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MICROBIAL SOLUTIONS

Charles River Cortex™

Creating centralized control for a decentralized approach

Features

- Client-server platform
- Real-time data tracking and trending
- Operational management of equipment fleet
- Rules-based email alerts
- Searchable audit log
- Customizable graphs and reports
- EndoScan-V™ integration*
- Available in six languages**
- Electronic signatures for all Endosafe® cartridge readers
- Enhanced user management profiles

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, current FDA warning letters and new global guidance documents communicate the increasing requirements on data integrity, making many organizations aware of existing deficiencies in their data and reporting. Charles River Cortex™ enables users to effortlessly improve their compliance status.

With the growing volume of quantitative LAL tests being performed today, electronic data generation is now an expectation, rather than the exception. It can be challenging to securely manage data and maintain oversight of multiple systems distributed throughout a facility, but advances in technology have made it possible to do just that.

As a client-server based data management platform, Charles River Cortex™ provides an integrated solution to securely consolidate, query and analyze all real-time endotoxin data for necessary internal QA and FDA trending reports. The decentralized, multi-client solution provides complete QA/QC control over instrumentation, allowing a number of client machines (i.e., PCs with the Cortex client software installed) to access the same database and server. Customers can compile and manage data from any of the Endosafe® rapid testing platforms, microplate readers and tube readers into a unified data infrastructure to gain complete insight on their manufacturing operation and process and make informed, confident decisions. Cortex allows users to proactively manage and monitor the operational integrity of the entire facility's equipment fleet including component effectiveness, calibration schedules, and system readiness within a single, end-to-end risk management environment.

User Benefits

- Enhanced data integrity status
- Increased visibility into key performance indicators
- Simplified investigations
- Elevated compliance position
- More efficient LAL testing operations

Real-time Data Tracking and Trending

Tracking and trending QC data is a proactive approach to risk management. With the ability to continuously monitor endotoxin results, users can analyze trends in real-time to maintain a complete state of control throughout their manufacturing facility. The Cortex database allows users to gain an understanding of their data and address inconsistencies, helping them to further streamline lab investigations. The platform has a flexible reporting framework, which enables users to build customized reports at any level of summarization. With the ability to filter and refine through preset views and columns, generate occurrence reports, determine action and alert limits, and track and trend on any field and set of data from all data generating platforms, users have complete flexibility on what they want to see from any data set, including statistical analytics, operator statistics and product information. If desired, users can export Cortex data to Excel for analysis and reporting that is compatible with other systems.

User Profile Management

With three levels of user management that mimic the nexgen-PTS™ profiles (i.e., administrator, manager and user), a user can be established to grant appropriate access to operators. Administrative rights allow access to the entire platform, including setup and setting changes. Managers can access the product database and configure operators. Users are able to view and print reports. Password protection adds an extra level of security, prompting for login credentials before accessing and performing functions. User Management with digital signatures allows for data to be directly imported from a device and permits restoration of databases for 21 CFR and data integrity compliance.

Supported Instrumentation

The Cortex software platform interfaces with any of the Endosafe® rapid testing systems, in addition to a variety of microtitre plate readers and tube readers, allowing users to monitor, record, approve and track equipment and system performance, and bring together all relevant operational data from within the same framework. With Endosafe® nexgen devices, users can manage their fleet of systems by creating a sample database, developing device users, scheduling calibration dates and disabling devices that have passed calibration dates. The platform provides email notification functionality for deviation of set rules and ranges (e.g., invalid test criteria or test failures) for Endosafe® nexgen systems that supports real-time data generation of critical in-process testing.

For systems that require EndoScan-V™ software as the data driver, Cortex can easily be configured to automatically import the exported data from version 5.5.4 and higher. Raw data files will remain with EndoScan-V™, as will the audit trails for the data generated in EndoScan-V™. Electronic signatures for data generated in EndoScan-V™ must be applied to the reports within the software.

Reassurance at a Glance

With the ability to deliver instant peace of mind or alert users to a developing issue, Charles River Cortex™ is the data integration solution that breaks down data silos and addresses today's data problems while there's time to correct them. Digital signatures and a field to add comments to all Endosafe® cartridge readers test records both allow end users to maintain data integrity and achieve compliance with 21 CFR Part 11.

*v5.5.4 and higher
** English, German, Italian, French, Spanish, and Portuguese

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