Handheld Analyzers for the Screening of Pharmaceutical Counterfeits

Counterfeit and substandard medicines have serious human health and economic costs
The magnitude of the counterfeit and substandard pharmaceutical problem has recently gained significant public attention due to a number of high profile incidents and greater media focus. The World Health Organization (WHO) estimates that up to 10% of the world’s drugs are substandard or counterfeit and are expected to reach $75B. Even more significantly, it is estimate that 700,000 lives will be lost each year due to counterfeit malaria and tuberculosis drugs alone (International Policy Network, 2009).

In some cases, product degradation may occur in the absence of any malfeasance, sometimes with equally serious consequences. Lack of confidence in the quality of medicines reduces patient compliance, lowers productivity, and decreases investment in innovation and local production. Whether due to poorly controlled supply chains and quality control procedures or outright criminal intent, counterfeit and substandard medicines represent a serious problem.

Traditional approaches to combating counterfeits are inadequate
For many years, pharmaceutical companies have relied on a combination of covert and overt security features in packaging and occasional forensic analysis to identify counterfeit drugs. However, counterfeiters have found ways to quickly and accurately replicate those features well enough to deceive authorities and patients. The only real way to reliably determine the authenticity of a suspect product has traditionally been through laboratory analysis by trained chemists. This approach, however, has limited throughput and until recently could only be used for a small fraction of all suspected samples and not for routine screening.

Portable analyzers bring pharmaceutical authentication from the laboratory to the field
In an age where smartphones and computers are becoming both smaller and more powerful, it may come as no surprise that the same trend is starting to catch on with sophisticated instruments formerly relegated to analytical chemistry laboratories. Instruments such as the Thermo Scientific portable analyzers are designed for ease of use so that users without advanced degrees can perform analysis for a wide range of applications.

The Thermo Scientific TruScan and TruScan RM analyzers, powered by Raman spectroscopy, and microPHAZIR RX analyzer, powered by NIR spectroscopy, offer two complementary approaches to authenticating pharmaceuticals. These analyzers use vibrational spectroscopy to compare the chemical “fingerprint” of a sample with an authentic reference. Spectroscopy is the characterization of a substance based on the way it interacts with light. The bonds between molecules react to photons of light to create very unique, distinct spectra characteristic of the type and number of bonds in the sample. Different types of bonds show up as peaks of varying intensity in the resulting spectrum, creating a unique “fingerprint” for a particular compound. These techniques have recently become available in a portable form factor in which the analysis is automated to provide meaningful answers to the user. Because the spectrum generated by the spectrometer represents all the components of

The TruScan analyzer can be used in the field to provide rapid identification of counterfeit pharmaceuticals.
a pharmaceutical dosage form including the active ingredients, excipients, fillers, dyes, and coating materials (and their relative concentrations) any slight deviation from the original formulation will lead to a detectable change in the resulting spectrum. This makes it virtually impossible for counterfeiters to fool the instrument. Substandard products with the right ingredients, but inadequate amounts of active ingredient, can also be identified by their spectra.

The concept of operations for these analyzers is quite simple. The instruments contain a database of pharmaceuticals created by the user. These authentic references are called methods and are easily created by scanning a known authentic substance with the instrument and saving the resulting spectrum to the instrument’s memory. Methods can be copied from one instrument to any number of additional instruments electronically such that fleets of instruments can be broadly deployed. When field users test a sample – whether it is a suspect sample or a random inspection – the instrument provides a simple “pass” or “fail” result based on sophisticated chemometrics comparing the spectrum of the sample with the reference spectrum. For samples that fail, the instrument can search its library to determine whether it matches another known substance or mixture of substances. All results are securely stored on the instruments until downloaded.

New technology provides a new approach to anti-counterfeiting

This remarkable innovation is allowing brand owners and government agencies to develop new and powerful approaches to their anti-counterfeiting strategies. The vast majority of the top twenty pharmaceutical manufacturers use the TruScan and/or microPHAZIR analyzers to verify the identity of either raw materials or finished products. Regulatory agencies in North America, Europe, Asia, and Africa have purchased the analyzers to bolster their anti-counterfeiting efforts. In some countries, regulatory authorities have successfully deployed significant numbers of the instruments to conduct random field screening from the ports of entry to the point of sale (pharmacies/markets). These have facilitated the seizure of thousands of counterfeit drugs that would otherwise have entered the supply chain with serious consequences.

Regulatory Agencies Currently Using Thermo Scientific Portable Analyzers
- FDA – United States
- SFDA – China
- NAFDAC – Nigeria
- NA-DFC (Badam Pom) – Indonesia
- Swiss Medic – Switzerland
- MHRA – United Kingdom
- Thailand FDA

The TruScan and TruScan RM analyzers, powered by Raman spectroscopy, and the microPHAZIR RX analyzer, powered by NIR spectroscopy, provide fieldable solutions in support of the war on pharmaceutical counterfeiters.