Title for Agile PAT session

“Proof-of-concept studies for API quantification in low-dosed formulations using deep UV-based spectroscopy measurements - A ETC case study”

Abstract

Since the issue of Process Analytical Technology (PAT) guidelines by FDA in 2004, a variety of in-line non-invasive sensors have been introduced and implemented on pharmaceutical manufacturing processes to provide real-time process monitoring and control. Most process analytical technologies have been developed for the manufacture of formulations with high drug loads (NIR). However, there is a lack of sensitive and robust analytical tools to provide real-time monitoring for low-dose drug formulations (<1%, w/w). Pharmaceutical scientists have used techniques such as light-induced fluorescence (LIF), x-ray fluorescence (XRF) and laser-induced breakdown spectroscopy (LIBS) for real-time monitoring of low-dose formulations with limited success in both development and manufacturing. Given the popularity of continuous manufacturing for drug substance and drug product, and the criticality for real-time analytics for control of these processes, there is a need for a process analytics tool providing an ability to monitor sub-percent drug levels in pharmaceutical liquid and solid formulations. ETC (Enabling Technologies Consortium™) selected and funded Photon Systems (Phase 1 proof of feasibility) to evaluate and demonstrate a real time analytical tool based on Deep UV LIF/Raman for a wide variety of APIs and excipients with low-dose formulations. Using slightly modified COTS UV instruments (TraC and RPL200) PSI demonstrated LOD/LOQs significantly better than the goal of <1%, in most cases well below 0.05%. Other testing aspects like repeatability (Precision) and moving powder (feed frame) are presented.