Tentative translation (as of August 17, 2011)

This English version of the Japanese guideline is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the Japanese text shall prevail.
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PFSB/CND (*Yakushoku-kanma)* Notification No. 1021-11
October 21, 2010

To: Directors of Health Departments (Bureaus),
Prefectural Governments

From: Director of Compliance and Narcotics Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Guideline on Management of Computerized Systems for Marketing Authorization Holders and Manufacturers of Drugs and Quasi-drugs

1. General Principles

1.1 Purpose

The purpose of this guideline is, as a revised version of the "Guideline on Control of Computerized Systems in Drug Manufacturing" (PFSB/CND Notification No. 11 dated February 21, 1992, revoked by the CND Notification No. 0330001 dated March 30, 2005), to ensure proper enforcement of the "Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices" (MHLW Ministerial Ordinance No. 136, established as of September 24, 2004; hereinafter referred to as "GQP Ministerial Ordinance") and the "Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs" (MHLW Ministerial Ordinance No. 179, revised as of December 24, 2004; hereinafter referred to as "GMP Ministerial Ordinance") by:

a) clarifying the requirements on computerized systems that are used by marketing authorization holders of Drugs or Quasi-drugs, or manufacturers of them, to whom the GMP Ministerial Ordinance are applied (hereinafter referred to as "Marketing Authorization Holders", etc.) in order to conduct their operations under the GQP Ministerial Ordinance and the GMP Ministerial Ordinance,

b) specifying the necessary matters during development of computerized systems, validation items to verify such systems, and the matters to be observed in operations management (e.g. maintaining the validated state, system retirement, etc.), in order to ensure such systems function as intended.

In this guideline, a term "computerized system lifecycle" is a comprehensive flow throughout development, validation, operational controls and retirement of computerized systems. The schematic overview of a computerized system lifecycle is shown in the Appendix 1 "A Lifecycle Model for Computerized Systems." The methodology shown in this guideline is a typical example and an alternative method may be applied if it fulfills the purpose of this document on an equivalent or higher level.

1.2 Computerized Systems under regulations

As this guideline covers systems under either GQP Ministerial Ordinance or GMP Ministerial Ordinance and interconnected computerized systems under both ordinances, the guideline does not use the identical terms to refer to organizations or responsibilities specified in GQP Ministerial Ordinance and GMP Ministerial Ordinances. However, operations such as validation and change/deviation control, etc. must be approved by Quality Unit, etc. under GMP Ministerial Ordinance, while those must be handled in the administrative system by Quality Assurance Department under GQP Ministerial Ordinance. Accordingly, Marketing Authorization Holders, etc. should clarify the responsibilities and authorities corresponding to each organization and responsibilities in "3. Documentation on Development, Validation, and Operations Management of Computerized Systems", taking into account their organization structures and the coverage of the system.

When "Use of Electronic Records and Electronic Signatures in Submission for Approvals, Licenses of Medical Products"(PFSB/ELD Notification No. 0401022 dated April 1, 2005) or "Enactment and Revision/Disposition for Ministerial Ordinances and Notifications Pertaining to the Manufacturing Controls and Quality Controls (GMP/QMS) of Drugs, Medical Devices, etc. accompanied by the Enforcement of the Law on Revising Partially the Pharmaceutical Affairs Law and the Law on Blood Collection and Donation Services Control" (PFSB/CND Notification No. 0330001, dated March 30, 2005; Title 3, Part3, Section 35) "Others (regarding Electromagnetic Records, etc.)" are applicable to the computerized systems that are covered by this guideline, the computerized systems

should also meet the requirements stipulated in the above notifications.

Particularly, the computerized systems which were developed or started operation prior to the effective date of this guideline, but were not developed, validated nor operated in accordance with "Guideline on Control of Computerized Systems in Drug Manufacturing" or other appropriate alternative approaches, shall be qualified.

1.3 Categorization

In order to determine activities to be conducted at stages of development, validation and operation (referring to "4.3 Conducting System Assessment"), category of the software that comprises the system should be determined in advance, depending upon the types of software.

Examples of criteria for categorization and general activities to be conducted in each category are shown in the Appendix 2 "Categorization and Activities Example."

2. Scope of Application

This guideline is applicable to the Marketing Authorization Holders, etc., who conduct their operations under GQP Ministerial Ordinance and/or GMP Ministerial Ordinance by using computerized systems. Following computerized systems (1) – (7) are examples of the systems within the scope of this guideline. Systems which are out of the scope of this guideline are listed in the Appendix 2.

(1) Systems to make decisions on market release of drugs and quasi-drugs, and to create and retain market distribution records
(2) Systems to create and retain manufacturing orders and manufacturing records, etc.
(3) Systems to control/manage manufacturing processes and to retain relevant data
(4) Systems to manage storage and inventory, etc. of raw materials and products (including intermediates; the same shall apply hereinafter)
(5) Systems to control/manage laboratory instruments used for QC tests and systems to retain QC test results and relevant data
(6) Systems to control/manage equipment and facilities, including HVAC and water supply systems, etc., which may have a significant impact on quality of products, and systems to retain relevant data
(7) Systems to create, approve and retain documents (SOPs, Quality Standard Code, Product Standard Code, etc.)

3. Documentation on Development, Validation, and Operations Management of Computerized Systems

For development, validation, and management in operation of computerized systems, the Marketing Authorization Holders, etc. should establish fundamental policies, etc. (hereinafter referred to as "Administrative Policy and Rules for Computerized Systems") in advance. Administrative Policy and Rules for Computerized Systems should address the following items;

(1) Fundamental policies on development, validation, and operations management of the computerized systems,

1) Purpose
2) Scope
3) Preparation and maintenance of system inventory
4) Basic concept
   - Software categorization
   - Risk assessment to assure product quality
   - Supplier assessment
   - Operations to be conducted in development, validation, and management in operation
   - Operations relevant to retirement of the computer systems

(2) Organizational structure, roles and responsibilities for development, validation, and operations management

(3) Documents to be created in development, validation, and operations management and their control methods

(4) Procedures to review and approve the completion of development, validation, and operations management

4. Development Operations

4.1 Documentation of Development Plan

The Marketing Authorization Holders, etc. should document a plan for development (hereinafter referred to as "Development Plan"). The development Plan should describe the following items;

(1) Purpose
(2) Conditions
(3) Organizations

1) Organization chart
2) Responsible persons
   ・Development Project Manager
   ・Validation Project Manager

(4) Schedule

4.2 Documentation of User Requirement Specification

The Development Project Manager should document requirements for the computerized system (hereinafter referred to as "User Requirement Specification"). The User Requirement Specification should include the followings;

(1) Applicable laws and regulations, and other stipulations, etc.
(2) Outline of hardware
(3) Requirements
   1) Outline of system functions
   2) Outline of operational requirements
   3) Outline of performance requirements
   4) Outline of countermeasure functions for system failures
   5) Outline of protection of information security
(4) Data
   1) Lists of input and output information
   2) Retention methods
(5) Interfaces (relevant to equipment and other systems involved, etc.)
(6) System environment
   1) Installation
   2) Layout
(7) Conditions for providing power supplies, grounding, etc.

4.3 Conducting System Assessment

The Development Project Manager should conduct the following activities in accordance with the Administrative Policy and Rules for Computerized Systems in order to define tasks to be conducted at each stage of development, validation and management in operation.

(1) Software categorization
(2) Risk assessment to assure product quality

(3) Supplier assessment

4.4 Documentation of Functional Specification

The Development Project Manager should approve the document created by the supplier on functional specification which describes specific functions and performances (hereinafter referred to as "Functional Specification") of the computerized system corresponding to the requirements in the User Requirement Specification.

4.5 Documentation of Design Specification

The Development Project Manager should approve the document created by the supplier on design specification which describes detailed functions (hereinafter referred to as "Design Specification") of the computerized system based on the Functional Specification. The following items should be specified in the Design Specification.

4.5.1 Hardware Design Specification

(1) Hardware configuration
(2) List of hardware and its specifications
(3) Interfaces
(4) Details of input/output signals
(5) Environment
    1) Installation details
    2) Layout of system devices
(6) Conditions for providing power supplies, grounding, etc.

4.5.2 Software Design Specifications

(1) Details of input/output information
(2) Files and data structure
(3) Details of data processing
(4) Structure of functions/modules
(5) Details of interfaces
(6) Software packages employed

4.6 Programming and Program Testing

The Development Product Manager should have suppliers produce and test the

programs as necessary. The following activities should be conducted in the programming and the program testing.

4.6.1 Programming

(1) The supplier should document program specifications (hereinafter referred to as "Program Specification") based on the Design Specification.
(2) The supplier should produce programs as specified in the Program Specification.

4.6.2 Program Testing

(1) The supplier should document their program testing plan which specifies program testing methods, judging methods and acceptance criteria for program testing results (hereinafter referred to as "Program Testing Plan").
(2) Based on the Program Testing Plan, the supplier should test programs and keep records.
(3) The supplier should judge whether the program testing results are acceptable or not.

4.7 System Tests

The supplier should perform system test upon the request from the Development Project Manager if necessary. The following activities should be conducted in the system tests.

4.7.1 Documentation of System Tests

Prior to the system test, the supplier should document a system testing plan (hereinafter referred to as "System Testing Plan"). System Testing Plan should specify the followings items;

(1) System testing environment (e.g., the installation status of hardware and the configuration of software).
(2) Test items and data to be applied
(3) Test methods and checking methods of the results
(4) Acceptance criteria for the system testing
(5) Schedule of the system testing
(6) Testing resources and organization

4.7.2 Execution of System Tests

(1) The supplier should execute the system tests and document its results (including issues arisen during the tests and corrective actions) in accordance with the System Testing Plan.
(2) The supplier should judge whether the test results are acceptable or not. The judgment should be based on the following aspects;

1) Function (as to whether the system demonstrates its functions as defined in the Functional Specification and the Design Specification, etc.)
2) Performance (as to whether the system achieves its responsiveness as designed in the Functional Specification and the Design Specification, etc.)

4.8 Acceptance Tests

In order to confirm that all or parts of function and performance of the system meet the User Requirement Specification, the Development Project Manager should have suppliers perform acceptance tests. Factory Acceptance Test (FAT) is to be conducted prior to delivery from the supplier's facility. Site Acceptance Test (SAT) is to be conducted at the system installation, etc. The Development Project Manager should choose one of them or both as appropriate, and have suppliers conduct it/them. The Development Project Manager should approve the results.

5. Validation Activities

5.1 Documentation of overall Validation Plan

When the Validation Project Manager leads the system validation in accordance with the Administrative Policy and Rules for Computerized Systems, the Validation Project Manager should document plans throughout the validation activities (hereinafter referred to as "Validation Plan"). The Validation Plan should be created based on the assessment results obtained in "4.3 Conducting System Assessment." However, in such a case where the validation activities are conducted along with the development activities, the Validation Project Manager should document the Validation Plan at the proper timing in the development stage.
Furthermore, in the case where validation becomes necessary in "6.6 Change Management", the Validation Plan should be prepared as appropriate depending on the situation of the change.
The Validation Plan should specify the following items. It should also describe risk

assessment in details and plans for supplier audit, etc., as necessary.

(1) Purpose
(2) Outline of system
(3) Organizational structure, roles and responsibilities
    1) Organization chart
    2) Validation Project Manager
(4) Applicable laws, regulations and other stipulations, etc.
(5) Validation strategy
    1) Scope of validation and activities to be performed, etc.
(6) Schedule
(7) Written procedures for control of change/deviation during the stage of validation

5.2 Design Qualification (DQ)

The Validation Project Manager should conduct the Design Qualification to verify that requirements specified in the User Requirement Specification are correctly reflected in the Functional Specification and the Design Specification, etc.

5.2.1 Documentation of Design Qualification Plan

The Validation Project Manager should document a plan for the Design Qualification (hereinafter referred to as "Design Qualification Plan"). The Design Qualification Plan should describe the followings items;

(1) Titles of target documents in the Design Qualification
(2) Specific methods employed
(3) Acceptance criteria
(4) Schedule
(5) Names of responsible persons and persons in charge

5.2.2 Execution of Design Qualification

(1) Persons in charge of the qualification should verify documents in accordance with the Design Qualification Plan and record its results.
(2) The Validation Project Manager should judge whether the results of the Design Qualification are acceptable or not.

5.2.3 Documentation of Design Qualification Report

The Validation Project Manager should document a report of the Design Qualification (hereinafter referred to as "Design Qualification Report"). The Design Qualification Report should describe the followings items;

(1) Titles of target documents in the Design Qualification
(2) Qualification results and corrective actions
(3) Names of responsible persons and persons in charge

5.3 Installation Qualification (IQ)

The Validation Project Manager should conduct the Installation Qualification in order to verify that the hardware of the computerized system and programs are installed properly as specified in the Design Specification, etc.

5.3.1 Documentation of Installation Qualification Plan

The Validation Project Manager should document a plan for hardware and software installation qualification (hereinafter referred to as "Installation Qualification Plan"). The Installation Qualification Plan should describe the following items;

(1) Titles of documents that the Installation Qualification is based on
(2) Hardware configuration and installed location
(3) Environmental conditions such as temperature, humidity and vibration, etc.
(4) Installation conditions of power supplies, grounding, etc.
(5) Specifications for communication lines and I/O
(6) Methods for verifying the hardware installation
(7) Methods for verifying the software installation
(8) Acceptance criteria
(9) Schedule
(10) Names of responsible persons and persons in charge

5.3.2 Performing Installation Qualification

(1) Qualification of hardware installation

1) Persons in charge of the qualification should confirm that hardware is installed appropriately. The confirmation should be conducted in accordance

with the Installation Qualification Plan and the results should be recorded.
2) The Validation Project Manager should judge whether the results of the hardware qualification are acceptable or not.

(2) Qualification of software installation

1) Persons in charge of the qualification should confirm that software including system software is installed appropriately and record the results.
2) The Validation Project Manager should judge whether the results of the software qualification are acceptable or not.

5.3.3 Documentation of Installation Qualification Report

The Validation Project Manager should document a report for hardware and software installation qualification (hereinafter referred to as "Installation Qualification Report"). The Installation Qualification Report should describe the following items;

(1) Titles of documents that the Installation Qualification is based on
(2) Qualification results and corrective actions
(3) Names of responsible persons and persons in charge

5.4 Operational Qualification (OQ)

The Validation Project Manager should conduct the Operational Qualification in order to verify that the computerized system provides functions and performances as specified in the Functional Specification, etc. in its operating condition.

5.4.1 Documentation of Operational Qualification Plan

The Validation Project Manager should document a plan for the Operational Qualification (hereinafter referred to as "Operational Qualification Plan"). The Operational Qualification Plan should describe the following items;

(1) Titles of documents that the Operational Qualification is based on
(2) Methods for verifying the functions in the operating condition
(3) Acceptance criteria
(4) Schedule
(5) Names of responsible persons and persons in charge

5.4.2 Performing Operational Qualification

(1) Persons in charge of the qualification should verify the system in accordance with the Operational Qualification Plan and record the results.

(2) The Validation Project Manager should judge whether the results of the Operational Qualification are acceptable or not.

5.4.3 Documentation of Operational Qualification Report

The Validation Project Manager should document a report for the Operational Qualification (hereinafter referred to as "Operational Qualification Report"). The Operational Qualification Report should describe the following items;

(1) Titles of documents that the Operational Qualification is based on
(2) Qualification results and corrective actions
(3) Names of responsible persons and persons in charge

5.5 Performance Qualification (PQ)

The Validation Project Manager should conduct Performance Qualification in order to verify that the computerized system functions and achieves its performance as specified in the User Requirement Specification, etc. in its operating condition.

5.5.1 Documentation of Performance Qualification Plan

The Validation Project Manager should document a plan for Performance Qualification (hereinafter referred to as "Performance Qualification Plan"). The Performance Qualification Plan should describe the following items;

(1) Titles of documents that the Performance Qualification is based on
(2) Methods for verifying the functions and performances in operation
(3) Acceptance criteria
(4) Schedule
(5) Names of responsible persons and persons in charge

5.5.2 Execution of Performance Qualification

(1) Persons in charge of the qualification should conduct Performance Qualification in accordance with the Performance Qualification Plan and record the results.

(2) The Validation Project Manager should judge whether the results of the

Performance Qualification are acceptable or not.

5.5.3 Documentation of Performance Qualification Report

The Validation Project Manager should document a report for the Performance Qualification (hereinafter referred to as "Performance Qualification Report"). The Performance Qualification Report should describe the following items;

(1) Titles of documents that the Performance Qualification is based on
(2) Qualification results and corrective actions
(3) Names of responsible persons and persons in charge

5.6 Partial Omission and Citation of Qualification

(1) In case where items to be verified, environment and conditions, etc. in "5.4 Operational Qualification (OQ)" are not different from those in "5.5 Performance Qualification (PQ)", the Operational Qualification is allowed to be omitted. However, in such a case, it is necessary to describe so in the "Validation Plan" or "Performance Qualification Plan", otherwise in either one of their report.
(2) In case where the FAT or SAT is performed and the Validation Project Manager considers its test methods and records are suitable, such test results is allowed to be cited in qualifications.

5.7 Documentation of Overall Validation Report

The Validation Project Manager should document an overall reporting throughout the validation stage summarizing results of each qualifications and an overall judgment.

6. Activities on Operations Management

6.1 Documentation for Operations Management

The Marketing Authorization holders, etc. should establish a document concerning the operations management of computerized systems (hereinafter referred to as "Operations Management Standard Code"). The Operations Management Standard Code should describe the following items. In particular, items to be managed following the written procedures under GQP Ministerial Ordinance or GMP Ministerial Ordinance should be clarified.

(1) Roles and responsibilities of management in operation

1) Organization chart
2) Operation Manager

(2) Operations of the computerized system

(3) Maintenance management

1) Daily checking
2) Periodical maintenance
3) Terms to be agreed on, in case where maintenance activities are outsourced

(4) Information security management

1) Controlling access privileges for persons in charge of input, modification, deletion of data, and prevention of unauthorized accesses
2) Control of identification components
3) Limited access to the hardware installation areas

(5) Backup and restore

(6) Change management

1) Change plan and procedures for approval
2) Impact assessment on changes
3) Other items necessary for changes

(7) Deviation (system failure) management

1) Organization, etc. to respond to the deviation (system failure) occurrence
2) Root cause analysis and impact assessment of the deviation (system failure)
3) Action plans to prevent recurrences
4) Recovery actions
5) Procedures and check items at resumption after system stoppage
6) Others items necessary for deviation management

(8) Education and training for persons in charge

(9) Self inspection

6.2 Documentation of Standard Operating Procedures for Computerized Systems

Written standard operating procedures for the computerized system (hereinafter referred to as "Standard Operating Procedures") should be established for each computerized system, and the computerized system should be operated in accordance with the procedure.

The Standard Operating Procedures should describe following items;

(1) Persons in charge of the system

(2) Operations of the computerized system

(3) Maintenance of the computerized system
(4) Information Security Management of the computerized system
(5) Operations management specific to each computerized system

6.3 Performing Maintenance and Checking Management

The Operation Manager should conduct the following activities in accordance with the Standard Code for Operations Management and the Standard Operating Procedures (hereinafter referred to as "Operations Management Code, etc.").

(1) The Operation Manager should have persons in charge conduct maintenance, and record and retain its results.
(2) The Operation Manager should confirm that maintenance and checking management is appropriately conducted by reviewing the maintenance and checking records.

6.4 Conducting Information Security Management

The Operation Manager should conduct the followings activities in accordance with the Operations Management Code, etc.;

(1) To configure access privileges of persons in charge of input, modification, deletion, etc. of data and to take preventive actions against unauthorized accesses
(2) To take appropriate measures to protect confidentiality in handling identification components, etc.
(3) To limit accesses to the hardware installation areas as necessary.
(4) To document and retain records on information security management

6.5 Backup and Restore

The Operation Manager should have the designated persons designated conduct the following activities in accordance with the Operations Management Code, etc.;

(1) To backup the software and the data
(2) To restore the software and the data for recovery from system failures
(3) To document and retain records on backup and restore

6.6 Change Management

The Operation Manager should have the designated persons conduct the following

operations in accordance with the Operations Management Standard Code;

(1) Operation to assess the impact of the change in computerized system and appropriate actions based on its results
In case where it is judged that validation is necessary, the stages "4. Development Operations" and "5. Validation Activities" should be conducted again, depending on the level of risk.
(2) Operation to identify the portions to be modified in the relevant documents regarding the procedures, and to make necessary revisions
(3) Operation to determine methods for notifying the changes to persons concerned and to provide education and training if necessary
(4) Operation to record the change control, to receive confirmation by the Operation Manager, to obtain approvals by the Operation Manager and the manager who is responsible for the change management under the GMP and/or GQP Ministerial Ordinance(s), and to retain the records

Change management in the systems under GMP Ministerial Ordinance should be conducted in accordance with the change control procedures under GMP Ministerial Ordinance. Even in such cases, activities (1) - (4) listed above should also be conducted.

6.7 Deviation (System Failure) Management
The Operation Manager should have the designated persons conduct the following operations in accordance with the Operations Management Standard Code;

(1) Operation to assess impact of the deviation(system problem) on quality of the products, to take appropriate measures immediately, to investigate root causes, and to implement necessary actions to prevent recurrence
(2) In case where the computerized system resumes its operations after the deviation (system failure), operation to verify that the recovery process has been executed properly.
(3) Operation to record the deviation(system failure) control, to receive confirmation from the Operation Manager, to obtain approvals from the Operation Manager and the manager who is responsible for the deviation management in the whole GMP area, and to retain records

Deviation management in the systems under GMP Ministerial Ordinance should be

conducted in accordance with the deviation control procedures required in GMP Ministerial Ordinance. Even in such cases, activities (1) - (3) listed above should be conducted.

6.8 Education and training

6.8.1 Creating Education and Training Plan

The Operation Manager should have the designated persons create an education and training plan for persons engaged in the activities using the computerized system in accordance with the Operations Management Code. It is desirable that the education and training is conducted in accordance with procedures required in GQP Ministerial Ordinance and GMP Ministerial Ordinance.

6.8.2 Providing Education and Training

The Operation Manager should have the designated persons conduct the following operations in accordance with the education and training plan,

(1) Operation to provide education and training for the persons engaged in the activities using the computerized system in accordance with the education and training plan, and to record it

(2) Operation to obtain an approval from the Operation Manager on the result of the Education and Training, and to report it to the Quality Assurance Manager or Manufacturing Control Manager or the Responsible Engineering Manager in written form

6.8.3 Retention of education and training records

The Operation Manager should retain the education and training records.

7. Internal Audit

7.1 Conducting Internal Audit

The Marketing Authorization Holders, etc. should have the designated persons conduct the followings operations in accordance with Operations Management Standard Code. Furthermore, it is desirable that the internal audit is conducted in accordance with the procedures established under GQP Ministerial Ordinance and GMP Ministerial Ordinance.

(1) Operation to conduct periodic internal audit in order to verify that the

computerized systems are controlled in accordance with this guideline.

(2) Operation to report results of the internal audit to the Quality Assurance Manager, Manufacturing Control Manager or Responsible Engineering Manager in written form.

(3) Operation to record the results of internal audit and to retain records.

7.2 Taking Corrective Actions

Based on the results of internal audit, the Marketing Authorization Holders, etc. should take corrective actions if necessary and have designated persons record the actions and retain records.

8. Retirement of Computer Systems

8.1 Documentation of Retirement Plan of Computer Systems

Upon retirement of a computer system, the Marketing Authorization Holders, etc. should document a plan on the retirement (hereinafter referred to as "Retirement Plan") as necessary, depending on the type, scale and category, etc. of the system. The Retirement Plan should describe the following items：

(1) Roles and responsibilities on the retirement
    1) Organization chart
    2) Responsible person for retirement of the computer system
(2) Computer system to be retired
(3) Items regarding data migration
(4) Items regarding information security
(5) Process of retirement of the computer system

Depending on the type, scale, and use of the computer system, and taking the following items into account, the process should be properly determined.

1) Risk assessment
2) Prerequisites
3) Schedule
4) Details on the retirement
    ・Hardware
    ・Software
    ・Data

・Documents (SOPs, records and written contracts, etc.)

(6) Acceptance criteria for a completion of the retirement

8.2 Documentation of Retirement Records

The responsible person for computer system retirement should retire the computer system in accordance with the Retirement Plan, create records, and retain them.

9. Document and Record Management

Documents and records that were established based upon this guideline should be appropriately stored and controlled in accordance with the procedures established in accordance with GQP Ministerial Ordinance or GMP Ministerial Ordinance. In the case where a system is under both GQP Ministerial Ordinance and GMP Ministerial Ordinance, it should be clarified in advance which Ministerial Ordinance is applied to the management of the system, in the Administrative Policy and Rules for Computerized Systems, etc.

10. Terminology

Operational Qualification (OQ)

To verify and document that the computerized system provides functions and performance specified in the Functional Specification, etc. in its operating condition

Operations Management

Operations to maintain a computerized system in a validated state, and to operate it properly based on the requirements specified in the User Requirement Specification, after the system has begun its operations

Operation Manager

A person who was designated by the Marketing Authorization Holders, etc., in accordance with the Operations Management Standard Code, responsible for conducting operations on management of a computerized system

Development Activities

Activities from planning, designing, building, testing, until acceptance testing of a target computerized system

Development Plan
A document to be created upon development of a target computerized system, which describes purpose of the system, operating conditions, responsibilities, organization, and schedule for the development

Development Project Manager
A person who is designated by the Marketing Authorization Holder, etc., responsible for development of a computerized system within the Development Plan

Functional Specification (FS)
A document which describes more specific functions, corresponding to the requirements specified in the User Requirement Specification

Supplier
One or more entities that develop(s) or integrate(s) a computerized system, and provide it to the Marketing Authorization Holders, etc., which is (are) generally referred to as "vendor"
In the case where system development is conducted in-house, the in house system developers are included in the supplier.

Supplier Assessment
Assessment conducted by Marketing Authorization Holders, etc. in order to determine suppliers, range of commission, and/or the methods of supplier audits if needed
It is generally performed at an initial stage of the development.

Supplier Audit
An evaluation/qualification of the comprehensive quality management system and capability of a supplier by a multilateral investigation into the supplier's quality control and quality assurance systems, its production history/capability, and its past achievements, etc.
There are two ways for auditing, one is on-site audit and another is document audit.

Validation Activities
Activities to verify that a computerized system has been designed and installed, and achieves required level of performance in its operational environment and condition, as

defined in the User Requirement Specification, etc.

Validation Project Manager
A person who is designated by the Marketing Authorization Holder, etc., in accordance with the Development Plan, responsible for conducting Validation Activities

Site Acceptance Test (SAT)
An activity by the supplier to confirm that all or parts of the functions and performances of the system meet the functional specification, in the operational environment on site Herein, the term "on-site" means the location where the Marketing Authorization Holder, etc. is about to install the system.

Factory Acceptance Test (FAT)
An activity by the supplier to confirm that all or parts of the functions and performances of the system meet the functional specification prior to shipping at development phase

Configuration
Activities to build up the combination of system components of hardware and software, and/or to set up the operational conditions, etc., before the use of a computer system
Namely, for the hardware portion, it means to build up and register the system components of computers, peripheral devices, and/or the parts (circuit boards, etc.). For the software portion, it means to set up and register the system component modules, environmental variables or parameters, etc. for system operation, without creating or changing software programs.

Computerized System
A process or operation integrated with a computer system, and business processes that utilize functions realized by computer systems

Computer System
A group of hardware components and associated software, designed and assembled to perform a specific function or group of functions

Responsible Person of Computer System Retirement
A person who is designated by the Marketing Authorization Holders, etc. in accordance with the Retirement Plan, responsible for retirement of a computer system

Identification Components
A combination of data or a combination of a device and data, such as ID and a password, in order to identify operators involved in the system operation

System Assessment
A comprehensive evaluation of the complexity and development method of the system software, degree of impact on the safety and quality of the products that are manufactured by the system, or the severity of electronic records that is created and retained by the system, as well as the status of quality assurance by the supplier during system development process, etc., in order to determine the validation activities and documents to be produced, etc., during the validation stage of the computerized system development

System Inventory
An aggregation of registered information on the computerized systems covered by this guideline for proper management
Such information is composed of, the name of each system, registration number, whether it is a subject of validation or not (i.e. category of the software), and the names of the persons in charge of the system, etc.

System Test
To verify that the system modules and/or programs function as defined in the Functional Specification and the Design Specification, in integrated state for operations

Installation Qualification (IQ)
To verify and document that hardware of the computerized system and its programs have been installed as specified in the Design Specification, etc.

Performance Qualification (PQ)
To verify and document that the computerized system functions and fulfills performance requirements as defined in the User Requirement Specification, etc., in operation

Design Specification (DS)
A document, which describes detailed specifications to build the computerized system that realizes specific functions as stipulated in the Functional Specification
It may be divided into a hardware specification document and a software specification

document.
Hardware Specification: it describes the specification and composition of hardware that constitute the system.
Software Specification: it describes functions in detail and composition of software that constitute the system.

Design Qualification (DQ)
To verify and document that the requirements specified in the User Requirement Specification are correctly reflected in the Functional Specification and Design Specification, etc.

Software Category
A group of software, in which the software with the same degree of trustworthiness should fall
A fundamental classification to distinguish features and characteristics of software

Program Specification
A specification document that describes what should be implemented in each module and/or program in order to realize the functions specified in the Design Specification

Program Test
A test to confirm that a module or a program functions as specified in the Program Specification on its own

Module
A minimum unit of function constituting software

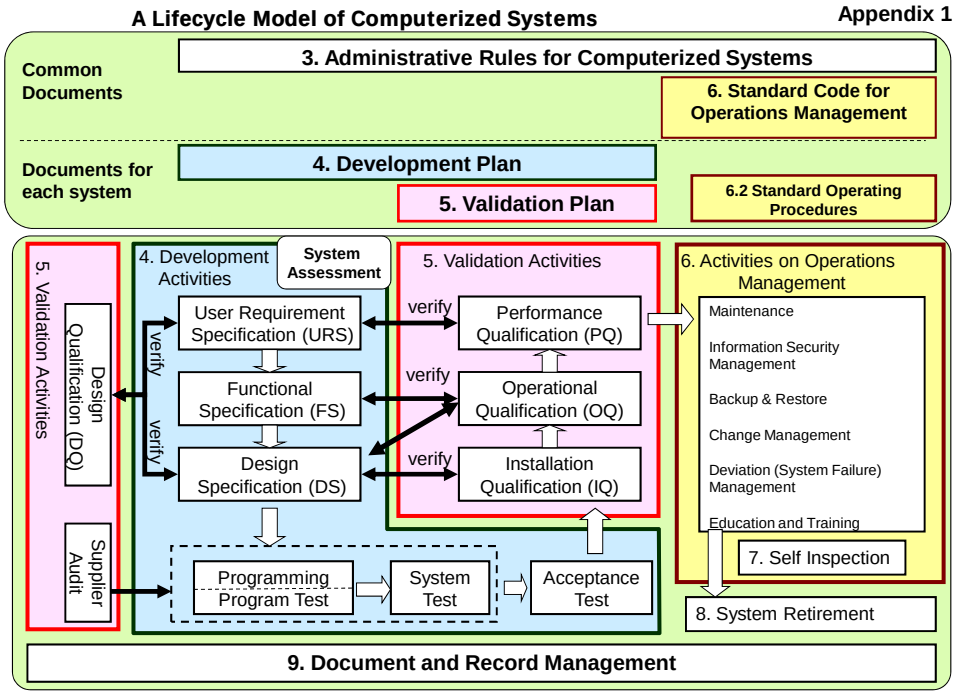
User Requirement Specification (URS)
A document describing functional requirement specification on the target computerized system

Risk assessment
A systematic process of organizing information to support a risk decision to be made within a risk management process
It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

Restore

To reinstate a system to a similar condition where the system backup was made, by loading the programs, parameters, and data, etc., from proper media in which they were backed up.

With regard to terms not mentioned above, refer to “Definitions” chapters given in GQP Ministerial Ordinance, GMP Ministerial Ordinance and other related notifications.



Appendix 2

Categorization and Activities Example

Category		Description		Development Plan	System Assessment	Registration to System Inventory	User Requirement Specification (URS)	Functional Specification (FS)	Design Specification (DS)	Supplier Audit	Acceptance Tests	Validation Plan/Report	Design Qualification (DQ)	Installation Qualification (IQ)	Operational Qualification (OQ)	Performance Qualification (PQ)	Standard Operating Procedures	Document Management	Remarks
1	Infrastructure Software	– The platform on which category 3-5 application software is implemented. – Software to manage operating environment.		O1 *1	O1 *1	O1 *1	O1 *1	O1 *1	O1 *1	–	O1 *1	O1 *1	–	M *2	O1 *1	O1 *1	O1 *1	O1 *1	*1 To be included in the activities for the application software (no need to prepare for itself) *2 Proper installation should be checked, and versions, serial numbers, etc. should be recorded.
2		Not in use		–	–	–	–	–	–		–	–	–	–	–	–	–	–	Not in use, in consistency with GAMP5
3	Non - configured Software	Commercial off-the-shelf software that is not configured to conform to business processes (including the application software with parameters specified at only runtime).	Computer systems integrated to manufacturing equipments, analytical equipments, and utilities.	M	M	M	M *3	O2	–	O2	–	M *3	–	M *2	O2	M *3	M *3	M	*3 Can be combined with the specifications and verification of functions for the equipment. For simple systems, can be substituted with calibrations.
			Stand–alone computer systems	M	M	M	M	–	–	O2	–	M	–	M *2	–	M	M	M	
4	Configured Software	Software configured to conform to user business processes (including 'macros' that run on application software). If a program has been modified, it is considered to be category 5.		M	M	M	M	O1	O1	O1	O1	M	O2	M	O1	M	M	M	Design specifications and documents regarding system built can be managed by the supplier(s).
5	Custom Software	Software designed and programmed to suit business processes (including 'macros' that run on application software).		M	M	M	M	M *4	M *4	M *4	O1	M	M *4	M	M	M	M	M	*4 Not mandated, if its function s are simple and can be designed by URS only.

M: Mandatory O1: Optional depending on system assessment results (basically required) O2: Optional depending on system assessment results (basically not required)
–: Fully optional

Out of Scope of this Guideline

Out of Scope of this Guideline	• Generic devices sold on the commercial basis, e.g. electronic calculators, digital clocks, read-only electric scales. • PCs and commercially available word processing software packages, spreadsheet software packages etc. that are widely used in common and not used in the activities under the GQP and/or GMP Ministerial Ordinances such as manufacturing records, release decisions.If such software is used in the activities under the GQP and/or GMP Ministerial Ordinances such as to prepare manufacturing records or to make release decisions, versions, model codes of PCs, serial numbers, etc. are to be registered onto the System Inventory.