

21 CFR Part 11 Validation



The Client: Client is Asia's leading biopharmaceutical company which manufactures generic active pharmaceutical ingredients.



Business Requirement



Validate the cloud based Learning Management System for 21 CFR Part 11 regulatory compliance



Design and execute test cases for Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)



End to end validation for different user roles and document all validation activities including test protocols, test scripts, test evidences and test reports



Our Solutions



Leveraged our jumpstart kit that includes Template, Guidelines, Checklists and Reports for 21 CFR Part 11 assessments



Developed and executed 1500+ test cases for IQ, OQ & PQ and 73 critical defects were reported



Performed exploratory testing as value addition and proposed a list of recommendations from user perspective



Created traceability Matrix that includes test cases linking requirements of 21 CFR Part 11



14 test cases were developed and reported to assess the system for 21 CFR Part 11 compliance



Business Impact



Successfully passed the external compliance audit



Documentation for all the validation activities with evidences for the purpose of audit trail

Technologies: Software : Microsoft Azure Cloud service | Defect tracking : Customized tool specialized for project

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Table of Contents 21 Cfr Part 11 Validation

1. Understanding the eBook 21 Cfr Part 11 Validation
 - The Rise of Digital Reading 21 Cfr Part 11 Validation
 - Advantages of eBooks Over Traditional Books
2. Identifying 21 Cfr Part 11 Validation
 - 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 21 Cfr Part 11 Validation
 - User-Friendly Interface
4. Exploring eBook Recommendations from 21 Cfr Part 11 Validation
 - Personalized Recommendations
 - 21 Cfr Part 11 Validation User Reviews and Ratings
 - 21 Cfr Part 11 Validation and Bestseller Lists

5. Accessing 21 Cfr Part 11 Validation Free and Paid eBooks
 - 21 Cfr Part 11 Validation Public Domain eBooks
 - 21 Cfr Part 11 Validation eBook Subscription Services
 - 21 Cfr Part 11 Validation Budget-Friendly Options
6. Navigating 21 Cfr Part 11 Validation eBook Formats
 - ePub, PDF, MOBI, and More
 - 21 Cfr Part 11 Validation Compatibility with Devices
 - 21 Cfr Part 11 Validation Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of 21 Cfr Part 11 Validation
 - Highlighting and Note-Taking 21 Cfr Part 11 Validation
 - Interactive Elements 21 Cfr Part 11 Validation
8. Staying Engaged with 21 Cfr Part 11 Validation
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers 21 Cfr Part 11 Validation
9. Balancing eBooks and Physical Books 21 Cfr Part 11 Validation
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection 21 Cfr Part 11 Validation
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine 21 Cfr Part 11 Validation
 - Setting Reading Goals 21 Cfr Part 11 Validation
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of 21 Cfr Part 11 Validation
 - Fact-Checking eBook Content of 21 Cfr Part 11 Validation
 - 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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