Journal of Chromatography
& Separation Techniques

News and Views

Modern Chromatographic Data Systems

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Modern chromatography data systems are improving regulatory compliance in pharmaceutical manufacturing. Delivering confident Quality Assurance and Quality Control is of critical importance in pharmaceutical manufacturing. It is critical that companies employ appropriate methods and tools to collect, manage and store complex information as Quality Assurance and Quality Control workflows involve analytical processes that generate large volumes of chromatography data. Data management systems must be sufficiently robust to guarantee reliability and consistency, as well as allowing full traceability and transparency to satisfy regulatory requirements. Automation of instrument control, data acquisition, results processing and reporting is crucial for data management in most chromatography workflows. However, many laboratories do not use these systems to fully integrate and automate their workflows. Instead, separate CDS solutions are often used by individual teams, or employed alongside partially paper-based data storage systems or spread sheets, essentially resulting in a disjointed approach to data management. Furthermore, since many CDS solutions were originally designed for the research laboratory rather than the regulated environment or were introduced before the recent focus on data integrity, many pharmaceutical manufacturers do not have the digital architecture or functionality to easily facilitate compliance. There are multiple reasons why it can be difficult to achieve the high standards of data integrity required for regulatory compliance using these fragmented or less sophisticated systems. Firstly, it can be challenging to reach the appropriate levels of data consistency and reliability. In particular, differences in how individual users integrate chromatogram peaks can be a major source of variability in chromatography workflows. Manual integration is often difficult to standardise and is complicated by overlapping peaks, poor peak symmetry or high levels of background noise. Auditors expect laboratories to demonstrate appropriate procedures to control and justify the use of manual integration, but this task is made more challenging if chromatography data is not organised centrally. Fragmented CDS solutions can also make it difficult to ensure transparent accountability across manufacturing workflows. Regulatory authorities now require end-to-end traceability for chromatography workflows and the association of raw data with contextual metadata such as analyst identity, method details, reference standards and details of any changes or deletions made. However, achieving this using paper-based approaches or spread sheets is far from straightforward and harmonising secure data storage between different systems presents a significant challenge. Indeed, if data is stored across disparate systems or recorded in multiple formats it can be a time-consuming process to recall all the information required to demonstrate compliance in the event of an audit. These issues demonstrate why it is challenging for manufacturers to ensure and demonstrate the standards of data integrity necessary to meet increasingly stringent regulatory standards. Therefore, the most forward-thinking manufacturers are replacing fragmented approaches to managing chromatography data with CDS solutions that are integrated across their entire workflow. By using the latest CDS solutions to bring workflows, instruments and operators under a single system, pharmaceutical companies can now harmonise the management, processing and reporting of chromatography data. One way in which modern CDS systems achieve this is by enabling method parameters to be downloaded directly to instruments without the need for any user input. This helps to ensure that all operators use standardised procedures, effectively minimising user-to-user variability and reducing out-of-specification results. Furthermore, to help improve consistency in data analysis, the most advanced CDS solutions now incorporate powerful tools to facilitate automated peak integration. By employing sophisticated algorithms to process results, these tools can reliably distinguish true peaks from noise and correctly identify peak boundaries. This enables manufacturers to minimise the use of manual integration, enhancing data consistency and boosting efficiency. A further advantage of using advanced CDS solutions to integrate an entire workflow is their ability to automatically record all the information necessary to demonstrate regulatory compliance in an audit. By storing a complete history of interactions with the system, these solutions make it easy to identify which user made changes at what time. This enables companies to achieve end-to-end oversight of their chromatography workflows and ensure complete traceability from measurement to reporting.

While most CDS software will record this detailed information, the process of reviewing audit trails can be a laborious task. In response, many CDS platforms now offer enhanced audit trail functionality to streamline this process. For example, solutions might incorporate powerful filtering and search tools, allowing laboratory managers to search for specific events and quickly identify non-compliant behaviour such as injections that have been interrupted or repeated to obtain the desired result. By using these solutions to manage their chromatography workflows, pharmaceutical manufacturers are better equipped to maintain the highest standards of data integrity and easily demonstrate regulatory compliance in an audit.

CONCLUSION

With regulatory bodies increasing their focus on the integrity of chromatography workflow data, manufacturers need robust and reliable data management systems to guarantee and demonstrate regulatory compliance. The latest CDS software solutions provide the necessary functionality to help companies achieve this by fully integrating their workflows, instruments and operators under the same system. With a single, networked software platform, manufacturers are now able to safeguard the consistency and reliability of their data, guarantee full traceability and more easily recall all relevant information in the event of an audit. By employing these advanced solutions, pharmaceutical manufacturers can now achieve the highest standards of data integrity, while also boosting productivity.

REFENRECES

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