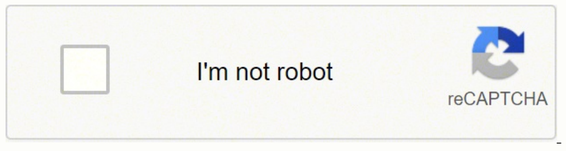


Next

Computerized system validation template

ROBERT SMITH

Quality/ Validation Engineer

Phone: (0123)-456-789 | Email: info@qwikresume.com | Website: Qwikresume.com

SUMMARY

Quality/ Validation Engineer with over 2 years of Information Technology experience with expertise in Computer System Validation (CSV) and Software Development Life cycle (SDLC) in FDA regulated Biotechnology and Pharmaceutical industry. Good working experience in FDA regulated environment with expertise in implementing 21CFR part11 compliance requirements and Annex 11, 21 CFR Part 210 / 211and 820. Experience in developing and reviewing User Requirements Specification (URS) and Functional Requirements Specification (FRS) documents.

CORE COMPETENCIES

SolidWorks, AutoCAD, CATIA, ANSYS, Minitab, Matlab, 5S, Kaizen, Poka-Yoke, Root Cause Analysis

PROFESSIONAL EXPERIENCE

Quality/ Validation Engineer

ABC Corporation - August 2009 – June 2010

Key Deliverables:

- Prepared a Validation Master Plan (VMP) for validating the Trackwise application.
- Involved in the complete system development life cycle and documentation.
- Authored User Requirement Specifications (URS) and Functional Requirement Specifications (FRS) by closely working with Business Analyst.
- Developed and reviewed Standard Operating Procedures (SOPs) for various functionalities of the system Reviewed the Test Strategy document prepared by the testing team and provided input on the validation requirements.
- Involved in creation, execution and responsible for pre and post-execution review of Unit Test scripts, Performance/Automated Test Scripts, Regression Test Scripts, IQ/OQ/PQ Test Scripts and UAT Test Scripts.
- Analyzed test scripts to check whether all functionalities have been covered within the compliance of 21 CFR Part 11 Responsible for Test Case Development, Execution and summarizing the results following strict FDA regulation - 21 CFR Part 11.
- Participated in system test script execution and documented results.

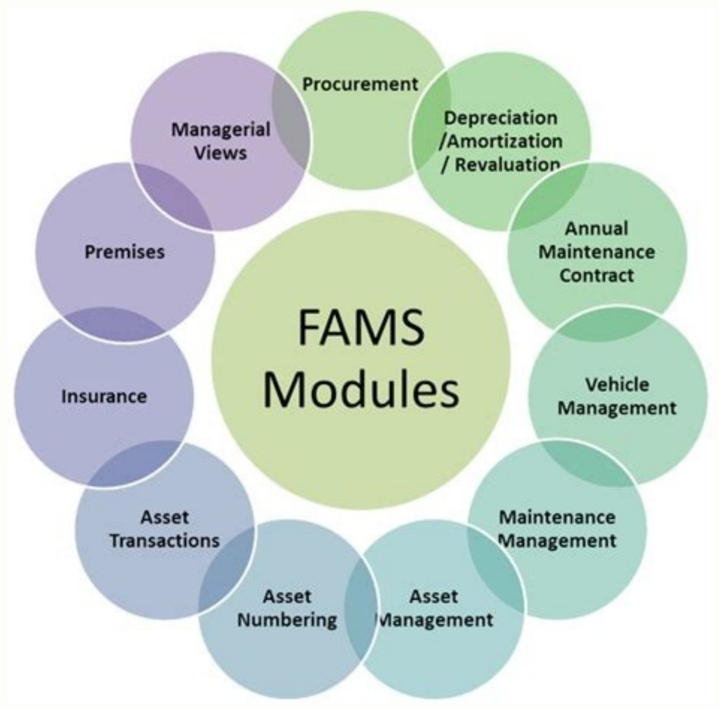
Validation Engineer

Optical Cable Corporation - 2008 – 2009

Key Deliverables:

- Collaborate with design engineer to define, develop and document special tools and equipment to support product verification and manufacturing test.
- Collaborate in development of first article assembly builds, prototypes, and evaluate testing specifications.

2259 Oak Street, Old Forge, New York, 13420



Endsley performance tool.xls

Pay for Performance Evaluation Tool

INSTRUCTIONS: Type only in the yellow fields. In row 3, enter the names of the health plans with pay-for-performance programs that you are evaluating. Beginning in cell B4, enter a "1" for each statement that is true; otherwise leave blank.

HEALTH PLAN	Quality Health Plan	Budget Health Plan	Middle Road Health Plan	Other	Other	Other	Other	Other
A health plan rep can explain the compensation formula and how it was derived.	1	1	1					
The program offers a "bonus" rather than a "withhold."	1							
Family physicians were involved in the program's design (e.g. selecting the measures).	1							
The performance measures are nationally recognized (by Medicare, the NCQA, etc.).	1	1	1					
The program offers non-financial assistance, such as guidelines, flowsheets and patient ed materials.	1		1					
The plan uses encounter data, not claims data.	1							
If encounter data is used, the health plan provides technical assistance for data collection.	1							
The potential incentive is 5 to 10 percent of income from the plan.	1		1					
TOTAL POINTS	8	2	4	0	0	0	0	0
EVALUATION	Go for it	Forget it	Possible	Forget it	Forget it	Forget it	Forget it	Forget it

KEY
0-2 points = Forget it
3-4 points = Possible
>4 points = Go for it

Red Hat Enterprise Linux 7
System Administrator's Guide

Deployment, Configuration, and Administration of Red Hat Enterprise Linux 7

Maxim Svistunov Marie Doleželová Stephen Wadeley
Tomáš Čapek Jaromír Hradílek Douglas Silas
Jana Heves Petr Kovář Peter Ondrejka
Petr Bokoč Martin Prpič Eliška Slobodová
Eva Kopalová Miroslav Svoboda David O'Brien
Michael Hideo Don Domingo John Ha

DEFINITIONS: Qualification: Qualification is the act of planning, executing and recording of tests on equipment and systems, which form part of the validated process, to demonstrate that it works correctly and leads to the expected results. IT Department: a. Overall technical responsibility for the project. Glossary An updated system description shall be maintained throughout the life cycle of system as per Annexure- IV. This master plan and the attachments shall be used as a framework for the life cycle approach for managing computerised systems. Supplier a. Suppliers can be vendors of commercial systems, companies that develop software on a contract basis, internal software development resources or a combination of the three categories. Annexure-II User Requirement Specification Document No.:……….. Prepared by: Reviewed by: Approved by: Validation team Quality assurance Head-Quality Assurance Date: Date: Date: Annexure-IV System Description Document No.:……….. Upgrade history Performance reliability Current range of functionality Status of validation documentation and updates Status of SOPs and updates Status of Qualifications Status of Authorizations/ security Status of affected SOPs for the changes Training Records (as per the existing Training SOP) Note: The above information shall be provided by respective section in-charge/designee and finally be compiled by user along with QA. Conclusion: Prepared By (Sign/Date) Checked By (Sign/Date) Reviewed By (Sign/Date) Approved By (Sign/Date) Executive/ Designee-Concerned Department Executive/ Designee-QA Head/ Designee-QA Head /Designee-Quality Note: This format shall be used in soft form. Will system to be used to support product release? Electronic records may be signed electronically. For the availability of computerized systems supporting critical processes, provisions shall be made to ensure continuity of support for those processes in the event of a system breakdown (e.g. a manual or alternative system). Quality Assurance a. Review and approval of procedures and other validation deliverables b. Providing Quality Assurance and Regulatory expertise. The system can be termed as non GxP system when it tails in all the following areas; The system does not have an impact on patient safety and product quality and data integrity. Performance Qualification (PQ): Performance qualification confirms that the system is capable and performing/controlling activities of the processes as intended according to URS in a reproducible manner while working in specified operating environment, which includes hardware arid software of the computer system. “/” forward slash as separator. Training for any new computerized system shall be provided by the software developer during the initial phase for individuals from Information Technology and Process owner, System Owner along with the core group. No. Equipment/ System Name Equipment/ System ID Make Capacity (if applicable) Location Qualification Completed on Requalification Due on 1. If the above listed prerequisites are not met, the validation exercise will be carried out separately (if required). It shall include at least following contents: Purpose of the System Main System function Regulatory Impact Computing Environment System Component System Interfaces Access and Security Control Actions in case of Failure Electronic Records & Signatures (If applicable) Category of the Computerized System and Justification. In general, Process for the security system shall be prepared and followed for Security in Computerized Systems and User Management respectively. Sr. No. Name of the System/ Equipment/ Instrument System/ Equipment/ Instrument ID Version number/ Code No. Location Application of use GxP/ Non GxP Software Category (as per GAMP5) Remarks Prepared By (Sign/Date) Checked By (Sign/Date) Reviewed By (Sign/Date) Approved By (Sign/Date) Executive/ Designee-Concerned Department Head/ Designee-Concerned Department Head/ Designee-QA Head /Designee-Quality Note: This format shall be used in soft form. Commercial Off-the-Shelf Software (COTS): Software defined by a market driven need, commercially available, and whose fitness for use has been demonstrated by a broad spectrum commercial users. IT-departments shall be considered analogous. The extent of security controls depends on the criticality of the computerized system. e. Qualifying the infrastructure. The system is not used for performing and supporting GxP regulated The system does not maintain and support business critical information. Annexure-XI HANDOVER CERTIFICATE This is to certify that the (Name of the system) version (version of the system) has been successfully qualified on (Test/Live Server) and is being (Finally/Provisionally) handed over for usage On (Date) Qualification performed by Validation Team: Sr. No. Name Designation -Department Signature/Date Approved by: Head- EG Head –Concerned Department Head- Quality Name Signature Date Note: This certificate can be modified as per requirement. It includes both, systems that cannot be configured to conform to business processes and systems that are configurable but for which only the default configuration is used. Typically, a basic assessment is sufficient for lower impact systems, while higher impact systems may require formal audits. Configured System: Configured systems are those which consist of standard system components and that enable configuration as per user requirement (the basic software is coded for general purpose and not as per specific customer requirement). Operational testing shall be carried out as per approved OQ protocol which shall be developed by the Validation team, reviewed and approved by QA. URS point no. f. Collect and provide inputs for risk assessment. Prepared By (Sign/Date) Reviewed By (Sign/Date) Approved By (Sign/Date) Executive/ Designee- QA Sr. Executive/ Designee- QA Head/ Designee- QA Annexure-VI Functional Design Specification Format for Functional Design Specification Document-First Page Company Name______________________________ Functional Design Specification Of__________________________ Document No. Make Capacity Effective Date Format for Functional Design Specification Document-Second page onwards Title: Functional Design Specification of ______________________ Document Number: Page X of Y Purpose Scope Responsibility System/Equipment Description Vendor Information Functional and Design Specification Material of Construction Safety Features List of support utilities List of the required documents Discussion and documentation of warranty: Familiarization, training and other vendor services. The trained group shall be further responsible for training the remaining users at various stages of the life cycle. The review shall include, but shall not be limited to, the current range of functionality, changes, deviation records, incidents, problems, upgrade history, performance reliability, security and status reports for validated state etc. Re-validation: Repeated validation of an approved system (or a part thereof) to ensure continued compliance with established requirement. Impact of proposed system on existing system, procedures etc. All documents shall be retained as per Document Data control procedure. Management systems for data and for documents shall be designed to record the identity of operators entering, changing, confirming or deleting data including date and time. Computerised systems exchanging data electronically with other systems shall include appropriate built-in checks for the correct and secure entry and processing of data, in order to minimize the risks. i. Ensuring that SOPs are developed covering use of the system and contingency situations and system recovery in case of system failure. b. Responsibilities include developing software and computer systems according to documented procedures. Risk Management: A systematic process for the assessment, control, communication and review of risk to quality. Computerized System Validation: It is a process of achieving and maintaining compliance with applicable GxP regulations and fitness for intended use of computerized systems. The depth and scope of the validation depends on the category of the System components and the complexity & criticality of the application. To ensure that System is fit for intended use. e. Providing adequate resources to support the system validation. Bespoke systems will require a full FDS whereas commercial off-the-shelf systems (COTS) will require a much simpler FDS. The validation exercise will follow the typical ‘V’ diagram approach as advocated by GAMP 5. For example; Operating Systems, Database engines, Programming languages etc. When the software application meets the following prerequisites, the validation activities for various units and locations can be clubbed together and carried out centrally by ensuring that all variables in the business processes are considered during Performance Qualification. Qualification or Validation can be performed either by a Validation team or by an approved external agency. URS shall be prepared as per Typical URS shall contain but not limited to or as appropriate Operational requirements Functional requirements Data requirements Technical requirements Interface requirements Environment requirements Performance requirements Availability requirements Security requirements Maintenance requirements Regulatory requirements Migration requirements Life cycle requirements Functional Design Specification: For complex Process Control Systems a functional design specification may be issued. h. Assist during Testing and Manage hand-over of completed Project. Computerized System: A computerized system consists of hardware, software and network components which together fulfill certain functionalities. Assessment team shall essentially include members from various disciplines like Process Owner, System Owner, User department, IT, Engineering, Quality Assurance. Training plan shall be prepared for individual System as per requirement and shall cover all user groups. f. Offering services to assist users in specifying, installing and validating the system. Post Implementation Review: Post implementation review shall be carried out through change control procedure. Any changes to a computerized system including system configurations shall only be made in a controlled manner in accordance with a defined procedure. DOCUMENT COMPLETION PROCEDURE: Each computerized system shall have a document completion procedure defined in the Standard Operating procedure which shall include but not be limited to; It shall be possible to obtain clear printed copies of electronically stored data which can be stored and archived for the retention period of the document. Formal assessment of the supplier shall be done as per SOP Documentation supplied with commercial off-the-shelf products shall be reviewed by regulated users to check that user requirements are fulfilled. e. Developing and providing functional specifications for the software and computer system. Electronic Records: Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system. The changes to any computerized system or hardware shall be done after ensuring backup of the applications, data etc. Regular virus checks of systems that are connected to a network and/or to the Internet, regular checks for hardware and software. f. Providing technical expertise for risk assessment for networked and ‘interfaced systems. Validation Protocol: The validation protocol is a written plan, stating how validation will be conducted, with roles and responsibilities of validation team, deliverables including test parameters, system characteristics, device checks and decision points on what constitutes acceptable test results. Prepared By (Sign/Date) Checked By (Sign/Date) Reviewed By (Sign/Date) Approved By (Sign/Date) Executive/ Designee-Concerned Department Head/ Designee-Concerned Department Head/ Designee-QA Head /Designee-Quality Note: This format shall be used in soft form. For example Building Management System; Automated manufacturing / Laboratory System; Document Management System; etc. Partial or reduced Qualification/Validation of the systems shall be done when changes made can have limited impact. Training Plans and Training documentation at various stages Supplier Assessment/ Supplier Agreement User Requirement Specification Traceability Matrix GxP Assessment Functional Design Specification Installation Qualification Operational Qualification User Manuals, training guides from Vendor. d. The Project team members shall represent their departments. A typical life cycle management model is shown in diagram below. The five step risk management process has been designed such that it may be scaled according to risk, complexity and novelty of individual systems, with each step of the process building upon the previous output; Risk Management shall be done based on understanding of following: Impact of the computer system on Patient Safety, Product Quality and Data Integrity. Validation Report: The validation report is written report on the validation activities, the validation data and the conclusions drawn. Data shall be secured by both physical and electronic means against damage. Meeting minutes or equivalent communication shall be made available to team members. Does system define materials (i.e., raw materials, packaging components, formulation) to be used? c. Providing documented evidence that the software has been developed in a Quality Assurance environment and tested during development. After completion of use of the system, the same will be retired following a defined retirement plan. Role Responsibility System Owner/User a. Ensuring that all software and computer systems in the department are listed in the list. Periodic review shall be carried out throughout the life of computer system to verify that the system remains compliant with relevant GxP requirements, fit for its intended use. Legacy System: Legacy systems are regarded as systems that have been established and in use for some considerable time. Regular back-ups of all relevant data shall be done. Annexure-V Computerized/ Automated System Re-validation / Re-qualification Planner S. Physical and logical security to limit access to the systems may be considered. 3. Other member may be included as required. An annual review period is recommended. Results of supplier assessment. To identify and define roles and responsibilities of key individuals during the acquisition,development, validation and deployment process; and Spread awareness to the audience on the various aspects of acquisition, development, validation and deployment of electronic systems. The summary report shall include this information Whether or not the qualification steps were followed Whether or not the expected results were attained. It provides evidence to reviewer and information to end users. “CSV” stands for Computer System Validation “/” forward slash as separator. Software is custom designed to suit the business process. Company shall consider formally assessing each supplier of GxP ‘regulated computerized systems and services. Annexure-XII User Acceptance Test USER ACCEPTANCE TEST OF_______________ Document No.: Page x of y APPROVAL PAGE Compiled by: ____ Validation Team Date Reviewed by: ____ Quality Assurance Date Approved by: ____________________________ Head- Quality Assurance Date Sr. Step Acceptance criteria Observation Result DEVIATIONS OBSERVED (If Any): CONCLUSION AND RECOMMENDTION: USER ACCEPTANCE TEST SIGN OFF: Compiled By Reviewed By Approved By Validation Team Quality Assurance QA Head Date: Date: Date: More Jobs Documents for External Validation Agency can also be accepted. Typical supplier assessment activities include but not limited to: Verification of supplier history. These arrangements shall be adequately documented and tested. The spreadsheets used for critical calculation to be validated as per SOP and shush sheet should be secure to avoid unauthorized access. As part of a risk management system, decisions on the extent of validation and data integrity controls shall be based on a justified and documented risk assessment of the computerized system. 9. Category 2: Custom Built (Bespoke) Hardware Component These are hardware components which are configured on standard hardware or customized as per requirement. d. Maintaining hardware and software inventory for computer systems. Is the system used to monitor, control, or supervise warehousing or distribution with a GxP implication? Handover certificate shall be prepared as per Annexure-XI, or it may be included in validation report or acceptance criteria. This documents links Installation and operational qualification, which tests design and function respectively. The execution process is conducted using specific pre-defined dataset or actual live data. Whenever the group of Equipments/ Instruments/ Systems consider for qualification / requalification denotes the equipment code as EQ. GxP / Non GxP part shall be entered in the list after assessment of the system as per Annexure-II. Migration of data to any proposed new system when the data is compatible to the flew system. Details Plan Trace point Plan Trace point Plan Trace point . However training of Users and post implementation review shall be done through change control procedure. It has a single database for all sites The hardware is qualified Network is Qualified The Software application is being used over LAN or web with firewalls for security. Software Category (As per GAMP 5): Category 1: Infrastructure Software: Infrastructure elements linked together to form an integrated environment for running and supporting applications and services, i.e. software used to manage the operating environment. g. Reviewing assessment/audit reports, responding to findings and taking appropriate actions to ensure GxP compliance. The Assessment can be done as per Annexure-II. FDS is normally written by the Vendor and reviewed and approved by user. The strategy and deliverables shall typically be as follows: Proposal and Approval of Change Validation Plan (CSVMP shall be considered as validation plan) Risk Assessment at various stages of the life cycle. Validation documentation shall include change control records (if applicable) and reports on any deviations observed during the validation process. Particular Information Time of warranty Warranty certificate Discussion on warranty Vendor Services agreement Reference Documents Attachment Deficiency and corrective action Summary and conclusion Review and Approval of the Functional Design specification: Note: Contents can be modified as per requirement. Instead, periodic calibration, system suitability (as applicable) and annual maintenance (i.e. AMC) shall be carried out to verify the performance of the instruments. c. Ensuring that all systems in the department are validated according to the project plan/ Validation plan. FDS shall be prepared as per Annexure-VI. Installation Qualification (IQ): The Installation Qualification (IQ) is the process of demonstrating that the system components have been installed according to the manufacturer’s specifications and that all deliverables are properly accounted for IQ protocols shall be developed on the basis of understanding of the system, URS, Software design specification and System provider’s recommendation and shall describe how system components shall be installed. Stored data shall be checked for accessibility, readability and accuracy. g. Preparation and review of documentation for network infrastructure. Does system deal with allocation identification code for raw material, formulated products, or package components? For example; SCADS, PLC, DCS, BMS etc. If relevant changes are to be made to the system (e.g. computer equipment or programs), then the ability to retrieve the data shall be ensured and tested. Contingency Plan and Disaster Management: Contingency plan and disaster management procedure shall be prepared considering impact on patient safety, data integrity and product quality in case of a system failure or a disaster. Does the system manipulate data or produce reports to be used by GxP quality related decision authorization/approval processes? Firewall and router is installed for protection of any external threats. It shall aim at ensuring that the system is continuing to perform as intended. i. Reviewing test and validation protocols and other validation deliverables. For detailed procedure of Training MAINTENANCE AND SUPPORT: Preventive maintenance shall ensure smooth and reliable operation on a day-by-day basis. The revalidation shall be done if there is any revision or updation of software. Traceability Matrix: A traceability matrix shall be prepared as per Annexure-III (or as per validation agency document) to ensure that all requirements are met and related documents can be traced immediately throughout the life cycle. Complete Qualification/ Validation of the systems shall be considered when changes made can have impact on the product Quality, patient safety and data integrity or the product characteristics. Requalification and Revalidation: The extent of qualification and validation activities and test to be carried out in both cases shall be based on outcome of periodic review, criticality of the system and risk involved. The documentation requirements for the deliverables shall be met. Each validation activity executed shall be recorded and signed by individuals and groups involved. List each individual software controlled sub-system; along with software categories. f. To provide Validation Summary Report and Requirement Traceability Matrix for Process Control Systems. Is system integral part of equipments, instrument, used for processing/ testing/ release/ distribution of the product/samples? Change in any validation activity from the initial plan (if any) shall be documented as per Change control procedure and can be attached as amendments to the respective validation document. Security and User Administration: System security is important to ensure confidentiality, authenticity and integrity of data. This activity shall be monitored by the System Owners or the IT Support group within the organization. The list shall be prepared as per Annexure-I. For critical data entered manually, there shall be an additional check on the accuracy of the data. This team shall comprise of members from the following and/ as required. Is the system used for GxP batch or batch records? Responsibility for contingency plan and disaster management shall be with IT Administrator and system owner. No. Content Page No. 1.0 Approval sheet 2.0 Introduction 3.0 Objective 4.0 Computerized Systems Validation Policy 5.0 Scope 6.0 Definitions 7.0 Role and responsibilities 8.0 Identification And Categorization of Computerized Systems 9.0 Validation Strategy and Deliverables 10.0 Supplier Assessment 11.0 Quality Risk Management 12.0 Validation Requirements 13.0 Documentation 14.0 Change Control 15.0 Training 16.0 Maintenance and Support 17.0 Document Completion Procedure 18.0 System Retirement 19.0 Project Activities Monitoring, Controlling and Reporting 20.0 References 21.0 Annexure 22.0 Abbreviation 23.0 Revision History Prepared by: Name Designation-Department Signature Date Reviewed by: Name Designation-Department Signature Date Approved by: Name Designation-Department Signature Date Authorized by: Name Designation-Department Signature Date The complexity of processes, management of data and its repeated use is the driving force for automation of processes using computerized system. All incidents, not only system failures and data errors, shall be reported and assessed. “YYY” stands for Equipment / Instrument/ System code. Is the system used to monitor, control, or supervise a GxP drug manufacturing or packaging process? For support the access is being provided to Vendors using remote control tools which have the provisions to restrict or allow view only and full access. · Procedure in place for maintaining compliance and fitness for intended use. Data generated by the computer system shall be regularly removed from the system’s hard disk(s) and archived to avoid overloading the hard disk(s) and loss of data. Disposal of software and hardware. Manufacturers shall be able to justify their standards, protocols, acceptance criteria, procedures and records based on their risk assessment. The Validation strategy for non GxP system shall be decided by the Project Team and Users. Deactivation of system (hardware/software/ network). Risk management shall be applied throughout the lifecycle of the computerized system taking into account patient safety, data integrity and product quality. The Application is managed centrally for all sites. 10. 6. If answer to all questions is ‘No’, then system is Non- GxP System. f. To witness Qualification activity. Computer System: A computer is a device that accepts information in the form of digitalized data and manipulates it for some result based on a program or sequence of instructions on how the data is to be processed. At the time of requalification revision number of the document shall be increased as 01, 02 and so on. The requirements shall be Complete, Unambiguous, verifiable, traceable, clear’ and consistent. This is always done in supervision of the IT Engineers and the System Owner. In addition, a project issue log, consisting of the issue, number and date, assignee, and resolution, shall be distributed to the project team members as necessary. Functional Specification (FS): Specifications that document functions, standards and permitted tolerances of systems or system components and which define the operating capabilities of the equipment/ system. IDENTIFICATION AND CATEGORIZATION OF COMPUTERIZED SYSTEMS: Identification of Computerized Systems: List of Computerized Systems including legacy systems that are used or planned to be used at individual unit shall be prepared. h. Informing users on critical software errors and workaround solutions and corrective action plans. e. Attend all team meetings or arranging for a substitute. Electronic signatures are expected to: have the same impact as hand-written signatures within the boundaries of the company, be permanently linked to their respective record, include the time and date that they were applied. Functional design specification. · Risk based tests against requirements as dictated by use (for simple systems regular calibration may substitute for testing) · Procedures in place for maintaining compliance and fitness for intended use. (Include all software categories.) Sub-system (PLC, HMI etc.) Category Conclusion: Based on above assessment, it can be concluded that the system under consideration is GxP I Non GxP System. For application software, detailed requirement of the controlling attributes such as password control, access level, and security system and data management shall be specified. Computerized systems validation is important to ensure compliance with regulations and to achieve business benefits; Management supports computer system validation as a business critical activity; All systems within the scope used in regulated environments shall be validated. 7. It shall be ensured that the system has been developed in accordance with an appropriate quality management system. Risk Assessment: It is a systematic method to assess and characterize the critical parameters in the functioning of a system. The compliance of these systems to GxP and regulatory requirements can be assured only if a life cycle approach is planned for systematic and documented planning, development, validation, implementation and post implementation activities. Assessment through Questionnaire (postal audit) or Vendor audit (site audit). i. Coordination with Vendors for support and maintenance j. Setting up controls for server access to user groups and vendors. For successful implementation, maintenance and operation of any system, training shall be conducted at various stages of life cycle. System retirement plan shall essentially include following: Assessment of impact on interfaced systems. g. Reviewing project plans h. Developing and reviewing procedures. b. Lay down specifications for software, hardware and computer systems. The changes are controlled by the System owners. The user requirements specification shall be used as the basis for the development of the system acceptance test procedures {Performance Qualification test protocol. Access to data shall be ensured throughout the retention period. Validation Agency (if any) a. To provide third party validation services b. Preparation of Validation Plan, if required c. Preparation of Risk Assessment Plan d. Carrying Functional Risk Assessments e. Developing and execution of Installation/Operational Qualification & Performance Qualification (wherever required) Protocols for Process Control Systems. “NN” denote revision number of document which shall start from “00” and shall change after every revision as 01, 02 and so on. Installation Qualification Protocol/ Report shall be prepared as per Annexure-VII. Creation, change, and cancellation of access authorizations shall be recorded. All the applications are running on the intranet and are not accessible outside Network. Category 5: Custom (Bespoke) Applications: These systems or subsystems are developed to meet the specific needs of the regulated company. The Functional Design Specification defines how the requirements outlined in the URS are implemented. 4. The competence and reliability of a supplier are key factors when selecting a product or service provider. d. Ensuring that QA and IT are notified before purchase of new systems. GxP Regulation: The underlying international pharmaceutical requirements, such as those set forth in the US FD&C Act, US PHS Act, FDA regulations, EU Directives, Japanese regulations, or other applicable national legislation or regulations under which a company operates. System retirement plan shall be prepared based on the risk involved and impact on other business process. Electronic Signature: A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature. WHO Technical Report Series, No. 937, Annexure 4, Appendix 5 MHRA GMP data integrity definitions and guidance for industry. Validation Protocol & Report: Validation protocols & reports (FDS, IQ, OQ & PQ) shall be prepared in-house or Vendor document can also be used, as it is, if fulfilling the regulatory and customer requirement. The Performance Qualification (PQ) ensures that the total system performs as intended in the specified operating range. Postal audit may be appropriate for suppliers of standard and configurable products and services. Does system employ any electronic signature capabilities or provide the sole record of signature on a document subject to review by regulatory agency? ROLES AND RESPONSIBILITIES : Specific organizational structure is responsible for proper distribution of work to achieve the validation target. · Possession of full life cycle documentation · Design and source code review The validation for process control system shall be carried out as per GAMP 5 guidelines using system implementation life cycle approach (defining activities in a systematic way from understanding requirements to system retirement). Annexure-VIII Operational Qualification Protocol/ Report Format for Operation Qualification Document-First Page Company Name___________________ Operation Qualification Of ___________________________ Document No. Equipment/System Identification No. Location Software Designer Effective Date Reference Document No. Format for Operation Qualification Document-Second page onwards Title: Operation Qualification Protocol/ Report of ____________________ Equipment/System Tag No.: Document Number: Page X of Y Protocol/ Report Approval Purpose Scope Responsibility Equipment/System Description Training of Personnel Pre-Requisite of Operation Qualification Operational and Functional Check Operation Acceptance Criteria Draft SOPs Verification and Training Deviations and corrective actions Abbreviation Reference Attachment Summary & Conclusion Certification Note: Contents can be modified as per requirement. Retention and controlled access of historic data for reference. j. Ensuring adequate training for the users. g. Offering support in case the user has a problem with the system. The document includes technical details on the functions & design of the system. SOPs for the Usage, maintenance, backup, business continuity plans Performance Qualification Post Implementation review Periodic review or verification Validation of, in use legacy systems shall follow the same principles as new systems with some exceptions. The time required to bring the alternative arrangements into use shall be based on risk and appropriate for a particular system and the business process it supports. Performance Qualification (PQ): Performance Qualification shall follow successful completion of Installation Qualification and Operational Qualification. Note: The above requirements may vary case to case basis. 13. Annexure-VII Installation Qualification Protocol/ Report Format for Installation Qualification Document-First Page Company Name________________________________ Installation Qualification Of _______________________ Document No. Equipment/System Identification No. Location Software Designer Effective Date Reference Document No. Format for Installation Qualification Document-Second page onwards Title: Installation Qualification Protocol/ Report of _____________________ Equipment/System Tag No.: Document Number: Page X of Y Protocol/ Report Approval Purpose Scope Responsibility Training of personnel Pre-requisite of Installation Qualification System/Equipment Description & Identification Safety features and alarms Installation verification Acceptance Criteria Deviations and corrective actions Abbreviation Reference Attachment Summary and Conclusion Certification Note: Contents can be modified as per requirement. 8. REFERENCES: GAMP5: Good Automated Manufacturing Practices 5: A Risk-Based Approach to Compliant GxP Computerized Systems. Does the system perform functions critical to personnel safety? The criticality and the potential consequences of erroneous or incorrectly entered data to a system shall be covered by risk management. Data storage and Archiving: The system owner with the support of IT and QA shall develop an archiving strategy for each system as per system requirement. Support and maintenance activity provided by the manufacturer or third party support vendors shall be onsite to the extent possible. i. Maintaining version control of the code. e. Providing detailed and complete set of requirements in a documented form. The electronic signatures shall follow the security norms to avoid misuse and sharing. Annexure-X Periodic Review Report Sr. No. System/Equipment/ Instrument Name System/ Equipment ID Make/ Model Equipment Serial Number Room Number Reference Document No. Review Points (as applicable but not limited to): Review of System Description (as per System description format) Review of cumulative and/or repetitive effect of all changes to include an assessment whether further action is warranted Review of all deviations/ Incidents/ Non-Conformances including frequency and reasons to determine whether there is a trend away from qualified state Review of appropriate maintenance and calibration records(as applicable) to determine whether there the system has been properly maintained Review performing trending, if applicable (e.g. system logo) Review system against applicable regulatory, GMP and site requirements established since the last periodic review/ qualification. b. As a minimum requirement, representation is necessary from the users, Quality Assurance and Information Technology c. For each team member a back-up shall be identified, mitigating the risk of unavailability of core members. c. Preparation/ Review of validation protocol/ report d. Ensuring the availability of information for the system inventory and configuration management. The new entrants shall be trained by the existing users of the computerized system preferably on the test environment. System Criticality Assessment: All systems shall be assessed at the initial stage of the project to decide whether it is Quality Critical, Business Critical or has no impact on Quality or Business. Requalification and Revalidation is of two types: Requalification and Revalidation after change: Computer System shall be subjected to Requalification/ Revalidation after assessment of changes made to the existing system components and supporting systems etc. In certain cases, the executed Operational Qualification documents can be taken from the vendor and reviewed by the validation team members for acceptance. This VMP and the validation documentation outlined above shall be created and stored for complete life cycle of the proposed system. Operational Qualification (OQ): Operational qualification is a functional testing to ensure that each component of a system perform as intended within the representative/ anticipated operating ranges according to Functional specification. An open system is a system which allows application portability, system interoperability, and user portability between many different computer vendor hardware platforms. OQ protocols shall be developed with consideration of following: Company policies and procedures Results of risk assessments carried out. Retraining shall be conducted as and when required based on evaluation of training needs of the users along with demonstration. The validation documentation and reports shall cover the relevant steps of the life cycle. A system including input of data, electronic processing and output of information to be used either for reporting or automatic control. For change or deletion of GMP-relevant data the reason shall be documented. Installation Qualification (IQ): Installation qualification is a documented verification that the systems as installed or modified, comply with the approved design and manufacturer’s recommendation. After the assessment, conclusion shall be drawn to identify that the system belongs to one of the following two categories: GxP System: Quality and Business Critical System The systems can be termed as GxP System when it tails under anyone of the following areas; The system has an impact on patient safety and product quality and data The system is used for performing and supporting GxP regulated The system maintains and supports business critical information. Hardware Category (As per GAMP5): Category 1: Standard Hardware Component These are standard hardware components which are commercially available and no customization is made. A list of core members and the backup shall be created and maintained with the system owner. Justification for Partial or reduced Qualification / Validation shall be available. If any of these deliverables are not considered in the validation cycle, the same shall be justified. For GxP System: For New Systems: Based on risk assessment, criticality and category of the hardware, software and other components of the system, Qualification and Validation strategy shall be developed. It can also be defined as a logical entity partially or entirely controlled by computers but may also include some equipment, utilities, sensors & actuators along with the governing procedures. · Record version number, verify correct installation · Risk based testing to demonstrate applicable works as designed in a test environment and within the business process. 12. Open issues shall be discussed as needed during project meetings. (Migration process shall be accurate, complete and verifiable). For GxP systems, all deliverables shall be listed at initial stage of the validation plan and verified for completeness and correctness after completion of all activities. Engineering Responsible for following activities related to Process Control Systems: a. Managing validation/project deliverables in line with the project plan. System retirement for individual computer system shall be made. Principle of Risk Assessment: The evaluation of the risk to the quality shall be based on scientific knowledge and ultimately linked to the protection of patient. A closed system is vice-versa to the above. Other Individuals and groups shall be identified, as necessary, by the Process or system owner, to assist in various activities where their area of expertise will facilitate the development and execution to assure the quality of the validation effort. Effective Date:……………………… Revision No.:……………… Do it yourself ISO 13485 or QSR 820 compliance Built in Microsoft® Word for easy editing, these medical device QMS templates are the quick and easy way to build a Quality Management System (QMS) compliant with the ISO 13485 standard or QSR 820 regulations. When third parties (e.g. suppliers, service providers) are used e.g. 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 agreements must exist between the manufacturer and any third parties, and these agreements shall include clear statements of the responsibilities of the third party. For example, calculation of Standard deviation, Mean, Minimum and Maximum value, Relative standard deviation, Weight variation programs calculation of percentage etc. Operational Qualification Protocol/ Report shall be prepared as per Annexure-VIII. 21 CFR Part 11 EU GMP Annex 11 PIC/S guide to good manufacturing practice for medicinal products annexes: Annex 11 – 1026 Computerised systems. The system not having such options shall be made compliant by developing procedural controls. c. Developing training material and delivering training on regulations and corporate standards. Supplier and system capabilities For tools to be used for risk assessment VALIDATION REQUIREMENTS: Validation of computer system shall be performed according to the validation process. b. Managing change control and escalating issues where necessary. The corrective action plan for these issues shall be implemented by having software’ corrections and evaluations, Training to users and procedural updation. OBJECTIVE: The Objective of this policy is to : Provide directives to develop the individual Electronic System Plan. This data shall be checked for accessibility, readability and integrity. e.g. Document numbering for installation qualification of RMG shall be done as: Installation Qualification Protocol IQP/CSV/RMG/01-00 Installation Qualification Report IQR/CSV/RMG/01-00 NOTE: 1. They are easy to use and will save you weeks, if not months, of time. Probability of occurrence User Requirements Regulatory requirements System complexity and novelty. After successful completion of qualification, provisional/ final handover of system shall be carried out. 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 shall be available. For example; Internally and externally developed IT applications/ process control systems, Custom ladder logic, Custom firmware etc. c. Assisting the team in identifying and selection of system vendors. Proofs of validation and related activities carried out, such as screen shots, calibration certificate, training records etc. All documents (where ever feasible) shall have unique identification number and version control. Storage area Storage period Storage condition Procedure for backup and restore. “-” stands for dash as a separator. d. Auditing computer systems together with the system owner for compliance with procedures. A person can be utilized in more than one role listed above as per requirement. The list shall include necessary information of system like Name of the System, version number, Location, Application or Use, Criticality i.e. GxP / Non GxP and Remarks, if any. Any change to this schedule/planner shall be recorded. Operational Qualification (OQ): The Operational Qualification (OQ) is a test of the functions to ensure that each component of a computer system performs as intended (predefined specification) within representative or anticipated operating ranges. The IQ is achieved by documenting all installation activities carried out to ensure it meets the acceptance criteria defined in the protocol. Design Specification (DS): Systems design is the process of defining the architecture, components, modules, interfaces, and data for a system to satisfy specified requirements. Consequently, there may be systems, whose operation, although important for the efficient and economic operation of the facility, cannot be considered critical to the quality of product and therefore will not be validated as part of this activity. Does the system have any impact with respect to patient safety or Product quality or business criticality? 14. Performance Qualification Protocol/ Report shall be prepared as per Annexure-IX. Frequency of backup storage verification Responsibility for backup and restore shall be with System owner or as defined in individual SOP. The diagram is shown below as reference: This model comprises of User Requirement Specifications (URS), Functional Specifications (FS), Configuration or Design Specifications (DS), configuration testing of code, Installation Qualification (IQ), Operational Qualification (OQ). Open Systems: An environment wherein system access is not controlled by person/s, responsible for the content of electronic records on the system. Annexure-III Traceability Matrix Document No.:……….. The validation documentation shall cover life cycle management approach for all process control systems. All documents shall be clear, legible and well defined. The model suggests that after completion of first validation exercise, the Process Control systems shall be governed by formal change control process during operation phase. System Owner/User Department, Quality Assurance, Information Technology, Engineering, System provider and/ or Outside validation agency. Operating software, application software, configuration settings and data shall be backed up on external media to ensure access, if on-line records are lost either through accidental deletion or equipment problems Backup and restore Procedure shall essentially include: Back up frequency . Any updates/patch or changes to applications should undergo the change control procedure However separate procedures can be developed for different computer systems by the system owner with the support of IT and QA, if required The Security and User Management Procedure for a specific system is in based on the criticality of the system and the system functions and risk assessment. Project Team : a. Members shall come from all departments that. Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed. GAMP 5; System Categorization: All GxP systems (as per above assessment) shall further be categorized as per GAMP 5. Following validation strategy shall be adopted for the GxP Systems: Validation deliverables shall include the requirement specifications, Qualification and validation protocols, risk assessment and strategies for contingency planning, data backup and system security along with others stated in the next point. 2. Consideration shall be given, based on a risk assessment, to building into the system the creation of a record of all GMP-relevant changes and deletions (a system generated “audit trail”). Collection of industry feedback. COMPUTER SYSTEM VALIDATION MASTER PLAN Document No. Version No. 00 Effective Date Review Date Total No. of Pages INDEX S. The total system includes all hardware and software components, associated equipment, people and procedures that make up the system. If data are transferred to another data format or system, validation shall include checks that data are not altered in value and/or meaning during this migration process. “ZZ” stands for serial number starting from 01 for individual Equipment / Instrument / System code. j. Informing users on new versions, For example, what is new and how the change can impact the validation state impact the validation state. Re-qualification of instruments shall not be performed. Documentation part plays a vital role in overall life cycle of Computer system in user and regulatory perspective. Revalidation or revalidation or requalification should cover all aspects of equipment’s and its controlling application. Sr. No. System/Equipment/ Instrument Name System/ Equipment ID Make/ Model Equipment Serial Number Room Number Intended use: Sr. No. System GxP Criteria Yes/No Remark 1. Numbering System for Qualification Documents The numbering system which shall be used for all documents related to Qualification and Validation shall be numbered as: “XXX/CSV/YYY/ZZ-NN” Where, “XXX” stands for Document Code mentioned as below table (may be of two or three characters) Document Name Document code Traceability Matrix TM GxP Assessment Checklist GAC Functional Design Specification* FDS User Acceptance Test UAT Installation Qualification Protocol IQP Installation Qualification Report IQR Operational Qualification Protocol OQP Operational Qualification Report OQR Performance Qualification Protocol PQP Performance Qualification Report PQR System Description SD *Equipment/ Instrument/ System Design Specification Sheet (DSS) may also be considered as per SOP wherever applicable. b. Managing project scope and change control and escalating issues where necessary. Team meetings shall be conducted to discuss progress, issues, and plans for the project. For example; Firmware based applications, COTS, Instruments etc. Generate Records to provide evidence of being in compliance with regulatory requirements. Category 3: Non-Configured Products: This category includes off-the-shelf products used for business purposes. For simple systems integrated with the equipment, may be qualified along with equipment qualification defining the test strategy. Data storage/ archiving may be in the form of NAS/Server, localized system server, hard disk, print. Wherever the software replaces a manual operation, it is recommended to continue performing the manual activity in parallel to the software implementation during this phase. The medical device QMS templates are used by our consultants in the field and are full of practical guidance and how-to instructions. This typically involves configuring predefined software modules. Validation schedule/ planner for applicable systems shall be in place at individual site which need to be prepared as per Annexure-V. Validation using approved validation protocol and reports shall also be performed for software and programs where calculations are carried out. Doc no. The results of the review are documented in a Periodic Review Report (as per Annexure-X) which will conclude either that the validation status is upheld or that revalidation is required. However the minimum requirements to be followed are User Requirement Specification User Acceptance test Training Standard Operating Procedures Supplier assessment is aimed to assess the computing environment, technology used and quality management system followed to develop the proposed system is adequate and to ensure that the proposed system components conform to the Quality Requirement defined by the organization. These include but are not limited to: Good Manufacturing Practices (GMP) Good Laboratory Practices (GLP) Good Distribution Practices (GDP) Good Engineering Practices (GEP) GxP Compliance: Meeting all applicable pharmaceutical and associated life science regulatory Network: A system (transmission channels and supporting hardware and software) that connects several remotely located, computers via telecommunications and allows information and resource sharing (hardware and software) between different computers along with data transfer to distributed workstations. For complex systems separate categorization may be carried out for different components modules. h. Developing and maintaining security controls. The type and extent of training shall be based on role and responsibility of each user group. 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. The User requirement shall specify the minimum hardware and Operating system for installation of application software. 5 Custom (Bespoke) Software (Software custom designed and coded to suit the business process) a. Internally and externally developed IT applications/ process control systems b. Custom ladder logic c. Custom firmware Same as configurable, in addition: · More rigorous supplier assessment. 11. e. Release of the computerized system for use in live environment. The level of effort, formality and documentation of Quality risk management process shall be directly related to the level of risk. The following decision tree can be used as a guide in determining the applicability of computer system validation to a particular computerized system; VALIDATION STRATEGY AND DELIVERABLES: Validation of computer system shall be carried out to ensure that all computer systems within the organization are developed, installed and implemented in a systematic way, performing as intended and to ensure that the systems are being maintained in a state of control throughout the life cycle in compliance with applicable GxP regulations. Does system affect regulatory submission/registration? Category 4: Configured Products: Configurable software products provide standard interfaces and functions that enable configuration of user specific business processes. Traceability matrix shall ensure the following Requirements are met and can be traced Requirements are verified. Issues shall be tracked to manage resolution details and approval activities. · Procedures in place for

managing data. 5. International Society for Pharmaceutical Engineering (ISPE); 2008. The systems have the advantages of online data creation, review, approval, archival, retrieval, storage, utilization and helps to reduce the overall resources required for paper-based data management. f. Providing resources for functional and performance testing g. Preparation/ Review of validation protocol/ report h. Providing user expertise inputs in the creation and review of validation deliverables. Qualification Summary Report: For complex computer systems, after successful completion of qualification activities a summary report may be prepared by a Validation team. Ideal for medical device companies who are preparing to commence manufacture of devices controlled by the FDA, TGA or any other regulatory authority. OQ Ref. Documentary evidence of each action listed above. Wide Area network (WAN), if any is provided by IT department. User requirement shall specify “WHAT is REQUIRED”. Any updation to legacy systems shall follow the change control procedure and the validation strategy as the new systems. This check may be done by a second operator or by validated electronic means. COMPUTERIZED SYSTEMS VALIDATION POLICY: The Computerized Systems Validation Policy specifies that, This Policy is owned by the Head-Quality; All electronic systems, procured or developed shall adhere to this policy; Any exception or deviation to this policy need to be documented and approved. Requirements of URS Reference trace points in FDS Verification plan and traceability IQ Ref. There are different QMS tools to identify, log, investigate, evaluate/understand, correcting discrepancies (while attempting to prevent their recurrence) and for recognizing potential discrepancies (to prevent their occurrence) Electronic Signature and its controls: All electronic records should have a handwritten review and approval cycle or an electronic signature. Revalidation of the computerized systems shall be done at every 3 years. The level of system components as per GAMP 5. Periodic Requalification and Revalidation: Recommendation for Periodic Requalification and Revalidation of the system shall be drawn based on periodic review of the software. are affected by the system. Following roles and responsibilities shall be followed by individuals and teams in the validation process. Annexure-IX Performance Qualification Protocol/ Report Format for Performance Qualification Document-First Page Company Name: _____ Performance Qualification of _____ Document No. Equipment/System Identification No. Location Software Designer Effective Date Reference Document No. Format for Performance Qualification Document-Second page onwards Title: Performance Qualification Protocol/ Report of _____ Equipment/System Tag No.: Document Number: Page X of Y Protocol/ Report Approval Purpose Scope Responsibility Training of personnel Pre-requisite of Performance Qualification Test Plan: Critical Variable and measuring response Test Parameter and Specification Acceptance Criteria Deviations and corrective actions Abbreviation Reference Attachment Summary and Conclusion Certification Note: Contents can be modified as per requirement. The extent of verification and validation shall be risk based depending on type of change and its impact on Product Quality, Patient safety and Data integrity. Project calendar shall be prepared to provide target time lines of each project activity and provision shall be available to record actual activity completion date. Example: Personal Area Network, Local Area Network, Wireless Local Area Network, Wide Area Network. Computer systems which are integrated with equipment for control, monitoring, operation and/ or’ recording shall be qualified along with the equipment qualification to have a complete operational and performance check. User Requirement Specification (URS): A requirement specification that describes what the equipment or system is supposed to do, thus containing at least a set of criteria or conditions that have to be met. Bespoke Systems / Customized System: Customized systems are those systems which consist of system components which are developed to meet specific needs of customer. Description of any deviation from expected results Follow-up activities to correct any deviations Statement of whether the overall qualification objectives are met and system can / cannot be used for further application. 4 Configurable Software Packages (Software, often very complex, that can be configured by the user to meet the specific needs of the user’s business process, software code is not altered) a. DAS b. SCADA c. PLC d. DCS e. BMS or EMS · Life cycle approach · Risk based approach to supplier assessment. Enables easier document identification. GAMP Category Software Type Examples Suggested Validation Approach 1 Infrastructure Software (Layered software, Software used to manage the operating environment) a. Operating systems b. Database engines c. Middleware d. Programming languages e. Statistical packages f. Network monitoring tools g. Scheduling tools h. Version control tools · Record Version (including service pack), verify correct installation by following approved installation procedure 3 Non-configured Software (Run-time parameters may be entered and stored, but the software cannot be configured to suit the business process) a. Firmware based applications b. COTS c. Instruments · Abbreviated Lifecycle approach · URS · Risk based approach to supplier assessment · Record version (and configuration of environment) and verify correct installation. Is the system used for GxP analytical quality control? The extent of validation shall depend on the risk, which the system has on Product Quality, Patient Safety, Data confidentiality, Data Integrity and Business Continuity and shall also depend on the type and complexity of the system; Validation Team shall include personnel from various disciplines based on the use of the system; Risk Based approach can be taken to optimize and focus overall efforts towards the Computer system validation process; This policy is applicable for computer system validation at _____ The Computerized System Validation Master Plan applies to all computerized systems which are used to perform and support GxP regulated activities. PROJECT ACTIVITIES MONITORING, CONTROLLING AND REPORTING: Project activities, tasks and their responsibilities shall be as per the Validation Master Plan. If answer of anyone above question is ‘YES’, then System under assessment is GxP system. All changes shall follow the ‘V’ model depending upon the impact assessment. PQ Ref. The root cause of a critical incident shall be identified and shall form the basis of corrective and preventive actions. During this review period, post go live malfunctions shall be monitored and reported through Maintenance/Breakdown Work Order or Deviation handling (or Non-conformance handling procedure and any changes through Change Management System These malfunctions or issues shall be classified as minor/ major, software issues, training issues, and Procedural issues while investigation. The changes shall be primarily done on the test environment and if found successful shall be extended to the live environment. Remote support and maintenance activity can also be done by the manufacturer or third parties with network controls and gateway securities in place. Correctness in operation and performance of these computerized systems becomes an important consideration since they manage the processes and will directly or indirectly impact consistency, reliability, accuracy of data, product quality, patient safety and data integrity. Closed Systems: An environment wherein system access is controlled by person/s, which are responsible for the content of electronic records on the system. d. Allowing users to audit the development process or the testing process. Sr. No. System/Equipment/ Instrument Name System/ Equipment ID Version Number System Component: Hardware Requirements: Software Requirements: Other components(if any): Access and Security Control: Actions in case of Failure: Electronic Records and Signatures (if applicable): Category of Computerised System and Justification: GxP / Non GxP : GAMP category: Category for System Components: Category for Software application Justification: Prepared By (Sign/Date) Checked By (Sign/Date) Reviewed By (Sign/Date) Approved By (Sign/Date) Executive/ Designee-Concerned Department Head/ Designee-Concerned Department Head/ Designee-QA Head /Designee-Quality Note: This format shall be used in soft form. Integrity and accuracy of backup data and the ability to restore the data shall be checked during validation and monitored periodically. (where applicable), shall be retained with respective documents. Annexure No. Title Annexure-I List of computerized/ automated systems Annexure-II GxP Assessment Checklist Annexure-III Traceability Matrix Annexure-IV System Description Annexure-V Computerized/ Automated System Re-validation / Re-qualification Planner Annexure-VI Functional Design Specification Annexure-VII Installation Qualification Protocol/ Report Annexure-VIII Operational Qualification Protocol/ Report Annexure-IX Performance Qualification Protocol/ Report Annexure-X Periodic Review Report Annexure-XI Handover Certificate Annexure-XII User Acceptance Test Terms/ Abbreviation Definition/Expanded Form COTS Commercial off the shelf URS User Requirement Specification FDS Functional Design Specification DQ Design Qualification IQ Installation Qualification OQ Operational Qualification PQ Performance Qualification US FD& C United State Food, Drug and Cosmetic Act US PHS United State Public Health Service FDA Food and Drug Administration EU European Union GMP Good Manufacturing Practice API Active Pharmaceutical Ingredient GCP Good Clinical Practice GLP Good Laboratory Practice GOP Good Distribution Practice GQP Good Quality Practice POMA Prescription Drug Marketing Act HSE Health, Safety and Environment IT Information Technology QA Quality Assurance SOP Standard Operating Procedure LAN Local Area Network VMP Validation Master Plan WAN Wide Area Network GAMP Good Automated Manufacturing Practices CSVMP Computer System Validation Master Plan QMS Quality Management System Change Control Number/ Document Amendment Number Reason for Revision Superseded Document Number Effective Date New Document Nil Annexure-I List of computerized/ automated systems Department:…….. Does system perform calculation/algorithms that will support a regulatory submission/registration? Data may be archived. User Requirement Specification: The User Requirement Specification is a detailed document which is written by the Users and describes the required functions of the computerized system and shall be risk based and GMP impact based. Such programs and files shall be individually password protected for regular usage. Procurement and implementation of any new system or any change in the existing system component shall be handled through Change Control procedure All changes to the computer system shall be evaluated for their impact on the system and to the System lifecycle documentation. If any of the deliverable is not planned for the validation cycle, the same shall be justified in the individual validation plan. Activities shall include: Regular removal of temporary files from the hard disk.

Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and ... A robocall is a phone call that uses a computerized autodialer to deliver a pre-recorded message, as if from a robot.Robocalls are often associated with political and telemarketing phone campaigns, but can also be used for public-service or emergency announcements. Some robocalls use personalized audio messages to simulate an actual personal phone call. 15.1 Perform an A1C test on all patients with diabetes or hyperglycemia (blood glucose >140 mg/dL [7.8 mmol/L]) admitted to the hospital if not performed in the prior 3 months.B. 15.2 Insulin should be administered using validated written or computerized protocols that allow for predefined adjustments in the insulin dosage based on glycemic fluctuations. 10/4/2020 · The Computerized System Validation Master Plan applies to all computerized systems which are used to perform and support GxP regulated activities. Consequently, there may be systems, whose operation, although important for the efficient and economic operation of the facility, cannot be considered critical to the quality of product and therefore will not be ... IPS System built by Singystic is a state-of-the-art manufacturing execution system (MES) that offers real-time costing. It is a modern alternative for small-to-medium-sized businesses that includes features such as accurate forecasting, tracing, and supply chain ... Think Exam provides a secure CBT platform to conduct online computer-based tests anytime, anywhere with superior infrastructure and high -end technology. And helps companies reduced the cost, time & effort.