

Material Tracking System

ACME Limited

Design Qualification Document

This user's guide includes the design qualification document defined for the application.

Prepared By: Omkar G

Version Number: 1.0.0

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1 PROTOCOL APPROVAL

Prepared By				
Name	Designation	Signature & Date		
Omkar Gaonkar	Technical Writer			
	Checked By			
Name	Designation	Signature & Date		

Approved By					
Department Name Designation Signature 8 Date					

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2 OBJECTIVE

The objective of this protocol is:

- i. To define the Design Qualification (139) requirements for the Minimal Tracking System.
- ii. The details in this document describe the Installation and configuration of the implantation of the Material Tracking System from a Business Technical and functional perspective.

3 SCOPE

The scope of this protocol include design qualification procedure of the Material Tracking System for ACME GENERICS LLP.

This protocol defines the procedure alums. Documentation, acceptance criteria & re-qualification criteria.

4 QUALIFICATION TEAM

Responsible staff from:

- i. I.T
- ii. Stores
- iii. QC
- iv. Quality Assurance

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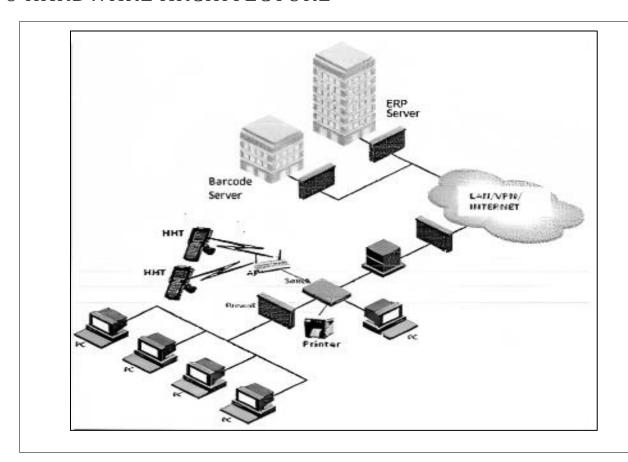
5 RESPONSIBILITIES

Responsible persons for validation activity as following:

Responsibilities	Details		
Vendor's	Supplying drawings, manual, certificates and necessary documents		
	for the generation and implementation of this protocol		
QA	> Preparation of the document		
	Checking of documents		
	> To verify the design activity as per document		
	Review the data documented during design qualification.		
	Final approval of protocol and report		
I.T, Warehouse and QC	Checking of document		
	> To provide area for design and make related arrangements		

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6 HARDWARE ARCHITECTURE

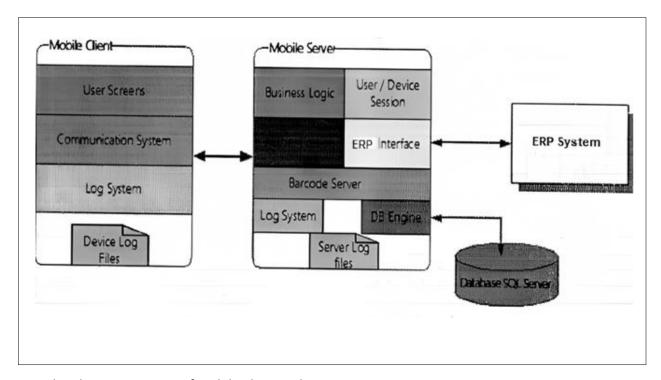


The application architecture will be "Central Server Architecture".

- 1. All the plants will access the data from the Central Server.
- 2. There will be a database server kept at ACME Generics LLP.
- 3. The mobile data transfer will be through Wireless.
- 4. The Server will be connected to SQL Database.
- 5. The work station will be directly connected to SQL Database.

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7 LOGICAL ARCHITECTURE



Logical Architecture consist of Mobile Client and Server

Mobile Client

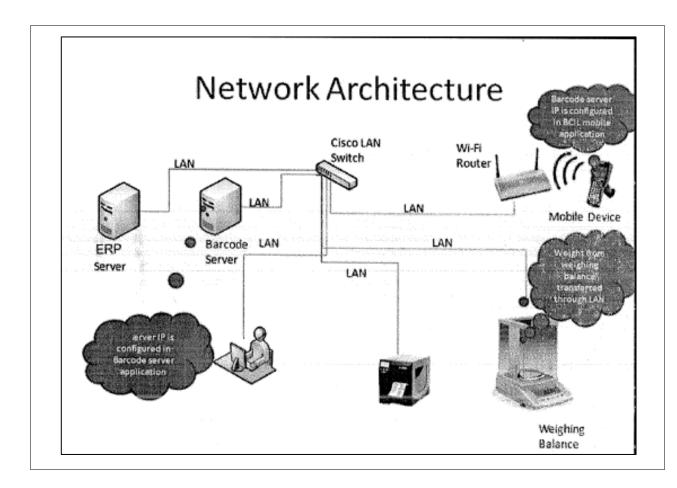
Mobile client will define the User Screens, Communication system with the mobile server and logs of the system in the mobile client

Mobile Server

Mobile server will consist of a barcode server and the barcode server will carry all the business logic, authentication, ERP Interfaces and updating data in SQL database.

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8 NETWORK ARCHITECTURE



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9 DEVIATION SHEET

Sr.No	Description of Deviation	GMP Criticality	Corrective Action	Need to be closed before OQ

Interferences			
Name			
Sign			
Date			
Department	Prepared By	Checked By	Verified By

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10 IDENTIFICATION OF PARTICIPANTS

In the list below all persons having participated in the execution of DQ and having signed on any of the tests are identified with their full name, department and function and their signature. With this signature the test participant confirms awareness of procedures to be followed in qualification tests and completion of associated documentation.

Review & Approval (Cipla Team)					
Department	Name	Designation	Signature & Date		
Warehouse					
IT					
QC					
QA					
Warehouse					

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