

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

Wenbin Ji

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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
5. Accessing Format For Protocol Deviation Report Free and Paid eBooks
 - Format For Protocol Deviation Report Public Domain eBooks
 - Format For Protocol Deviation Report eBook Subscription Services
 - Format For Protocol Deviation Report Budget-Friendly Options

6. Navigating Format For Protocol Deviation Report eBook Formats
 - ePub, PDF, MOBI, and More
 - Format For Protocol Deviation Report Compatibility with Devices
 - Format For Protocol Deviation Report Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Format For Protocol Deviation Report
 - Highlighting and Note-Taking Format For Protocol Deviation Report
 - Interactive Elements Format For Protocol Deviation Report
8. Staying Engaged with Format For Protocol Deviation Report
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Format For Protocol Deviation Report
9. Balancing eBooks and Physical Books Format For Protocol Deviation Report
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Format For Protocol Deviation Report
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Format For Protocol Deviation Report
 - Setting Reading Goals Format For Protocol Deviation Report
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Format For Protocol Deviation Report
 - Fact-Checking eBook Content of Format For Protocol Deviation Report
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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