HOW ARE YOU ADDRESSING RISK MANAGEMENT AND DATA INTEGRITY?

A Drug’s safety requirements extend beyond clinical trials and must be upheld through a rigorous QC testing program. As the foundation for cGMP compliance, data is an essential component of an organization’s quality system. Dr. Ulrich Herber, Senior Global Product Specialist Manager at Charles River Microbial Solutions exchanges with us on the challenges to securely collect, manage, and maintain data that is accurate and valid.

Why is Data Integrity at the heart of the industry lately?

Data drives every decision in the lab, so ensuring it is accurate, relevant, and reliable is critical to support confident decisions on product quality and safety. Patients expect their medications to be safe and effective. With an increase in FDA warning letters and cGMP inspection violations, regulatory agencies are setting the expectation that organizations be proactive in their efforts at adhering to data integrity standards. Newly issued global guidance documents communicate the increasing requirements on data integrity, making many organizations aware of existing gaps and deficiencies in their data and reporting.

How can risk management and data integrity be addressed in the manufacturing area?

Maintaining the long-term safety of a manufacturing environment while meeting the demands of compliance is a microbial quality control manager’s top priority. The need to investigate out-of-specification (OOS) results continues to be one of the most commonly observed cGMP issues during quality control laboratory inspections, so having access to accurate, relevant and reliable data is essential to support confident decisions on product quality. Moreover, FDA warning letters and new global guidance documents communicate the increasing requirements on data integrity, making many organizations aware of existing gaps and deficiencies in their data and reporting. If you’re concerned about maintaining your data integrity compliance status, managing your equipment or upcoming regulatory inspections, you need to take control of your equipment, data, and reporting with reliable tools.

How does the Charles River Micro QC solution portfolio fit in this data integrity driven environment?

Charles River purposely-built the Microbial Solutions portfolio of Endosafe® endotoxin testing, Accugenix® microbial identification and Celsis® microbial detection solutions to provide users with the critical, decision-driving data necessary to help bring products to market safely and efficiently.

In a data integrity driven approach, we have developed ENDOTOXIN TESTING solutions which reduce much of the subjectivity associated with the traditional qualitative gel-clot test. Endosafe® LAL cartridge technology supports micro QC managers’ efforts to produce rapid, accurate endotoxin results while adhering to rigorous data integrity standards. The robust assay optimizes the use of LAL, requiring minimal preparation, no preparation of standard curves and no technical training, removing as much potential for human error as possible. The flexible Endosafe® testing platforms all generate objective electronic data, calculations and analysis performed by the readers, thereby removing user subjectivity, providing a clear picture of product quality that is essential to both mitigate risk and maintain cGMP.

Environmental monitoring (EM) program requires accurate IDENTIFICATION OF MICROORGANISMS. Many phenotypic identification methods rely on visual reads of the assay, depending mainly on human interpretation of the final result. Errors or misinterpretation in phenotypic assay readouts can lead to inaccurate data, which jeopardizes data integrity. Accugenix® identification services and Axcess® system offer controlled genotypic and proteotypic methods that provide objective results.
Relevant reference libraries and consistent procedures optimized for pharmaceutical applications further promote accurate results and minimize the breach of integrity with critical microbial identification data.

In order to minimize contamination risk and maximize control over microbial testing, the recent trend toward the “four eyes principle,” as a safeguard against subjectivity in result reporting, suggests that the occurrence of analyst-dependent errors is becoming more recognized in traditional testing. Relying on self-governed methods such as visual inspection can yield inconsistent results through differences in opinion, experience, or even an analyst’s visual acuity. When combined with a manual or analyst-dependent result reporting process, establishing a reliable audit trail can be challenging, generating unnecessary risk. Efficient quality control labs realize that RAPID MICROBIAL DETECTION, such as the Celsis® system, not only provide functional operation benefits for day-to-day efficiency, but also mitigate subjectivity from testing through the use of objective and reagent-based automated testing, coupled with comprehensive data analysis and result reporting software.