Soft Copy	The electronic copy of the Master Document filed in the applicable, secured directory. Soft copy has the signatory's names and required dates typed into the file prior to issue.
Authorised Copy	A printed hardcopy photocopied version of the Master Document, which is authorised by a signed, dated and stamped in red .
Uncontrolled copy	Any document, which is printed from the electronic copy or photocopied version without having red stamp on it. Each quality document has a footer statement of "This is not an approved copy unless stamped red"
Hardcopy Only Documents	Documents that are not maintained electronically. Documents are generally of externally derived origin but are being incorporated into Site's Quality System.
Satellite file Location	A set of relevant hardcopy documents remotely located to ensure ready access to the documents by all employees. These locations have designated numbers that are included in the Database record for each document.
TPM Dispatch Records	Third Party Manufacturing Dispatch Records.
GMP	Good Manufacturing Practice.

Related Documents

Form-395	SOP Ready for Signing
Form-410	Document Location in Satellite File
Form-415	Library Log Form
Form-455	Incident or Investigation Report Form
Form-495	Form Ready for Signing
Form-505	Document Creation or Change Request
Form-530	Reading Compliance Form
Form-535	GMP Agreement Log
TEM-080	Internal Audit Report Template
TEM-085	Training Report Template
TEM-090	Form, VD Template
TEM-095	SOP Template
TEM-110	In-house Manual Template
TEM-100	Quality Assurance Agreement Template
TEM-105	Third Party Manufacture Dispatch Report Template
TEM-120	Vendor Audit Report Template
TEM-130	Position Paper Template
QMS-010	All Documents - Classification, Definition and Approval Matrix
QMS-030	Preparation, Maintenance and Change Control of Master Documents
QMS-020	Documentation Rule for GMP Documents
QMS-025	Quality Documentation - Control, Tracking and Distribution
QMS-080	Audits

3.4. Document Approval

3.4.1. When the document is completed, inform the DCO.
The following data must be provided to the DCO:

1 Document Title
2 Document Type
3 Document Owner
4 Signing – the signatories of the document (prepared, checked, authorised) (see SOP **QMS-010**)
5 Cross References – to other Controlled Documents
6 Distribution

3.4.2. The signatories of the document can be determined using the Approval Matrix, see **SOP QMS-010.** The 'Prepared by' signature is the document author. The 'Checked by' signature is the author's manager, or a person with relevant technical knowledge.

3.4.3. The DCO will circulate the document for appropriate approval.

3.4.4. The DCO will issue the document by:

1 Placing the document in the appropriate "Live" folder in the database
2 Sending required "Authorised Copy" with red stamp, sign and date to the Satellite file locations for Teams to use.
3 Satellite File Administrator removes superseded copy (if applicable) for return to DCO and files new document.
4 If the document is to be placed other than in the Satellite File, a **Form-405** must be printed and filled in and placed in the Satellite file so the remote document can be located in future.
5 The File Administrator then advises Team of new document to read and to sign the "Reading Compliance" form attached.

3.5. Responsibilities of Signatories

3.5.1. Signatories will receive documents for signing with the "SOP Ready for Signing" routing sheet (**Form-395**), or "Form Ready for Signing" routing sheet (**Form-495**) and, if applicable, attached superseded version of the document.

3.5.2. Signatories of documents are required to review the new document for:

Correctness, effectiveness and clarity.

Appropriateness and scope of EHS statement

Document Revision History

3.5.3. For new SOPs and Forms, the "Checked By" signatory, usually the line manager, is to indicate if the document will be referenced in MI Sheets.

3.5.4. For new SOPs, if a Satellite File list is attached, the "Checked By" signatory is to indicate to which Satellite Files Authorised copies of the SOP are to be

8.1. **Logging of Technical Files**

8.1.1. Forward the file to the DCO who will number and log it into the database.

8.1.2. The file is stored in the Technical File compactus.

8.2. **Project Files and External Manuals (Operation/Equipment Manuals)**

8.2.1. Fill in the **Library Log for Equipment Manuals** and send to the DCO who will number and log into the database.

8.2.2. The DCO will print a "Print Approval Request" showing the details of the database record. This is to be filed in the front of the document file.

8.2.3. A label should be generated and placed on the spine of the file stating the manual number and location. The file is then placed in the technical file compactus location. Manuals may be stored in Production locations as per Satellite File locations.

9. Obsolete Quality Documentation

9.1. Electronic copies of SOPs, Training Session Plans, Presentations, Forms, Policies and Visual Displays etc are retained in "Obsolete" folder of the Document Database. See SOP QMS-010 to get the retention times for quality documents.

9.2. Obsolete documents can be burnt into a computer disc for easy storage and accessibility.

9.3. To retrieve a copy of an obsolete document, contact the DCO.

10. Audit Reports and Quality Assurance Agreement

10.1. **Audit Reports**

Audit reports are logged in the Documentation Database according to **SOP QMS-080.**

10.2. **Quality Assurance (GMP) Agreements**

Quality Assurance (GMP) Agreements are prepared by the Quality assurance Department and are written to outline the basic responsibilities and actions undertaken by Site and any contracted party who has direct impact in the manufacturing stages of product.

10.2.1. GMP agreements have a specific format for their numbering system as illustrated by the following format:

GMP-XXX.Y.Z

Where:

XXX = Number allocated to specific organisations (as listed in the table below)

12. Appendix 2 – Templates for creation of new documents

The following Templates are to be used for the applicable Quality Document type:

Audit Reports	TEM-080
Forms and Visual Display	TEM -090
Investigation/Incident Meeting Minutes	Form-455
Training Report	TEM -085
Quality Manuals (in-house)	TEM -110
Position Paper	TEM -130
Quality Assurance (GMP) Agreement	TEM -100
SOP template	TEM -095
TPM Dispatch Report	TEM -105
Vendor Audit Reports	TEM -120

Note: Policies and Manuals may utilise a customised format relevant to the purpose of the document but must still comply with Corporate Guidelines.

