

Applications of vibrational spectroscopy and hyperspectral imaging for the analysis of substandard and falsified medicines.

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Access to quality medicines is an essential right of the patients. However, in 2017, the World Health Organization estimated that 1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified. This reinforces the fact that post-marketing surveillance (PMS) of medical products by strong national regulatory authorities (NRA) is crucial. To achieve an efficient PMS, the NRA need analytical tools at the inspection, screening, confirmatory and forensics levels to control the physicochemical properties of the samples.

Because of their fast, non-destructive, and relatively affordable character, vibrational spectroscopy tools are unavoidably present at each step. Handheld devices are particularly useful during inspection and screening phases since these tools can identify and/or quantify active pharmaceutical ingredients (API) even through opaque packaging in seconds. However, they generally need exhaustive and up-to-date databases for each specific product. Another limitation is the work and time needed before going into the field to develop and validate the chemometric models. Indeed, this mandatory step requires highly skilled scientists and a prior collection of certified references of the medicines to analyse.

Benchtop systems and among them imaging systems are particularly useful in the confirmatory and forensic steps. Indeed, the imaging systems enable the visualization and identification of a large range of both organic and inorganic compounds used as API or excipients. In addition, thanks to the high spatial resolution, it allows the detection of trace contaminants. This information may be of particular interest during prosecutions and the clustering of criminal cases. Nevertheless, the extraction of the relevant information from the raw measurements requires once again intensive work by highly trained staff.

In conclusion, vibrational spectroscopy tools have particularly interesting features for the PMS of medicines, but research is still needed to make them easier to set up and use by NRA inspectors and non-specialists.