RISK BASED QA PROGRAM; HOW DOES IT WORKS?

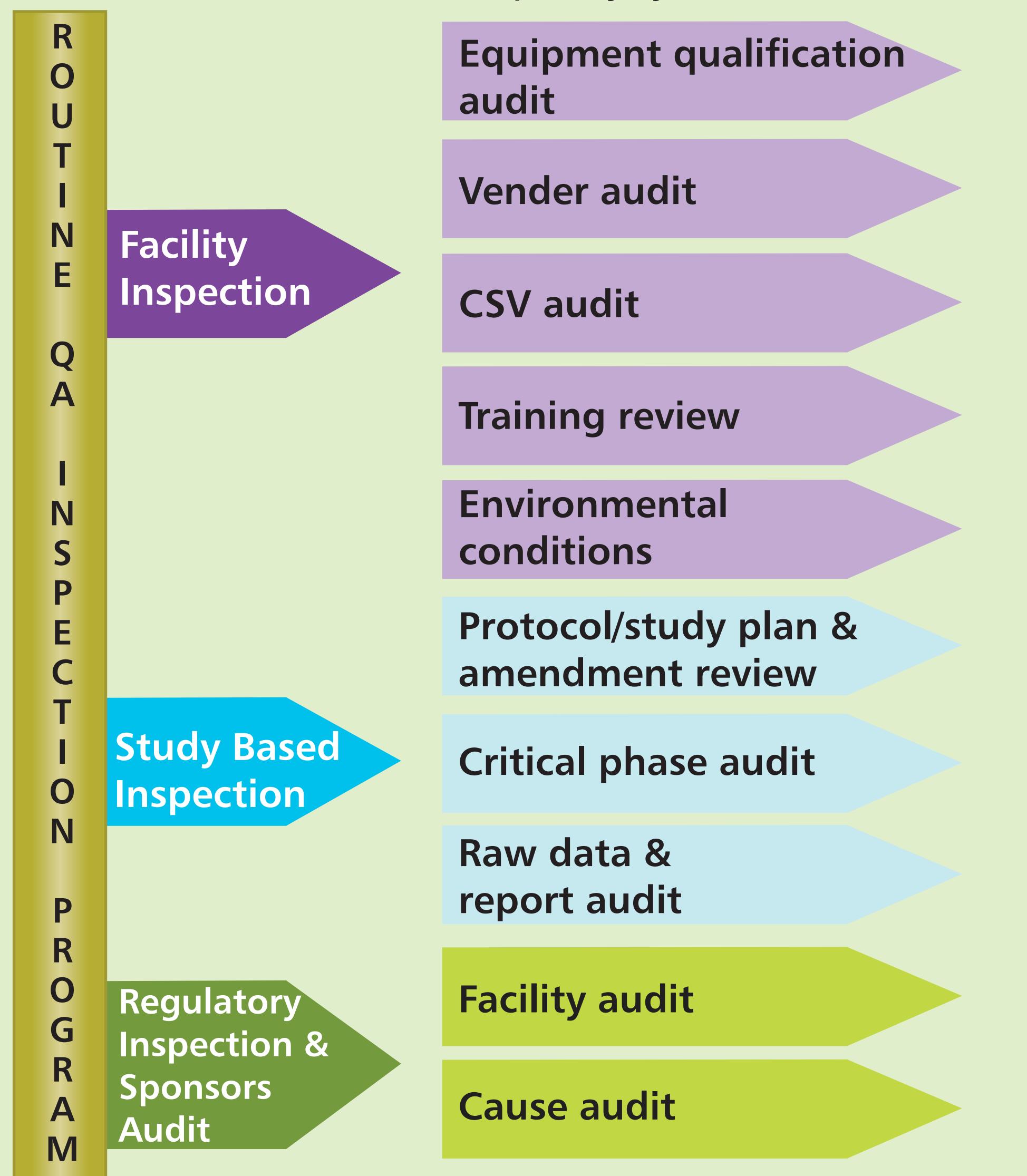
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ABSTRACT

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.



Quality metrics Trend of observations Critical areas Critical process(es)/functions Performance metrics Root cause for each critical observation **Knowledge of each Process** and associated risk Change in regulatory needs or regulations

ASSESSMENT AND IDENTIFICATION OF RISK

Tools: Quality Metrics, Regulatory inspection experience, knowledge of each process



CONTROL TO ALLEVIATE THE RISK

Controls: QC activities, In-process QC, Use of validated computerised systems, Multi-directional audit



SET UP OF QA PROGRAM BASED ON RISK

Tools: Frequent audit for identified areas and activities, In-process QC, Pre-study/process audit, Process specific audit



RISK MANAGEMENT (PERIODIC REVIEW)

Review: Effectiveness of QA and QC tools applied, significant change in process, technologies, personnel and work flow

CONCLUSION

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 risks associated with studies, facilities and quality system.