

mobiVUE PMMS (Pharmaceutical Manufacturing Management System)

Ajanta Pharma Limited

The document details the summary of solution architecture and approach for the development of mobiVUE PMMS for Ajanta Pharma Limited. The document is based on the visit to the Guwahati plant of Ajanta Pharma Limited and inputs gathered, discussions held between BCI & Ajanta Pharma Limited.

This document will represent the Issuance module covering below modules

1. Weighing Calibration

*Note: This may not be a comprehensive report and needs verification and confirmation by Ajanta Pharma Limited.*

Project Scope: Weighing Calibration module

Software Requirement Specification (SRS)

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**Version: 1.0**

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| REVISION NO. | DATE | PREPARED BY | REVIEWED BY | COMMENT |
| 1 | 1-03-2021 | Abhishek P Palwankar | Hamir Thakur | Initial Document |

REVISION HISTORY

**Abbreviations:**

**Client: Ajanta Pharma Limited**

**Vendor:** Bar Code India, henceforth, will be referred as BCI.

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# Specification Organization

The objective of this document is to provide underlying concepts, procedures, and formats used in the design, development and installation of this software application. This specification consists of three sections organized as follows:

**Section 1: Introduction**

This section provides hardware requirements and documentation conventions.

**Section 2: User Interface**

This section depicts screen design and logic flow, and is categorized into two groups:

* Application Function Module
* Common Routine

**Section 3: System Architecture**

This section provides information of system architecture.

# Introduction

## Intended Audience and Reading Suggestions

The scope of this document is to provide the understanding of this solution to user & development teams associated with the application development & implementation.

This document major emphasizes on providing clear understanding **of mobiVUE PMMS**

This solution comprises of:

* Web Application
* Mobile Device Application
* Web Services
* SAP Interfaces

## Project Scope mobiVUE PMMS

The project scope is to develop and implement the Automation System at Warehouse, Manufacturing and Finish Goods for Ajanta Pharma Limited, the solution will facilitate user to manage the storage of inventory at warehouse and also helps in efficient allocation of Material for Sampling and Dispensing. Barcode Labels will be generated for the received Material Packaging i.e. Containers or Bags against the Gate Entry Number; the application also provides identification for Equipment, Dispensing Booths, Weighing Machine, In-process machines, Pallets, Trolleys and process/dispensing rooms.

The application will be integrated with the Weighing Machine which will help to capture weight automatically, this help as it provides control on inventory as no wrong Material or quantity can be issued.

The system will be integrated with the SAP and will control the flow of information from application to database and vice- versa. Each and every transaction will be recorded along with the time stamp which will help user to access any process related information as and when required.

This would require development of Wi-Fi enabled application for real time transactioni.e.the data will be captured in real-time, once the data has been collected, the database can then provide useful reports about status of material.

The entire solution consists of followings:

* Web Application
* Mobile Device Application
* Web Services
* SAP Interface with PI Server

# Software/Hardware Requirements

Below are the hardware and the software requirements of the application:

\*TO BE CHANGED AS PER APPLICATION REQUIREMENT

## Plant Server (Both DB and Application)

The solution would require the high performance server with minimum following:

Server will be placed as 1 for prod & 1 for DEV/QA

|  |  |
| --- | --- |
| **Descriptions** | **Qty** |
| HPE DL20 Gen10 4SFF SERVER : 1 x INTEL XEON E-2136 6C 3.3GHz Processor rail kit, 1xLP riser, HP drive cage | 1 |
| HPE 16GB 2Rx8 PC4-2666V-E STND Kit | 2 |
| HPE 1TB SATA 7.2K SFF SC DS HDD | 2 |
| HPE 500W FS Plat Hot Plug LH Power Supply Kit | 2 |
| 3years 4hour response 24x7 warranty | 1 |

## Desktop Computers

Desktop would require following specifications:-

* I3/i5 Processor with Windows 7 operating System
* 16 GB RAM
* 100GB HDD
* Dot net Framework 4.0

## Hardware Requirements

Hardware required for the application:

* Android Mobile Device
* Zebra Barcode Label Printer

# User Interface Specification Conventions

This section specifies the user interface portion of the application.

**Section Organization**

The User Interface Specification presents screen displays or “**Dialogs**”.

**Documentation Conventions**

This section incorporates illustrations of the application user interface. Each screen display “Dialog” consists of the screen display image, a process name, a paragraph documenting the processing required for the dialog, a paragraph listing the navigation options, and a table listing for each variable field on the dialog, its database source or destination, format, and any instructions required to process the field.

The following section contains a sample dialog with each area identified.

# System Log

System shall maintain internal logs for application.

## Error Logs

These logs will contain any errors encountered during runtime for faster resolution of any problem post deployment.

# Architectural Design

\*TO BE CHANGED AS PER SYSTEM REQUIREMENT

Overall System consists of:

* Web Application
* Device Application
* Web Services

## Web Services

This application will handle the device request in real time. Most of business logic on scanning will run on this module. Web Service will be hosted in IIS Services, Web Services will run on central server.

## Device Application

This application will include warehouse process modules. Application will directly communicate with user input and process the request to communication server.

## Web Application

A Web Application will be developed using which users will create the master data, download details from SAP, prints item barcode label etc. It also helps to generate and display related transaction reports to End Users in real time.

# Application Modules

## Application Login

This login module will provide access to the application modules. Here the admin/user needs to enter the login detail to enter in the application and to perform the desired actions.

**Process:** User needs to enter the User Name/ID and Password in display fields and press the Login button. Application will validate the user credential.

*User will be able to view only those screens/ modules of which he has been given access rights to.*

**Validation**

* User Name/ ID will be unique for all users.
* User Name/ ID and Password length will be set.

After successful login application menu screen will appear; this screen will have the Master and Transaction options etc.

## Weighing Calibration

**Activities**

|  |  |
| --- | --- |
| **Module Description** | This module will be used to Calibrate the weighing balance as per the planner |

|  |  |
| --- | --- |
| **Pre-Conditions** | Weighing balance should be connected to network. |

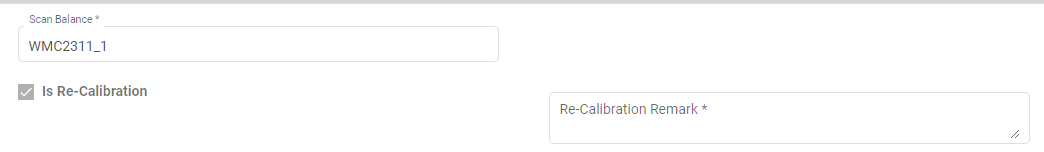
|  |  |
| --- | --- |
| **Process Steps** | 1. User will login PMMS Application using valid User ID and Password in Web application on a Desktop. 2. System will validate the User ID and Password and display the Main Menu in the device. 3. User will select the "**Weighing Calibration**” menu from the list. 4. "**Weighing Calibration**” screen will be displayed. 5. Scan the Balance barcode applied on the balance 6. System will display mode as (Daily, Monthly or Others). 7. If balance calibration is done first time for the month then system will display “Monthly” and user can only change it to “Others” mode but not “Daily”. 8. If monthly calibration is done for the month then system will display Daily and user can change to “Others” and “Monthly”. 9. If user selects “Others” then user has to specify the reason for the same and also if the calibration for the day is repeated then system will display “Others” mode. 10. System will display other balance details as Make, Model, Capacity and check list 11. User will complete the check list and then click on “Next” button. 12. System will display weighing criteria as weight 1, weight 2 and weight 3. 13. User will scan the Standard Weight Box barcode and system will display standard weight from master against the Standard Weight Box ID. 14. Then scan the weighing balance barcode to capture weight from balance. 15. System will validate the weight captured and weight 1. 16. If weight capture and weight 1 are as required then system will proceed for further calibration else mention “Calibration Failed” and stop calibration. 17. Then follow the same process for weight 2 and weight 3. 18. For monthly and others system will perform full Calibration, for that below test will be performed.     1. **Eccentricity Test**        1. System will display the calibration mode as “**Eccentricity Test**”        2. And standard weight as 30% of balance capacity.        3. User will scan the Standard Weight Box barcode and system will display standard weight from master against the Standard Weight Box ID.        4. Then place the standard weight at Center of the balance.        5. Capture weight by scanning balance barcode        6. Then place the standard weight at Left back side, Left Front side, Right back side and Right front side of the balance.        7. Then capture each side weight individually.        8. Then system will display whether calibration was satisfied or non-satisfied**.**     2. **Linearity Test**        1. System will display the calibration mode as “**Linearity Test**”        2. User will scan the Standard Weight Box barcode and system will display standard weight from master against the Standard Weight Box ID.        3. Then place the standard weight at Center of the balance.        4. Capture weight by scanning balance barcode        5. System will display message as “Satisfied” or “Non-Satisfied” and user will click on “Satisfied” or “Non-Satisfied” after verifying the weights.        6. Then capture different weight for 5 time using different standard weights and follow same process.        7. Then system will display whether calibration was satisfied or non-satisfied**.**     3. **Repeatability Test**        1. System will display the calibration mode as “**Repeatability Test**”        2. And standard weight as 30% of balance capacity        3. User will scan the Standard Weight Box barcode and system will display standard weight from master against the Standard Weight Box ID.        4. Then place the standard weight at Center of the balance.        5. Capture weight by scanning balance barcode        6. Then capture different weight for 10 time using different standard weights and follow same process.        7. Then system will calculate the Mean, Standard deviation and %RSD using formulas**.**        8. Then system will display whether calibration was satisfied or non-satisfied**.**     4. **Uncertainty Test**        1. System will display the calibration mode as “**Uncertainty Test**”        2. As per the standard deviation observed from repeatability test uncertainty will be calculated.        3. Formula   Uncertainty = Standard deviation x 2                          --------------------------------           Weight of standard  (as per calibration certificate)   * + 1. Then system will display whether calibration was satisfied or non-satisfied. |

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| **Post-Conditions** | Balance can be used for weighing while receipt of material, dispensing, in process, wt. verification. |

|  |  |
| --- | --- |
| **Validations** | 1. System will validate whether balance is created in weighing scale master. 2. Validate at each mode whether the weight is as required. |
| **Sample Screen Design** |  |

Changes

1. Only configured tests are required while doing Weighing Machine Calibration. These configurations can be done at Weighing Machine + Frequency level.
2. Add provision to enter manual weighing data, if weighing machine is not able to connect.
3. Re-Calibration feature



### Reports

Reporting module will provide access to the data that will be helpful in making well-informed strategic decisions, reduces risk, and increases productivity. The reporting interface will be user-friendly, application users can easily generate, and view required data.

The application will generate customized reports based on required data fields and time interval selected / entered by users; Microsoft Crystal Reports/ RDLC Reports will be generated which can be exported into defined excel file/ PDF format as and when required.

Reports can be defined as private for restricted viewing – or made public, giving access to information based on access rights assigned to the particular user / group.

1. Balance Verification
2. Balance Calibration Record

# SRS Scope Change Process

## Before Sign Off

Any changes in SRS need to be informed in writing by Company Name. It will be incorporated / confirmed only after doing detailed feasibility study by BCI.

## After Sign Off

Any changes in proposed solution after approval of this document by Ajanta Pharma Limited are subjected to confirmation from BCI, taking feasibility constraints into account. These changes will be incorporated (if any) into the solution only after delivering proposed solution & may be charged as extra.

The changes in proposed solution before & after acceptance will be mutually agreed and duly signed and accepted by Ajanta Pharma Limited & BCI.

## SRS Acceptance

Agreed and Accepted by Ajanta Pharma Limited and Bar Code India

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| --- | --- | --- | --- | --- | --- |
| **Prepared by:**  **BCI** | **Name: Abhishek P Palwankar** | **Signature** |  | **Date:** |  |
| **Core Team :** | **Name:** | **Signature** |  | **Date:** |  |
| **Process Owner:** | **Name:** | **Signature** |  | **Date:** |  |
| **Approved by:**  **QA** | **Name:** | **Signature** |  | **Date:** |  |