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New possibilities in real-time quality control with new generation machine vision technology

Nika Oman Kadunc

REDSTART Instrumentation Ltd., Slovenia

The aim of improving the quality of pharmaceutical end products and optimizing production efficiency drives the need for progress in real-time quality control with process analytical technology (PAT) tools for monitoring critical quality and performance attributes. Multiparticulate dosage forms – using coated or uncoated pellets or granules – are increasingly used in the production of solid dosage forms as they enable favorable release profiles of active ingredients. With these, the Critical Quality Attributes (CQAs) that affect the physicochemical properties of drug substances and final dosage forms are particle size, particle shape and, with coating applications, also coating thickness and coating uniformity. We present a new generation machine vision system as a PAT tool for fast and accurate automatic in-line assessment of particle CQAs in real-time. The measurements are made with high accuracy

and high speed: 1,000,000 particles per minute. This allows for reliable size distributions and highly accurate evaluation of size and shape parameters in real-time – important for a reliable process feedback. For the first time, the high statistics in real-time enable advanced data analyses for measuring coating uniformity, which currently cannot be determined with any other in-line PAT methods. The machine vision technology brings advantages over other PAT techniques as it provides means of contactless, non-invasive, non-destructive, fast and accurate automatic measurements of particles together with easy implementation and calibration. The benefits of the presented PAT technology offer new possibilities for optimizing and a better understanding of production processes and, subsequently, of the end product quality assurance.

nika@redstart-instrumentation.com