



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION FOR ERP SYSTEM

**DESIGN QUALIFICATION
FOR
ERP SYSTEM**



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QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION FOR ERP SYSTEM

By ERP System Pvt. Ltd.:

| Prepared by (Implementation Department) | | |
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1.0 Introduction

This document shall provide information about the design specification for implementation of ERP software at

1.1. Objective

The objective of this document is to define the design specification for ERP that must support the business needs of

1.2. Scope

This document is the one that describes the requirement of the system. It is meant for use by the developers and shall be the basis for validating the final delivered system. Any change made to the requirement in the future will have to go through a formal change approval process. The developer is responsible for asking for clarifications, wherever necessary, and shall not make any alteration without the permission of the client.

1.3. Responsibilities Overview:

| ERP Systems Pvt. Ltd | |
|--|---|
| 1. Developing the system | 1. Review and approve the design qualification document |
| 2. Installation of software on the client's hardware | |
| 3. Conducting user training | |
| 4. Providing technical support | |
| 5. Preparation of required design qualification document | |

1.4. General Description:

1.4.1. General Software and Hardware Constraints

The system at the server side has provision to run Windows server (2008 or above). The system at the client side has provision to run on Windows 7 or above. The System has compatible with the existing LAN infrastructure at

1.5. Configuration:

1.5.1. Physical Security

Physical security describes security measures that are designed to deny access to unauthorized personnel (including attackers or even accidental intruders) from physically accessing a building, facility, resource, or stored information. Server room should be access by only authorized person. Access log should be maintained in software or in log register.

| Req. No. | Requirements |
|----------|--|
| 1.5.1.1 | Physical Restriction to unauthorized user should be there. |



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1.5.2.Logical Security:

Logical Security consists of software safeguards for an organization's systems, including user identification and password access, authenticating, access rights and authority levels. These measures are to ensure that only authorized users are able to perform actions or access information in a network or a workstation. It is a subset of security. The Logical security configuration and security policies of Server operating system and application software as per following

A) Server Operating system

| Req. No. | Description | Policy Requirement |
|-----------|---|--------------------|
| 1.5.2.A.1 | Minimum password age | 30 Days |
| 1.5.2.A.2 | Maximum password age | 60 Days |
| 1.5.2.A.3 | Minimum password length | 7 character |
| 1.5.2.A.4 | Password must meet the complexity requirement | Yes |
| 1.5.2.A.5 | Enforce password history | 24 Remember |
| 1.5.2.A.6 | Account lockout duration | 5 min |
| 1.5.2.A.7 | Account should be locked invalid login attempts | 5 attempts |
| 1.5.2.A.8 | Audit account login events should be defined for success or failure login | Yes |

**DESIGN QUALIFICATION FOR ERP SYSTEM****B) Application Software (ERP)**

| Req. No. | Description | Policy Requirement |
|-----------|---|--------------------|
| 1.5.2.B.1 | Minimum password age | 30 Days |
| 1.5.2.B.2 | Maximum password age | 60 Days |
| 1.5.2.B.3 | Minimum password length | 7 character |
| 1.5.2.B.4 | Password must meet the complexity requirement | Yes |
| 1.5.2.B.5 | Account lockout duration | 5min |
| 1.5.2.B.7 | Account should be locked invalid login attempts | 5 Attempt |
| 1.5.2.B.8 | Audit account login events should be defined for success or failure login | Yes |

1.5.3. User Role/Authorization Control Requirements

| Req. No. | Requirement Description |
|----------|---|
| 1.5.3.1 | The system must support at least the following user roles but not limited to: 1.Administrators |
| 1.5.3.2 | It shall not be possible to user to login into server operating system. |

1.5.4. Time Synchronization

| Req. No. | Description |
|----------|---|
| 1.5.4.1 | The date and time shall be synchronized with application server |



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2.0 Technical Requirements:

2.1 Hardware Requirements

2.1.1 Server Specifications

A server is a system (software and suitable computer hardware) that responds to requests across a computer network to provide, or help to provide, a network service. Servers can be run on a dedicated computer. Servers operate within client-server architecture, servers are computer programs running to serve the requests of other programs, the clients. Thus, the server performs some task on behalf of clients. The clients typically connect to the server through the network.

The function of a computer server is to store, retrieve and send or "serve" data to other client computers on its network. Several individual computers on the network might make a request for the same file at essentially the same time, so the server must be equipped with hardware that has high-speed capabilities; and it must be running software that is designed to support multiple simultaneous file retrieval operations. Providing database access is one of the most important functions of a server.

The requirement specification of server shall be as follows:

| Req. No. | Description | Minimum Requirement |
|---------------------------|------------------|-------------------------------|
| Application Server | | |
| 2.1.1.1 | Make | IBM or equivalent |
| 2.1.1.2 | Model | X3200 or higher |
| 2.1.1.3 | Processor | Intel Xeon E3 or higher |
| 2.1.1.4 | Clock Frequency | 2.0Ghz or higher |
| 2.1.1.5 | RAM | 8 GB or higher |
| 2.1.1.6 | Capacity of HDD | 500 GB or Higher |
| 2.1.1.7 | Operating System | Windows Server 2008 or higher |
| 2.1.1.8 | License of OS | Should be available |
| 2.1.1.9 | Power Supply | 220 - 240VAC |
| 2.1.1.10 | IP address | Should be available |



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2.2 Software Requirements (ERP Software):

| Req. No. | Description | Software Specification |
|---|-----------------------|------------------------|
| Application Software | | |
| 2.2.1 | Software Name | ERP |
| 2.2.2 | Application Build No. | 79 or above |
| 2.2.3 | License | Should be available |
| Antivirus Software (For Clients) | | |
| 2.2.4 | Software Name | Any reputed |
| 2.2.5 | License | Should be available |
| Antivirus Software (For Server) | | |
| 2.2.6 | Software Name | Any reputed |
| 2.2.7 | License | Should be available |

2.3 Environmental Conditions

The environmental condition of all network components, storage and server room should be in the specified range as follows:

| Req. No. | Description | Specified Requirement |
|----------|---------------------------------|-----------------------|
| 2.3.1 | Operating temperature (°C) | 10° to 30°C |
| 2.3.2 | Operating Relative humidity (%) | 10% to 90% |



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3.0 Data Requirements:

3.1 Audit Trail Requirements:

Event log shall be generated as per requirements outlined below.

| Req. No. | Requirement Description |
|----------|---|
| 3.1.1 | The system event log must track the following: <ul style="list-style-type: none">• Change in user authorization• User login/logout.• Create/Delete/Modify/Authorize/Un-authorize records with the user.• Alarms/Faults/Messages/Reports generated during operation |

3.2 Data Backup Requirements

| Req. No. | Requirement Description |
|----------|---|
| 3.2.1 | All GxP Impacted data should have backup. |
| 3.2.2 | Backup frequency should be defined. |
| 3.2.3 | Backup logs should be available |
| 3.2.4 | Backup path should be available |

3.3 Data Restoration Requirements

| Req. No. | Requirement Description |
|----------|--|
| 3.3.1 | Restoration facility should be available |

3.4 Data Archival Requirements

Not applicable

3.5 Data Migration Requirements

Not Applicable

4.0 Lifecycle Requirements:

4.1 Documentation Requirements

| Req. No. | Description |
|----------|---|
| 4.1.1 | Specification Document |
| 4.1.2 | List of Active ERP client stations |
| 4.1.3 | Server Technical Agreement |
| 4.1.4 | ERP Software Configuration Document for Server |
| 4.1.5 | Antivirus Software License Copy/Media |
| 4.1.6 | Licenses of all installed software Copy / Media |



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| Req. No. | Description |
|----------|--|
| 4.1.7 | List of ERP Business Process System users |
| 4.1.8 | ERP Software Installation Manual at Client |
| 4.1.9 | Server Installation Procedure |

4.2 Standard Operating Procedures

For Lifecycle management of ERP Infrastructure Standard Operating Procedures, as relevant for below list shall be created:

| Req. No. | Description |
|----------|------------------------------------|
| 4.2.1 | Access Control |
| 4.2.2 | Password Policy |
| 4.2.3 | Administrator SOP |
| 4.2.4 | Data Backup and Restore Management |
| 4.2.5 | Disaster Management and Recovery |
| 4.2.6 | User creation and deletion |
| 4.2.7 | Process wise SOP,s. |

As the ERP infrastructure system servers are managed by IT, the above standard procedures shall be developed by IT to ensure the requirements are addressed.

5.0 Functional and Operational Requirements

| 5.1 Functional and Operational Requirements for Centralized System Administration Module | |
|--|--|
| 5.1.1 | Show Current Users |
| 5.1.2 | Show Locked Users |
| 5.1.3 | Examine Session Log |
| 5.1.4 | Application Module Control |
| 5.1.5 | Application Wise User Roles |
| 5.1.6 | Application Wise Program Access Rights |
| 5.1.7 | Location Wise Users |
| 5.1.8 | Generate Password and Pin |



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5.1 Functional and Operational Requirements for Centralized System Administration Module

| | |
|--------|---|
| 5.1.9 | Location – Application wise user accounts |
| 5.1.10 | Special Access Privileges |
| 5.1.11 | Transaction Series Control (Post - GST) |

Reference: Description of Functional and Operational Requirements for Centralized System Administration Module (Annexure 1)

5.2 Functional and Operational Requirements for Setup Module

| | |
|--------|--|
| 5.2.1 | Item Type |
| 5.2.2 | Item Sub-type |
| 5.2.3 | Item Master |
| 5.2.4 | Purchase group |
| 5.2.5 | Location/ item type / sub type wise purchase group |
| 5.2.6 | PO Standard terms |
| 5.2.7 | Manufactures Masters |
| 5.2.8 | Bought-out Item wise Approved Manufacturers |
| 5.2.9 | Analysts |
| 5.2.10 | QC Standards |
| 5.2.11 | QC Properties Groups |
| 5.2.12 | Common QC Properties |
| 5.2.13 | Item's QC Specifications |
| 5.2.14 | Production Centre |
| 5.2.15 | Production Stages |
| 5.2.16 | Production Stage wise Activities |
| 5.2.17 | Bill of Process Definition |
| 5.2.18 | Vendor Master |
| 5.2.19 | Customer Master |



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5.2 Functional and Operational Requirements for Setup Module

| | |
|--------|--|
| 5.2.20 | Sales Division |
| 5.2.21 | Standard Payment Terms |
| 5.2.22 | Stores |
| 5.2.23 | HSN & SAC Codes Masters (Single Entry) |
| 5.2.24 | General Preference |

Reference: Description of Functional and Operational Requirements for Setup Module (Annexure 2)

5.3 Functional and Operational Requirements for Purchase Module

| | |
|-------|-----------------------------|
| 5.3.1 | Vendor Item Catalog |
| 5.3.2 | Purchase Order |
| 5.3.3 | Purchase Order Amendment |
| 5.3.4 | Un-Authorization Work Bench |
| 5.3.5 | Document Closing Work Bench |

Reference: Description of Functional and Operational Requirements for Purchase Module(Annexure 3)

5.4 Functional and Operational Requirements for Manufacturing Inventory Module

| | |
|--------|-------------------------------------|
| 5.4.1 | Goods Receipt Note |
| 5.4.2 | Goods Receipt From Others |
| 5.4.3 | Purchase Return Note |
| 5.4.4 | Material Issue To Production |
| 5.4.5 | Material Issue To Other Department |
| 5.4.6 | Material Issue To Others Location |
| 5.4.7 | Material Issue to others |
| 5.4.8 | Shortage Stock Adjustment |
| 5.4.9 | Excess Stock Adjustment |
| 5.4.10 | QC Intimations For Testing of GRN |
| 5.4.11 | QC Intimation for Re-Testing of GRN |



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5.4 Functional and Operational Requirements for Manufacturing Inventory Module

| | |
|--------|-----------------------------|
| 5.4.12 | Un-authorization Work Bench |
| 5.4.13 | Document Closing Work Bench |

Reference: Description of Functional and Operational Requirements for Mfg. Inventory Module (Annexure 4)

5.5 Functional and Operational Requirements for Quality Control Module

| | |
|--------|---|
| 5.5.1 | QC Register Entry For GRN's |
| 5.5.2 | QC Analysis Update For GRN's |
| 5.5.3 | Extend AR Validity for GRN's |
| 5.5.4 | QC Register Entry For Production |
| 5.5.5 | QC Analysis Update For Production |
| 5.5.6 | QC Register Entry For Intimation |
| 5.5.7 | QC Analysis Update For Intimation |
| 5.5.8 | GRN's pending for QC |
| 5.5.9 | Intimations pending for QC |
| 5.5.10 | Production batches pending for QC |
| 5.5.11 | QC Specifications due for renewal query |
| 5.5.12 | Item's re-testing history query |
| 5.5.13 | QC test property trend report |
| 5.5.14 | QC assay test trend report |
| 5.5.15 | Un-Authorization Work Bench |

Reference: Description of Functional and Operational Requirements for Quality Control Module (Annexure 5)

5.6 Functional and Operational Requirements for Production Module

| | |
|-------|-----------------------------------|
| 5.6.1 | Production Batch Order |
| 5.6.2 | Store Requisition from Production |
| 5.6.3 | Batch Production Activity Log |



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5.6 Functional and Operational Requirements for Production Module

| | |
|--------|---|
| 5.6.4 | Production Transfer Note |
| 5.6.5 | Material Return From Production |
| 5.6.6 | Store requisition from Other Department |
| 5.6.7 | Open Completed Batches |
| 5.6.8 | Location Wise Production Query |
| 5.6.9 | Production Batches Release Query |
| 5.6.10 | Un-authorization Work Bench |
| 5.6.11 | QC Intimation for Production Batch |
| 5.6.12 | Document Closing Work Bench |

Reference: Description of Functional and Operational Requirements for Production Module (Annexure 6)

5.7 Functional and Operational Requirements for Sales Inventory Module

| | |
|--------|--------------------------------------|
| 5.7.1 | Sales Order Rates (SOR) |
| 5.7.2 | Sales Order Rates Amendment |
| 5.7.3 | Invoice using sales order rate (ISO) |
| 5.7.4 | Sales return note (SRN) |
| 5.7.5 | Finish Goods Inward (FGI) |
| 5.7.6 | Finish Goods Outward (FGO) |
| 5.7.7 | Goods Receipt Note- Trading (GRT) |
| 5.7.8 | Write Back Memo (WBK) |
| 5.7.9 | Write Off Memo (WOF) |
| 5.7.10 | Sales Stock Balance Query |
| 5.7.11 | Un authorization Work Bench |
| 5.7.12 | Document Closing Work Bench |

Reference: Description of Functional and Operational Requirements for Sales Inventory Module (Annexure 7)



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5.8 Functional and Operational Requirements for Quality Assurance Module

| | |
|-------|---|
| 5.8.1 | Purchase Requisition |
| 5.8.2 | Store Requisition from Other Department |
| 5.8.3 | Un-Authorization Work Bench |

Reference: Description of Functional and Operational Requirements for Requisition Module (Annexure 8)

5.9 Functional and Operational Requirements for Requisition Module

| | |
|-------|--|
| 5.9.1 | Item Wise Manufactures (QA Approval) |
| 5.9.2 | Item's QC Specifications (QA Approval) |
| 5.9.3 | Bill of Process (QA Approval) |
| 5.9.4 | Vendor-Item Manufacturer's (QA Approval) |
| 5.9.5 | Production Batch Release (By QA In-charge) |
| 5.9.6 | Production Batch Release (By QA Manager) |

Reference: Description of Functional and Operational Requirements for Quality Assurance Module (Annexure 9)

6.0 External interface, performance and timing requirements

6.1 User Interface and Capacity

| Req. No. | Description |
|----------|--|
| 6.1.1 | System has designed in such a way that one module can be accessed by multiple users, however the same user may not access the same module by logging into two different workstations |
| 6.1.2 | ERP display correct time and date |
| 6.1.3 | System support access right and user right for transaction where the administration must have complete control over the system |
| 6.1.4 | The ERP has provision to support more than 10 concurrent user accounts based on license procured |



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6.2 Security and Access Control Requirements

| Req. No. | Description |
|----------|--|
| 6.2.1 | Proper alarms will be raised if the user has entered wrong user name or password, and the user must not be able to access the module if erroneous log-in information is entered. |
| 6.2.2 | System has provision to track of log information regarding user activity |
| 6.2.3 | System has designed in such a way that the system administrator must be the only one who can change but cannot access user's passwords(In case password is lost) |
| 6.2.4 | System has provision to assign username and password for all users who are authorized to access the system |
| 6.2.5 | System has provision for three levels of password |

7.0 Design Constraints

7.1 Software Constraints

The system at the server side has provision to run on Windows server (2008 or above).The system at the client side has provision to run on Windows 7 or above.

7.2 Hardware Constraints

a) Xeon 2.0GHz with minimum 8GB RAM / 500GB HDD/1Gbps Ethernet – Application Server

8.0 Regulatory:

| Req. No. | Description |
|----------|---|
| 8.1 | System has provision to create individual unique users and function wise rights are assigned |
| 8.2 | After a configurable period of time, system will automatically ask user to enter new password. In this procedure system will ask for existing password & new password and this new password should not be same as existing password |
| 8.3 | System has provision for user's password to comply with minimum 7 length requirement. |
| 8.4 | System has password complexity feature like <ul style="list-style-type: none">➤ At least one upper case character➤ At least one lower case character➤ At least one numeric character➤ At least one special character |
| 8.5 | The authorized user can change the system data & time |

Security Policy for accessing servers and configuring server policies are separately being defined in IT SOP.



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9.0 Abbreviations:

| ABBREVIATION | FULL FORM |
|--------------|--|
| CSV | Computerized System Validation |
| URS | User Requirement Specification |
| PIC/S | Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme |
| US FDA | United States Food and Drug Administration |
| CFR | Code of Federal Regulations |
| EU | European Union |
| ERP | Enterprise Resource Planning |
| DQ | Design Qualification |
| ERP | Enterprise Resource Planning |
| RM | Raw Material |
| PM | Packing Material |
| FG | Finished Goods |
| IM | Intermediate Material |
| GMP | Good Manufacturing Practices |
| A/C | Account |
| Qty. | Quantity |
| QA | Quality Assurance |
| IT | Information Technology |
| INV | Manufacturing Inventory |
| PUR | Purchase |
| PRD | Production |
| QCS | Quality Control |
| SLM | Sales |



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| ABBREVIATION | FULL FORM |
|---------------------|--|
| DMS | Document Management System |
| MNT | Maintenance |
| STM | Setup |
| CSA | Centralized System Administration |
| SOP | Standard Operating Procedure |
| LL | Loan License |
| LOD | Loss on dry |
| GxP | Good "X" Practice where X = M, C, D, E M = Manufacturing C = Clinical D = Documentation E = Engineering |
| PRQ | Purchase Requisition |
| PO | Purchase Order |
| GRN | Goods Receipt Note |
| GRO | Goods Receipt From Others |
| GRL | Goods Receipt From Other Location |
| PRN | Purchase Return |
| MIL | Material Issue To Other Location |
| MIO | Material Issue To Others |
| MIP | Material Issue To Production |
| MID | Material Issue To Other Department |
| SSA | Shortage Stock Adjustment |
| ESA | Excess Stock Adjustment |



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| ABBREVIATION | FULL FORM |
|--------------|---|
| MRD | Material Return From Other Department |
| QIN | <ul style="list-style-type: none">• QC Intimation for Testing of GRN• QC Intimation for Re-Testing of GRN• QC Intimation for Production Batch |
| QCG | <ul style="list-style-type: none">• QC Register Entry for GRN• QC Analysis Update for GRN |
| QCP | <ul style="list-style-type: none">• QC Register Entry For Production• QC Analysis Update For Production |
| QCI | <ul style="list-style-type: none">• QC Register Entry For Intimation• QC Analysis Update For Intimation |
| BOP | Bill of Process |
| SRP | Store Requisition From Production |
| SRD | Store Requisition From Other Department |
| MRP | Material Return From Production |
| IMT | Intermediate Material Transfer Note |
| PTN | Production Transfer Note |
| SOR | Sales Order Regular |
| ISO | Invoice Using Sales Order Rates |
| FGI | Finished Goods Inward |
| FGO | Finished Goods Outward |
| SRN | Sales Return Note |
| GRT | Goods Receipt Note- Trading |
| WBK | Write Back Memo |
| WOF | Write Off Memo |