Handok Incorporated Reduces Paper by 90% While Ensuring Compliance

RESULTS

- 46% reduction in batch release time
- 50% increase in weighing and dispensing efficiency
- 50% reduction in time to complete Quality Assurance reviews
- 90% paperless operation company-wide



APPLICATION

A Manufacturing Execution System (MES) was needed at Handok Inc. to streamline pharmaceutical manufacturing processes and ensure GMP compliance in global operations.

CUSTOMER

Handok Inc. is a pharmaceutical innovator focused primarily on prescription drugs, consumer health care products, medical devices, food supplements, and medical nutrition. Handok's clinical research center has a history of spearheading clinical trials in Asia and participating in global trials run by multinational partners

CHALLENGE

Expanding into the global pharmaceutical market meant that Handok would be met with an increasing number of compliance requirements. Not only would the organization be subject to global regulations, such as GMP, but it would also be required to prove that it was meeting 21 CFR Part 11 regulations. While the regulations could be met with manual data collection, the process was cumbersome and unreliable.

SOLUTION

Before implementing a MES, trying to connect real amounts of raw material and pre-mix with the electronic data in ERP/SAP systems required constant attention, excessive paperwork, and frequent changes. Even so, mismatches still occurred during manufacturing execution. QA, Manufacturing Planning, and Manufacturing Team operators are using Syncade every day during every manufacturing procedure.

Ey Seo,Manufacturing Planning Team Leader





PHARMACEUTICAL

Handok has eliminated manufacturing discrepancies by implementing Emerson's Syncade Weigh & Dispense module. Operators are guided through defined workflows, and the amount of material dispensed is consistent, even between different operators. Dispensation is tracked electronically, removing the likelihood of errors in recording material usage.

More importantly, the tracking features ensure consistency of product, not only helping Handok comply with GMP practices, but also providing an easily accessible, reliable audit trail for Quality Assurance and audit purposes.

Handok has also implemented the Document Control & Archiving and Security & Audit modules. With Syncade document management, staff no longer need to manually document procedures. All documents and their history are visible and searchable in a centralized database. Storage footprint and costs are reduced, as documents no longer need to be housed in a secure, costly facility. Compliance audits are simplified as records can be located and reproduced from one location.

The management approval process has been dramatically streamlined. Logbooks for batch management and SOPs that used to be maintained manually are now in electronic format. Secure signed approval for SOPs can be given remotely, any time, from any location, via a web interface.

Implementing an MES has provided tangible benefits. The organization has seen a reduction in costs related to storing documentation, and an overall improvement in productivity, including reductions in errors and batch release time. The time to complete QA reviews has been cut in half. As Handok Inc. continues to expand, MES implementation will free the organization from unnecessary tasks, allowing Handok to focus on innovation.



The big advantage of Syncade is standardization. SOP and batch records that used to require manual maintenance are now created and signed electronically. Data and record alignment have reduced Handok's manual errors.

Ey Seo,Manufacturing Planning Team Leader

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