COMPUTER SYSTEM GxP AND PART 11 EVALUATION FOR ERP SYSTEM

ERP SYSTEM		
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1.0 APPROVAL – COMPUTER SYSTEM GxP AND PART 11 EVALUATION:

The GxP Assessment checklist for installed ERP System has been approved for release by the management of .....

COMPUTER SYSTEM GxP AND PART 11 EVALUATION FOR ERP SYSTEM

		Activity	Name & Designation		Sign.	Date
-		Prepared by	Project Leader (Validation)			
		Department	**Name**	**Designation**	**Sign.**	**Date**
	Reviewed by	Information Technology				
		Purchase				
		Warehouse				
		Quality Control				
		Production				
		Quality Assurance				
		Engineering				
	Approved by	Quality Assurance				

2.0 REVISION HISTORY:

Version/Revision Number	Revised Date	Reason for Revision
00		

3.0 OBJECTIVE:

The objective of this evaluation checklist is to identify and establish the GxP and part 11 system classifications for the ERP System operations. This evaluation is performed by answering a series of questions concerning its functionality and intended use.

This evaluation also offers a documented rational for the classification of the ERP system. A conclusion at the end of the evaluation will document the GxP and part 11 nature of the system and level of validation necessary for 21 CFR Part 11 compliance.

4.0 INTRODUCTION:

4.1 Definitions

The purpose of this section is to define the terminology used in the GxP section of this validation document.

Important Definitions:

European Standards – Refer to Annexure 11 European B – 1049.

21 CFR Part 11 – Refer to department of Health and Human Services, Food and Drug Administration, 21 CFR Part 11 Electronic Records; Electronic Signatures.

Agency – Refer to the Food and Drug Administration (FDA)

Computerized System – Any programmable device or information system including its software, hardware, peripherals, procedures, users, interconnections, and inputs for the electronic processing and output of information used for reporting or control.

Included in this definition are laboratory instruments, control systems, and computer system (including hardware, software, peripheral devices, personnel, and documentation) e.g., manuals and standard operating procedures. Third-party application software as well as internally developed application software is also included into this definition.

Some examples are: Automated manufacturing equipment, process control systems, automated laboratory equipment, laboratory data capture system, computers running laboratory, clinical and manufacturing database systems.

Laboratory System: Any programmable device including its software, hardware, peripherals, procedures, users, interconnections and inputs for the electronic processing and output of information used for reporting or control (examples automated manufacturing equipment, process control systems, automated laboratory equipment, laboratory data capture system, computers running laboratory, clinical and manufacturing database systems).

Process Control System: Any system with hardware and /or software that automatically monitors and controls a process to insure the output of the process conforms to pertinent manufacturing specifications.

4.2 Glossary

Application: Software installed on a defined platform/hardware providing specific functionality.

Bespoke/customized computerized system: A computerized system individually designed to suit a specific process.

Commercial of the shelf software: Software commercially available, whose fitness for use is demonstrated by a broad spectrum of users.

IT infrastructure: The hardware and software such as networking software and operation systems which makes it possible for the application to function.

Life cycle: All phase in the life of the system from initial requirements until retirement including design, specification, programming, testing, installation, operation, and maintenance.

Process owner: The person responsible for the business process

System owner: The person responsible for the availability, and maintenance of a computerized system and for the security of the data residing in system.

Third party: Parties not directly managed by the holder of the manufacturing and authorization.

4.3 Rationale:

It is the policy of ....., to ensure all computerized systems currently in use or to be implemented, are assessed to determine their GxP and part 11 applicability.

GxP systems are required to follow the system life cycle to ensure that the systems operate as per their intended use. Part 11 systems are required to comply with applicable ER/ES requirements.

General:

4.3.1 Risk Management

Risk management should be applied throughout the lifecycle of the computerized system taking into account patient safety, data integrity and product quality.

As part of risk management system, decision on the extent of validation and the data integrity controls should based on a justified and documented risk assessment of the computerized system.

4.3.2 Personnel

There should be close corporation between all relevant personal such as Process Owner, System Owner, Qualified Persons and IT. All personal should have appropriate qualification, level of access and defined responsibilities to carry out their assigned duties.

4.3.3 Suppliers and Service Providers

4.3.3.1 When third parties (e.g. suppliers, service providers) are used to provide, install, configure, integrate, validate, maintain (e.g. via remote access), modify or retain a computerized system or related service or for data processing, formal agreement must exist between the manufacturer and any third party. IT-department should be considered analogous.

4.3.3.2 The competence and reliability of a supplier are the key factors when selecting a product or a service provider. The need for an audit should be based on a risk assessment.

4.3.3.3 Document supplied with commercial off-the-shelf products should be reviewed by the regulated users to check that user requirements are fulfilled.

4.3.3.4 Quality system and audit information relating to suppliers or developers of software and implemented systems should be made available to inspector on request.

Project Phase:

4.3.4 Validation

The validation documentation and reports should cover the relevant steps of the life cycle. Manufactures should be able to justify their standard, protocols, acceptance, criteria, procedures, and the records based on the risk assessment.

Validation document should include change controls record (if applicable) and reports on any deviations observed during the validation process.

An up to date listing of all relevant systems and their GMP functionality (inventory) should be available. For critical systems an up to date system description detailing the physical and logical arrangements, data flows and interfaces with other systems or processes, any hardware and software pre-requisites, and security measures should be available.

User Requirement Specification should describe the required functions of the computerized should be traceable throughout the life cycle.

The regulated user should take all reasonable steps, to ensure that the system has been developed in accordance with an appropriate quality management system. The supplier should be assessed appropriately.

For the Validation of bespoke or customized computerized system there should be a process in place that ensure the formal assessment and reporting of quality and performance measure for all the life-cycle stages of the system.

Evidence of appropriate test methods and test scenarios should be demonstrated. Particularly, system (process) parameter limits, data limits and error handling should be considered. Automated testing and test environments should have documented assessment for their adequacy.

If data are transferred to another data format or system, validation should include checks that data are not altered in value and / or meaning during this migration process.

Operational Phase:

4.3.5 Data

Computerized System exchanging data electronically with other system should include appropriate built-in checks for the correct and secure entry and processing of data, in order to minimize the risks.

4.3.6 Accuracy Checks

For critical data entered manually, there should be an additional check on the accuracy of the data. This check maybe done by a second operator or by validated electronic means. The criticality and the potential consequences of erroneous or incorrectly entered data to a system should be covered by risk management.

4.3.7 Data Storage

Data should be secured by booth physical and electronic means against damage stored data should be checked for accessibility, readability and accuracy. Access to data should be ensured throughout the retention period.

Regular back-ups of all relevant data should be done. Integrity and accuracy of back-up data and ability to restore the data should be checked during validation and monitored periodically.

4.3.8 Printouts

It should be possible to obtain clear printed copies of electronically stored data.

For records supporting batch release it should be possible to generate printouts indicating if any of the data changed since the originally entry.

4.3.9 Change and Configuration Management

Any change to a computerized system including system configurations should only be made in a controlled manner in accordance with a defined procedure.

4.3.10 Periodic Evaluation

Computerized system should be periodically evaluated to confirm that they remain in a valid state and are complaint with GMP. Such evaluations should include, where appropriate, the current range of functionality, deviation record, incidents, problems, upgrade history, performance, reliability, security and validation status reports.

4.3.11 Security

4.3.11.1 Physical and /or logical controls should be in place to restrict access to computerized system to authorized persons. Suitable methods of preventing unauthorized entry to the system may include the use of keys, pass cards, personal codes with passwords, biometrics, restricted access to computer equipment and data storage areas.

4.3.11.2 The extent of security controls depends on the criticality of the computerized system.

4.3.11.3 Creation, change and can cancellation of access authorizations should be recorded.

4.3.11.4 Management systems, for data and for documents should be designed to record the identity of operators entering, changing, confirming or deleting data including date and time.

4.3.12 Batch Release

When a computerized system is used for recording certification and batch release, the system would allow only qualified persons to certify the release of the batches and it should clearly identify and records the person releasing or certifying the batches. This should be performed using electronic signature.

4.3.13 Business Continuity

For the availability of computerized system supporting critical processes, provisions should be made to ensure continuity of support for those processes in the event of a system breakdown (e.g a manual or alternative system).

The time required to bring to bring the alternative arrangement into the use should be based on risk and appropriate for a particular system and the business process it supports. These arrangement should be adequately documented and tested.

4.3.14 Achieving

Data may be archived. This data should be checked for accessibility, readability and integrity. If relevant changes are to be made to the system (eg. computer equipment or programs). Then the ability to retrieve the data should be ensured and tested.

4.4 Scope

This GxP Evaluation applies specifically to the 21 CFR monitoring systems associated with the operations in th**e .....**

4.5 Hardware Components

Client system with processor

4.6 Software Components

ERP applications software for generating transactions and report.

4.7 References

Document Identification	Document Title
21 CFR Part 11	U.S Department of Health and Human Services, Food and Drug Administration, 21 CFR Part 11 Electronic Records, Electronic Signatures.
Annexure 11 European B – 1049	Refers to European standard Annexure 11.
Guidance on scope & Application	U.S Department of Health and Human Services, Food and Drug Administration, Guidance for industry, Part 11 Electronic records, Electronic Signatures – Scope and Application.

4.8 Roles and Responsibilities

The roles and responsibilities for the review and approval of this GxP evaluation are defined below. Signature on the approval page by these groups implies an assumed responsibility for the content, accuracy and relevance of the signed document to the signer's area of expertise as well as agreement, resource commitment and accountability for document content and specified activities. The following three functional groups participate in the GxP Evaluation for this computerized system. The approval signatures on this document from the functional areas must be that of a .....employee.

Functional Group	**.....**
Technical Owner	Information Technology
Business Owner	User Department
Quality	Quality Operations

Information Technology Department

The unit is that organization or group designated by ....., as the system technical owners to ensure that all applicable regulations, corporate policies and procedure are followed. The IT unit is responsible for the following items:-

- Maintain technical information for the troubleshooting, maintenance, operation, modifications and upgrade of the system to support business operations in which this system is used.
- For initial and on – going validation of GxP applicable computerized systems.
- For System administration functions.

User Department

The ultimate responsibility for the determination of the GMP status of the system.

Responsibilities include-

- Complete and ensure the accuracy of the content in this evaluation.

Quality Operations Department

The quality unit is that organization or group designated by ....., to ensure that all applicable regulations, corporate policies and procedure are followed. The quality unit is responsible for the following items:

- Maintain a high level of knowledge and understanding of applicable regulations and the application of those regulations to the business operations supported by the system.
- Maintain independence and objectivity relative to the system development, implementation, use and maintenance processes.

4.9 System Description

ERP software offers access to view and generate the data and generate the reports for corresponding data for the following module-

- Requisition module
- Mfg. Inventory module
- Purchase module
- Quality Control module
- Production module
- Sales Inventory module
- Centralized System Admin module
- Setup module
- Quality Assurance

5.0 21 CFR PART 11 SCOPE:

21 CFR PART 11 foresees the customer to define which data are critical and must be subjected to individual data validation. For this reason the software foreseen high level customization by means of a table of a command subjected to 21 CFR PART 11 record.

This table defines for each action made by the operator if the operator will or will not be asked for authentication.

Data or access level subjected to 21 CFR PART 11 authentications:

- A form will prompt the operator for the authentication (username and password)
- After authentication on the same form will be requested to define the reasons for which the user want to change actual data(in case to changing occur)
- After description on the reasons of a change user will be prompt for the new value to be set (only in case of changing occur).
- Software will log requested information in a record together with the data and the time of the record. Moreover for each user level defined is possible to have a different table for the action to be subject to 21 CFR PART 11 record. Note that this level of authentication is an additional level of security. A user must be logged in with the username and password to carry out any changes to even those without the additional level of security.
- Whenever the users try to change a value or start a function by means of a button that is configured for the 21 CFR PART 11 record, the user will be prompt for the input of the password and all the other data required.

6.0 GxP SYSTEM DEFINITION:

The following items represent an overview of a definition for a GxP system:-

- The system is used in any phase of material handling, manufacturing, packing or testing for the Manufacturing of drug products or drug substances, which may affect product quality of the release status of the material.
- The system contains or generates data that will be used in or for support of product testing and release, clinical studies or regulatory submissions.
- The system has a role in creation, control, or application of labelling, lot numbers, or expiration dating to a product sample or kit.
- The system is used to compile information for establishing priorities of work, e.g. tracking of a typical and maintenance records for management.

- The system is an information system that supports GxP applications (including LAN/WAN servers).
- The following section provides a detailed rationale for determining GxP applicability of the system.

6.1 Par 11- Electronic Record/ Electronic Signature Evaluation

6.1.1 Definitions

The purpose of this section is to define the terminology used in the part 11 section of this validation document.

Important Definitions

21 CFR Part 11- Refers to the Department of Health and Human services, Food and Drug Administration, 21 CFR Part 11 Electronic Records, Electronic Signatures.

Electronic Record - Is any combination of text, graphics, data, audio, pictorial or other information representation in digital from that is created, modified, archived, retrieved, or distributed by a computer system. Only records by an agency regulation (FDA, Food, Drug & Cosmetic Act: or Public Health Services Act) to be maintained for inspection or to be submitted to an agency are considered to be "created' until it is committed to durable media.

Part 11 Record- Records that are required to be maintained by predicate rules and that are maintained in electronic format in place of paper format and are relied on to perform regulated activities Records submitted to the FDA, under the predicate rules in electronic format. A record that is not itself submitted, but is used in generating a submission is not a part 11 Record unless it is required to be maintained by a predicate rule and is electronic format.

Electronic Signature - Is a digital representation of any symbol or series symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Electronic Signature System – Electronic signature that are intended to be equivalent of handwritten signatures, initials and other general signing required by predicate rules that are applied to the electronic record. For a signature to be considered an electronic signature under 21 CFR part 11 it must be executed as the conscious action of the owner with the specific meaning (approval, release ,review).

7.0 GxP ASSESSMENT:

GxP Evaluation checklist are attached in Annexure 1.

8.0 ABBREVIATIONS:

Acronym	Description
GxP	Good "X" Practice where X = M, C, D, E M = Manufacturing C = Clinical D = Documentation E = Engineering
GMP	Good Manufacturing Practices
cGMP	Current Good Manufacturing Practices
USFDA	United States Food and Drug Administration
EU	European Union
CFR	Codes of Federal Regulations
ID	Identification
ERP	Enterprise Resource Planning
SOP	Standard Operating Procedure
BMR	Batch Manufacturing Records
BPR	Batch Packing Records
NA	Not applicable
QA	Quality Assurance