



Quality Risk Management in a GLP Laboratory

The larger the organization, the more important it is to enact strategic initiatives to achieve harmonization across all parts that make up the whole. While successful business operations depend on streamlined practices, harmony is especially crucial when it comes to quality risk management (QRM) for an organization engaged in safety work.

A systematic process for the assessment, control, communication, and review of risks to patient safety, product quality, and data integrity, QRM is based on a framework consistent with the International Conference on Harmonisation (ICH Q9), and consists of first identifying hazards then analyzing the risks associated with exposure to those hazards.

Dedication to QRM benefits all parties. From a client perspective, the outcomes of a QRM program should be seamless and transparent, equating to an organization's ability to deliver premium service, regardless of where within the organization a client does business. From an organizational standpoint, an effective QRM program draws upon expertise and input from many contributors, and provides an operational playbook by which to standardize operations, achieve efficiencies, and promote best practices across multiple sites.

In the following case study, we explore an example of how Charles River identified risks associated with variations in cage wash monitoring frequency across numerous sites. After complete assessment and evaluation of data collected, they determined a frequency associated with optimum outcomes and least risk, resulting in time and cost savings which ultimately had a positive impact on client studies.

Situation/Challenge:

Across Charles River's safety assessment sites, the schedule for monitoring cage sanitization varied. Per ongoing QRM, the organization set out to establish a standard operating procedure that set the optimum frequency of this monitoring.

Risk Problem/Question:

Acknowledging the potential for contamination (e.g., *E. coli*) and the need to repeat studies, the team asked, "What is the risk to the health of the animals and the study if cage washers failed to adequately sanitize the cages/accessory equipment? What if the failure was only detected after 3 months?"

Results/Conclusion:

Mapping the cage wash process, evaluating personnel function and performance, and understanding safeguards that were in place, the team determined the probability was very low that a failure occurring in the cage washing process would result in equipment being used in an animal room. Moreover, the impact of a failure, regardless of monitoring frequency, remained unchanged, as did the detection of a failure. Armed with this information, the team proposed that cage wash monitoring be conducted quarterly across all sites. This change saved time and costs for sites that were monitoring monthly, and provided a standard and reduced risk for sites that were monitoring less often. The adoption of a quarterly cage wash monitoring across all Charles River's safety sites created efficiencies that in turn benefitted the client with the assurance of both healthy animals and adequate personnel to serve their studies.