

Standard Operating Procedure

Title: Preparation, Maintenance and Change Control of Master Documents

EHS Statement

There is no EHS impact.

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Procedure

1. A New Product

A new product normally originates from Supply Chain.

The first step towards the manufacture of any new product must be the preparation and provision of a local Master File.

This Master File may be developed from Technical Documents, information from the Company from which the data was obtained, or from Local Development work.

The information contained in the Master File is the PRIME SOURCE of information for both new product applications to the Regulatory bodies and/or export regulatory authorities and for preparing local manufacturing documents.

- 1.1. Each Master File defines critical processes and must contain information in the following sections:
 - a) Product Formulation
 - b) Method of Manufacture,
 - c) Raw Material Descriptions, Specifications and Test Method
 - d) Product Specifications (In-process, Release, Expiry, Stability) and Test Method
 - e) Analytical Methods - Finished Product
 - f) Description and Specification of Packaging Components
 - g) Stability Data
 - h) Technical Reports and other relevant data.

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- 5.3. For new components, (Packaging and Raw Materials), their descriptions and Code Numbers are allocated by the QA Department.
- 5.4. Where a change needs to be made to an In-house Master File document, which is of an urgent nature, then the change may be made directly on to the original and authorised by the Technical Service Manager or delegate. The circumstances under which these changes can occur are restricted to changes that do NOT affect the registered details and those which are typographical errors. All in-house Technical documentation changes must be actioned through the Technical Service Department.
- 5.5. Documents are identified using a unique number. The number consists of a prefix, a core number and suffix, e.g. **S-XXX-YY.A**.

Prefix ID

The prefix ID identifies the document type as listed in SOP **QMS-010**

Core Number

This number is the unique number taken from the product code number. If a number of product codes use the same document, then the core number is the lowest of the associated code numbers.

Suffix

Suffix is alphanumerical and consists of the year and the version number. The version number is alphabetical, e.g. Second version modified in year 2001 will be written as 01.B

Updating documents

The prefix and core number remain the same and the suffix changes in accordance with the year it was modified and the number of times it has been modified within that year. The core number may change where a number of product codes are represented by the document and the lowest core number product becomes obsolete.

6. Preparation and Change to Master Documents

6.1. Reason for new or revision to Documents

New document requests usually result from the introduction of new product, new material (ingredient/ components), and new process or procedure or where a need has been identified to a gap with existing documents.

Revision to existing documents usually results from specification or process change or corrections. Revision of can be initiated by way of Master Document Change Control Form (**Form-365**)

6.2. Preparation of new Master Document

6.2.1. A request to Create/Cancel Controlled Document Form (**Form-505**) can be initiated by anyone in the manufacturing. The Technical Service Staff receives the request with all relevant information attached for the creation of a new document. A document number will be assigned for the new document and place in the Draft folder in the Master document database.

6.2.2. The request is then evaluated for the following

- Validity of the request
- Possible regulatory impact on all Markets affected by the proposed change
- Impact to documentation policy and requirement for prior management approval.
- Impact to related master documents and Bill of materials.

6.2.3. Once the evaluation has been completed the request is either rejected, returned to the initiator or processed for new master file.

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- 6.3.16. When signed, make appropriate number of official masters as specified in the following table and stamped with "This is an Official Master if Stamp Is in Red" sign and date. Distribute the authorised copies in the satellite files of relevant departments according to section 4 of SOP **QMS-010**.
- 6.3.17. Remove the original electronic version in the Superseded folder from Live folder of the database. Replace it with the changed file with appropriate version number from Draft folder.
- 6.3.18. Update master document list. Retrieve the hard superseded copy from the master document file, stamp with "Superseded" and place it in the superseded master document file.
- 6.3.19. File one changed and approved hard copy in the master document file.

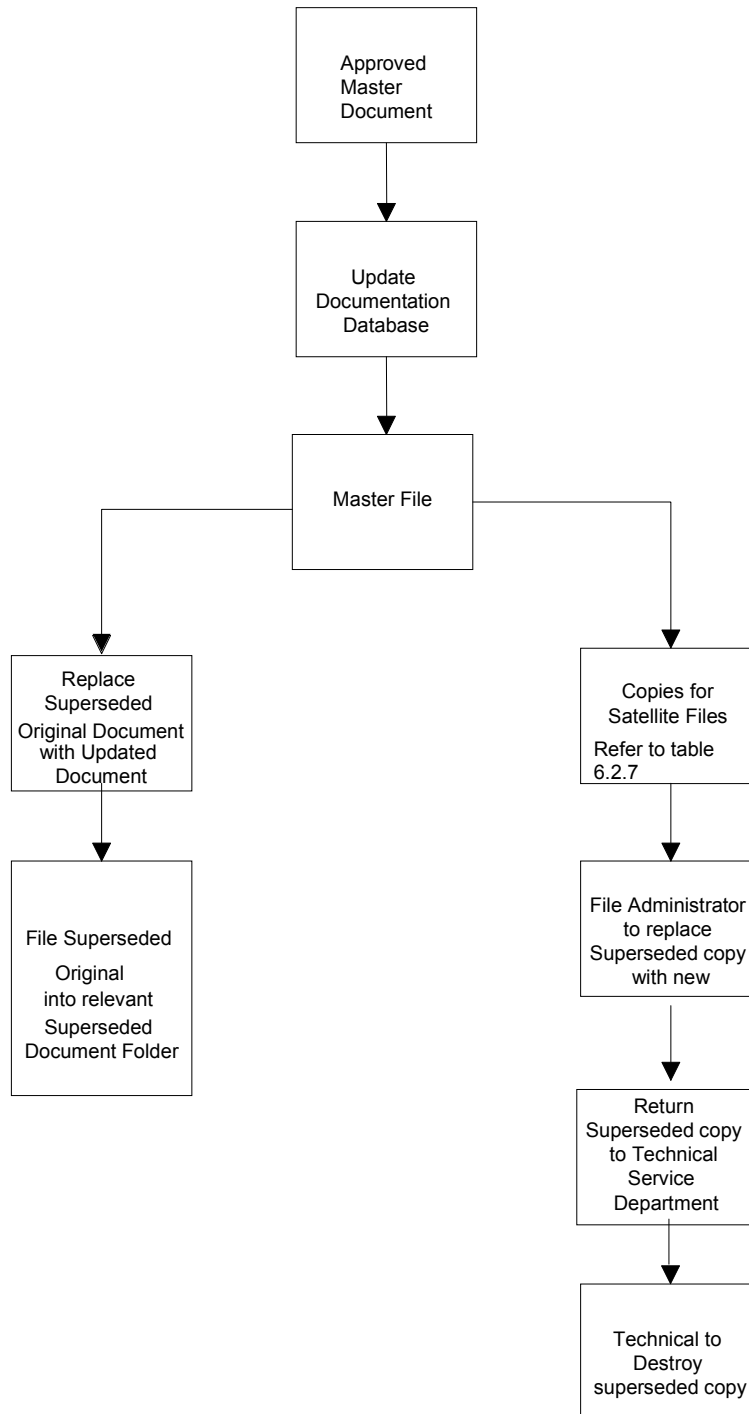
7. Category and Examples of Changes

Specification change	Any change to a specification, BOM or data sets. This includes but is not limited to: <ul style="list-style-type: none">➤ Raw materials, Packaging components, In process testing, Packaged product and equipment specifications➤ BOM for bulk and finished products➤ Data sets for starting materials or finished products
Analytical method change	Any change to or deletion of a testing procedure or inclusion of a reduced testing schedule. This includes but not limited to: <ul style="list-style-type: none">➤ Raw materials, packaging components, in process products, packaged products and calibration tests
Raw materials change	<ul style="list-style-type: none">➤ Any change to a raw material supplier, manufacturing site, manufacturing process, mode of transport or storage of containers.
Packaging components	Any change other than artwork to a packaging component. This includes but is not limited to: <ul style="list-style-type: none">➤ Bottles, caps, tubes, foils etc (e.g. thickness, materials, dimensions)
Manufacturing process change	Any change to the processing procedure. This includes but is not limited to: <ul style="list-style-type: none">➤ Manufacturing process (e.g. stirring time, blending time, order of addition drying time or temperature where variation is not specifically covered in the manufacturing instructions)➤ Packaging process (e.g. cap torque, filling temperature, line set up and shut down procedure, fill volume, blister seal temperature etc)➤ Cleaning process (e.g. time, temperature, method, cleaning agents etc)➤ Introduction of a new product to the manufacturing facility.➤ Transfer of an in-house manufactured product to an alternate manufacturing site.
Equipment /Computer change	Any modification or alteration to equipment or the environment where the equipment operates, or the relocation of the equipment from one place to another or the introduction of new equipments or consumables to existing equipments. This include but is not limited to: <ul style="list-style-type: none">➤ Manufacturing equipments (e.g. manufacturing and storage tanks, blenders, stirrers, compressing machine, drying oven, granulators, fluid bed dryers, storage hoppers, transfer lines etc)➤ Purified water system (e.g. Pumps, valves, dosing mechanism etc)➤ Packaging equipment (vision system, capper, labeller, bottle blower, shrink wrapper, cartonner, case packer etc)

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11. Appendix 2 - Flowchart for Distribution of Master Documents



12. Summary of Changes

Version #	Revision History
QMS-030	New