An Analytical Device to Catch Counterfeits in Developing Countries

Most of the attention given to analytical techniques in the authentication world is typically focused on field analysis. This is because of the great advantage of having the laboratory present at the site when and where the question of 'what is it?' is at hand. The time savings for investigators, law enforcement, and brand owners is, as a result, considerable.

Most of these techniques have acknowledged limitations of some sort, however, and none of the field analyzers would have caught – for example - the contaminated Heparin which relied on altered sulfated chondrotin as an active ingredient (according to the FDA, only nuclear magnetic resonance could have detected the problem at first).

This case notwithstanding (most counterfeits are not so sophisticated, neither are most counterfeiters in the molecule bending business), in developed nations, most companies and investigators have laboratories for more complete analysis and back up of their field units. And there are now innumerable applications available for all types of analytical techniques, field or laboratory.

Greatest Need

The greatest need, however, is in developing countries, many of which lack even basic analytical equipment. Or, if such countries have the equipment, they often cannot afford the solvents, supporting maintenance, or spare parts to keep the machines running. Often this equipment must operate in rooms that are not climatically controlled where heat and humidity can wreak havoc on testing procedures. Clean rooms are very rare. Voltage fluctuations are common.

Serge Rudaz, PhD, of the Laboratory of Analytical Pharmaceutical Chemistry at the School of Pharmaceutical Sciences - University of Geneva, University of Lausanne and his band of enthusiastic students from the pharmacy school and the Fribourg College of Engineering and Architecture stepped up to this challenge five years ago. He and his colleagues approached this problem with 15 years experience with capillary electrophoresis and the goal of developing a training machine based on this technology that could be used to train students and users in other countries.

Typically these machines can cost up to $80,000 and require substantial volumes of high purity organic solvents for operation. But when Dr Rudaz contacted manufacturers of such machines, they had little interest in developing a special training version given that part of the goal was to develop one which used very little solvent. He then began working with the Fribourg College of Engineering and Architecture to design and build a machine of their own.

Focus on Low Cost

As Dr Rudaz understood that most of the problems with counterfeits in developing nations involved products which had no active ingredients, or diluted concentrations of active ingredients, the focus was on a low cost machine that would detect fakes with these characteristics.

Capillary electrophoresis identifies molecules by size and electrical charge. The machine they designed can detect active ingredients and concentration level. So if malarial drugs are diluted, their machine will reveal it. Many other drugs have been tested effectively as well.

A few weeks ago, the first machine was delivered to the National Health Laboratory at Bamako University in Mali and is now operational. There are still voltage fluctuations that need to addressed, but engineers are working through those problems.

An operator of the machine needs to have some technical skill in sample preparation, collecting data, and interpreting information, but does not have to be a trained chemist. Compared to most analytical machines, it is easy to operate. It requires a sample size of about 50 micro-liters to charge the vial, but only uses 10 to 20 nano-liters per analysis. A much smaller charge level and a much lower amount of solvent than is typically required.

Great Contribution

Dr. Rudaz acknowledges there are still limitations with his machine as it focuses on the presence of active ingredients and dilutions. But that is the type of counterfeiting most prevalent in the developing world. Products without active ingredients don't medicate or cure and the patient remains sick or dies. Diluted products, meanwhile, will probably not work and, in the case of antibiotics and anti-malarials, will have the societal impact of creating organisms which are resistant to available medicines. Helping in the fight against these types of counterfeits is a great contribution.

While the machine that Dr. Rudaz and his team developed costs far less than $80,000 of a typical machine and is much cheaper to operate, a final cost is difficult to establish. Final terms of ownership of IP and agreements need to be worked out between the two universities.

Knowledge Transfer

Moreover, the machine is designed only for knowledge transfer. Dr Rudaz expects that most users of their machine will use it for two to three years, and then after training and becoming familiar with capillary electrophoresis, they will shop for machines with more capabilities and features.

He views his machine, therefore, as a training device, as a means of teaching people how to use capillary electrophoresis, and not the final solution for a laboratory. If his work motivates a manufacturer to produce a more competitive, more inexpensive to operate unit for developing nations, then all the better.