# GLSU Business Consulting compliance-center™ Offering

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# Introductions

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# Agenda

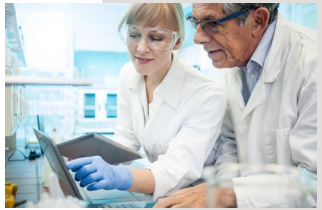
- fme Overview
- Background
- Computer Software Assurance (CSA) Overview and Benefits
- Demo
- Q&A

# Overview

Who are we?

Your partner for digital transformation.

It’s fme you love to work with.



## Life Sciences

- Pharmaceuticals
- Medical Devices
- Test & Measurement Equipment, Manufacturing
- And more

## Non-Life Sciences

- Banking, Insurance & Financial Services
- Automobiles & Motor Vehicles
- Food & Beverage
- Electricity, Oil & Gas, Energy, Utilities & Waste
- Freight & Logistics Services, Transportation
- And more

# fme Services Portfolio

End-to-End Client Support Services

## Business Consulting

- Governance Definition
- Advisory Services
- Process Optimization
- Change Management
- Vendor Oversight
- Program Management
- Maturity Assessments
- Roadmaps

## Technology Platform Services

### Implementation Services

- Requirements Analysis
- Data Model Design
- Solution Design
- Configuration
- Custom Development
- Systems Integration
- Testing & Validation
- Deployment and Go-Live Support

### Migration Services

- Source/Target Mapping
- MetadataAssist™
- Data Migration
- Content Migration
- Metadata Transformation
- Consolidation
- Content & Data Archive
- Cleansing & Enrichment
- Factory Enablement

### Managed Services

- Release Impact Assessment
- Maintenance Release Management
- Application Management
- Business/System Admin Services
- Small Projects Implementation
- Infrastructure Hosting and Cloud Services
- PlatformAssist™

## Training Services

- Training Needs Assessment Planning
- Training Material Preparation (Standard/Bespoke, Classroom, On-line)
- Train-the-Trainer Sessions
- End-User Training Sessions

# Background

- The FDA conducted a Case for Quality initiative to determine why so few companies were investing in automated solutions and why so many continued running long-outdated software versions:
  - Companies are focused more on compliance than on overall quality.
  - By directing activities towards the creation of documentation to remain “compliant,” less attention was placed on activities and investment in overall quality.
  - The burden of performing document-centric compliance activities of rigorous and exhaustive testing has prevented the progression to more advanced automated manufacturing and other improved quality practices
  - Study participants reported that the burden of computer software validation was, in some cases, twice the cost of the system
- The FDA released the draft guidance for a new risk-based approach called Computer Software Assurance (CSA) in September, 2022

# What is CSA?

Computer Software Assurance

| Traditional CSV | Modern CSA |
| --- | --- |
| Focused on creating extensive documentation | Focuses on more testing to achieve higher confidence |
| Driven by testing everything, but often misses higher risks | Applies Risk-based assurance, focusing on the right level of rigor to address risks in patient safety, product quality or data integrity |
| Ignores previous work performed | Leverages prior assurance activities |

# Benefits of CSA

- Reduces test scripts and tester errors
- Validation time cut by 50% or more, with faster implementation as a whole
  - Driven by not testing low-risk requirements
- Lower overall project cost
- Higher morale, quality, and productivity
- More time for critical thinking instead of generating documentation

# compliance-center Concept

- Electronic-based, paper-less CSA validation method
- Risk Based methodology approach for validation of computer systems
- Used to determine which requirements and system functionalities matter most
- Less testing and documentation
- Complexity of testing effort determined by risk assessment outcome
- Source material
  - GAMP 5
  - FDA Original CSV Guidance (General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Jan. 11, 2002)
  - Draft FDA CSA Guidance (Computer Software Assurance for Production and Quality System Software, Sept. 13, 2022)
  - EudraLex, Annex 11

# compliance-center risk framework

## Two Part Risk Assessment Process

1. System Level Risk Assessment

- Operational Risk: Intended Use of Software (CSA not applicable for Medical Device Software)
- Technical Risk: Complexity of System (i.e., Custom, Configured, Not Configurable)

2. Process Level Risk Assessment

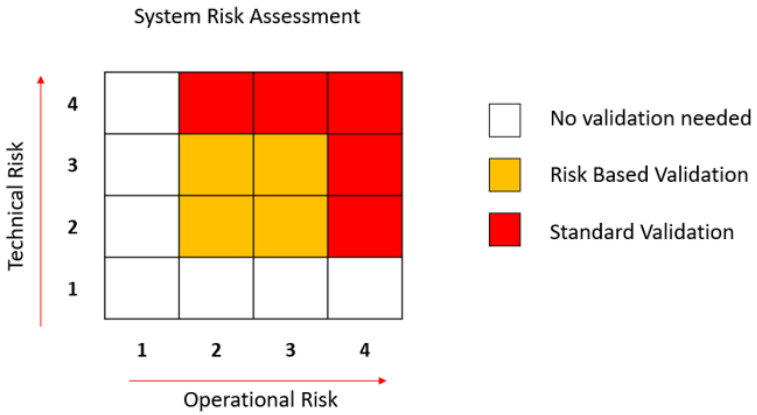
- Only applicable for systems that meet specific System Risk category
- Identify and risk assess processes carried out in system

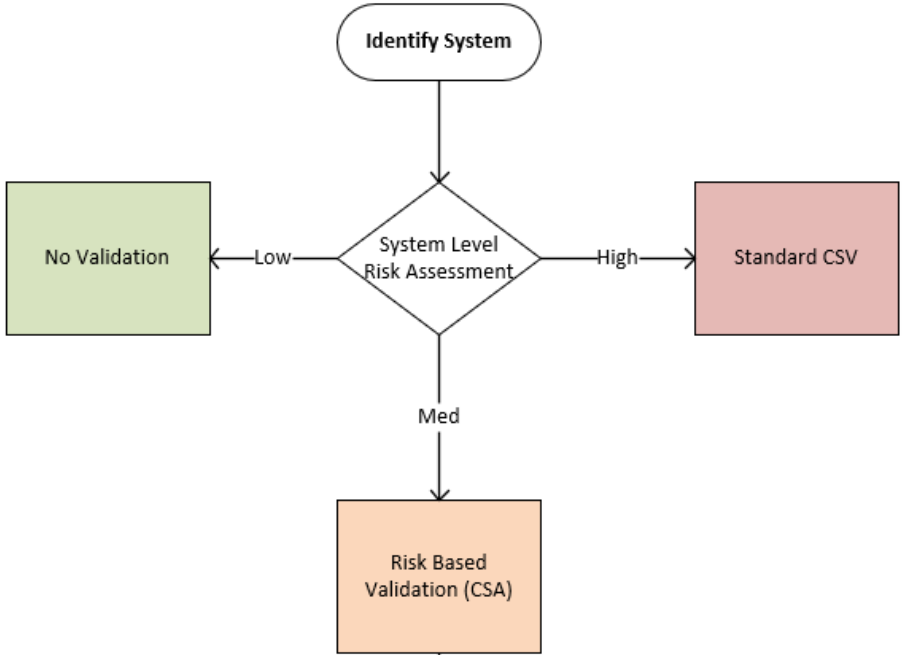
# System Level Risk Assessment

## Determine Validation Approach

Assess system based on:

1. Technical Risk
    a. Risk Level 1: (GAMP category 1) infrastructure software
    b. Risk Level 2: (GAMP category 3) Standard purchased products that is not configurable
    c. Risk Level 3: (GAMP category 4) Standard purchased products that are configured
    d. Risk Level 4: (GAMP category 5) Custom software
2. Operational Risk (examples taken from FDA guidance document)
    a. Risk Level 1: no impact to patient safety, product quality, or data integrity (ex.: general business process or operations software)
    b. Risk Level 2: small impact (ex: production/qms support software)
    c. Risk Level 3: moderate impact (ex: production/qms software)
    d. Risk Level 4: high impact (ex: Medical Device software



# Process Level Risk Assessment

For Medium Risk Systems

Process Risk Assessment

Step 1: Establish Risk Class

| Risk Severity | Low | Med | High |
|---|---|---|---|
| High | 2 | 1 | 1 |
| Med | 3 | 2 | 1 |
| Low | 3 | 3 | 2 |

Probability of Failure

**Severity**: impact on patient safety, product quality, data integrity, and/or business process impact

**Probability**: likelihood of failure, consider if function is OOB or configured, leverage vendor validation

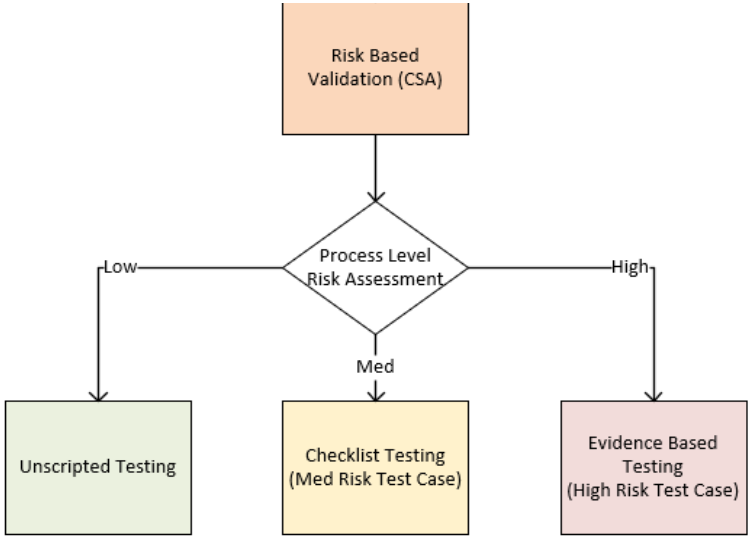
Step 2: Determine Final Risk Priority

| Risk Class | High | Med | Low |
|---|---|---|---|
| 1 | Med | High | High |
| 2 | Low | Med | High |
| 3 | Low | Low | Med |

Detectability of Failure

**Detectability:** Likelihood that failure would be detected prior to causing harm

**Low Risk Priority**: Unscripted/Ad Hoc Testing
**Med Risk Priority**: Checklist based Testing
**High Risk Priority**: Standard scripted testing



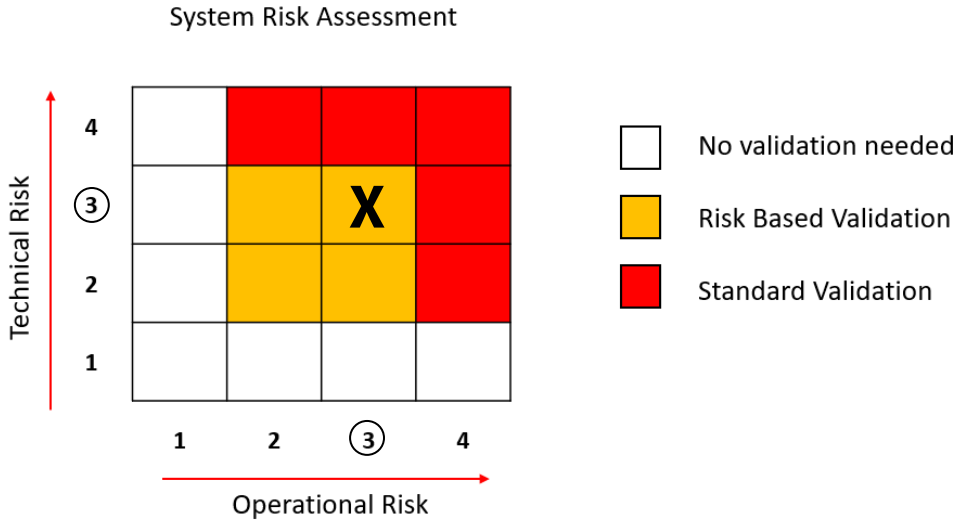
# Risk Assessment Example

System Risk Level: Medium Risk

System: eQMS system

Technical Risk: 3 (GAMP category 4: Standard Purchased, Configured Product)

Operational Risk: 3 (Moderate Impact, production/QMS software)



# Risk Assessment Example

Process Risk Assessment for Medium Risk System

eQMS System with System Risk Level of Medium, all features are OOB except Complaint Management which was highly configured

| Process | Severity | Probability | Detectability | Risk Priority | Accept Vendor Testing? | Testing Approach |
|---|---|---|---|---|---|---|
| Deviation Management | Low | Low | High | Low | No | Unscripted/Ad Hoc Testing |
| Audit Management | Low | Low | High | Low | Yes | No Testing Needed |
| Complaint Management | Med | High | Med | High | No | Standard Scripted Testing |
| Product Containment | High | Low | Med | Med | No | Checklist Based Testing |

**Severity**: impact on patient safety, product quality, data integrity, and/or business process impact

**Probability**: likelihood of failure, consider if function is OOB or configured, leverage vendor validation

**Detectability:** Likelihood that failure would be detected prior to causing harm

# Requirements

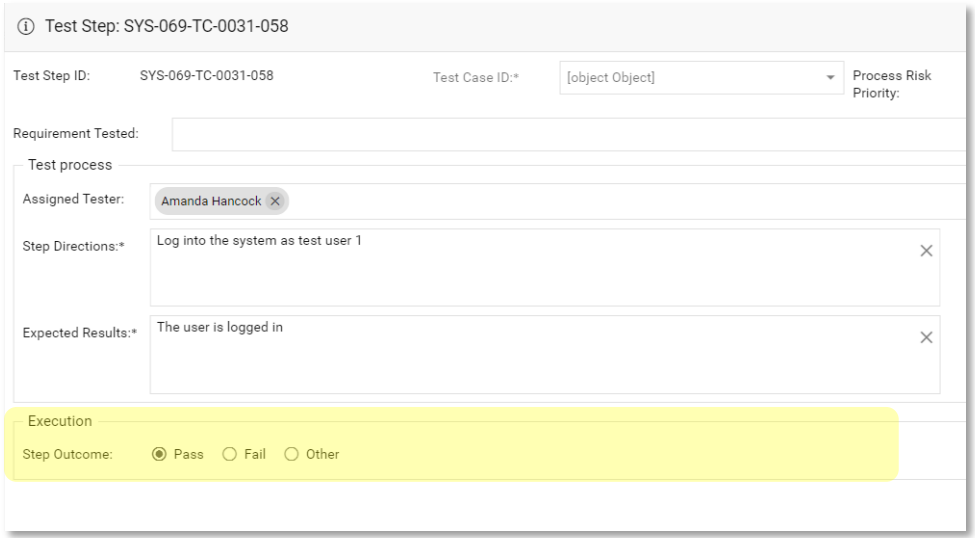
- User Requirements are associated with the identified and risk assessed Processes
- Process level risk rating cascades down to the requirements and subsequently determines the Test Case Format
- Facilitates the development of Test Cases that make logical sense with a format that is determined by the risk level of the process, rather than risk level of individual requirements

| Process | Req. ID | Requirement | Process Risk Level | Test Case Format |
|---|---|---|---|---|
| Deviation Management | REQ-001 | The system shall allow initiation of a deviation record. | Low | Unscripted |
| Deviation Management | REQ-002 | The deviation record workflow shall include an optional review step. | Low | Unscripted |
| Complaint Management | REQ-003 | The system shall associate a product with a complaint record, if applicable. | High | Standard Scripted Testing |

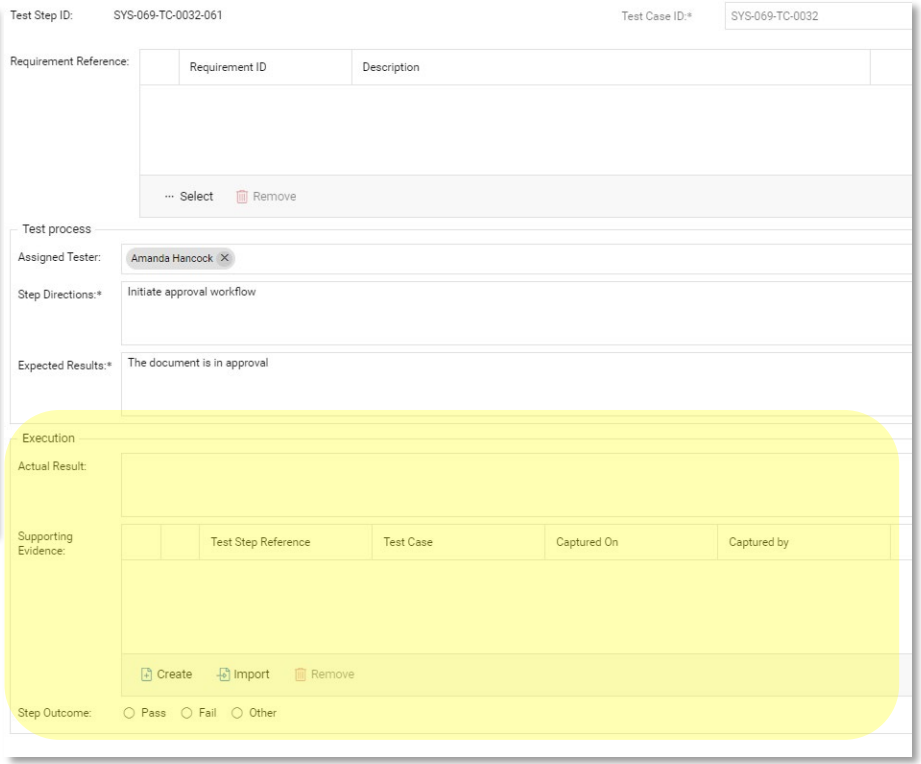
# Test Step Format

Med Risk vs High Risk

## Medium Risk




## High Risk



# Demo

# Q&A

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