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Automating the Validation Process of Pharmaceutical Applications

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***Abstract*—Now a days, all the major industries that are using the software applications to carry out the business activities and one of them is pharmaceutical industry. There are so many applications available for pharmaceutical domain such as Oracle ERP, SAP ERP, LIMS, QAMS, and Documentum etc. All these applications needs to be validated based on GAMP5 and 21 CFR part 11 guidelines before they start using them. According to Jason Young, these guidelines are necessary because "they provide framework for protecting public health, assure safety and quality to product". To perform and complete the validation huge amount of documentation needs to be done and executed according to the company policy and based on the GAMP category of the application. All most all the enterprise applications fall under GAMP Category 4 because they are configurable applications. Our research is to eliminate the manual efforts in the preparation of these validation documents by automating the entire process. In the validation process of a critical GAMP Category 4 application, there are so many deliverables for entire validation activity. They are System risk assessment, Regulatory scope determination, Validation Plan, User Requirement Specifications Document, Functional Specification Document, Design Specification Document, Functional Risk Assessment, Installation Qualification Protocol, Installation Qualification Test Data Document, Installation Qualification Report, Operational Qualification Test Data Document for each module of the application, Operational Qualification Report, Performance Qualification Test Data documents for each module of the application, Performance Qualification Report, 21 CFR Part 11 Report, Traceability Matrix, and Validation Summary Report. For all these deliverables, different levels of reviews and approvals (authorizations) are required. These authorizations depend on the policies of the company. To perform validation activity for a critical application in any company requires a lot of manual efforts, huge amount of papers and more time. By automating this process the organizations can save huge amount of time, resources and money.**

I. Introduction:

This research is to develop a tool to generate the deliverables of the validation process of a pharmaceutical application based on GAMP5 and 21 CFR Guidelines. Validation is "establishing documented evidence that provides a high degree of assurance that a Specific process will consistently produce a product meeting its pre-determined specifications and quality attributes." (FDA 1987). Currently there are some applications like Documentum and DMS are in use just for authorizing the deliverables based on the organizational responsibilities. In this practice the users need to create the deliverables manually and they have to use these authorization tools for performing the reviews and approvals of those documents. But through our process we can provide a chance to the users to generate all the deliverables of the validation process automatically and they can also complete the authorizations to complete the reviews and approvals of the deliverables. Through the automated process system can generate the soft copies of all the deliverables in the required format like .pdf or .docs. Users can print the documents as required. With the help of this application a single user can generate all the deliverables of the validation activity. The major phase which required more efforts is OQ phase. A lot of test cases needed to be prepared to complete this phase and they have to execute all the test cases based on the application flow. Our tool will automatically generate the test cases for all transactions of the application based on the input fields of each page.

II. The Problem:

In pharmaceutical application validation process, huge amount of efforts such as human resources, time and money are required to complete the process. Lot of deliverables (documents) need to be prepared and huge amount of secured physical area is required to store those documents. According to GAMP 5 Simplified V model specified by ISPE, the activities of a validation activity **are "Validation Plan, User Requirements (URS), Functional Specification (FS), Design Specification (DS), Installation Qualification (IQ) Functional Testing or Operational Qualification (OQ) Acceptance Testing or Performance Qualification (PQ) Validation Report"**. For all these activities number of deliverables needs to be prepared based on the GAMP 5 category of the application. The major activity which requires more documentation is

Operational Qualification. In Operation Qualification phase of the validation process, the users need to write detailed test cases for each module of the application which they are validating. There is no tool available for this process to generate these test cases automatically. In writing of the test cases the users need to write every step involved in completing the transaction and they have to type everything manually while running the application. No similarity will be there for the transactions. The test cases are different for every transaction. As this required more efforts to prepare the documents it consumes a lot of money and resources.

III. The solution:

Our research involves in developing a tool that automate the validation process. All the phases of the validation process will be automated with the help of a programming language. For the initial deliverables of validation process like Validation Plan, Regulatory Scope determination, System Risk Assessment we can pre-configured in the system to generate the deliverables. According to GAMP 5 there are **"4 categories in computer applications"** and they are as tabulated below.

Table 1 GAMP 5 Software Categories

SL. No	GAMP Category	Example Applications
1.	Category 1	Infrastructure Software
2.	Category 3	Non Configurable Software
3.	Category 4	Configurable Software
4.	Category 5	Bespoke software

The complexity of the validation activity can be varied based on the GAMP category of the application. Most of the enterprise applications fall under the GAMP software category of 4. All the deliverables will be pre-configured in our system based on the GAMP category. All the necessary information will be taken from the users in the form of input data based on the functionality of the application which we are validating and our system will generate the softcopies of those deliverables based on the information provided by the end users. The important and more complex phase of the validation process of software application which belongs to any software category of GAMP 5 is Operation Qualification (OQ) Phase. In this phase the test cases for each module will be prepared and executed. A long lasting definition of OQ is **"documented verification of that all aspects of . Equipment that can affect the product quality operate as intended throughout all anticipated ranges**" .For Operational Qualification phase, we have to configure our system based on the application. That means the configuration for initial phases is same for all the applications and the configuration for OQ phase is different and it will be varied from application to application. As said by Janko Jovanovic (2010) "**Every Web application is unique, but many of them contain common features. Although the implementation of any one of these features will vary".** Every software application follows a unique approach in terms of user interface to perform the transactions like forms, navigation between the pages of the application, reports and messages. The error and information messages also similar for all the transactions of the application. So our tool should allow the user to configure it based on the application which they are validating it. The user needs to generate the test cases for each transaction or module. So in our tool we have to provide the option to add the required number of input fields of a specific transaction and we should also provide an option to enter the specifications of each field of the transaction. So the user needs to specify the fields of the transaction and they have to copy and paste the specifications, which were given by the developers of the application, of each input field and they have to click a button to generate the input fields. All the test cases which are generated will be saved in the database and while executing the test cases they will be appeared in a tabular format. The user will open the application which they are validating along with the test cases in our tool. For each test case we have to provide an option for the user to capture the required screen of the application. User will be allowed to capture multiple screens for a single test step based on the requirement. All the screens will be saved with unique numbering convention. An option will be provided to the user to mark the transaction as pass or fail in the application. At last the user can generate a test case document for that transaction by simply clicking a button. In that document, which is generated after execution, all the test steps will be displayed in a tabular format, the test results of each step will be displayed as either pass or fail against each test step, and concerned screen shots of each test step will also be displayed in the document. Users will be having an option to generate the report for the OQ activity after completing the activity. So user don't need to type the test cases in a word document and they don't need to capture the screens and don't need to paste in the required documents. Everything will be done through our automated process. The following images describes the basic flow of generation of the test cases for a transaction of an application, which has just 2 input fields.

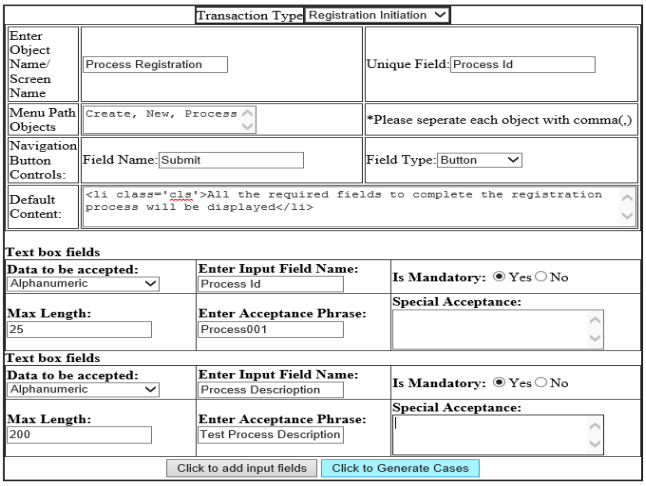

Figure 1 Example screen to enter the fields of transaction

STEP #	STEP DESCRIPTION	Input Field	Input Value	ACCEPTANCE CRITERIA	RESULTS/ SCREEN SHOT ID	PASS/ FAIL (P/F)
1	Click 'Create → New → Process → Process Registration' menu	N/A	N/A	• The Process Registration Initiation Screen should be displayed with all the required input fields to complete the registration Initiation task. • All the required fields to complete the registration process will be displayed		
2	Click the 'Submit' Button	N/A	N/A	• The alert message 'Enter Value For: Process Id' should be displayed by the system		
3	Click 'OK' at the alert and Enter the required value having less than or equal to '25' characters into 'Process Id' textbox and click the 'Submit' Button	'Process Id'	Process001	• The alert message 'Enter Value For: Process Description' should be displayed by the system		
4	Click 'OK' at the alert and Enter the required value having less than or equal to '200' characters into 'Process Description' textbox and click the 'Submit' Button	'Process Description'	Test Process Description	• The Conformation message should be displayed as 'Process Registration Initiated Process Id: ' along with 'Home' and 'Next' buttons.		

Figure 2 Test cases for a transaction

IV. Benefits of the Proposed System

- 80% of preparation time of test data can be saved.
- 95% of review time of test data can be reduced.
- 50% resources can be reduced.
- We can do paperless validation so that we can reduce the money spent for papers and document storage risk can be eliminated.
- Manual errors while doing the validation can be reduced.

V. References

1. Guideline For Quality Assurance In Blood Establishments, July 11, 1995. www.fda.gov/./guidancecomplianceregulatoryinformation/guidances/blood/ucm164981.pdf.

2. Risk-Based Validation – The Benefits of the GAMP® Approach, 2012 Kevin C. Martin Chair, GAMP® Americas Sr. Vice President Azzur Group LLC.

3. The Integration of Information Security to FDA and GAMP 5 Validation Processes, 2015 – SANS Institute.

4. ISPE -GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems, 2005 -www. Ispe.org/gamp-5.

5. ISPE Baseline® Guide, Vol. 3: Sterile Manufacturing Facilities (First Edition) .

6. Designing the User Interface for Business Web Applications, Janko Jovanovic, February 25th, 2010. http://www.smashingmagazine.com/2010/02/25/designing-user-interfaces-for-business-web-applications/