

RISK BASED QA PROGRAM; HOW DOES IT WORKS?

Dr. Labhu U. Sanghani

Director - Global QA, Jai Research Foundation, India

ABSTRACT

In a GLP context risk is defined as the combination of the probability of issues or problems occurring in GLP system that impact the integrity of the data and the overall GLP compliance of the study. The addition of concept of risk based inspection program will increase the QA focus in utilising the resources in an effective way and in proportionate with the identified risk associated with studies, facilities and quality system.

