Abstract

The aim of improving the quality of pharmaceutical end products and optimizing production e f ciency 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 pro fles of active ingredients. With these, the Critical Quality Attributes (CQAs) that a fect the physicochemical properties of drug substances and fnal 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 realtime. 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 frst 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, noninvasive, non-destructive, fast and accurate automatic measurements of particles together with easy implementation and calibration. The bene fts of the presented PAT technology o fer new possibilities for optimizing and a better understanding of production processes and, subsequently, of the end product quality assurance.trolled studies with a larger sample size are needed. Despite the increasing challenges of rising product variety and complexity and the necessity of economic manufacturing, a comprehensive and reliable quality inspection is often indispensable. In consequence, high inspection volumes turn inspection processes into manufacturing bottlenecks. In this contribution, we investigate a new integrated solution of predictive model-based quality inspection in industrial manufacturing by utilizing Machine Learning techniques