

# RDMI

**SWAT IMPLEMENTATION STRATEGY  
AND  
FDA SOFTWARE VALIDATION TEST  
FOR  
MAINTENANCE MANAGEMENT SYSTEM  
MoCA FOR WINDOWS 95/98/NT/2000**

PREPARED BY:

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## **Implementation and Testing Process Plan:**

This report contains a system implementation and validation plan for **MoCA for Windows**, a computerized maintenance management software, based on Good Manufacturing Practices (GMP).

As a pre-requisite, client has already purchased MoCA for Windows Soli version and has adhered to GMP standards. This would include the company Quality Statement and complete operating procedures. In fact, the GMP Documentation for the company in the form of a Quality Manual has been developed.

MoCA for Windows, a maintenance management software provides the backbone for the Validation Test Process. The three basic elements of the Validation Process are 1) MoCA Software Soli version, 2) Implementation, Data Setup and Training and 3) Validation Test.

This implementation plan presents a logical approach for balancing these elements towards the achievement of the client's GMP requirements and maintenance management goals and objectives. RDMI will manage this project in accordance with project management techniques. The RDMI's project manager will act as the contact person for the client. The project manager, who will be co-ordinating directly with the Maintenance Engineer and QA Coordinator, will provide timely updates on project status, schedule changes, data conversion, training requirements, and a project summary analysis.

A five step approach to the implementation is as follows:

**Step One - Implementation Seminar**

**Step Two – Critical Equipment and PM Database Development and Process Review**

**Step Three – Critical Parts Inventory Database Development and Process Review**

**Step Four – Validation System Development and Process Review**

**Step Five – Software System Training**

The steps of the implementation plan outlined here are the fundamental steps that must be addressed to ensure a successful implementation. RDMI offers to complete each step jointly with the project team. Each step must be addressed by either RDMI or the client's internal staff to achieve the intended benefits of a maintenance information management system. *RDMI will make a good faith effort to complete each step for the client within the time period specified by the proposal.*

***Step One:***

### **Implementation Seminar**

RDMI's project manager will conduct, at the *client's facility*, an implementation planning seminar, and direct initial activities of the project. This seminar shall include users from Maintenance, Quality Assurance, MIS, Accounting, Production, Purchasing and other

concerned departments. The goals of the project will be established and agreed upon during this meeting. In establishing our strategy we will determine how best to allocate RDMI and client's resources in order to ensure a successful and timely project completion. The implementation seminar will provide the foundation and guidelines to ensure a timely and smooth implementation.

The seminar will serve to:

- Set objectives/goals and review time frame
- Establish criteria for measuring the success of the project
- Review project time line
- Review the Quality Manual and Procedures
- Define and establish coding standards as per Quality Manual
- Review existing practices and procedures
- Define/review maintenance procedures
- Verify hardware requirements/networking issues
- Establish working process for storeroom control and work order management.

*Step Two:*

### **Critical Equipment and PM Database Development and Process Review**

RDMI will perform a review of existing equipment database and develop a technical specification for review. Based on RDMI's recommendations and guidelines established, the database will be converted to meet GMP requirements. Database verification is essential to ensure continuity in management analysis and reporting. The decision about how to convert the data, whether manual or electronic, will be made during this step.

RDMI will work in conjunction with client's personnel to develop an equipment database and Preventive Maintenance database on predetermined critical and production equipment as outlined in the SOP or GMP documents. This joint session will provide a systematic design for the client to review and implement as a template to use on remaining critical and non-critical equipment. The following data will make up CMMS's equipment and Preventive Maintenance databases, and for the purpose of Validation Process:

*Equipment:*

- Equipment types categorization, numbering and description
- Model number, serial number
- Equipment Location
- Cost centers
- Department
- Components
- Spare Parts Listing

*Preventive Maintenance:*

- Task number scheme with identification on Safety Task
- Task scheduling information (start date, scheduling type, and scheduling frequency)
- Equipment listing
- Task Instruction\* (as specified by existing procedures and equipment manuals.)
- Required parts and tools

\* *Data entry person to be made available by the client.*

***Step Three:***

**Critical Inventory Database Development and Process Review**

RDMI will work in conjunction with the client to develop an efficient and streamlined storeroom. From this joint session a systematic design will be outlined for the client to review and implement. RDMI will also work with the client to develop basic storeroom operational procedures.

- Define inventory check out and return procedures
- Stock locations strategies
- Future Bar code practices and implementation strategy
- Staffing requirements

Inventory integration will be provided in accordance with the SOP and GMP guidelines. RDMI will set up the main storeroom for use with CMMS, including future Barcode capability and use. RDMI, with the help of storeroom clerk or the client's data entry person, will assist in collecting and entering inventory data.

The following data will be collected and an inventory database developed to meet SOP and GMP requirements.

- Inventory database development for Critical Items: Item number, description, type and, location.
- Identification of Items for Food Safety
- Re-order points and quantities will be established along with vendor information and pricing.
- A Physical Inventory of your storeroom will be performed with the help of storeroom clerk; including minor reorganization of inventory if necessary and acceptable to your staff.

Written recommendations on streamlining storeroom operations may be provided on request.

***Step Four:***

**Validation System Development and Process Review**

RDMI will work in conjunction with the Quality Assurance Coordinator to develop Validation Process System. From this joint session a systematic design will be outlined for the client to review and implement. RDMI will also work with the client to develop basic procedures such as:

- Define GMP Operating Procedures
- Development of Key Performance Indicators (KPIs)
- Design and development of Control Documents
- Design and development of GMP Reporting documents. See Appendix for a sample report.

Integration will be provided in accordance with the SOP and GMP guidelines. RDMI, with the help of QA staff, will assist in collecting and entering data.

Written recommendations on Validation Process will be provided. A Validation Process document for the MoCA System will be submitted at the end of the Project. See Appendix A for a sample outline for the document.

***Step Five:***

**Software System Training**

During this step a RDMI Engineer will provide hands on system training to the Project Co-ordinator. This training will cover the day-to-day use of the software. The training will adhere to SOP and GMP Validation Process requirements with a maximum of two individuals may be trained. Actual client's database will be used for the training as a review process to verify configuration, data integrity and validation.

**VALIDATION TESTING PROCESS**  
**BASED ON**  
**GOOD MANUFACTURING PRACTICES (GMP)**

**PLANT AND PREMISES EQUIPMENT MAINTENANCE SYSTEM**  
**FOR**  
**ABC PHARMACEUTICALS INC.**

**MoCA FOR WINDOWS 95/98/NT/2000**  
**SOFTWARE VALIDATION TEST PROTOCOL**

**(SAMPLE OUTLINE)**

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## Sample Test

### MoCA FOR WINDOWS 95/98/NT SOLI VERSION

#### FACILTY, BUILDING AND AREA SETUP

No.	Validation Steps	Expected Outcome	Actual Outcome	Conformity	Tested By
<b>1.0</b>	<b>Facility Setup:</b>	Facility data is created.		CONFORMITY    ___	Performed By:
1.1	Choose Main - Main Program from the menu bar to open Facility Window	MoCA prints facility information on all reports.		MINOR NON-CONFORMITY    ___	Date:
1.2	Enter 8 Character Facility ID, tab to Description field and enter full name of your facility.			MAJOR NON-CONFORMITY    ___	Reviewed By:
1.3	Tab again and enter Country, City, Prov/State and Postal/Zip.				Date:
1.4	Click on Save Button.				
<b>2.0</b>	<b>Building Setup:</b>	Building data is created.		CONFORMITY    ___	Performed By:
2.1	Choose Main - Main Program from the menu bar to open Facility Window.	MoCA prints building information on the work order and many reports to specify equipment location.		MINOR NON-CONFORMITY    ___	Date:
2.2	Click on Building button. Enter 8 Character Bldg ID, tab to Description field and enter full name of the building.			MAJOR NON-CONFORMITY    ___	Reviewed By:
2.3	Tab again and enter Account No., Actual Space and Useable Space.				Date:
2.4	Click on Save Button.				

<b>3.0</b>	<b>Area Setup:</b>				Performed By:
3.1	Choose Main - Main Program from the menu bar to open Facility Window. Click on Building button.	Area data is created.		<b>CONFORMITY</b> ___	Date:
3.2	Click on Area button. Enter 8 Character Area ID, tab to Description field and enter full name of the Area.	MoCA prints area information along with building information on the work order and many reports to specify exact equipment location.		<b>MINOR NON-CONFORMITY</b> ___	Reviewed By:
3.3	Tab again and enter Account No., Actual Space and Useable Space.			<b>MAJOR NON-CONFORMITY</b> ___	Date:
3.4	Click on Save Button.				