

ISO 13485:2016 Gap Analysis Checklist

4 QUALITY MANAGEMENT SYSTEM

ISO 13485:2016 Gap Analysis Checklist New 2016 Requirements are Shaded in Yellow		
REQUIREMENTS		OBSERVATIONS
4.1	General Requirements	
4.1.1	Is there a Quality Management System in place that has been established and documented to meet the requirements of the ISO 13485:2016 Standard and the applicable regulatory requirements?	
	When the standard specifies that a requirement, a procedure, an activity or arrangement be "documented", is it implemented and maintained?	
	Are the role(s) undertaken by your company under the regulatory requirements (as a manufacturer, a distributor, an authorized representative, or an importer) documented?	
4.1.2	Determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization	
	Is a risk-based approach to the control of processes applied?	
	Are the sequence and interaction of the processes determined?	
4.1.3	Determine criteria and methods needed to ensure that both the operation and control of these processes are effective	
	ensure the availability of resources and information necessary to support the operation and monitoring of these processes	

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web objective to apply stoichiometric principles to calculate the appropriate chemical equation for the reaction between iron metal and a solution of copper i sulfate introduction in the form of finely split powder copper metal is produced as a byproduct of the process as iron ions the ion meta dissolves

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web october 3 2017 abstract the techniques used in this lab are quantitative transfer and vacuum filtration with the reaction of 8 001 grams of copper ii sulfate CuSO_4 and 2 0153 grams of iron powder Fe the goal of this experiment was to determine the product of copper ii sulfate with iron

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web procedure 1 find the mass of a clean dry 100 ml beaker and record 2 measure out 8 00 grams of copper ii sulfate onto a piece of filter paper taking the filter paper s mass into account add these to the beaker 3 measure 50 0 ml of water in the cylinder and add it to the beaker 4

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web stoichiometry lab the reaction of iron with copper ii sulfate the study of stoichiometry deals with the calculation of quantities in a chemical reaction how much product will be produced how much reactant do you need to make that much product

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web description great lab for use during stoichiometry unit in chemistry reinforces ideas of mole ratios and stoichiometry calculations by measuring the mass of iron that reacts and the mass of copper metal produced students can calculate the ratio of moles of reactant to moles of product this experimental mole ratio from lab can be compared

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web in this experiment we will use stoichiometric principles to deduce the appropriate equation for the reaction between metallic iron and a solution of copper ii sulfate this reaction produces metallic copper which is seen precipitating as a finely divided red powder

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web in this lab we will use experimental evidence and the principles of stoichiometry to determine which ion is formed in a single replacement reaction between iron and copper ii sulfate pre lab assignment in preparation for the lab activity we will investigate another single replacement reaction between copper and silver nitrate

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web through this experiment we sought to use stoichiometric principles which derive from stoichiometry the study of substance quantities in ratio or proportion in a chemical reaction in this lab experiment the principles help distinguish the equation between iron powder and aqueous copper ii sulfate in the iron copper ii sulfate redox reaction

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web this experiment is focused on a reaction between iron metal and a solution of copper ii sulfate we are able to figure out the chemical equation between the two by using stoichiometric principles the iron displaces the copper ii sulfate ions the copper ii is then reduced and gains electrons

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web stoichiometry can be defined as the relationship between the relative quantities of substances taking part in a reaction or forming a compound stoichiometric principles can be used to deduce the appropriate chemical equation for a reaction in our experiment we used solid iron in the form of powder was added to a solution of copper ii sulfate

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web under the finalize of the experiment it was found that iron was the limiting reactant and iron ii sulfate was a product of the reaction between 7 0002g away cooper ii sulfate and 2 0101g iron metal which produced 2 3037g of copper product with a percent yield of 100 72 introduction

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stirring the solution adding water then removing water adding acetone heating the acetone on low

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