EGNYTE + Life Sciences

GxP Risk Assessment for Computerized Systems

Introduction

There are numerous computer systems used in the life sciences industry. In GxP environments, however, validating and documenting mission-critical systems are required to ensure the integrity of data and audit-readiness. Yet, given the number of systems used, it is unclear which electronic systems require validation and which do not. In our view, a rational, data-driven assessment of a given system helps companies focus their limited resources on validating the right software for GxP environments.

The checklist below provides a framework for evaluating which software should/not be validated. We have taken a numerical approach to help individuals use data in quantifying risk and final decisions.

Our framework

For those evaluating whether a system in a GxP environment should be validated, we advise a four-category assessment. Each category has multiple requirements that can be evaluated numerically. Then, the sum of all categories yields an objective conclusion regarding the risk of a given computerized system.

The four categories include:

1. Proximity to patients
2. Proximity to regulators
3. Use in decision-making
4. Chain of custody

Each of these categories helps identify the systems role in life sciences products and quantify the risk associated with compliance.

Who this checklist is for:

IT	Quality	Clinical	Manufacturing
IT Managers	Quality Managers	Clinical Data Manager	Directors of CMC
IT Directors	Quality Directors	Clinical Operations Managers	Directors of Manufacturing IT
VP of IT	Validation Managers	Directors of Clinical IT	VP of Manufacturing & Supply Chain
	Computer Systems		
	Validation teams		

Scoring matrix, methodology

Approach

In this assessment, we enumerate specific workflows that a computerized system may be involved with. Based on each workflow, we have pre-estimated a 'risk score' associated with each. The higher the score, the higher likelihood you will need to validate the requisite system.

Some workflows have high risk and almost always need to validated, like systems used to submit data to a regulatory agency. While others, lower risk depending upon the scenario. This framework allows you to evaluate different uses for a given system and compose a final risk score to determine whether the system should be validated or not.

Our risk score range: 1 to 6

Methodology

In the checklist below, review whether a given system pertains to a line item and, if so, mark 'Yes'. If not, then 'No' in the middle column. For rows that you have marked 'Yes', enter the Risk Score associated with that line in the right-most column titled "Risk Score for 'Yes'". Doing so will simply make it easier to tabulate the subtotal Risk Score for that section.

Once you've assessed risk across each of the 4 categories, you can total the 4 subtotals in the final table at the end.

Final score

Depending on the system you are evaluating, your final score will vary. *If your total score is larger than 6*, our recommendation is that you validate. Further, this assessment can provide tangible data to managers and business stakeholders for why they should invest in a stronger compliance posture for a given piece of software.

Assessment

Category 1: Proximity to Patients

	Items	Yes/No?	Risk Score	Risk Score for 'Yes'
☐	System holds, tracks, or modifies patient-acquired data			
☐	System holds, tracks, or modifies protocols related to patients			
☐	System holds, tracks, or modifies metadata related to patients			
☐	System holds, tracks, or modifies identifiable patient data			
☐	System is used during a clinical trial			
☐	System holds, tracks, or modifies de-identified patient data			
			Subtotal:	

Category 2: Proximity to Regulators

	Items	Yes/No?	Risk Score	Risk Score for 'Yes'
☐	System archives data directly related to a submission			
☐	System holds, tracks, or modifies components of regulatory submissions (e.g. IND, NDA, etc.)			
☐	System holds, tracks, or modifies materials that assert medical claims			
☐	System holds, tracks, or modifies data previously requested during a regulatory audit			
☐	System holds, tracks, or modifies Standard Operating Procedures (SOPs)			
			Subtotal:	

Category 3: Use in Decision-Making

	Items	Yes/No?	Risk Score	Risk Score for 'Yes'
☐	System holds, tracks, or modifies data produced in a GxP environment			
☐	System holds, tracks, or modifies metadata produced in a GxP environment			
☐	System holds, tracks, or modifies data used to revise a regulated GxP process			
☐	System used to analyze data produced in a GxP environment			
			Subtotal:	

Category 4: Chain of Custody

	Items	Yes/No?	Risk Score	Risk Score for 'Yes'
☐	System holds, tracks, or modifies data created by combining one or more data sets produced in a GxP environment			
☐	System holds, tracks, or modifies metadata used in combination with GxP data			
☐	System used to analyze data produced in a GxP environment			
			Subtotal:	

Final Score

Items	Risk Score
Category 1: Proximity to Patients	
Category 2: Proximity to Regulators	
Category 3: Use in Decision-Making	
Category 4: Chain of Custody	
	Total Score: