Validation Report

Synopsis: when introducing a new application within a pharmaceutical company (or even making changes to older applications), every little detail is thoroughly documented. From the conception of the idea, through its development and deployment, all the way to its eventual retirement, each step along the way is maintained in accordance with specific regulations set forth by the FDA. And trust me, there are a lot of steps.

Below is a sample Validation Report, a document that serves as the pretty red bow atop all these documented steps. It serves as the final verification that a new application has been successfully tested and is fit for use, and is normally the first document an auditor will request to see. It also contains something called a Traceability Matrix, essentially a list of requirements the application was set out to do matched with confirmation that it can now do them. I've removed the final two pages of that matrix as it's just a repeated table with those requirements/results.

[redacted] - Validation Report

1.0 Approvals

Name of System Owner	[redacted]
Title of System Owner	Director, Information Technology
Signature of System Owner / Date	[redacted] **Executive Director of Information Technology, will approve on behalf of** [redacted]

(Note: Electronic Signatures should only be used if all parties have the ability to eSign.)

2.0 Introduction

This Validation Report covers the [redacted] system upgrade to version 9.2.3 as it was tested against the requirements outlined in the System Requirements Specifications, dated 11-Sep-2012.

3.0 Summary of Acceptance Testing

3.1 Testing Schedule

The [redacted] system was subjected to user acceptance testing from 12-Sept-2012 to 14-Sept.2012.

3.2 Testing Results

46 test cases were executed as part of User Acceptance Testing of the [redacted] system. 44 of the 46 test cases passed upon initial execution. Overall, 45 test cases were passed.

Test case #2 was stopped during testing; the test requires a stable connection to the network, and the test was unable to be completed as the tester was executing remotely. The test will be re-executed post-production, and maintained with the UAT output.

Test case #22 failed during testing. In the new version (in OCJR1.KCI), there are key data items that are failing to populate e.g., PATIENTiD, in the Header section of the "Create Pivot Panel" dialog box. Instead, an error is generated when attempting to create one. Although on occasion we have created pivot panels, it's not commonly used. This is considered an advanced feature of the [redacted] system, generally used by programmers. However, programmers most often prefer to do an ImportSQL in lieu of creating a pivot panel. As such, this test will not be viewed as an impediment to the [redacted] upgrade, and will be address post-production.

3.3 Validation Summary

3.3.1 System Risk Assessment Results

Prior to User Acceptance Testing, a System Risk Assessment was conducted to assess risks associated with bring the system to a validated state. All risks identified in this assessment were addressed or deemed acceptable.

Risk Description	Measures and Controls	Resolution
New functionality will be included in this release. A number of processes and features in the previous version have been modified, and the interface will appear slightly different in appearance to the users.	User Acceptance Testing will be conducted to mitigate the risk associated with changed or new functionality. Operational users will provide feedback to the System Owner on the usability and performance to ensure that all required features are sufficient. Face to face and web-based training will also be provided to the users. Additionally, subject matter experts will review assigned components of the system prior to test script creation to confirm the new functionality is as it was originally proposed/intended.	User Acceptance Testing was successfully conducted by end users of the system. All known issues as a result of UAT will be addressed following the system's upgrade, and are not considered a risk to the release.
PRA has limited internal technical resources to support new features and functionality knowledge following the release of the newest version of [redacted]	The project team will be working closely with ICS to document process to increase internal knowledge of the new functionality. Additionally, an admin manual will be completed, and web based training licenses have been obtained for administrators.	Administrators will partake in training of the new features of the upgrade to be able to support the [redacted] upgrade moving forward. An admin manual has been put into place to support the administrators, as well.
PRA has limited operational resources for test case creation/execution	Data Management will be consulted for test script creation. Individuals from the Clinical Informatics group will be identified for testing purposes, as well as from an array of other groups to ensure appropriate feedback is received.	All necessary test scripts were provided prior to the testing effort. End users of the system were identified and provided leading up to testing, and all test scripts were executed successfully.
The details provided in the vendor supported documents is currently lacking and written at a high level.	A general user guide and other training materials will be created to assist in the level of documentation detail. Additionally, final drafts will be available post-UAT to incorporate all useful feedback.	The user guide will be finalized following the [redacted] upgrade, and will be available for view in PRA's corporate docbase.

Risk Description	Measures and Controls	Resolution
The External Help Desk (EHD) must support [redacted] in its production use. Currently, there is little material to support the EHD once the system has been deployed.	More information from the vendor, such as reference materials and manuals, will be requested to support the EHD following system deployment.	More information from the vendor, such as reference materials and manuals, will be requested to support the EHD following system deployment.

3.3.2 21 CFR Part 11 Compliance

The [redacted] system has been reviewed in an effort to ensure compliance with FDA's 21 CFR Part 11 regulations. These reviews were completed 12-Sept-2012 using PRA's 21 CFR Part 11 System Assessment Checklist. During these reviews, no issues were identified that would affect the system's compliance with 21 CFR Part 11 regulations.

3.3.3 Readiness for Release

The [redacted] system upgrade is ready for release to production as of 14-Sept-2012.

3.4 Referenced Documents

All signed SDLC documents and testing output will be stored PDF format in PRA's Corporate Docbase. These PDF renditions may be found in the following location:

|| [redacted] | Final Copies.

PRA will provide SDLC documents for use during audits. All documents referenced herein can be found in the [redacted] SDLC folder in Webtop.

4.0 Traceability Analysis

A traceability analysis is included as attachment A to this document. This analysis associates test cases and results to system requirements as stated in the System Requirements Specification.

5.0 Attachments

A. Traceability Analysis

SRS Item	Test Case	Result
A.1.1; A.1.2; A.1.3; A.1.4; A.1.5,A.9.1	1	Pass
B.2.1	2	Not Executed
A.2.1	3	Pass
A.2.2	4	Pass
A.2.3	5	Pass
A.2.4	6	Pass