

# 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

# 21 Cfr Part 11 Validation

**Tao Wei**



**21 Cfr Part 11 Validation:**

The book delves into 21 Cfr Part 11 Validation. 21 Cfr Part 11 Validation is a crucial topic that must be grasped by everyone, ranging from students and scholars to the general public. The book will furnish comprehensive and in-depth insights into 21 Cfr Part 11 Validation, encompassing both the fundamentals and more intricate discussions.

1. This book is structured into several chapters, namely:

- Chapter 1: Introduction to 21 Cfr Part 11 Validation
- Chapter 2: Essential Elements of 21 Cfr Part 11 Validation
- Chapter 3: 21 Cfr Part 11 Validation in Everyday Life
- Chapter 4: 21 Cfr Part 11 Validation in Specific Contexts
- Chapter 5: Conclusion

2. In chapter 1, the author will provide an overview of 21 Cfr Part 11 Validation. This chapter will explore what 21 Cfr Part 11 Validation is, why 21 Cfr Part 11 Validation is vital, and how to effectively learn about 21 Cfr Part 11 Validation.

3. In chapter 2, this book will delve into the foundational concepts of 21 Cfr Part 11 Validation. This chapter will elucidate the essential principles that need to be understood to grasp 21 Cfr Part 11 Validation in its entirety.

4. In chapter 3, the author will examine the practical applications of 21 Cfr Part 11 Validation in daily life. The third chapter will showcase real-world examples of how 21 Cfr Part 11 Validation can be effectively utilized in everyday scenarios.

5. In chapter 4, this book will scrutinize the relevance of 21 Cfr Part 11 Validation in specific contexts. The fourth chapter will explore how 21 Cfr Part 11 Validation is applied in specialized fields, such as education, business, and technology.

6. In chapter 5, this book will draw a conclusion about 21 Cfr Part 11 Validation. This chapter will summarize the key points that have been discussed throughout the book.

This book is crafted in an easy-to-understand language and is complemented by engaging illustrations. It is highly recommended for anyone seeking to gain a comprehensive understanding of 21 Cfr Part 11 Validation.

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