

# Standard Operating Procedure

## Title: Preparation, Maintenance and Change Control of Master Documents

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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 alphanumeric 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.

6.2.4. Open template located in the template folder of the database. Prepare new document with the history page.

6.2.5. Circulate document for review and approval. Update in the Status Box of the Database.