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 incorectly 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 'NA': 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

Tim Thurnblad

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Table of Contents Format For Protocol Deviation Report

1. Understanding the eBook Format For Protocol Deviation Report
    - The Rise of Digital Reading Format For Protocol Deviation Report
    - Advantages of eBooks Over Traditional Books
2. Identifying Format For Protocol Deviation Report
    - Exploring Different Genres
    - Considering Fiction vs. Non-Fiction
    - Determining Your Reading Goals
3. Choosing the Right eBook Platform
    - Popular eBook Platforms
    - Features to Look for in an Format For Protocol Deviation Report
    - User-Friendly Interface
4. Exploring eBook Recommendations from Format For Protocol Deviation Report
    - Personalized Recommendations
    - Format For Protocol Deviation Report User Reviews and Ratings
    - Format For Protocol Deviation Report and Bestseller Lists

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