



Quality Agreements SOP

SOP EXCERPT BEGINS

Procedure	Action	Responsibility
5.1	Development of Quality Agreement	
	Design the Quality Agreement to include, but not be limited to, the following subjects: <ul style="list-style-type: none"> • Responsibility of the Quality Agreement • Provision for Amendment Requirements of the Quality Agreement • Definition of the Service Being Provided by the CMO and/or Vendor (Supplier) • Information Sharing Requirements • Right to Audit • Notification of Regulatory Agency Inspections • Applicable Safety Requirements • Service or Supply Requirements • Testing and Release Requirements • Quality Roles Between Contracting Company and its Approved CMO Quality Operational Groups • Notification of Change • Notification of Recall/Product Retrieval • Notification of Deviations and Related Investigations to Procedures • System and/or Equipment Qualification and Validation Requirements • Storage and Control Documents • Storage and Shipping of Product • Revision Log • Approvals • Deliverable Acceptance/Rejection Criteria 	GMP Operational Department and Quality Assurance Department
	Determination of Need for Quality Agreement	
	The need for a Quality Agreement with a vendor or supplier will be determined by, but not limited to, the following criteria: <ul style="list-style-type: none"> • Results of vendor or supplier assessment • Criticality of vendor or supplier to operational requirements • Clinical development phase • Commercial production use 	GMP Operational Department and Quality Assurance Department

SOP EXCERPT ENDS



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