BIOMÉRIEUX

ENSURING **DATA INTEGRITY** WITH VITEK® 2 COMPACT

PIONEERING DIAGNOSTICS

ENSURING DATA **INTEGRITY** WITH

Ensuring data integrity in your quality program can seem like a daunting task. Analytical equipment in all areas of the lab are constantly collecting data points and this data needs to be properly managed to ensure not only the quality of the products you manufacture but also compliance with local and international regulatory agencies. It's important for the manufacturers of these analytical systems to provide the necessary tools for users to achieve these goals. VITEK 2 COMPACT has been designed with your needs in mind with a number of features to help you comply with these goals.

Why is Data Integrity Important?

In recent years, data integrity has been a major issue in the pharmaceutical industry. The FDA has cited data integrity issues in warning letters, often related to data that is easily manipulated. Some examples of data integrity observations are listed below.

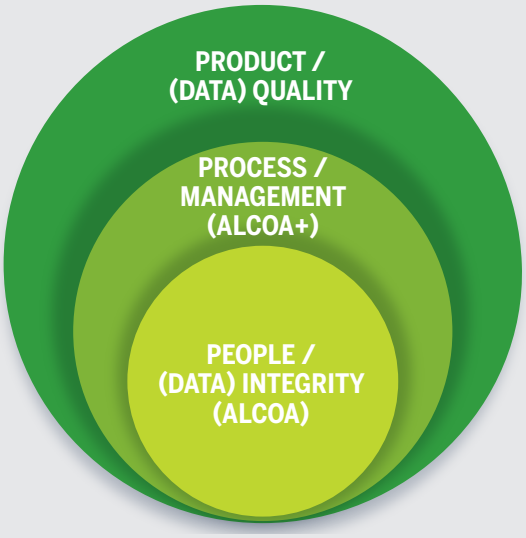
FDA CITATION	WARNING LETTER CITATION DETAILS
Your firm to establish laboratory controls that include scientifically sound and appropriate specifications...	... you did not apear to routinely identify (i.e., to species level) bacterial and fungal isolates recovered during environmental monitoring of your aseptic processing room. FDA Warning Letter, March 2017[1]
Failure to record activities at the time they are performed.	... you did not have worksheets for recording microbial test results and that you failed to contemporaneously document microbial limits test results for <redacted> API batch <redacted>. FDA Warning Letter, August 2016[2]
Failure to follow and document laboratory controls at the time of performance;	... you did not have worksheets for recording microbial test results and that you failed to contemporaneously document microbial limits test results for <redacted> API batch <redacted>. FDA Warning Letter, August 2016[2]

VITEK 2 COMPACT Enables Productivity and Compliance

- Automated objective microbial identification
- Contamination resistant closed test reagents
- 21 CFR Part 11 mode
- Connection to LIMS
- Barcoded reagents
- Audit Trail
- Secure user logins
- Auto or manual data backup
- Electronic signatures
- Validation and networking packages
- Customizable knowledge base
- Extensive field support teams

VITEK® 2 COMPACT

Regulatory agencies like the FDA expect data to be reliable and accurate and they've provided guidance on how to accomplish this. Issued in 2016, *Data Integrity and Compliance with cGMP: Guidance for Industry* presents the principles of ALCOA. This guidance designates that data should be **Attributable**, **Legible**, **Contemporaneously recorded**, an **Original** or true copy and **Accurate**. Expanding ALCOA to include all data and process/management, they added that the data should be **Complete, Consistent, Enduring** and **Available** for inspection. Comprehensively, these principles are often referred to as ALCOA+. Clearly the importance of accurate, traceable data is paramount to ensure a robust quality program for any manufacturer.



VITEK 2 COMPACT helps comply with ALCOA+ principles

bioMérieux has long been focused on helping our customers ensure the quality of the data they collect from our systems. In 2004, we launched the VITEK 2 COMPACT which is still the #1 ID solution in the pharmaceutical industry today. With automation of data collection at the source, manufacturers are able to minimize the risk of analyst error and generate an objective result. 21 CFR Part 11/Annex 11 specifications have been part of bioMérieux's development requirements since the inception of VITEK 2 COMPACT. In addition, a number of features help our customers ensure their data complies with ALCOA+ principles as shown below.

ALCOA+ PRINCIPLE	VITEK 2 COMPACT FEATURES
Attributable	• User login allows analyst names to be recorded with each sample • Audit trail attributes samples to specific users
Legible	• As the raw data, the final data point of VITEK 2 COMPACT includes the biochemical test results in addition to the ID in human readable format. Final result is validated with an e-signature. • Data is saved in digital form and cannot be altered • Manual or automated data backup options are available and collect data from both active and inactive memory. If failures occur, users are notified and the failure and reason are recorded in the audit trail.
Contemporaneous	• Date and time stamps are included on electronic signature of results and all actions recorded in audit trail
Original	• Data recorded electronically is original data
Accurate	• Reports provide complete data including biochemical test results, genus and species level bionumber match and % of confidence. • Electronic signature allows review of results before finalizing to verify accuracy. • QC organisms are designated as controls to ensure accurate card performance. • Within the virtual cassette workflow a reconciliation is performed at the load chamber level that compares the virtual cassette information (barcode, cards and card type) to the actual cassette loaded into the instrument.
Complete	• Offline test results may be included with VITEK® results and associated with the isolate for a complete report.
Consistent	• Audit trail records user actions with date and time stamp
Enduring	• Electronically recorded results may be archived indefinitely • Customers may set a retention period based on their needs • Automatic or manual backup options are available
Available	• Result data can be recalled from the archive • Audit trail actions can be queried and reported

The compliance partnership

Compliance relies on the features provided by the vendor and how the user implements those features to ensure compliance. Through our extensive development and support programs, we disseminate regular updates to our VITEK® 2 COMPACT system including knowledge base and data integrity enhancements. Data integrity continues to be a focus for bioMérieux with investments in hardware and software updates to meet the needs of industrial manufacturers.

The importance of accurate microbial identification

The field of microbiology is dynamic with new organisms being characterized and known organisms being reclassified based on current scientific knowledge. Many environmental organisms remain uncharacterized and thus unknown to identification platforms. An evolving knowledge base that is relevant to the organisms in manufacturing facilities is key to producing the most accurate identification results. Accurate data is the key to making the right decisions about the status of manufacturing environments and thus plays a role in data integrity.

VITEK 2 COMPACT's knowledge base is built using a robust population approach. This approach incorporates the intraspecies diversity intrinsic to any microbial species. Using organisms grown under variable conditions and from different geographic areas to populate our knowledge base, VITEK 2 COMPACT ensures inclusion of typical and atypical strains to provide the most accurate ID possible. While no microbial identification system covers the entire breadth of species found in the environment due to the dynamic nature of microbiology, VITEK 2 COMPACT's robust knowledge base contains the majority of frequently occurring organisms in manufacturing environments enabling accurate results.

Validation

Validation of analytical equipment directly contributes to data integrity by verifying the information generated by the system is fit for use. bioMérieux offers two approaches to valdating VITEK 2 COMPACT; self-guided or on-site service.

Our detailed validation guide provides a low cost validation option while the onsite service leverages the quality and compliance expertise of a third party specialist to provide a convenient and comprehensive approach. In either situation proper documentation is critical for archival purposes in case of audits. With multiple options for system validation, bioMérieux provides a validation path for any size industrial manufacturer to document compliance of VITEK® 2 COMPACT.

The future of data in pharmaceutical manufacturing quality programs

Pharmaceutical manufacturing companies no longer just make product. They also make data. This data underpins all of manufacturing including quality programs. It's important therefore to properly manage this data at all points of collection. As automation increases so will the amount of data generated. This offers manufacturers the opportunity to use their data to increase efficiency and identify problems before they become critical. VITEK 2 COMPACT is an integral part of this data collection by providing feedback on the status of environments within the manufacturing facility.

Key Takeaways

- Data integrity is a topic which manufacturers need to consider when selecting a microbial ID system.
- While compliance always relies on a combination of system features and user implementation, VITEK 2 COMPACT's extensive feature set allows users to comply with ALCOA+ principles.
- With regular software updates, VITEK 2 COMPACT maintains an evolution of data integrity features with a goal to make compliance easier.
- Focusing on data accuracy through robustness and quality, our ID knowledge base continues to evolve to meet the needs of manufacturers making VITEK 2 COMPACT the #1 ID system in the pharmaceutical industry.

References:

1. 21 CFR 211, Current Good Manufacturing Practice for Finished Pharmaceutical Products
2. European Union Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use

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