1 Purpose

The purpose of this Guideline is to provide the regulatory requirements for the management of master GMP documents; issued, controlled and used to verify compliance with required codes of GMP and/or other relevant Quality and Compliance Standards. Recommendations are also included on how to achieve compliance.

2 Scope and Applicability

Master GMP documents issued and used by manufacturing functions, departments or sites to verify compliance with Good Manufacturing Practice (GMP) and/or other relevant Quality and Compliance Standards.

3 Definitions

3.1 GMP Master Document

An approved, version controlled GMP document is any policy, procedure, guideline, protocol, report, controlled form or template in paper or electronic form that is required for compliance with the GMP codes of practice and/or company Standards.

Notes:

(i) These documents are considered to be “records”.

(ii) Where a record, outlined above, contains raw data, these should be managed in accordance with the Quality and Compliance Manual guideline

4 Responsibilities

4.1 Management

Management is responsible for:

- Establishing procedures, guidelines and instructions within its function, department or site, to ensure compliance with document management practices as outlined in this guideline.

- Ensuring the preparation, review, approval and availability of master GMP documents required within its area of responsibility and provision of training where necessary.

4.2 Quality Assurance (QA)

QA within the functions, departments or sites is responsible for:

- Providing advice and support to management in the preparation of master

Relevant staff and line management/process managers must review the document to ensure that it is technically sound, scientifically valid and can be implemented.

Approval of the document must be by appropriate and authorized personnel. Additionally, QA must review the document to ensure that the GMP requirements have been met.

5.4 Effective Date

The document must contain an effective date, taking into account any implementation and/or training requirements, which must be completed prior to its use.

5.5 Control and Access to Master GMP Document

Once approved, the master GMP document must be returned to and retained by authorized personnel. Access to the master must be restricted.

Where appropriate, the master GMP document must be retained in a secure archive.

A copy of the master GMP document may be taken and made available for use. For example, a master SOP and master batch manufacturing record may be copied and distributed for use.

In some cases, however, the master document may be the working copy for a given GMP activity, for example, protocols for validations and/or qualification. Procedures for the control of these documents, for example, documenting the location of and accountability for the document may be required. This is of particularly importance during the final review/approval of completed documents, as this may involve staff outside of the immediate location of the GMP activity.

Where the master document is used to generate the working copies, the reproduction process must not allow any errors to be introduced or any reduction in clarity or legibility from the original. The master and copies taken from it must be distinguishable.

Where work is undertaken by a third party on behalf of the GMP function, department or site, clear responsibilities for the preparation, issue, use and archiving of the master must be defined in a Quality Agreement (contract).

5.6 Documents Available Electronically

Where documents are prepared and approved electronically, the above requirements in 5.2- 5.5 apply, and the systems must be validated.

In particular, system safeguards and procedures must be in place to ensure that the master file is protected and not accessible to change and/or deletion by the user.
A business continuity plan must be in place, in the event of electronic

