What Does Your Plant Spend on Raw Material Identity Verification?
The Answer May Surprise You

Executive Summary
Drug manufacturers must verify the identity of their incoming raw materials prior to release into the production process. For some, meeting this requirement involves extracting and testing samples from a small fraction of their incoming containers; for others it means testing every single package. Regardless, all find thorough and compliant material identity verification a costly exercise, with costs that span operational, personnel, facility planning, capital equipment, maintenance and consumables. Just how costly can it get?

As we trace both the apparent and hidden costs of laboratory-based identity testing, the answer may surprise you. Fortunately, the advent of new handheld verification technologies has enabled drug manufacturers to reduce production costs while simultaneously increasing productivity and decreasing risk. Enterprising pharmaceutical plant and quality managers have implemented 21 CFR Part 11-compliant instrumentation capable of performing identity testing reliably at the loading dock through packaging materials — without hiring additional expertise. Thermo Scientific TruScan is an example of just such a system. With considerable ease of implementation, global manufacturers are reporting immediate workflow benefits. Initial estimates of financial returns are on timescales as rapid as a few months from implementation.

A Glimpse into the Future
Envision a scene where your raw material inspection process is barely perceptible, a seamless process. A delivery truck arrives at the loading dock with materials needed for this week’s production runs. Scanners download the latest analytical methods specific to your corporation from the server, and then chemically analyze the contents of each package as it is unloaded in real-time. Quality Control (QC) releases the materials for manufacturing before your employees sign to accept the delivery. Immediate identification is complete for 100 percent of the incoming material, and any out-of-specification result will be triggered at the loading dock. As the truck pulls away, handlers begin moving the QC-released containers into the warehouse. This is the future of raw material inspection. Although much of that vision is realizable today, most facilities live in a very different world.

The Costly World of Laboratory-Based Identity Testing
Good manufacturing practices require drug manufacturers to conduct raw materials release testing, including tests which confirm the identity of the materials received. The extent of identity testing necessary for compliance depends on the governing regulations for the market the facility will serve in addition to more stringent corporate mandates for inspection rates as a differentiator or means to further protect their customers and suppliers. Some facilities may only be required to verify the identity of a small fraction of their incoming containers; for others it is a strict requirement to test every incoming package. Regardless of the rate of inspection or method used, identity testing is a capital-intensive and operationally-expensive undertaking that grows with volume and variation in materials.

Today, the vast majority of pharmaceutical manufacturing facilities rely on laboratories (internal or external third-party test labs) to perform their raw materials identity testing. The resources needed to conduct laboratory-based identity testing are significant and their magnitude may not be readily apparent: labor, space, instrument time, sampling and testing consumables, as well as working capital are all consumed or occupied in the process. In addition, laboratory testing introduces risk and uncertainty to the production schedule. Figure 1 depicts the typical workflow associated with acceptance and processing of an incoming container and its representative sample for identity testing.
Laboratory Identity Testing Consumes Manufacturing Resources
As you can see from the diagram, the laboratory-based identity verification consumes or occupies a significant number of manufacturing resources. Each year, plant personnel spend countless hours moving materials, sampling them, and documenting the samples for tracking purposes. The materials themselves occupy space in the sample room, quarantine cage, and warehouse that could be used for other purposes. In addition, valuable capital used to purchase the materials is trapped in the inventory that remains quarantined.

Laboratory Identity Testing Consumes QC Resources
Similarly, QC finds laboratory-based identity testing resource-intensive. Over the course of a year, lab personnel dedicate numerous hours to sample preparation, analysis, data review, and documentation. Identity testing occupies valuable instrument time that could be used for other analyses. Furthermore, consumables like sample vials and reagents along with chemical disposal fees only add to the costs of laboratory-based testing. Because these tests support commercial manufacturing, they often take priority over other projects that compete for the same resources.

Laboratory Identity Testing Introduces Production Uncertainties
Laboratory-based identity verification methods also introduce often-overlooked production risks that have the potential to impact product quality, yield and production schedule. Opening a container to extract a sample increases its chance of material contamination and rejection of the final product. Furthermore, sampling and lab analysis adds variability to material release times. Samples also have the potential to be accidentally contaminated, destroyed, lost, or mislabeled in the process. Incorrect transcription of information, data, and results has inadvertently resulted in numerous cases of unnecessary, time-consuming investigations. These errors, when coupled with the natural ebbs and flows of work in a laboratory, translate to variability in turnaround times for materials release and have the potential to delay operations. If left unchecked, the logistics of materials inspection may impair the ability to forecast production equipment and personnel scheduling – a direct stress on plant productivity. Many facilities hedge their associated quality, yield, and release time risks by holding additional raw materials and final product inventory; both of which add measurable cost to the operation and final product.

Handheld, Non-Contact Tools Streamline Identity Verification
If the sole purpose of identity testing is to confirm the chemical identity of the material inside a container, why not do so at the loading dock upon receipt of the materials? Until recently, that simply was not possible. Identity testing required bulky instruments suitable only for use in the controlled environment of a laboratory, and the most widely-used analytical testing techniques required direct contact with the material.

Over time, however, the pharmaceutical industry has turned its attention to techniques such as near-infrared and Raman. These spectroscopic techniques are beneficial because they enable identification of materials through packaging such as glass and plastic, eliminating direct sample contact. Regulatory agencies have also taken notice, and the major pharmacopeias such as the United States Pharmacopeia (USP) and the European Pharmacopoeia (EP) were edited to support their implementation.

Greater interest in these techniques has spurred innovation; over this same period, technological advances have produced portable analyzers that operate reliably outside the laboratory. Chemical identity verification at the loading dock is finally possible, and ongoing advances are making it highly advantageous.

An instrumentation revolution is underway taking full advantage of recent advances in miniaturization to offer extreme portability – a measure of not only size but ruggedness and embedded intelligence as well. Durable, handheld instruments capable of non-contact analysis with on-board decision making have enabled truly untethered identity verification. As Figure 2 demonstrates, the use of these tools greatly streamlines the identity testing process.

Handheld Tools Reduce Costs
Pharmaceutical manufacturers deploying handheld spectroscopic analyzers within their raw material identity testing program enjoy a number of valuable benefits. Most notably, companies have reduced their overall production costs. Increased efficiency makes the identity test itself less expensive, of course, but that is only the beginning; rapid results from handheld analyzers enable facilities to begin the shift towards just-in-time delivery of materials with newfound assurance. With little appreciable delay between receipt of materials and release for manufacturing, plants have drastically cut inventory levels and their associated costs. Better use of warehouse, quarantine, and sample room space has eliminated costly expansion projects. Others have reduced the warehouse space they have had to outsource. These cost benefits have been significant.
Handheld Tools Increase Throughput
Some facilities, particularly ones with frequent changeover between products, have found the transition to non-contact, handheld instrumentation a quick way to increase production throughput and flexibility. By decreasing the time it takes to release a new raw material, plants have been able to ramp up production processes more quickly. Faster raw material release has made it easier to recover from production deviations by minimizing the associated impact on manufacturing schedules. Hours previously spent moving materials or processing samples have been redirected toward tasks on the critical path of production, decreasing the overall cycle time of the plant. The use of portable analyzers has enabled these facilities to be more productive with their existing resources.

Non-Contact Tools Decrease Risk
Most manufacturers also appreciate the additional security they bring to their supply chain when they employ non-contact, handheld instruments to verify the chemical identity of their materials at the loading dock. With less opportunity for contamination (both of the sample and the material itself) and with greater predictability in the turnaround time for identity verification results, plant managers have more confidence in their ability to meet the demand forecasts. In fact, seamless identity verification tools make it cost-effective for plant managers to increase the rate of material identity testing in order to reduce even further the risk of failed production runs. In some cases there may be ancillary benefits to mitigate worker exposure to harmful substances by virtue of inspection without exposure or contact.

Handheld Tools Complement the Laboratory
Laboratories appreciate the productivity boost they gain by transferring the bulk of their identity testing to the loading dock. Without hiring additional resources, the QC group can reduce the standard turnaround time on other laboratory-based analyses and accelerate timelines on projects that have fallen behind schedule.

The Right Tool is the Key to Success: Choose TruScan
Choosing the right solution for identity testing is the best way to ensure your manufacturing facility will enjoy the benefits of reduced costs, increased throughput, and decreased risk. Managers are using instruments that are designed specifically for chemical identity verification in the highly regulated pharmaceutical industry – instruments that are capable of performing reliably at the loading dock, without directly contacting the sample, and without the assistance or guidance of instrument experts. TruScan®, shown in Figure 3, embodies the above characteristics and is the only handheld, ruggedized Raman-based system on the market today.

Reliable, Operator-Independent Results at the Loading Dock
TruScan is a lightweight, rugged, handheld material identity verification tool that has streamlined the raw material inspection workflow for pharmaceutical manufacturers. The instrument operates accurately and reliably outside the controlled environment of the laboratory. It provides on-the-spot, operator-independent “pass/fail” results (not just data), enabling experts and non-experts alike to perform identity testing.

Accurate, Non-Contact Identity Verification
TruScan is a Raman spectrometer. Raman spectroscopy’s strength in differentiating between very similar chemical compounds is well established3,4, and the technique compares favorably to other spectroscopies.5 Its popularity in the pharmaceutical industry is growing due to its extremely low false-negative rate and even lower false-positive rate6, as well as its ability to test both solids and liquids through translucent packaging.

Regulatory Compliance – Increased Inspection Can Be A Key Differentiator
TruScan has harnessed the power of Raman for the pharmaceutical industry. Not only is the unit sufficiently rugged for use at the loading dock, but TruScan’s non-shedding materials and chemical-resistant seals make it suitable for classified manufacturing spaces and decontamination procedures. The instrument supports compliance with a battery of regulations and guidelines, including 21 CFR Part 11. Qualification and validation packages are also readily available.

Easy Implementation and Low Cost of Ownership Mean Fast ROI
With TruScan, you can empower your facility to reduce production costs and risks while at the same time increasing throughput within just a few weeks. The system’s simplicity of design and inherent analytical specificity offer rapid instrument qualification as well as robust method development and validation. Once validated, the system requires little to no instrument down time for maintenance or modeling updates to assure continued analytical accuracy and it rapidly scales as your production needs grow. TruScan easily interfaces with existing bar code symbology and LIMS packages. Operations personnel can be trained in the routine use of TruScan within a few hours as the instrument quickly becomes a seamless part of their materials handling process. The combination of these attributes yields efficiency and a low cost of ownership. Recurring benefits are extensive; companies can often demonstrate a tangible return on the investment in TruScan within months.
Spend Less on Material Identify Verification – Embrace the Future with TruScan

While it is true that drug manufacturers must verify the identity of their raw materials, it no longer needs to be a costly laboratory-based testing process that expends valuable resources. Using instruments such as TruScan, operations personnel are seamlessly and reliably performing identity tests at the loading dock, through material packaging, and without consulting instrument experts for guidance.

For some, TruScan is an ideal solution to complement existing methods and investments in the laboratory and in the sample room. Plant managers who must increase production rates, bring in new production materials, and transfer processes from one facility to another have come to rely on TruScan. Similarly, manufacturing and quality organizations who have faced increased rates of inspection – particularly the transition to 100 percent identity testing – have found TruScan to be an essential part of their expanded inspection procedures.

The advent of handheld identity verification technologies has enabled many forward-thinking manufacturers to reduce production costs while simultaneously increasing productivity and decreasing risk. With TruScan’s ease of implementation, you too can reap the benefits of efficient material identity verification in a matter of a few weeks. Identity testing is a requirement; how you choose to fulfill this requirement is up to you.

References

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3 United States Pharmacopeia – National Formulary General Chapter <1120> Raman Spectroscopy (USP 30 –NF 25 S2 to USP 31-NF16 S2)
5 Ahura Scientific White Paper TSWP01: FTIR, NIR and Raman Spectroscopy for Pharmaceutical Raw Material Inspection