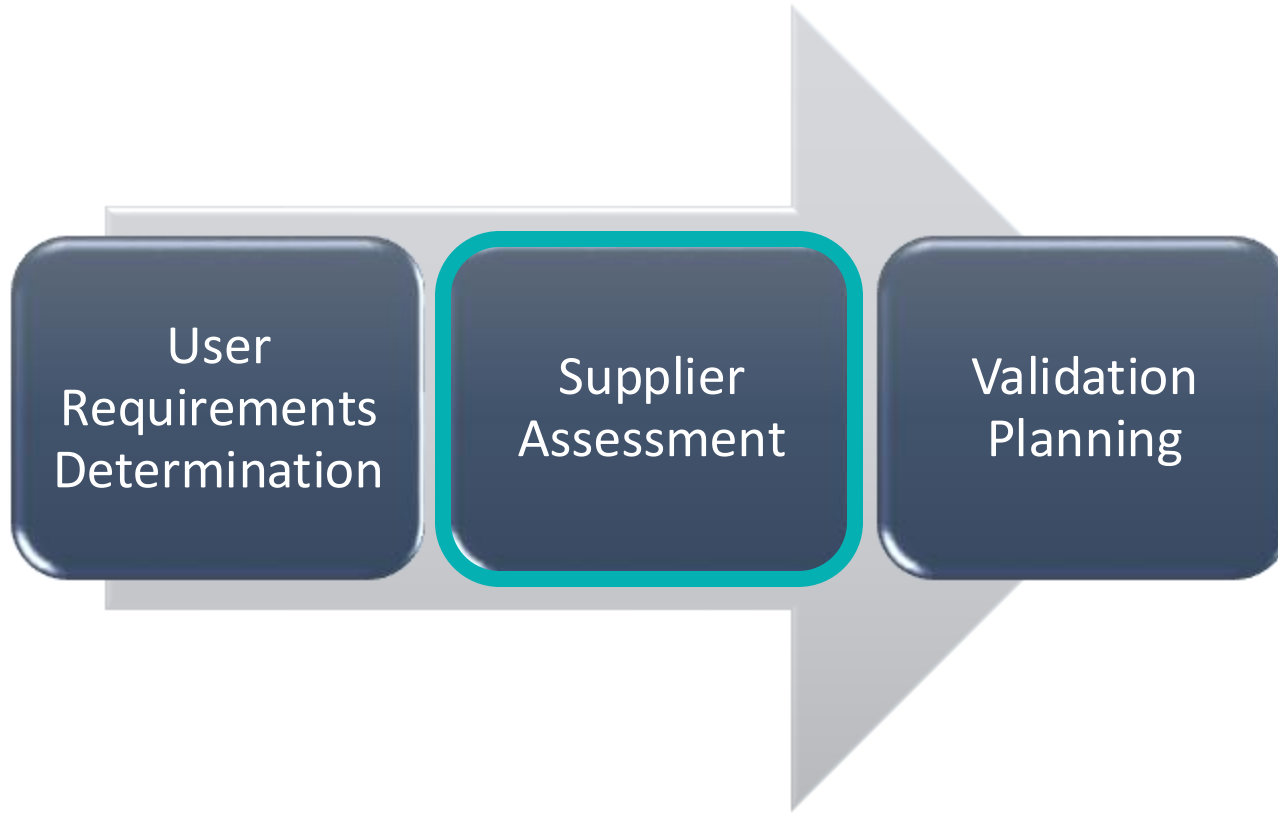
Onboarding a Computer System



Onboarding a Computer System



Onboarding a Computer System



Leveraging Vendor Involvement

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“2.1.5 Regulated companies should seek to maximize supplier involvement throughout the system life cycle in order to leverage knowledge, experience, and documentation, subject to satisfactory **supplier assessment**.”

Supplier Assessment

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“2.1.5 Justification for the use of the supplier documentation should be provided by the satisfactory outcome of supplier assessments, which may include supplier audits.”

**Implement Risk-Based Auditing Techniques
to Assess Supplier Capabilities and Mitigate
Potential Quality Risks Effectively**

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Supplier Assessment Types per GAMP 5

1. Basic assessment based on available information
2. Postal/email audit using a questionnaire
3. On-site audit by relevant specialist, auditor, or audit team



Option #1: Basic Assessment

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“10.4.2 A basic assessment may be based on:

- A review of public domain information including information regarding certification
- Market reputation
- Knowledge and experience of prior performance
- Discussions with other regulated companies”

Option #2: Postal/Email Audit w/ Questionnaire

Postal/Email Audits using a questionnaire...

- provide a mechanism for reducing costs.
- provide a good understanding of the supplier's systems.
- can be escalated to an onsite/virtual online audit.
- can reduce the length of an onsite/virtual online audit.

Option #2: Postal/Email Audit w/ Questionnaire

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“10.4.3.3 Postal/email audit questionnaires ... may include the following:

- Company overview including any product-specific locations
- Organization, roles and responsibilities, staff training and experience
- Key products and/or service history and development plans
- QMS implementation at company level and for product-related processes
- Product/project management
- Software development life cycles processes and deliverables
- Software development life cycle support processes
- Service delivery processes
- User training
- Production support/maintenance
- IT infrastructure management and control
- Security
- Use of subcontractors, including both external organizations and individuals”

Option #3: On-Site Audit

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“10.4.5.2 ... the purpose of the audit is to establish, through questioning and inspection, the adequacy of the supplier’s operations, and to identify any concerns and to bring them to the attention of the regulated company’s management.”

Option #3: On-Site Audit

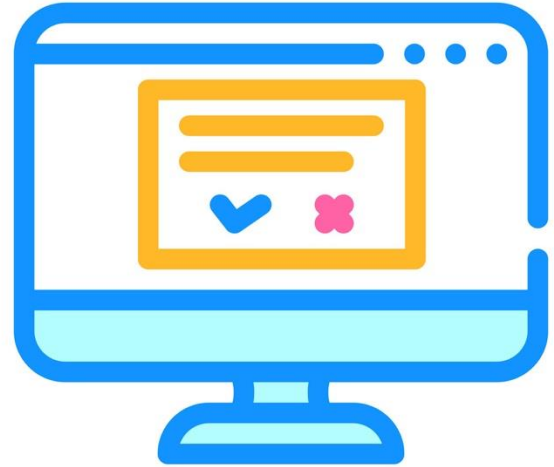
Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“10.4.4.2 *Example*: A regulated company had decided that a follow up audit of a software product supplier is needed.

- ❑ The test strategies adopted at each stage of development
- ❑ Evidence of both structural and functional testing
- ❑ Evidence that each key function of the product has been tested thus providing traceability
- ❑ Evidence of stress testing, and testing of abnormal conditions
- ❑ The use of testing tools
- ❑ Involvement of the supplier QA function in the testing process
- ❑ The independence and qualifications of testers and reviewers
- ❑ Verification that traceability from requirements through to testing is available and adequately documented”

Supplier Assessment Outcome

1. Supplier Acceptance and Rejection
2. Corrective Actions and Follow-up Audits
3. Re-Evaluation



Required Actions for Leveraging Vendor Documentation

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Leveraging Vendor Documentation

Per “ASTM E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment”:

“6.8.1 Vendor Documentation, including test documents may be used as part of the verification documentation, providing the regulated company has **assessed the vendor** and has evidence of:

6.8.1.1 An acceptable vendor quality system,

6.8.1.2 Vendor technical capability, and

6.8.1.3 Vendor application of GEP such that information obtained from the vendor will be accurate and suitable to meet the purpose of verification.”

Leveraging Vendor Documentation

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“25.8.1 In order to leverage supplier testing, the regulated company should first consider:

- The extent, coverage and quality of the supplier testing to determine how much reliance can be placed on the supplier testing and what additional testing will be needed. An SME review of supplier test cases and records may be required to justify this.
- How supplier test records can be made available for appropriate assessment and review by regulated company.
- How traceability between the regulated company’s requirements and the supplier’s test cases will be established and maintained, if required.”

Leveraging Vendor Documentation

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“2.1.5 Documentation should be assessed for suitability, accuracy, and completeness. **There should be flexibility regarding acceptable format, structure, and documentation practices.**”

Leveraging Vendor Documentation

Per “ASTM E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment”:

“6.8.2 If inadequacies are found in the vendor quality system, technical capability, or application of GEP, then the regulated company may choose to mitigate potential risks by applying **specific, targeted, additional verification checks or other controls** rather than repeating vendor activities and replicating vendor documentation.”

Assess Against Vendor Documentation

Additional Customer Requirements

Example: User must be able to generate all company specific deliverables.

Satisfied by vendor testing for document creation functionality.

Example: User must be able to login with company-specific corporate credentials via single sign on.

Not satisfied by vendor testing due to unpredictable third-party software setup options with different identity providers.

Ranking for Customer Business Risks

Example: System must be able to log consumable usage for restricted items (Classified as High Legal Risk)

May be satisfied by vendor testing for in-line execution electronic signature functionality.

May not be satisfied by vendor testing if company has a procedure that requires all high-risk items to be tested internally.

Customer Specific Configuration/Setup

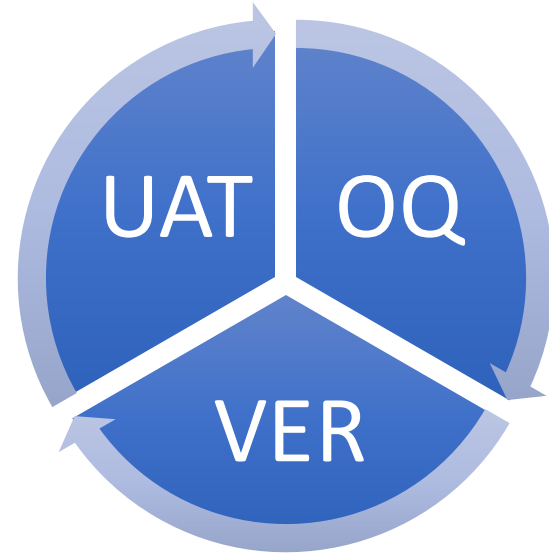
Example: User may only create content within Customer Specific process parameters.

Not satisfied by vendor testing due to unique configuration setting combinations applied during setup for a given customer.

Identify Testing Gaps and Consolidate

System Acceptance Testing (SAT)

- New Tests Needed per Customer Requirements
Single Sign-On Test Case (UAT)
- Re-Testing Needed per Customer Procedures
Execution with Electronic Signatures Test Case (OQ)
- Setup Testing Needed per Vendor Procedures
Configuration Settings Test Case (VER)

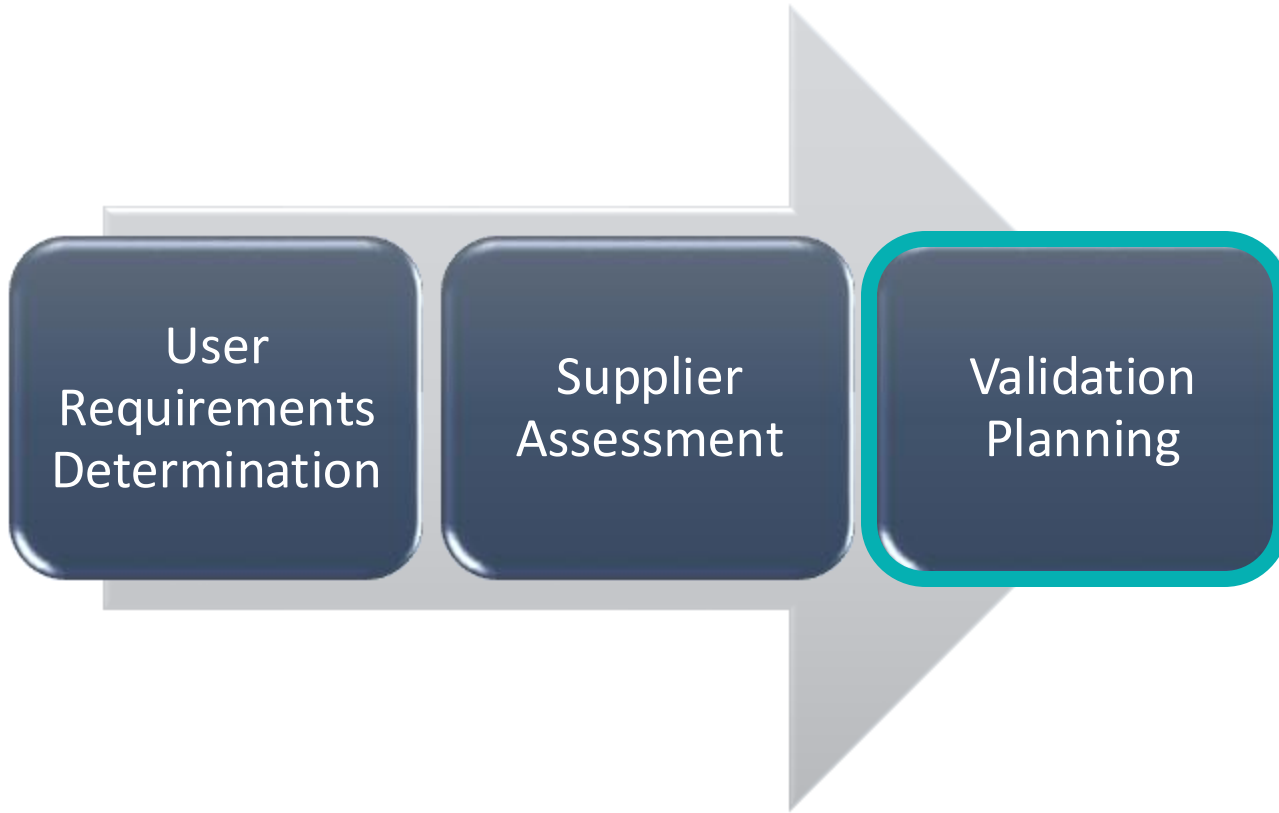


Leveraging Vendor Documentation

Per “ASTM E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment”:

“6.8.3 The decision and justification to use vendor documentation, to support the verification of critical aspects of the manufacturing element, should be based on the intended use of the manufacturing system, and should be **documented and approved by SMEs** including the quality unit.”

Onboarding a Computer System



Make a Validation Plan That Includes Intent to Leverage

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“2.1.5 Planning should determine how best to use supplier documentation, including existing test documentation, to avoid wasted effort and duplication.”

Make a Validation Plan That Includes Intent to Leverage

- **Vendor Documentation (Customer to Assess for Acceptance)**
 - Requirement & Functional Specifications
 - Product Risk Assessment
 - Installation & Functional Testing
 - Trace Matrix
- **Customer Documentation**
 - User Requirements (intent to only add specific needs)
 - Business Risk Assessment (intent to only assess with new criteria)
 - Gap Testing (intent to only test items not tested by the vendor)
 - Trace Matrix (intent to only trace new requirements)

Support and Maintenance

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Support and Maintenance

Per “ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems”:

“7.13 The supplier should support and maintain the system in accordance with agreed contracts.”

- For changes/updates/patches, consider the following:
 - Has the software changed its intended use?
 - Has the risk increased or decreased for a particular new feature/operation of the system?
 - Has new functionality been introduced and has the supplier tested the changes?

**Develop Clear Quality Agreements that set
Expectations for Supplier Performance and
Regulatory Compliance**

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What Is a Quality Agreement?

Per “Contract Manufacturing Arrangements for Drugs: Quality Agreements FDA Guidance of Industry”:

“A quality agreement is a **comprehensive written agreement between parties** involved in the contract manufacturing of drugs that defines and establishes each party’s manufacturing activities in terms of how each will comply with CGMP.”

Supplier Quality Agreements

Benefits include:

- Clarity and reduced confusion
- Mitigation of risks
- Enhances regulatory compliance
- Improved product quality
- Stronger supplier relationships
- Legal Protection



Quality Agreement - Inclusions

Per “Contract Manufacturing Arrangements for Drugs: Quality Agreements FDA Guidance of Industry”:

“It will define key manufacturing roles and responsibilities. It will establish expectations for communication, providing key contacts for both parties. It will specify which products and/or services the owner expects from the contract facility and who has final approval for various activities.”

Quality Agreement - Inclusions

Per “Contract Manufacturing Arrangements for Drugs: Quality Agreements FDA Guidance of Industry”:

“Most quality agreements contain the following sections:

- Purpose/Scope — to cover the nature of the contract manufacturing services to be provided
- Definitions — to ensure that the owner and contract facility agree on precise meaning of terms in the quality agreement
- Resolution of disagreements — to explain how the parties will resolve disagreements about product quality issues or other problems
- Manufacturing activities — to document quality unit and other activities associated with manufacturing processes as well as control of changes to manufacturing processes
- Life cycle of, and revisions to, the quality agreement”

Quality Agreement - Exclusions

Per “Contract Manufacturing Arrangements for Drugs: Quality Agreements FDA Guidance of Industry”:

“Quality agreements should not cover general business terms and conditions such as

- Confidentially
- Pricing or cost issues
- Delivery terms
- Limits on liability or damages.”

Quality Agreement - Exclusions

Per Science Pharma “How to divide responsibilities in a GMP-related contract? A quality agreement is the answer”:

Category	Commercial Contract	Quality Agreement
Purpose	Specifies terms of sale of goods or services	Establishes quality standards and quality control procedures
Parties	Typically between the company and the client / partners	Usually between suppliers and recipients of goods or services
Clauses	Concerning prices, payment terms, delivery terms	Focused on meeting specific quality standards , testing procedures, and inspection
Responsibility	Associated with delivering goods or providing services	Relates to ensuring quality and compliance with GMP standards
Penalties	Related to breach of contract terms, such as contractual penalty	May include penalties for failure to meet quality standards or non-compliance

Closing Points & Key Take Aways

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Closing Points & Key Take Aways

- ✓ Prioritize assessing your supplier
 - Which assessment type works for you?
 - Do not assume what your vendor has is enough
 - Take a risk-based approach
- ✓ Upon a successful supplier assessment, leverage documentation!
 - Include intent to leverage in your Validation Plan
 - Do not repeat testing unnecessarily
- ✓ Reassess when it comes to changes/updates/patches
- ✓ Develop a clear quality agreement with the supplier

References

- ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems (2022)
- ASTM E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment (2012)
- U.S. Department of Health and Human Services Food and Drug Administration: Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance of Industry (2016)
- Science Pharma “How to divide responsibilities in a GMP-related contract? A quality agreement is the answer”:



Thank You



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