Material analysers: the portable solution

Portable and handheld near-infrared raw material analysers offer pharmaceutical companies unparalleled convenience and functionality, increasing the efficiency of raw material identification and improving the bottom line.

One highly burdensome good manufacturing practice (GMP) is testing raw materials to identify them. GMP guidelines specifically require suitable procedures or measures that guarantee the identification of a material. In some cases, 100% of raw material containers may require testing.

Identification testing protocols have used UV/VIS, near-infrared and infrared spectroscopy, wet chemical or various chromatographic methods. These conventional processes involve harvesting samples from warehoused raw materials, through a controlled chain of custody, to an analytical laboratory for testing.

While the existing identification process is effective and accurate and the actual testing time is short, the overall process is extremely time-consuming, due to sample transport requirements.

Portable solution

The introduction of portable and handheld analysers significantly enhances workflow and productivity in pharmaceutical manufacturing. By moving the testing tool from the laboratory to the point of need, the time required for testing and the associated costs can be reduced, while manufacturing efficiency can be improved.

On-the-spot identification and qualification of incoming pharmaceutical raw materials can be rapidly determined by staff without specialised experience and with minimal training. In many cases, the identification of powdered material can be performed through the bag liner containing the raw material without opening the bag.

This approach saves time and eliminates exposure risks – for the operator and the material. Workers benefit when heavy containers can be inspected in situ, as their exposure to dusting materials is reduced.

The material benefits from the maintenance of aseptic conditions and constant humidity. Moisture content in raw material is known to play an important role in material stability and processibility, and this information can be obtained from a single near-infrared measurement – near-infrared is quite capable of measuring moisture content.

At-line PAT

As well as improving raw material testing efficiency, handheld analytical systems can play an important role in process monitoring. The FDA Process Analytical Technology (PAT) initiative has reopened the door for pharmaceutical manufactures to employ process analytical systems, just as other industries have been doing for decades.

While the PAT initiative has stimulated interest in analytical control systems, practitioners have principally focused on real-time, in-line measurement systems. The effective deployment and use of invaluable in-line analytical technology requires process and infrastructural expertise that must be developed over time.

> Results can be obtained by manufacturing personnel in seconds.

The introduction of portable analytical systems enables the use of at-line PAT control systems, which are highly applicable to current batch production methods and typical of modern pharmaceutical manufacturing processes.

Portable technologies enable the migration of analytical systems out of the laboratory onto the manufacturing floor. Results can be obtained by manufacturing personnel in seconds, avoiding the queue for central analytical laboratory resources.

At-line control systems offer the advantage of simpler, less expensive and more rapid deployment possibilities, compared with conventional in-line control systems, while the difficulties associated with sampling systems and associated risk assessments are minimised, if not eliminated.

This approach fulfils the need for faster analytical data, which can be used to optimise process control, but with reduced deployment barriers.

Handheld technologies, such as PHAZIR near-infrared based systems, can provide valuable information for applications in areas such as warehouse raw materials, material dispensing, drying, coating and other in-process operations through to packaging and content uniformity in finished products. Handheld analysers offer a significant opportunity for manufactures requiring faster analytical information, deployment and payback. END

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Company profile

Polychromix Inc is a leader in miniature and portable analysis tools. The company's innovative products enable the migration of traditional analytical instrumentation from the lab to the point of need for fast, accurate, non-destructive material analysis.

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