

3M Integrated Packaging Tool, Version 4.05 Built to Enable FDA 21 CFR Part 11 Compliance; Additions Include Enhanced Functionality and Smart Device Manager

3M announced today the introduction of the 3M Integrated Packaging Tool, version 4.05. The new version incorporates capabilities that enable the integrity of electronic records and facilitate adherence to compliance recommendations of the U.S. Food and Drug Administration (FDA) related to CFR Part 11. Compliance with this regulation is an important issue for companies in the pharmaceutical, medical device and medical supply industries.

"We've been working with a number of companies in these industries for quite some time and are excited to deliver what we consider to be a key enabler to meet this significant need," said Mike Haldane, business manager, Industrial Services and Solutions Division.

"The intent of CFR Part 11 is to ensure data integrity, by setting minimum standards for accuracy, trustworthiness and reliability of records," said Nancy Alcorn, business process consultant, Industrial Services and Solutions. "Computerized systems should provide the same degree of confidence as paper systems. The ability to store and retrieve ever-growing quantities of e-data is a challenge for most companies and should be an integral component of any comprehensive CFR Part 11 compliance plan."

Although there is much discussion concerning how companies will be able to certify compliance with CFR Part 11, 3M's viewpoint is that the packaging information management system should provide time-stamped audit trails, record retrieval, system security and electronic signatures. The new version of the 3M Integrated Packaging Tool is a significant upgrade to the company's centralized, data-enabled, web-based application, with the capabilities needed to meet those requirements. Other key additions to the software's functionality include field level controls (e.g., drop-down menus, masked data and concatenated fields), event-driven workflow, web-based drag and drop, additional standard reports, an enhanced user interface and the complete integration of 3M's patent-pending Smart Device Manager component.

The Smart Device Manager extends printing capabilities to the manufacturing or distribution floor, while still enabling centralized management of packaging data and artwork. Smart Device Manager supports bi-directional communication with a variety of devices, enables simultaneous printing to multiple printers and gives users a single console view of all device activity within a workgroup, facility or enterprise. Smart Device Manager further enables reconciliation of all print jobs, which for life sciences companies in particular is critically important for purposes of quality control and compliance.

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