



[Home](#) » [Materials Tracking: It's All in the Data](#)

Materials Tracking: It's All in the Data

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Drugmakers are using MES and ERP more effectively and harnessing the power of new data acquisition tools.

Pharmaceutical manufacturers are struggling to make sense of the data that surrounds them. This challenge starts with determining what to measure, how to measure it and how regulators will react. Those on the cutting edge envision a system in which process analytical technologies (PAT), automation and process control combine to improve product quality and work processes.

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That day may still be far off, but drug manufacturers have enthusiastically adopted data systems for tracking material from the ingredient stage through finished, packaged product. Material tracking is regulated, but nowhere as comprehensively as production processes, since ingredients and equipment do not come into direct contact with people. Consequently, manufacturers can apply best software, hardware and work practices from other industries and expect little to no regulatory fallout.

Dealing with Data Overload

"We were drowning in data, and starving for knowledge," says Phil Geisler, director of information management at DPT Laboratories (San Antonio, Texas), a mid-sized contract manufacturer of solid, semi-solid, and liquid dosage forms, describing the situation that existed before the company implemented enterprise resource planning (ERP) software eight years ago. DPT used to rely on manual data input into orphan or off-the-shelf applications like Microsoft Excel.

ERP helped DPT manage raw materials and ingredients, resource costs, and multiple formulas for a single product while keeping track of costs and best practices, all within the confines of applicable regulations (e.g., GLPs, cGMPs, 21 CFR Part 11). The ERP system served admirably as a data repository, but was inadequate for the company's reportwriting and project-specific tasks.

As ingredients, intermediates and products are traced through production, DPT's quality departments rely on Millennium software from Waters (Milford, Mass.), which controls and stores data generated by chromatography systems. The ERP system then archives material "footprints" generated by Millennium for regulatory and general record-keeping. When the batch is complete, ERP does the accounting for productivity, waste, material and labor utilization, and other metrics of process economics. For reports, DPT turns to Crystal Reports, an enterprise reporting module from Business Objects (San Jose, Calif.).

DPT differs from most pharmaceutical manufacturers in how it shares ERP data and generates reports from it, allowing employees, rather than an IT person, to delve in and mine the system for data most important to their specific functional area. The result has not been chaos, as was feared, but improved report quality, Geisler says.

However, DPT still enters data, including variables related to manufacturing, manually, through terminals hard-wired to the IT system. The company uses some sensors and automated recorders for environmental measurements, but operators still punch values into terminals. Scanning, sensing and wireless devices aren't being used today, but their implementation is probably inevitable, Geisler says.

Combining Static and Dynamic Data

The day when static data (such as locations and numbers of objects) can be combined with dynamic data (such as temperature, pressure) is not far away, predicts Tracy Hillstrom, group manager for data capture systems at Intermec (Everett, Wash.). "It's not too much of a stretch to imagine a combined temperature sensor embedded in a bar code or RFID device, where all the temperature data is accessible wherever the product may be."

She adds, "You may need to measure a product's temperature constantly as it works its way through the process. The data are captured periodically, shot through to a host system, and stored as part of the batch record."

Intermec develops automated data collection systems based on one- and two-dimensional bar coding, and radiofrequency identification (RFID) tags for manufacturing, transportation and logistics.

The company introduced two advanced data products about six months ago: the Windows-powered CV30 fixed-mount computer and the EL10 scan engine. Enabled with Bluetooth and Wi-Fi networking

capability, the CV30 serves as a data entry or access point, either at fixed locations in manufacturing suites or on machinery such as trucks or forklifts. According to Intermec, the EL10 scan engine is the first data-entry device for supply chain management that employs micro-electro-mechanical systems (MEMS) to facilitate data capture. MEMS are routinely employed in sensors that measure acidity, temperature, pressure and acceleration (as in vehicle impact bags). Here, the MEMS components – highly polished silicon structures that are part mirror, part semiconductor – guide the scan line for a bar code reading device.

Integration is the Trend

"A good deal of data are still entered manually, but the trend is towards more automation and integration," observes Steven Cagle, a vice president at Sparta Systems (Holmdel, N.J.). Sparta sells the TrackWise Enterprise Process Management product, whose modules include packages for quality, document management and regulatory affairs.



This sensor was designed for biopharmaceutical applications, and offers wireless PDA access to sensor data.

Mainly designed to eliminate paperbased processes, TrackWise improves process control by eliminating errors and streamlining workflow through rapid information retrieval. TrackWise also integrates with ERP, MES, environmental and laboratory information management systems (LIMS); the system is being used by drug companies that include AstraZeneca, Bayer, Forest Laboratories, Roche and Novartis.

Supervisors may enter production deviations or information may be generated by MES, ERP or environmental monitoring systems. The quality system then evaluates the deviation and performs root-cause analysis. Data can be entered in a number of ways, but at this point, Cagle says, most companies are doing it manually.



Another must-have for data systems is compliance with 21 CFR Part 11, the FDA directive on electronic documents and signatures. Sensicast Systems (Needham, Mass.) offers its SensiNet wireless sensor to monitor temperature, humidity, vibration, energy consumption, air quality and other physical measurements. Compared with cabled networking, wireless systems offer processes the same benefits as home data networks: lower cost, wider/more customizable coverage area and more measurement points.

The wireless sensing and monitoring network is deployed mostly for environmental measurements. "This is not process control," CEO Gary Ambrosino explains. In-reactor measurements demand a shorter measurement time frame and higher sensitivity than environmental monitoring.

Getting More from MES

Repository applications like ERP and MES that serve as intermediaries between data input and re-use provide peace of mind, but only if they are optimized for that purpose.

Pharmaceutical and biotech companies are somewhat behind in best-practice utilization of MES systems, says Jim Thompson, vice president in the healthcare practice at software firm UGS. Having a well designed, verified and validated manufacturing plan is a good first step, but not everything. "Many companies use MES as a net to catch problems," he says. MES systems are integrated with equipment and quality systems, individuals enter data, and alarms sound when problems arise. "That is not in itself a bad idea, because at least you are catching problems and probably remediating them, but it is not sufficient," Thompson adds.

UGS has developed a better way by using electronic monitoring as the gatekeeper in process design: to move it upstream of MES so that problems can be caught and addressed during simulation or, at worst, at some point during limited production runs. Once the process is well defined, UGS recommends using MES to execute it. This exercise falls under the general heading of "manufacturing process management" (MPM).

"Once MPM tools are in place, process information is ported downstream to the MES, which is still playing its proper role as a guardian to assure that parameters remain within constraints," Thompson explains. But significantly, when problems lead to generation of non-conformance reports, these are registered and monitored in the context of the MPM. It can be especially helpful to "decouple" manufacturing execution and manufacturing process planning, Thompson says, when products are manufactured in more than one plant, particularly in separate jurisdictions where batch sizes and equipment will probably differ. "In those situations, you want to re-use manufacturing process knowledge and experience. To do this, one needs a planning environment that can track and understand multiple variants within the manufacturing process plants, and then execute them on different shop floors," he adds.

UGS products in this category fall under the Tecnomatix brand. Within this grouping are specific modules appropriate for capture of pharmaceutical manufacturing-related data. The X-Factory database allows real-time data capture and Factory Link is a SCADA application that connects directly with equipment, instruments, and operators, while serving as the interface between the plant floor and the MES system.

When the connection is with workers, the MES presents screens, through a web browser, that instruct the operator on which subsequent operations to perform, or that request data entry. Screens may also call up data collected elsewhere, for example, quality specifications residing in the system or specific to a particular batch. The system operates similarly to MES appliances in aerospace and engineering industries, where workers rely on handheld devices to guide them through a complex series of steps. Tecnomatix supports handheld devices that operate through standard communications protocols, but UGS does not sell the devices.

Pharmaceutical manufacturers often overlook the benefits of automating collection of data related to operational efficiency. While this type of information is relatively unregulated compared with batch records, it can play havoc with bottom lines. "There are billions of dollars lost to inefficiencies in manufacturing," says Joe Ringwood, vice president of operations at Systech (Cranbury, N.J.). "Capturing it in all its forms and returning it to intelligence is of tremendous value."

Just as manufacturing has MES, packaging lines utilize packaging execution systems (PES). The difference, in terms of real-time measurement, is that the former operates on a minute or hour time scale, whereas PES measurements occur within milliseconds. Only automated detection and data utilization work at these speeds. PES systems utilize many of the tools of MES – bar codes and RFID – plus specialized machine-vision systems.

Systech offers three software packages for pharmaceutical packaging. The Senti family of machine-level products, primarily for machine vision and device setup, operates through optical character recognition/ verification, bar coding, and inspection-level attributes such as object presence, shape, defects, count and color. Systech's Adviser line of management software operates up one level and incorporates modules for overall equipment effectiveness (OEE) and tracking and tracing. The server-based, plant-level application, Guardian, manages packaging operations plant-wide and integrates with other enterprise manufacturing and operation software. All three products comply with cGMPs, 21 CFR Part 11 and GAMP regulations. Alarm conditions communicated through software include downtime events, line statistics (run time, setup time, changeover time, idle time), product/reject counts, overall line efficiency and availability.

Drug manufacturers must collect and maintain (and have available for FDA audits) an enormous amount of data, but the value of information from those data is potentially huge. Automating data collection is a first step to ensuring that more of these data become valuable knowledge.



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