Reducing Human Error in Pharmaceutical Manufacturing

by Loren Sciaky

As most pharmaceutical manufacturers know, one of the fastest and easiest ways to ensure product quality is to reduce the impact of humans on the manufacturing process.

Using Micro Motion flowmeters, one major pharmaceutical manufacturer has substantially improved process reliability and product quality, and at the same time, reduced operating costs by removing human-induced variation and error from the manufacturing process. In this case, the example focuses on the manufacture of gelatin capsules.

The Process

The production process essentially consists of two parts: gelatin mixing and capsule manufacturing. In the latter, "hot gelatin" mixtures are dispensed into long capsule machines. The machines form and bake the capsules, which range in size from 1/8 to 3 inches.

The pharmaceutical manufacturer cited in this case operates its capsule production facility 24 hours a day, year-round. Four shifts of 12 operators are responsible for mixing gelatin for 48 capsule machines. Micro Motion flowmeters are used in the gelatin mixing, or "jelly melt" part of the process. Using more than 1300 different formulas, dyes are measured and added to clear gelatin in specified quantities.

Before Automation

Prior to automation, formulas were stored manually in recipe card files. The appropriate recipe was selected by an operator, and the dye was measured by hand in a flask. For small doses, measurement readings varied as much as 50 percent from operator to operator. With Micro Motion sensors and a control system, an operator selects the desired recipe from a computer disk and starts the batch flow. The flowmeter measures and disperses precisely the same amount of dye each time the batch is run.

Colored dyes are contained in twenty 60-gallon tanks. Each container is connected to a sensor — the jelly melt area uses D6, D12 and D25 sensors. Flow for all 20 dyes is routed from the sensors through precision valves to controller/dispensers. An operator inserts a computer diskette, which contains the desired color recipe, into the controller and selects the recipe. A computer reads the data and the output is sent to Micro Motion flowmeter transmitters, which control the valves mounted in the line. The sensors measure dye into the dispenser in quantities from 5 to 1800 cc. Accuracy is between ±2% at 5 cc, to ±0.2% at 1800 cc.

The operator dispenses dye into as many as 12 mixing pots at a time, then fills them with clear gelatin. The clear gelatin is stored in twenty-four, 500-gallon holding tanks and measured into mixing pots using a Micro Motion DL200. The dye and gelatin are mixed by hand in a "hot gelatin" blending process with large egg-beater type blenders. The mixtures are then taken to the capsule machines for gel cap production.

Sensors are cleaned-in-place with an alcohol-based solvent, which clears the flow loop of dye from batch to batch.

In designing the system, Micro Motion emphasized precision control valves as a critical process element. Since repeatability is a primary concern, reliable flow control is as important as accurate measurement.

Outcome

The parameters used in this application met several requirements:

- Dye must be measured accurately and measurements must be consistent.
- The potential for human-induced variation must be removed from the flow measurement system to reduce costs.
- The system must be easy to use and understand.

Micro Motion flowmeters, with their outstanding performance characteristics, such as high accuracy and repeatability, met and exceeded these requirements.

For more information on Micro Motion flowmeters, circle 11 on page 16.

Micro Motion flowmeters provide proven reliability, reducing human error in the process.