Quality Documents	Prefix ID
1. SOP	Area specific e.g QMS
2. Forms	Form
3. Policies	POL
4. Visual Display	VD
5. Audit Reports	AUD
6. Quality Manual	MAN
7. Training	TRN
8. QA (GMP) Agreements	GMP
9. Investigation/Incident Meeting Minutes	INV/INI
10. Position Paper	POS
11. Quality Template	TEM
12. Vendor Audit Report	AUD-vendor no
13. TPM (Third Party Manufacture) Dispatch Report	TPM
14. Technical Files	TF
15. Project File	PF
16. Maintenance and Operation Manual	MAN
17. Procedural Manual	MAN
18. Presentation	PPT
19. Regulatory Standards	STD
20. Compendia	-

Master File Documents	Prefix ID
1. Control Method	CM
2. Specification (Raw Material/Finished Product/Packaging)	SPC
3. Formulation	FLN
4. Packaging Material Specifications and Test Report	PMS
5. Manufacturing Formula	MF
6. Manufacturing Instruction	MI
7. Bill of Materials	BOM
8. Stability Specification	SS
9. Finished Goods Specification and Test Report	FGS
10. Raw Material Specification and Test Report	RMS

2. Definition of all types of Quality Documents

Packaging Specifications	Packaging Development	Procurement	Technical Service Manager	N/A

4. Approval Matrix for Master File Documents

NOTE: Not all documents may be required for the Master File.

Prefix ID	Document Type	Quality Assurance	Technical	Production	Regulatory
CM	**Control Method**	LM	TSM/TPM	-	-
SPC	**Specification**	LM	TSM /TPM	-	RAM
FLN	**Formulation**	QAM	TSM /TPM	PM	RAM
PMS	**Packaging Material Specification-Test Report**	QAM	TSM /TPM	PM	RAM
MF	**Manufacturing Formula**	QAM	TSM /TPM	PM	RAM
MI	**Manufacturing Instruction**	QAM	TSM /TPM	PM	-
BOM	**Bill Of Materials**	QAM	TSM /TPM	PM	-
SS	**Stability Specification**	LM	TSM /TPM	-	-
FGS	**Finished Goods Specification and Test Report**	LM	TSM/ TPM	-	-
RMS	**Raw Materials Specification and Test Report**	LM	TSM /TPM	-	-

Keys:

QAM	Quality Assurance Manager	TSM	Technical Service Manager
PM	Production Manager	TPM	Technical Project Manager
RAM	Regulatory Affairs Manager	LM	Laboratory Manager

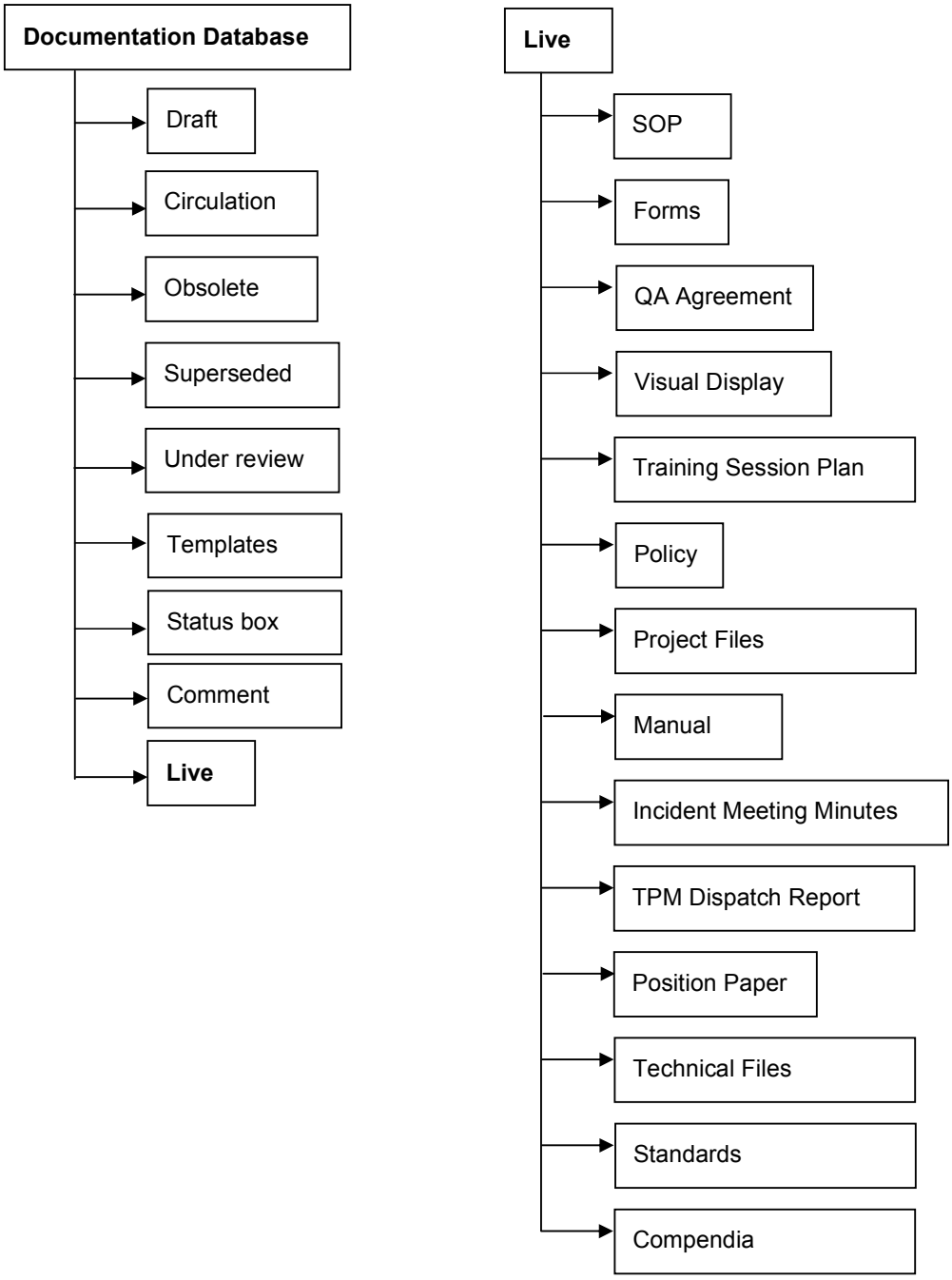
A delegate may be authorised to sign on behalf of the nominated, responsible person.

5. Review Period for Master File Documents

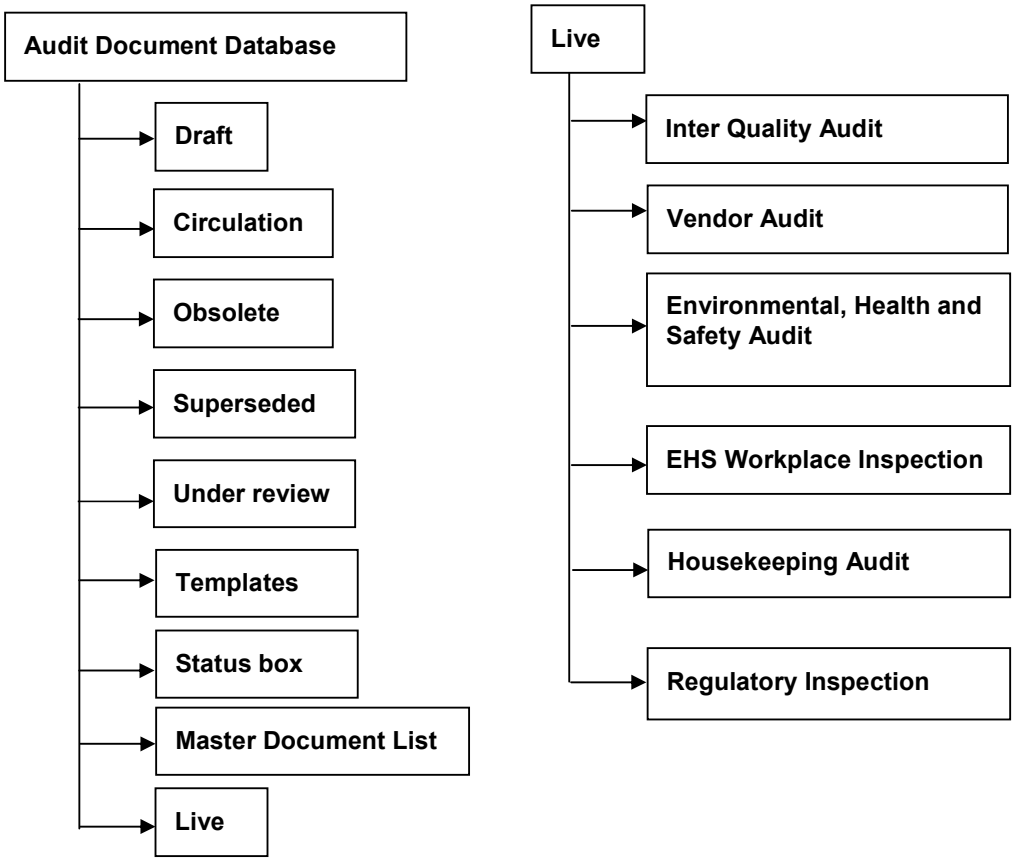
Prefix ID	Document Type	Review Period
CM	**Control Method**	3 years unless change initiated
SPC	**Specification**	3 years unless change initiated
FLN	**Formulation**	3 years unless change initiated
PMS	**Packaging Material Specification and Test Report**	3 years unless change initiated
MF	**Manufacturing Formula**	3 years unless change initiated
MI	**Manufacturing Instruction**	3 years unless change initiated
BOM	**Bill Of Materials**	3 years unless change initiated
SS	**Stability Specification**	3 years unless change initiated
FGS	**Finished Goods Specification and Test Report**	3 years unless change initiated
RMS	**Raw Materials Specification and Test Report**	3 years unless change initiated

Document	Technical	QA Dept	Regulatory
Manufacturing Formula (MF)	• Complies with registered Product Details and other registered details • Batch size stated in line with machine capability and registered details	• Reflects bulk formulations used in production • Batch size stated in line with machine capability and registered details	• Complies with registered Product Details and other registered details
Manufacturing Instruction (MI)	• Complies with registered Product Details and other registered details • Based on local production knowledge and validation	• Based on local production knowledge and validation	
Bill of Materials (BOM)	• Complies with registered Product Details and other registered details • Batch size stated in line with machine capability and registered details	• Based on local production knowledge and validation	
Stability Specification (SS)	• Compliance with registered Product Details or other registered details • Updated to current pharmacopoeia • Reflects stability of product	Analytical • Updated to current pharmacopoeia • Reflects stability of product	Not applicable
Raw Material Specification and Test Report (RMS)	• Complies with registered Product Details • Reflects current pharmacopoeia • Reflects current in-house specification (where applicable)	Analytical • Reflects current pharmacopoeia • Reflects current in-house specification (where applicable)	Not applicable
Finished Goods Specification and Test Report (FGS)	• Complies with registered Product Details • Reflects current pharmacopoeia • Reflects current in-house specification (where applicable)	Analytical • Reflects current pharmacopoeia • Reflects current in-house specification (where applicable)	Not applicable

8. Document Database for Quality Document



10. Document Database for Audit Document



11. Summary of Changes

Version #	Revision History
QMS-010	New

