YY Plant, XX Pharmaceutical Co., Ltd.

Data Integrity Master Plan

Rev.01

(Blue texts indicate examples.)

Document prepare and approval

Position	Name	Signature	Date
Prepared by:			
DI Manager			
Approval: The policies, procedures, plans etc., set forth in this document are hereby approved, and it is hereby ensured that necessary resources are allocated.			
General manager of plant			
Director of Quality Assurance Department			

Revision History

Rev.	Creator	Date	Reason for revision
01			New document

Table of Contents

1. Objectives

- This Master Plan has been prepared to comprehensively control activities related to data integrity (DI) at YY Plant of XX Pharmaceutical.
- This Master Plan specifies methods for identifying risks at manufacturing sites and for introducing DI-related requirements and basic concepts to employees, processes, systems, etc.

2. Background

- In recent years, regulatory agencies have strengthened regulations and oversight for DI. As a result, guidances on data integrity are being issued in succession.
- DI is important in order to ensure the quality/efficacy/safety of drugs, and data must meet the ALCOA requirements.
- Flexible, risk-based strategic actions are required in order to prevent and detect DI problems.

3. Scope

- This document applies to XX Pharmaceutical's YY Plant. (It is possible to apply this document to each plant respectively, or to all plants holistically. Also, it is possible to apply this to data management at contractors.)
- This document applies to all GMP data handled in the processes controlled by XX Pharmaceutical's YY Plant (preparation, handling, review, reporting, and storage). (It is also possible to apply this document to data for technical transfer or that of CMO.)

4. Policy

- DI activities mainly focus on the following 3 points.
  [1] Establishment of governance system
  [2] Actions on DI based on risk management
  [3] Creation of DI culture (communication plan)

- Refer to the following guidances:
  [1] **PIC/S:** Draft Guidance "GOOD PRACTICES FOR DATA MANAGEMENT AND INTEGRITY IN REGULATED GMP/GDP ENVIRONMENTS"(8/2016)
  [2] **ICHQ10:**"Pharmaceutical Quality System"(10/2010)

[3] **(Other, add as necessary)**

5. Schedule

– (Using tables, Gantt charts, etc., outline the schedule of overall DI activities at the manufacturing site.)

6. Roles and Responsibilities

Management:

- Approves the DI Master Plan and provides necessary resources.
- Receives periodic reports on the progress of DI activities and gives necessary instructions.

DI Team:

- Consists of members from Quality Assurance Department, QC, IT, and manufacturing unit.
- Prepares, maintains and controls the DI Master Plan and reviews it as necessary.
- Provides support for DI activities in each workplace and manages progress.
- Periodically reports progress to management.

Quality Assurance Department:

- Understands the requirements under the draft PIC/S guidance on DI and confirms that quality control is implemented appropriately based on the concept of DI.

Manufacturing Unit:

- Understands the requirements under the draft PIC/S guidance on DI and confirms that manufacturing control is implemented appropriately, based on the concept of DI.

Managers of each Department, Persons in charge of DI (Subject Matter Experts):

- Participate in risk assessments and the development of risk reduction measures.

Validation Manager:

- Understands the requirements under the draft PIC/S guidance on DI and confirms that validations are implemented appropriately based on the concept of DI.

IT Manager:

- Mainly supports assessments related to equipment and systems. If any unacceptability is detected, supports measures against it.

Self-inspection Manager:

- Understands the requirements under the draft PIC/S guidance on DI and confirms the state of conformance at the time of self-inspection where necessary.
- Incorporates DI-related inspections into the annual self-inspection plan.

Training Manager:

- Understands the requirements under the draft PIC/S guidance on DI and prepares training materials related to DI.
- Specifies DI-related education in the annual plan for education and training in each area.

Employees:

- Immediately report to manager any DI-related problems or concerns when these are noticed or felt.
- Understand how to contact the hotline, etc.

7. Risk Management

A) Assessment on DI management procedure: The following items are assessed using Appendix 1.
   - Procedures for creation and control of records and data
   - Operating procedure for paper media
   - Operating procedure for electronic media, etc.

B) Assessment on equipment/system: Perform assessment of QC laboratory equipment/system using Appendix 2. Then expand this to manufacturing areas, utilities and quality systems.

C) Implementation and monitoring of corrective actions: Supervise progress in accordance with the standard operating procedure "CAPA Control (Document No. XXX)."

8. Governance

A) Management Review:
   - At least once every quarter (in principle, March, June, September, and December), the progress of DI activities, identified risks, etc. shall be reported using Appendix 3.

- If there is any finding related to DI in the self-inspection, the details of the issue shall be shared, and efforts shall be made to prevent recurrence by horizontal expansion to other processes.
- In addition to the above, if any critical issue that may affect product quality is found as a result of the assessment, or if any delay occurs in the plan, it shall be reported appropriately.

B) GMP Self-inspection:

- Incorporates items related to DI into the self-inspection program.
- Summarizes both the trend of and measures against DI deficiencies observed in the given year and reports them to management in the management review, etc.

C) Hotline Establishment (if not yet established):

- Consider assigning personnel to whom concerns can be reported, or questions can be asked.
- It should be possible to communicate with the personnel directly and anonymously, not through managers or management.

9. Communication Plan

A) Annual GMP Training:

- Plan to have external consultants provide education and training on Quality Culture to management and persons in administrative positions.
- Plan annual DI training in each area.

B) Communication:

- The DI team publishes monthly DI newsletters to promote employee understanding.

10. Document Control

– Documents and records created in connection with the activities on this matter shall be controlled in accordance with the standard operating procedure "Document Control (Document No. XXX)."

11. Deviation Control

– If any matter considered as a deviation from GMP is found during the activities on this matter, handle it in accordance with the standard operating procedure "Deviation Control (Document No.

XXX)."

12. Change Control

– If any GMP-related changes required by the activities on this matter arise, handle these in accordance with the standard operating procedure "Change Control (Document No. XXX)."