Moving to New Technologies: Transmission Raman for Content Uniformity (CU) Testing

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Only a few years ago, Raman spectroscopy was widely introduced in the routine analysis of the pharmaceutical industry. At this time the implementation of rapid, non-invasive and non-destructive analytical techniques to identify incoming goods - such as (portable) Raman and NIR spectrometers - were essential to meet regulatory requirements. Whereas NIR spectroscopy is already used for some time for quantitative analysis in the pharmaceutical industry, the field of application of Raman spectroscopy has been limited mainly to qualitative analysis, yet.
The availability of the first Transmission Raman spectrometer, which also meets the comprehensive regulatory requirements in the GxP environment, opens up a new, extensive deployment scenario, which is difficult to cope with common analytical techniques regarding the ever-increasing regulatory requirements for test scope and frequency as well as the need for increased efficiency in the highly competitive business of generic drugs.

In this lecture the pilot project for the introduction of the transmission Raman spectroscopy for routine analysis at Novartis will be presented. Among other things, the following questions will be answered:

- What are the advantages over other analytical techniques such as HPLC or NIR spectroscopy?
- What are the efforts and challenges regarding device qualification, method development and validation?
- What is the regulatory framework for the application of quantitative Raman spectroscopy in the pharmaceutical industry?
- How can you ensure that the method will still deliver reliable results in a few years?