



Customer Story

Biopharmaceutical CMO Bridges Data Integrity Gap

Keeping an Eye on Data Quality

EXELEAD is a biopharmaceutical contract manufacturing organization (CMO) specializing in complex injectable formulations, including liposomal drug delivery technology and PEGylation. Their core focus is on formulations meant for rare disease or small populations. EXELEAD takes products from Molecule to Market for their clients, as such strict quality standards are followed during every phase of manufacturing – including adhering to 21 CFR Part 11 regulations in the lab.

Loopholes in 21 CFR Part 11 Security

EXELEAD's daily lab routine includes running fluorescence assays to do analyte concentration checks on their client's formulations. Data integrity was an area of vital interest to the FDA (Food and Drug Administration) during a recent on-site visit, and EXELEAD wanted to make sure there were no shortcomings on their end as part of an ongoing commitment to quality processes. Analysts in the lab did some in-depth sleuthing to see if access to the methods used and data collected with their existing fluorescent spectrometer and software were compliant with 21 CFR Part 11 regulations, and identified important shortcomings. Data and methods could

be modified without leaving a trail – a significant 21 CFR Part 11 violation. With the vendor having no plans of fixing the shortcomings, EXELEAD's IT team was left with the only option of controlling data access using Microsoft® Windows® permissions. This is not an acceptable practice for meeting the FDA data integrity requirements.

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Gordon D. Sturgeon

QC Instrument and Systems Specialist at EXELEAD

Locking Things Down

EXELEAD decided to test PerkinElmer's FL 6500™ Fluorescence Spectrometer with Spectrum FL Enhanced Security (ES) software and do a head to head comparison with their existing system. Gordon D. Sturgeon, a QC Instrument and Systems Specialist at EXELEAD, found that the FL 6500's capability went way beyond their existing system, and gave him more flexibility to run a wider range of applications. With the Spectrum FL Enhanced Security (ES) software, Gordon and his IT team could also see full software audit trails and confirm data integrity was maintained. The user-friendly interface of FL6500 with Spectrum FL Enhanced Security (ES) software enabled Gordon to effortlessly run experiments and gather data in a matter of few minutes.

Gordon stated, "The instrument is well designed and although its performance exceeds our needs, it is ideal for attracting future clients. The software is very user friendly and the Enhanced Security portion is critical to our facility – our site is heavily GMP regulated and the adherence to 21 CFR Part 11 is a significant portion to data integrity."

The FL 6500's Spectrum FL Enhanced Security (ES) software uses a database format for a more advanced level of security and also includes electronic audit trails, required user login and electronic signatures. Multiple user levels with admin-settable permissions gave EXELEAD full control over who could acquire, review, and modify data and methods – attributes for enhancing the integrity of data and maintaining compliance with 21 CFR Part 11 regulations.

Step-up in Data Integrity

PerkinElmer's FL 6500 Fluorescence Spectrometer with Spectrum FL Enhanced Security (ES) software maintains data integrity and enables EXELEAD to be fully compliant with 21 CFR Part 11 regulations. So the next time the FDA pays them a visit, they'll have complete assurance to the integrity of the data and adherence to ALCOA throughout the data lifecycle.

While PerkinElmer's FL 6500 Fluorescence Spectrometer with Spectrum FL Enhanced Security (ES) software will provide on-going compliance to 21 CFR Part 11 regulations and ensure data integrity, it is critical for end users in a GxP environment to have their systems validated for the specific intended use and in its intended environment. PerkinElmer's OneSource® Compliance provides complete computerized system validation (CSV) to address this need. The group has performed well over 600 CSV projects and has a global reach for providing the service. Using the industry best practice approach of GAMP 5, computerized system validation is first approached with a risk assessment of the system and the intended use. CSV is delivered using a least burdensome approach in order to maximize compliance and getting the instrument to a "ready to use" state in the GxP space as soon as possible.

Featured Products

FL 6500 and FL 8500 Fluorescence Spectrometers with Spectrum FL Enhanced Security (ES) software <http://www.perkinelmer.com/category/fluorescence-spectrophotometry-fl>