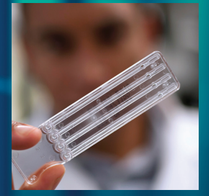
HOW ARE YOU ADDRESSING RISK MANAGEMENT AND DATA INTEGRITY?



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. Consequently, 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. It can be challenging to securely collect, manage, and maintain data that is accurate and valid. 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.

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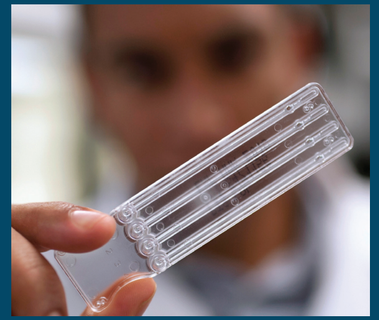

ENDOSAFE®
ENDOTOXIN TESTING

Through reducing much of the time, accessories, and subjectivity associated with the traditional qualitative gel-clot test, Endosafe® LAL cartridge technology has long supported micro QC managers' efforts to produce rapid, accurate endotoxin results while adhering to rigorous data integrity standards. The need for the preparation of standard curves and long incubations has been eliminated, as our cartridges provide quantitative results in 15 minutes. The robust assay optimizes the use of LAL, requiring minimal preparation and no technical training, removing as much potential for human error as possible. The flexible Endosafe® testing platforms all generate the objective electronic data that has become the expectation in today's high volume testing environment. Calculations and analysis performed by the readers likewise remove user subjectivity, providing a clear picture of product quality that is essential to both mitigate risk and maintain cGMP compliance. **Discover how to remove subjectivity from your endotoxin testing at www.criver.com/cartridges**

ACCUGENIX®
MICROBIAL IDENTIFICATION

Accurate identification of microorganisms is an important part of a comprehensive environmental monitoring (EM) program. 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 well-designed and 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. **Learn how to minimize contamination risk and maximize control over EM at www.criver.com/accugenix**

CELSIS®
RAPID MICROBIAL DETECTION

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 apparent 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 generate unnecessary risk. Efficient quality control labs realize that rapid microbial methods, 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. **Learn the operational and risk mitigating advantages of Celsis® at www.criver.com/celsis**

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