

Process QSEs Worksheet

QSE: Purchasing and Inventory			
Components	Is content contained in one or more of your controlled document(s)?		Notes
	Yes	No	
“Selection and qualification, based on ability to meet laboratory expectations”			
“Purchase of materials or services”			
“Supplier, contractor, consultant evaluation”			
“Inspection and verification of received materials”			
“Storage and handling of materials”			
“Inventory management”			
“Identification and tracking of critical materials and services”`			

QSE: Equipment			
Components	Is content contained in one or more of your controlled document(s)?		Notes
	Yes	No	
“Selection qualification (SQ) and acquisition”			
“Equipment qualifications”			
“Calibration program”			
“Maintenance program”			
“Decommission of equipment no longer in use”			
“Equipment files and records”			

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QSE: Process Management			
Components	Is content contained in one or more of your controlled document(s)?		Notes
	Yes	No	
"Analysis, design, and documentation of the laboratory's path of workflow and QSE activities"			
"Process validation and/or verification"			
"Process control"			
"Change management"			

QSE: Documents and Records			
Components	Is content contained in one or more of your controlled document(s)?		Notes
	Yes	No	
"Document management system"			
"Record management system"			

QSE: Information Management			
Components	Is content contained in one or more of your controlled document(s)?		Notes
	Yes	No	
"Planning for overall information needs"			
"Confidentiality of information"			
"Security for data access"			
"Integrity of data transfers or transmissions"			
"Provision for information availability during downtime"			