Note: This document is considered effective as of the final approval date of this page

| **Regression Protocol Approval** | | | |
| --- | --- | --- | --- |
| ***Print Name and Title*** | ***Department Name*** | ***Signature*** | ***Date*** |
| ***Business Owner Name:***  Eric Strait | Legal |  |  |
| ***System Owner Name:***  Benjamin Zuffi | IT |  |  |
| ***Quality Assurance***  Asif Haque | Quality Assurance |  |  |
| ***Document Author (IT-Validation)***  *Raghuraj Sharma* | IT |  |  |

Table of Contents

[1. PURPOSE 3](#_Toc84271831)

[2. SCOPE 3](#_Toc84271832)

[3. RESPONSIBILITIES 3](#_Toc84271833)

[4. DEFINITIONS AND ABBREVIATIONS 3](#_Toc84271834)

[5. EXECUTION PROCEDURE 3](#_Toc84271835)

[6. ACCEPTANCE CRITERIA 4](#_Toc84271836)

[7. REFERENCES 4](#_Toc84271837)

[8. EXECUTION ENVIRONMENT 4](#_Toc84271838)

[9. REGRESSION TEST CASE 5](#_Toc84271839)

[A. TESTING: 7](#_Toc84271840)

[Appendix A: Signature Log 13](#_Toc84271841)

[10. TEST REPORT 14](#_Toc84271842)

[10.1 TEST RESULTS 14](#_Toc84271843)

[10.2 SUMMARY OF DEVIATIONS 14](#_Toc84271844)

## PURPOSE

The purpose of this Regression protocol is to verify that DocuSign System continues to operate as expected after changes described in the Change Request.

After execution is completed, results will be summarized at the end of this plan and will be considered as a report.

## SCOPE

The scope of this regression protocol is to ensure that the DocuSign System continues to operate as expected after changes to the system where no impact is anticipated, such as changes to the system environment. This will be accomplished by verifying that the major functionality supporting the business process are working as expected.

It is not intended as a system test or user acceptance test of the application. If it were executed in its entirety, all system components within the scope of this document will have been tested**.**

## RESPONSIBILITIES

|  |  |
| --- | --- |
| **Role** | **Responsibilities** |
| System Owner | * Reviews and approves the Regression Protocol |
| Business Process Owner | * Reviews and approves the Regression Protocol |
| Quality | * Ensures compliance with D’s procedures and regulatory requirements * Pre and Post Review and approves the Regression Protocol |
| Validation | * Authors the Regression Protocol * Executes Regression Protocol as necessary |

## DEFINITIONS AND ABBREVIATIONS

Additional definitions not defined in this document can be found in *IT-003 Computer Systems Validation.*

## EXECUTION PROCEDURE

During the course of the execution, the executor shall:

* + Perform the Regression testing per the instructions in this protocol
  + Attach the printouts as instructed. Initial, date and label with corresponding section/step number, and unique page numbers (e.g. Page 1 of 12)
  + Sign and date on the “Tester signature” block

After the execution of, a member of Quality (or its designee) will review the completed Regression Protocol and sign and date on the "Reviewer signature” block.

In addition, each individual who has entered data or signed within this protocol must enter their identity information in the signature log at *Appendix* **A.**

Any deviation encountered shall be documented and resolved per *IT-006, Test Deviation and Resolution.*

## ACCEPTANCE CRITERIA

* + Acceptance criteria of the individual test in Sections 9 is successfully met;
  + Deviations are identified, documented, and resolved according to *IT-006, Test Deviation and Resolution.*

## REFERENCES

* + IT-003 Computer Systems Validation
  + IT-006, Test Deviation and Resolution

## EXECUTION ENVIRONMENT

Testing will be executed in Demo environment.

## REGRESSION TEST CASE

| Test Execution Preparation |
| --- |
| 1. DocuSign Demo environment 2. Unless otherwise specified in the individual test scripts, use Google Chrome |

| TST 1 – DocuSign regression testing |
| --- |
| **Acceptance Criteria:**  Verify the following:   1. Test was executed successfully, and all issues are resolved |

| Test Preparation/Setup (TEP) | | | |
| --- | --- | --- | --- |
| 1. Identify/Create valid users in DocuSign 21 CFR Part 11 module.  | **User Role** | **User** | **Email** | **User’s User Name** | | --- | --- | --- | --- | | DS Sender/Admin | User1 |  |  | | DS Signer | User2 |  |  | | DS Signer | User3 |  |  | | | | |
| 1. An envelope to be created in DocuSign <Envelope1> | | | |
| 1. A word document <Document1>to be uploaded to <Envelope1> | | | |
| 1. A PDF document <Document2> to be uploaded to <Envelope1> | | | |
| 1. From the settings->Signing Settings set the Date format as DD-MMM-YYYY | | | |
| 1. Make sure that the Audit Logs are available for the User1 | | | |
|  |  |  |
|  |  |  |

## TESTING:

| Step | Step Instructions | Expected Results | Observed Results | Accept? (Y/N) Initials/Date |
| --- | --- | --- | --- | --- |
| 1. | Login to DocuSign as Sender <User1> in DocuSign demo.  Confirm that Sender <User1> can successfully login to DocuSign. | Sender <User1> successfully logged into DocuSign. | As Expected  Not As Expected | Yes  No  Initials/Date: |
|  |  |  |
| 2. | 1. Click Start > Send an Envelope 2. Click Upload > browse and select   <Document1> > Open   1. Click Upload > browse and select   <Document2> > Open  Confirm that one or more documents can be added to an envelope.   * 1. **Attach screenshot(s).**  1. Add Signers <User2> and <User3> as recipients by adding name and e-mail address under Add Recipients to the Envelope, <Envelope1>. 2. Check the box for Set signing order.   **b) Attach screenshot(s).**  Confirm that serial signing order can be  defined. | One or more documents can be added to an envelope. | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
|  |  |
|  | Serial signing order can be defined. |  |
|  |  |  |
| 3. | Click Next   1. Scroll to signature fields for   <Document1> and drag and add a Signatures tags next to Signers <User2> and  <User3>’s names.   1. Scroll to signature fields for   <Document2> and drag and add a Signatures tags next to Signers <User2> and  <User3>’s names.  Confirm that signature tags can be added to the envelope, <Envelope1>.   1. **Attach screenshot(s).**   Click Send.  Confirm that <Envelope1> is sent successfully to Signers <User2> and <User3> for e-signature.  **b) Attach screenshot(s).** | Signature tags can be added to the envelope, <Envelope1>.  <Envelope1> is sent to Signers <User2> and <User3> for e- signature. | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
| 4. | Open the in-process <Envelope1> and click on Correct tab.  Change the routing order for Signers <User2> as 2 and <User3> as 1.  Click Next. Click Correct  Confirm that <Envelope1> is corrected and re-send.  **Attach screenshot(s).** | <Envelope1> is corrected and re-send. | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
| 5. | Login to DocuSign as  Signer <User3>.  Click on Action Required tab. Click on “Sign” for <Envelope1> and then authenticate as <User3>  Click Continue > Start > Sign icon (for  <Document1>)  Select Signing Reason as “I approve this document” and click on ‘Sign’ button  Click Sign (for <Document2>) Select Signing Reason as “I approve this document” and click on ‘Sign’ button  **Attach screenshot(s).**  Click Finish and click Next in Authenticate to Continue.  Enter username and password of <user 3>. | Signer <User3> can e-sign the <Envelope1> in DocuSign. | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
| 6. | As Signer <User2>, Go to the email and open the <Envelope1> email received from <User1>.  Click on “Review Document” link and Login.   1. **Attach screenshot(s).**   Click Continue.  Click Start > Sign (for <Document1>) Select Signing Reason as “I approve this document” and click on ‘Sign’ button  Click Sign (for <Document2>) Select Signing Reason as “I approve this document” and click on ‘Sign’ button   1. **Attach screenshot(s).**   Click Finish and click Next in Authenticate to Continue.  Enter username and password of Signer <user 2>. | Signer <User2> can e-sign the <Envelope1> in DocuSign. | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
| 7. | Wait for few minutes,  Confirm that Completed: <Envelope1> email is received by <User1> along with signed  <Document1>, <Document2>.  **Attach screenshot(s).** | The Completed: <Envelope1> email is received along with signed <Document1>,  <Document2>. | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
| 8. | Login to DocuSign as  Signer <User1>  Navigate to the Manage tab and click on the sent option from the Envelope section  Click on the subject link of the <Envelope1>  Open the document  Verify that the date format of the signatures.  **Attach screenshot(s).** | The date format in the signatures should be in DD-MMM-YYYY | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
| 9. | Navigate back to the sent folder and click on the Download dropdown of the <Envelope1> and click History option  Verify that the pop up window displays the Envelope History  Verify under the Activities section application displays the following   1. User name 2. User API 3. Signature ID 4. Adopted Signature ID   **Attach screenshot(s).**  Close the popup window | In the Envelope History application should display the following   1. User name 2. User API 3. Signature ID 4. Adopted Signature ID | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
| 10. | Navigate to the Reports tab and click on the Envelope option from the left navigation  Click on the View button for the ‘Envelope Report’ and Run the report and download the report  Verify that the download report has the Date and time columns separately.  **Attach screenshot(s).** | The downloaded report should show the date and the time columns separately | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |
| 11. | From the application navigate to the settings page and click on the Audit Logs option present under Auditing section  Click on the Filters and select custom option to input From and To date ranges and apply.  Verify that the application displays the audit logs for the specified date range  **Attach screenshot(s).** | Application should display only the audit logs only in the specified date range | As Expected  Not As Expected  See Attachment(s): | Yes  No  Initials/Date: |

|  |  |
| --- | --- |
| **Test Result** | **Comments** |
| * **Pass** * **Fail** |  |

|  |  |
| --- | --- |
| **Tester Signature** | **Date Executed** |
|  |  |

|  |  |
| --- | --- |
| **Reviewer Signature** | **Date Reviewed** |
|  |  |

## Appendix A: Signature Log

By signing below, you are attesting to having read and understood the contents of this Smoke Test Plan, that you are familiar with the associated business process and how DocuSign System supports the procedures relevant to your testing responsibilities, and that you will seek additional guidance and/or training where required.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Printed Name | Signature | Initials | Date signed |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |
| 7 |  |  |  |  |
| 8 |  |  |  |  |
| 9 |  |  |  |  |
| 10 |  |  |  |  |
| 11 |  |  |  |  |
| 12 |  |  |  |  |
| 13 |  |  |  |  |
| 14 |  |  |  |  |
| 15 |  |  |  |  |

Note: additional copies of this page may be made and paginated as needed. Page of

## TEST REPORT

## TEST RESULTS

* + - **Testing passed**, meeting the acceptance criteria specified in section 6 of this document.
    - **Testing failed**, not meeting the acceptance criteria specified in section 6 of this document.

Were there any deviations encountered?

☐ Yes (describe in section below) ☐ No

## SUMMARY OF DEVIATIONS

.

|  |  |  |
| --- | --- | --- |
| **POST-EXECUTION APPROVALS** | | |
| Quality |  | *Sign & Date* |

**REVISION HISTORY**

| Rev. | Author | Description of Changes | Justification for Changes |
| --- | --- | --- | --- |
| 03 | Raghu Sharma | 1. Updated the Test Set up, Test Step1 and Step3 2. Added Step8, Step9, Step10 and Step11 3. Updated the Document ID from the Header. | 1. Regression Protocol for DocuSign. Refer to Change Request CC-2022-003 |
| 02 | Raghuraj Sharma | 1. Updated Header, Step-1 to Step-6 in Section 9-A | 1. Regression Protocol for DocuSign. Refer to Change Request CC-2021-003 |
| 01 | Raghuraj Sharma | 1. Updated Step-2, Step-5 and Step-6 in Section 9-A | 1. Regression Protocol for DocuSign is updated as per Deviation D01 of Change Request CC-2020-002 |
| 00 | Raghuraj Sharma | 1. New. | 1. Regression Protocol for DocuSign. Refer to Change Request CC-2020-002 |