

QMS CHECKLIST

IDENTIFY WHETHER YOUR QMS IS COMPLIANT
TO THE UPCOMING ICH GCP ADDENDUM



HERE IS A QUICK 5-POINT CHECKLIST TO HELP YOU IDENTIFY WHETHER YOUR QMS IS COMPLIANT TO THE UPCOMING ICH GCP ADDENDUM

QMS CHECKLIST		YES/NO
1	Do you have systems to identify critical processes and data for assuring human subject protection and reliability of study results?	
2	Do you have systems to identify, evaluate and control the risks to the critical processes and data, both at system and clinical trial level?	
3	Do you have systems to communicate the risks to the stakeholders?	
4	Do you periodically review the risk control measures for effectiveness?	
5	Do you report the quality management approach implemented in the Clinical Study Report?	