.

Document Number:

Revision:

InfoCard Information

Status:

Date Information

Effective:

All dates and times are in

Table of Contents

1.0   PURPOSE

This document establishes User Requirement Specifications (URS) for MasterControl's Application Suite for use at our client intended usage based on MasterControl best practice configuration specification for the Mobile site.

2.0   SCOPE

User requirements define the intended use and critical/important aspects of the software. They are high-level, user-centric descriptions of what the software needs to do. User Requirements do not explain how the software should act (such as clicking a button to save), nor do they present design information, specific data handling or functional requirements. User Requirements are tested via Transfer Performance Qualification (TPQ) testing and a traceability to that testing is provided within this document. Regulatory Requirements and testing are documented in a separate Regulatory Requirements Specification.

This document contains the usage requirements for the MasterControl Mobile application. It also presents the MasterControl tests (trace matrix) that exercise these requirements.

Summarizing results for TPQ executions are presented in line with requirements throughout the documents. Additional testing details are provided as hyperlinks within each result set.

3.0   VALIDATION TEST HISTORY

Date	Execution ID	Build Number	Tests Executed
15 Apr 2022 2:06 PM	16591	2022.2.0.184	3 (0 failed)

4.0   TEST DEVIATION SUMMARY

Deviation Number	Affected Requirement	Deviation Type	Status
No deviations were found during the execution of this URS.			

5.0   APPLICATION OVERVIEW

The MasterControl™ Application Suite is a web-based software package designed to automate various Quality Management Systems (QMS). The system is designed with a base software package that has additional modules that can be added per required function. Each functional module or system of the MasterControl™ Application Suite is controlled and monitored by the Application Administration Interface (Portal Module). The Application Administration Interface is the security, configuration, user management, reporting and audit / change control center of the MasterControl™ Application Suite and serves as the main user interface to the application.

For detailed configuration information for the Mobile module, refer to the MasterControl Mobile Best Practice Specification for the appropriate MasterControl version.

6.0   USER REQUIREMENTS AND TRACE

URS ID	Description	Test #	Result
1	**Mobile Interface** *The following will be tested as part of the Workflow.*	---	---
1.1	A full license user verifies that the Mobile website matches the data within the standard website for the following: • My Tasks • InfoCard search results • Main file viewing • Explorer	S-17547	PASS 16591
1.2	A basic license user verifies that the Mobile website matches the data within the standard website for the following: • My Tasks • InfoCard search results • Main file viewing • Explorer	S-17547	PASS 16591
2	**Document Module Usage**	---	---
2.1	*A Document InfoCard is launched on the standard site onto a 2-step workflow, including a collaboration step.*	---	---
2.2	A Packet Task is launched on the standard website.	S-17548	PASS 16591
2.3	The Packet Task appears in the Mobile user's My Tasks list on the Mobile website.	S-17548	PASS 16591
2.3.1	The Mobile user can perform the following in the collaboration workspace: • View the main file • Add a comment	S-17548	PASS 16591
2.3.2	A Document Admin ends collaboration for the Packet Task on the Desktop site.	S-17548	PASS 16591
2.3.3	The Mobile user can reject and approve document packets on approval steps through the Mobile site.	S-17548	PASS 16591

URS ID	Description	Test #	Result
2.3.4	The approved and released InfoCard displays when search via the following: • Mobile site search functionality • Mobile site Explorer	S-17548	PASS 16591
3	**Training Module Usage** *The following will be tested as part of the Workflow.*	---	---
3.1	*Ensure a document InfoCard in the released vault is linked to a Course InfoCard in the released vault with an associated Exam in the released vault and associated to a Job Code in the released vault with a released full license user and a released basic license user trainee InfoCards associated to the Job Code, allowing a training task to launch to the trainees.*	---	---
3.2	A full license user can view the following in their My Tasks on the Mobile site: • Training Tasks with Exams	S-17549	PASS 16591
3.3	A trainee cannot retake an exam on the mobile site more times than is configured, using at least one (1) retake configuration.	S-17549	PASS 16591
3.4	A training task is relaunched to the trainee automatically on the Mobile site when the trainee fails the associated exam, and it is rejected by the Training Verifier.	S-17549	PASS 16591
3.5	Rejection comments can be viewed on the Mobile site when a training task is rejected by the Training Verifier.	S-17549	PASS 16591
3.6	A trainee can complete a training task on the Mobile site that is linked to an exam and Document InfoCard.	S-17549	PASS 16591
3.7	Trainees can view the main files of document InfoCards that are associated to a training task through the Mobile site after completing the associated training task.	S-17549	PASS 16591
3.8	A basic license user can view the following in their My Tasks on the Mobile site: • Training Tasks with Exams	S-17549	PASS 16591

7.0   VIDEO REVIEW/ANALYSIS LOG

This table summarizes any videos that the validation team reviewed/analyzed as required per the MasterControl Validation Video Review Methodology MEMO. It includes the test ID number, the

test run ID(s), the URS ID numbers, and references the video review notes that were logged for each.

Test ID	Run ID(s)	URS ID Steps(s)	Validation Video Review Analysis Notes(s)
N/A			

8.0 REVIEWER NOTES

No Reviewer Notes generated. There were no issues found during this Review.

9.0 REVISION AND APPROVAL HISTORY

All approvals are maintained and controlled in the MasterControl™ electronic system.

Document Number: URS-0176   **Revision:** 01
Title: Mobile URS v2022.2
Effective Date: 21 Apr 2022

All dates and times are in US/Mountain.

Mobile URS v2022.2

Protocol Collaboration

Name/Signature	Title	Date	Meaning/Reason
Kirsty Massman (KMASSMAN)	Validation Engineer III	30 Mar 2022, 02:48:57 PM	Complete

Protocol Approval

Name/Signature	Title	Date	Meaning/Reason
Nghi Tran (NTRAN)	Validation Engineer I	15 Apr 2022, 11:28:01 AM	Approved

Execution Analysis

Name/Signature	Title	Date	Meaning/Reason
Nghi Tran (NTRAN)	Validation Engineer I	18 Apr 2022, 09:07:05 AM	Complete

Tech Review

Name/Signature	Title	Date	Meaning/Reason
Kirsty Massman (KMASSMAN)	Validation Engineer III	18 Apr 2022, 11:35:39 AM	Complete

Quality Review

Name/Signature	Title	Date	Meaning/Reason
Michelle Leckie (MLECKIE)	Validation Engineer	21 Apr 2022, 11:09:31 AM	Complete

Validation Approval

Name/Signature	Title	Date	Meaning/Reason
Brent Page (BPAGE)	Director of Engineering	21 Apr 2022, 11:46:18 AM	Approved

Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Michelle Leckie (MLECKIE)	Validation Engineer	21 Apr 2022, 11:10:00 AM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Scott Dickey (SDICKEY)	Validation Engineer III	21 Apr 2022, 11:46:18 AM	Email Sent
Jonathan LeBaron (JCLEBARON)	Quality Engineer	21 Apr 2022, 11:46:18 AM	Email Sent
David Baldwin (DBALDWIN)	Vice President of Engineering	21 Apr 2022, 11:46:18 AM	Email Sent

Colman Lloyd (CLLOYD)	Validation Engineer I	21 Apr 2022, 11:46:18 AM	Email Sent
Jeff Peterson (JVPETERSON)	Quality Manager	21 Apr 2022, 11:46:18 AM	Email Sent
Jake Walton (JWALTON)	Director, Quality & Compliance	21 Apr 2022, 11:46:18 AM	Email Sent
Brent Page (BPAGE)	Director of Engineering	21 Apr 2022, 11:46:18 AM	Email Sent
Adam Berrio (ABERRIO)	Director, Engineering	21 Apr 2022, 11:46:18 AM	Email Sent
Nghi Tran (NTRAN)	Validation Engineer I	21 Apr 2022, 11:46:18 AM	Email Sent
Kirsty Massman (KMASSMAN)	Validation Engineer III	21 Apr 2022, 11:46:18 AM	Email Sent
Michelle Leckie (MLECKIE)	Validation Engineer	21 Apr 2022, 11:46:18 AM	Email Sent