1   Purpose

The purpose of this Guideline is to provide requirements in the definition and documentation of raw data and also to outline recommendations on how to achieve compliance.

2   Scope and Applicability

This Guideline is applicable to any site, function and departments undertaking work, or providing support services, required to meet Good Manufacturing Practice (GMP) and/or International Organization for Standardization (ISO) standards.

3   Definitions

3.1   Raw Data

Raw data are defined as any work sheets, records, memoranda, or notes that are the result of original observations, findings, measurements or activities. This Guideline deals with those raw data that are necessary for the reconstruction, evaluation, and/or assurance of the integrity of a process, work project or report.

Raw data may be in the form of paper, computer readable media, magnetic media, photographs or film, microfilm or microfiche. Raw data may be created through handwritten notes, dictated observations, recorded data from instruments, data entered directly into a computer either manually or through an instrument interface or data printed automatically from devices.

3.2   Derived Data

Derived data are data that are produced or obtained from other data. Such data result when raw data elements are used in calculations, algorithms or other manipulations or evaluations to derive additional data.

4   Responsibilities

Functional Line Management are responsible for ensuring, with QA input where appropriate, that procedures for managing raw data are defined and that the raw data are securely retained and can be retrieved throughout their retention period.

5   Guideline

5.1   General Standards

Raw data must be recorded immediately, accurately and, excluding those data directly entered into a computer, legibly in indelible ink or equivalent onto a durable medium.

Raw data must be signed or initialed and dated by the individual responsible for recording those data. For computerized systems, the individual responsible for direct data input shall be identified at the time of data input.