

Standard Operating Procedure

Title: All Documents – Classification, Definition and Approval Matrix

2. Definition of all types of Quality Documents

(This table does not include Master file documents).

Document Type	Definition
Standard Operating Procedure (SOP)	Standard Operating Procedures (SOPs) are issued to specifically instruct employees in areas of responsibility, work instructions, appropriate specifications and required records SOPs outline procedures, which must be followed to claim compliance with GMP principles or other Statutory rules and regulations. Procedures can take the form of a narrative, a flow chart, a process map, or any other suitable form, however must be written in appropriate, effective grammatical style.
Form	A document which is to be printed at the time of use and filled out for the purpose of becoming a record (e.g. Line Opening Form), or for the purpose of becoming Visual aid.
Policy	Statement from Management on the use and application of certain activities and processes within the organization.
Visual Display	A form requiring no additional data to be added (i.e. written information) which provides visual information to instruct in the process, e.g. <i>Tablets visual Defects</i> . The information can be in the form of pictures or photographs; flowchart; operating instructions; or a notice. The Visual Display is usually located in a permanent position, however maybe in use for a specific period of time, e.g. for a single batch. Pages from a single Visual Display must be located together in a specified location. A location form (FM-0194) must be placed in the Satellite File so the VD can be located if superseded or cancelled. (See SOP A.8.1)
Audit Report	An audit is a systematic and independent review to verify compliance, suitability and/or data integrity. Audits report may assess: systems, processes, procedures, facilities, products, records and/or data for compliance with policies, standards, procedures, guidelines, regulations or regulatory submissions
Quality Manual	Instructions written in-house to be followed for the use of equipment, systems or processes.
Training Session Plan	The aim of the Training Session Plan is to overview and describes the rationale behind a process. Training Session Plans cross-reference relevant SOPs and Production Documentation.
Quality Assurance (GMP) Agreement	An Agreement is written to outline the basic GMP responsibilities and actions undertaken by Sydco and any contracted party who has direct impact in the manufacturing stages of product (including contract manufacture, secondary packaging, storage and distribution).
Investigation/Incident Meeting Minutes	A report where an investigation or incident causalities and findings are documented in systematic order.
Position Paper	A Position Paper is created when Sydco reviews its current manufacturing products and processes against the code of GMP and decides to perform in excess of the stated requirements or to not perform them. The Position Paper should outline the actual requirement stated in the relevant document, the rational as to why Sydco is doing something different to the requirement and a risk assessment which identifies why this is acceptable.
Quality Template	A template is for creating a particular documentation.
Vendor Audit Report	Audit report prepared after vendor evaluation.
TPM Dispatch Record	This is a delivery docket created and issued by a company contracted to supply products manufactured for sydco