

VxT Risk-Based Performance Qualification (PQ) Protocol for MasterControl Documents Version 2022.3

Prepared by MasterControl, Inc.

For



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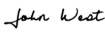





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Revision History

Revision	Date Issued	Revision Description	Preparer
1.0	30 Sept 2022	Initial Version	Himanshi Jain MasterControl Inc.

Protocol Approval Page

By signing / dating in the space provided below, the following UNC Advanced Cellular Therapeutics Facility representatives indicate approval of this protocol for execution at their facility(ies).

Title	Name (Printed)	Signature	Date
Assistant Director of Cellular Therapy Production	Dr John West	DocuSigned by:   Signer Name: John West Signing Reason: I approve this document Signing Time: 05-Oct-2022 13:41 EDT 614380A30FA44FFF97714EFD5E8493A3	
Assistant Director of QA/QC	Colin Mudd	DocuSigned by:   Signer Name: Colin Mudd Signing Reason: I approve this document Signing Time: 05-Oct-2022 13:51 EDT 1B02F4E348F2418D81910D16C582929F	
Associate Director of Quality Assurance	Dr. Kimberly Kasow	DocuSigned by:   Signer Name: Kimberly Anne Kasow Signing Reason: I approve this document Signing Time: 05-Oct-2022 23:38 EDT 0389751811D94948BEFFA58F275F4C96	

This protocol was executed by and completed on: _____

By signing / dating in the space provided below, the following UNC Advanced Cellular Therapeutics Facility representatives indicate approval of the completed protocol results and the associated objective evidence.

Title	Name (Printed)	Signature	Date

Signature Log

Each person who will execute tests or serve as a reviewer for this protocol must sign, initial and date in the space below prior to executing this protocol or beginning their review as appropriate.

Role	Name Printed	Signature	Initials	Date
Tester	Seer Pharma			
Reviewer	Colin Mudd			

Purpose

This document contains the test scripts to be executed in support of the VxT Risk-Based Performance Qualification activities at UNC Advanced Cellular Therapeutics Facility for the MasterControl™ Software Suite Documents Module. To review the risk assessment used to determine the usage testing in the risk-based PQ protocol. Please review the UNC Advanced Cellular Therapeutics Facility Initial Risk Assessment document.

The completed protocol associated execution notes and objective evidence will be maintained as a part of the UNC Advanced Cellular Therapeutics Facility validation records and used in the determination of the MasterControl™ Application Suites readiness for use.

Full details of the project and the validation activities are available in the Validation Plan (VP) for the MasterControl™ Software Suite.

Scope

This document applies to the VxT Risk-Based Performance Qualification activities for the testing of the MasterControl™ Application Suite Documents Module and associated document control process functions, at UNC Advanced Cellular Therapeutics Facility facilities.

Definitions

See Definitions Glossary in the Validation Toolkit.

See MasterControl™ Help Menu for legend of icons and their meanings.

System Overview

The MasterControl™ Application Suite is a software package, providing automated Workflow and document management capabilities in a configurable software system that maintains electronic records for a multitude of quality processes.

MasterControl™ is considered a configurable software package. UNC Advanced Cellular Therapeutics Facility implementation of the MasterControl™ System was developed by configuring the pre-defined modules of MasterControl™ software to meet the user operation requirements / process needs. UNC Advanced Cellular Therapeutics Facility configuration may not include all functionality listed below or may exceed it.

The MasterControl™ Documents module provides electronic document management capabilities, allowing management of any file type in a controlled environment. Documents are version controlled; access protected by user privileges and can be sent through pre-defined approval Workflows.

The MasterControl™ Collaboration function extends Documents functionality by allowing Users to interactively develop documents. Multiples redline files are retained to build a history of changes while collaboration leaders retain control over the final file version.

User Roles and Responsibilities:

MasterControl™ Sub/Systems Administrator is responsible for:

- Creating new documents and storing them in the system
- Controlling the MasterControl™ system configuration and design
- Maintaining System / User security settings
- Correcting system issues as applicable
- Assisting the Systems Administrator with MasterControl™ System operations
- Creating and maintaining the Approval Workflows within the MasterControl™ System.
- Ensuring Documents, Proper System Usage and Current Configuration meet the defined company procedures.
- Assisting Users in day-to-day operation of system as required.

All Creator-Reviser and Document Admin personnel are responsible for:

- Creating new documents and storing them in the system
- Making revisions to existing documents
- Reviewing the submitted documents accuracy
- Approving or rejecting documents tasked to them for signature
- Adding comments / reasons for rejected documents

Pre-Determined (or selected) approval personnel are also responsible for:

- Assigning additional review and approval personnel to the approval packet Workflows as required.

Viewer / View Only Personnel are responsible for:

- Using MasterControl™ as the ONLY source for approved controlled documents for the document types defined as being controlled by the system.

Performance Qualification (PQ) Overview

The Performance Qualification testing of the MasterControl™ Documents module shall consist of the following general Workflow tests based on the usage methods defined at UNC Advanced Cellular Therapeutics Facility .

- Password, Electronic Signature
- Audit Settings, Audit Log
- Audit Trail
- Vaults
- Users

Acceptance Criteria: Successful completion of each of these usage test methods shall indicate the systems acceptability for use and indicate the system as being in a validated state.

Pre-Test Setup Activities

The following is a list of tasks that must be completed before executing the MasterControl™ Documents PQ protocol. These tasks identify the Documents configuration created for UNC Advanced Cellular Therapeutics Facility . Prior to testing, verify the test environment is configured as indicated. This will help ensure that the scripts in this document can be performed smoothly, without interruption. All items are meant to create a test environment. If executing on the production database, avoid names that may interfere with configuration of the production environment (e.g., use 'ZPQ-' etc. as part of each name).

Pre-test Readiness



Ensure testing device is set up to vendor Hardware/Software and client device recommendations.

Test Environment	
Equipment used	
Workstation Asset Tag #	
Operating System (include Service Pack, if any)	
Web Browser Name and Version	
Software Build #	
Start Date	

Test Environment Setup

The following is a list of tasks that must be completed before executing the MasterControl™ Documents PQ protocol. These items work collectively to a test environment. If executing on the production database, avoid names that may interfere with configuration of the production environment (e.g. use 'ZPQ' etc. as part of each name).

- Create the following Users (assign the specified roles)

User Number	Name	Role	Supervisor	E-Mail Address
User2	PQ TEST2	Doc Admin-F	SYSADMIN	
User3	PQ TEST3	Public-Create-F	SYSADMIN	

Note: If the E-mail receipt is not being verified in the test environment or e-mail addresses are not being set for a given user enter N/A.

Note: Upon first-time login with each user created for this PQ, a message will appear prompting the user to take an optional informational tour of MasterControl™ and answer security questions.

Pre-Test Verification

- Sign to Confirm all configurations have been created/verified and made available based on usage requirements.

- Ensure Audit Trail settings are on prior to PQ execution: Enabled ☐ Disabled ☐

If disabled, provide justification: _____

- E-mail configuration: Enabled ☐ Disabled ☐

Note: If e-mail configuration is disabled in the test environment the tracking screen will identify that e-mails have been triggered but no physical e-mails will be received.

- Do not proceed if the IQ and OQ / TOQ have not been successfully completed and approved. The MasterControl™ Software Suite must be in a fully configured status to properly test this protocol; the protocol should be modified for use with the customer's defined Workflow.

Pre-Test Verified By:

Tester: _____ Date: _____

Reviewer: _____ Date: _____

Optional

Performance Qualification (PQ) Testing

This section of the protocol contains the testing scripts to be conducted during the PQ execution. These scripts were developed based on the systems functionality of the MasterControl™ Software Suite and collected into the UNC Advanced Cellular Therapeutics Facility defined usage method. Testers will conduct each section noting the actual results and collecting the defined objective evidence for the testing activities.

It is the assumption of this protocol that the tester has received adequate training for the navigation and function of the module being tested.

Recording “pass” into the Actual Results column during formal PQ execution indicates that the actual result matched all expected results for that specific step. All steps should be successfully completed, or any failures evaluated, and any workaround documented as a deviation. Acceptance of the workflow may be identified as accepted with limitations if a suitable workaround to all identified failures is documented and accepted by management.

Objective Evidence Capture







Screenshot Required.







Printout Required.



Note: A camera or visual verification may be used on the Mobile Device if screenshots are not easily able to be captured via the device itself. In cases where visual verification is used this verification should be noted in an execution notes document with the Tester(s) Name, Initials, Test Step, and details of the verification activity for the noted test step.





Note: Upon completion of a step, if a tracking page screenshot is not available for the user logged in, the tester is instructed to use the SysAdmin account to view the tracking page for proof of appropriate document Workflow.


Test	Task	Expected Result	Actual Result
Password, E-Signature			
1.1.1	<p>Login as SYSADMIN in Master Control.</p> <p>Navigate to User Management in Portal. Click on Users to create new User.</p> <p>Enter following in User Profile:</p> <p><u>User Information</u></p> <p>User: USER2</p> <p>First Name: PQ</p> <p>Last Name: TEST2</p> <p>Supervisor: SYSADMIN</p> <p><u>Role Assignment</u></p> <p>Assigned Roles: Doc Admin-F</p>	New User created and data entered in noted fields.	<p>Pass/Fail: _____</p> <p></p> <p>(User Profile)</p>
1.1.2	<p>Enter 8-character password including only Alphabets- 'P@ssword' for Login Password.</p> <p>Try to save User Profile.</p>	User profile cannot be saved as Login password requires alphanumeric character.	<p>Pass/Fail: _____</p> <p></p> <p>(User Profile-Error message)</p>
1.1.3	<p>Add number 1 in the end of password to make – 'P@ssword1'.</p> <p>Save User Profile.</p> <p>Log out.</p>	User Profile can be saved without any error.	<p>Pass/Fail: _____</p>
1.1.4	<p>Login as USER2 with following information:</p> <p>USER ID: USER2</p> <p>Password: P@ssword</p>	The user did not log in successfully.	<p>Pass/Fail: _____</p> <p></p>
1.1.5	<p>Login as User created in above steps-USER2 using password set in above step.</p>	Logged in successfully.	<p>Pass/Fail: _____</p>
1.1.6	<p>Create a new Document Infocard Type "FORM" with subtype as "General".</p> <p>Name the Title as "PQ TEST 0.1".</p> <p>Add a word document under Main File.</p> <p>Fill in all the required fields.</p> <p>Click on Save.</p>	The user can successfully create a document Infocard.	<p>Pass/Fail: _____</p> <p></p>

Test	Task	Expected Result	Actual Result
1.1.7	<p>As the same User2 Quick Approve the Document Infocard "PQ TEST 0.1".</p> <p><u>User Information</u> User: USER2 Electronic Signature: P@\$word</p> <p>Click on Submit.</p>	<p>The user cannot Quick Approve the Document Infocard as the system prompts a message of Invalid Electronic Signature.</p> <p>Note: The Password and Electronic Signature are same for the users.</p>	<p>Pass/Fail: _____</p> 
1.1.8	<p>As the same User2 Quick Approve the Document Infocard "PQ TEST 0.1".</p> <p><u>User Information</u> User: USER2 Electronic Signature: P@ssword1</p> <p>Click on Submit.</p>	<p>The user can successfully approve the Infocard.</p> <p>Note: The Password and Electronic Signature are same for the users.</p>	<p>Pass/Fail: _____</p> 
Audit Settings, Audit Log and Audit Trail			
1.1.9	<p>Login as SYSADMIN and Navigate to the Portal hub and search for Audit under System Settings.</p> <p>Under Change Reason Settings if Disable radio button is selected switch to Enable.</p> <p>Note: If the Change Reason Settings is Enabled then this step is N/A.</p> <p>Click Save and a Change Reason window will pop up.</p> <p>Mention PQ TESTING in the text box and Click Save.</p>	<p>The user was successfully logged in.</p> <p>The settings were saved correctly.</p>	<p>Pass/Fail: _____</p> 

Test	Task	Expected Result	Actual Result
1.1.10	<p>Same as SYSADMIN Navigate to the Documents module.</p> <p>Search for Document Infocard "PQ TEST 0.1". Open the Infocard and click on Edit option to change the following information.</p> <ul style="list-style-type: none"> Title as PQ TEST 0.2 Add a Custom Field Value as Engineering from Specification (Fieldname) Add a Custom Field Value as UNC University from Site (Fieldname). <p>Click Save and a Change Reason window will pop up.</p> <p>Mention PQ TESTING in the text box and Click Save.</p>	<p>The user can search the Document Infocard.</p> <p>The changed were saved successfully.</p>	<p>Pass/Fail: _____</p> 

Test	Task	Expected Result	Actual Result
1.1.11	<p>Same as SYSADMIN Navigate to the Portal module and open the Audit Log.</p> <p>Select Documents under Application. Click Search.</p> <p>Note: The report may take some time to generate.</p> <p>Search for PQ TEST 0.1 under Old Value column.</p> <p>Click on (i) icon under Actions column.</p>	<p>The user can open the Audit Log and view.</p> <p>The user can view the Document Infocard Old Value.</p> <p>The user can view the following details:</p> <ul style="list-style-type: none"> Title Old Value: PQ TEST 0.1 Title New Value: PQ TEST 0.2 Custom Fields Data New Value: Engineering & UNC University <p>The user can also view other details related to the Document Infocard such as:</p> <ul style="list-style-type: none"> Infocard Details Change Location/Time User Information (User who made the changes). 	<p>Pass/Fail: _____</p> 
1.1.12	<p>Same as SYSADMIN Navigate to the Documents module.</p> <p>Search for Document Infocard "PQ TEST 0.2". Open the Infocard.</p> <p>Click on Versions tab on the top-right hand side and search for (Audit Trail) icon.</p> <p>Click on the icon.</p>	<p>The user can view the details related to the document Infocard.</p>	<p>Pass/Fail: _____</p> 

Test	Task	Expected Result	Actual Result
Vaults			
1.1.13	<p>Login as SYSADMIN in Master Control.</p> <p>Navigate to User Management in Portal. Click on Users to create new User.</p> <p>Enter following in User Profile:</p> <p><u>User Information</u></p> <p>User: USER3</p> <p>First Name: PQ</p> <p>Last Name: TEST3</p> <p>Supervisor: SYSADMIN</p> <p><u>Role Assignment</u></p> <p>Assigned Roles: Public-Create-F</p>	<p>New User created and data entered in noted fields.</p>	<p>Pass/Fail: _____</p> <p>(User Profile) </p>
1.1.14	<p>Log in as USER2 Navigate to the Documents module.</p> <p>Search for Document Infocard "PQ TEST 0.2". Open the Infocard.</p> <p>Download both Native and PDF version of the main file.</p>	<p>The user can search for the Document Infocard.</p> <p>The user can download and view both the version of the main file attached to the Infocard.</p>	<p>Pass/Fail: _____</p> <p></p>
1.1.15	<p>Log in as USER3 Navigate to the Documents module.</p> <p>Search for Document Infocard "PQ TEST 0.2". Open the Infocard.</p>	<p>The user can search for the Document Infocard.</p> <p>The user cannot download native version of the main file.</p> <p>The user can only download a PDF version of the main file.</p>	<p>Pass/Fail: _____</p> <p></p>
Users			
1.1.16	<p>Login as SYSADMIN in Master Control.</p> <p>Navigate to User Management in Portal.</p> <p>Search for the USER3.</p> <p>Click on disabled icon.</p> <p>Note: Mention PQ TESTING in the Change Reason dialogue box.</p>	<p>The user can successfully view the USER3</p> <p>The user was disabled.</p>	<p>Pass/Fail: _____</p> <p></p>

Test	Task	Expected Result	Actual Result
1.1.17	Visit to the MasterControl Test website and log in as USER3.	The user cannot get logged into the system as the account was disabled in the step 1.1.15.	Pass/Fail: _____ 

This completes the VxT Risk-Based Protocol for MasterControl Documents for Version 2022.3.

Documents PQ

Test acceptance criteria met?

☐

Test Passed

☐

Test Passed with Limitations*

☐

Test Failed*

Was a Deviation or Bug reported during testing:

☐

YES*

☐

NO

*Comments Required

Tester Comments

Reviewer Comments

Tester: _____ Date: _____ Reviewer: _____ Date: _____

Attachments Log

For any attachments (eg. Test screenshots) that have been generated enter the details in the following table.
If there are no attachments to the PQ Protocol, mark this table as "N/A".

Number	Description	Date/Initials

Discrepancy Log

The Discrepancy Log provided below will be used to track the status of all deviations created during PQ testing.

DISCREPANCY LOG

Deviation Report #	Test Section	Step No.	Description	Recorded By/Date	Closure Date/Initials

DEVIATION REPORT

Protocol No.:	Test Section No.:	Step No.:	Deviation No.:
Deviation Description:			
Deviation Classification:	<input type="checkbox"/> Configuration Error <input type="checkbox"/> Protocol Error <input type="checkbox"/> Software Error <input type="checkbox"/> Tester Error <input type="checkbox"/> Other		
Reported By:		Date:	
Resolution/Explanation:			
Reported By:		Date:	
Results:	<input type="checkbox"/> Retest PASS <input type="checkbox"/> Retest FAILED <input type="checkbox"/> No Retest Required		
Testing Completed By:		Date:	
Reviewed By:		Date:	
Closed By: (<i>Verify Resolution/Corrective Action has been completed</i>)		Date:	

Certificate Of Completion

Envelope Id: EC294E3995CA44D1838BC064389DAB44

Status: Completed

Subject: Complete with DocuSign: 2022-VAL-012 UNC Advanced Cellular Therapeutics Facility _v2022.3_VxT ...

IRB Number / PI Name: ACT Facility

Source Envelope:

Document Pages: 23

Signatures: 3

Envelope Originator:

Certificate Pages: 6

Initials: 0

Colin Mudd

AutoNav: Enabled

312 South Building

Envelopeld Stamping: Disabled

CB 4000

Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Chapel Hill, NC 27599-4000

colin_mudd@med.unc.edu

IP Address: 152.23.50.240

Record Tracking

Status: Original

Holder: Colin Mudd

Location: DocuSign

05-Oct-22 | 13:30

colin_mudd@med.unc.edu

Signer Events**Signature****Timestamp**

John West

John West

Sent: 05-Oct-22 | 13:30

john_west@med.unc.edu

Viewed: 05-Oct-22 | 13:40

UNC-CH: School of Medicine

Signed: 05-Oct-22 | 13:41

Security Level: Email, Account Authentication
(Required)

Signature Adoption: Pre-selected Style

Signature ID:

614380A3-0FA4-4FFF-9771-4EFD5E8493A3

Using IP Address: 152.23.54.208

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

I approve this document

Electronic Record and Signature Disclosure:

Accepted: 06-Jan-22 | 12:59

ID: 13e6246d-98b2-4bf5-bf3a-7cf0200f8a38

Colin Mudd

Colin Mudd

Sent: 05-Oct-22 | 13:41

colin_mudd@med.unc.edu

Viewed: 05-Oct-22 | 13:51

Security Level: Email, Account Authentication
(Required)

Signed: 05-Oct-22 | 13:52

Signature Adoption: Pre-selected Style

Signature ID:

1B02F4E3-48F2-418D-8191-0D16C582929F

Using IP Address: 152.23.50.240

With Signing Authentication via DocuSign password

With Signing Reasons (on each tab):

I approve this document

Electronic Record and Signature Disclosure:

Accepted: 16-Nov-21 | 11:35

ID: a5a13bcf-53d8-4449-b8fe-35523c0a3f55

Signer Events	Signature	Timestamp
Kimberly Anne Kasow kkasow@med.unc.edu UNC-CH: School of Medicine Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 03897518-11D9-4948-BEFF-A58F275F4C96 Using IP Address: 45.37.101.214 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 05-Oct-22 13:52 Viewed: 05-Oct-22 23:38 Signed: 05-Oct-22 23:38
Electronic Record and Signature Disclosure: Accepted: 21-Dec-21 19:19 ID: 2753e39f-18b8-4107-8e3d-ef79c0cab5db		
In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	05-Oct-22 13:30
Certified Delivered	Security Checked	05-Oct-22 23:38
Signing Complete	Security Checked	05-Oct-22 23:38
Completed	Security Checked	05-Oct-22 23:38
Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

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You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

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of such request you must state your email address, full name, mailing address, and telephone number.

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To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an email to docusign-hsr@unc.edu and in the body of such request you must state your email, full name, mailing address, and telephone number. The study team may request a reason for withdrawal from the study. There are no consequences to you for choosing to withdraw your consent.

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