

Deviations Summary Report

Total # of Open deviations: 1

Total # of Open deviations with a risk assessment of 'Major': 1

Deviation #: 2

Deviation Type: Defect

Protocol Section #: 7.1.

Risk: Major

Test Case #: 5 **Step #:** 47

Status: Open

Description: Expected Result: The XYZ data field accepts data from the automatic data collection tool.
Actual Result: The XYZ data field does not accept data from the automatic data collection tool.

Root Cause: Upon investigation, it was determined that Data Collection tool had been incorrectly configured for the development environment.

Corrective Action: 1. The Data Collection tool needs to be reconfigured for the Validation environment.
2. Data Collection tool configuration needs to be added to the Installation Qualification for the production environment.

Summary: This deviation is currently open.

Total # of Closed deviations: 2

Total # of Closed deviations with a risk assessment of 'N/A': 2

Deviation #: 1

Deviation Type: Script Error

Protocol Section #: 6.3.

Risk: N/A

Test Case #: 3 **Step #:** 10

Status: Closed

Description: During protocol execution, the Tester identified a script error.

Format For Protocol Deviation Report

Mark A. Suckow, Bill Yates



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