

## **437n Use and Implementation of Pat Tools for Particle System Characterization and Reaction Analysis**

*Benjamin Smith, Will Kowalchyk, and Terry P. Redman*

The FDA driven PAT initiative has encouraged the use of in-situ analytical tools over a broad range of unit operations, for full process understanding, characterization and control. This paper will emphasize the use of specific PAT tools for the understanding, optimization and control of chemical reactions and particulate processes in a pharmaceutical production environment.

A series of in depth case studies will be presented, highlighting the depth and scope of information that can be obtained by the in-situ examination of chemical reactions and particulate processes on a production scale. These case studies will include a PAT reaction analysis example using METTLER TOLEDO ReactIR. Additionally there will be a focus on particulate process monitoring on the API and drug product side with case studies using METTLER TOLEDO Lasentec FBRM for crystallization, milling and granulation operations, with recommendations on rapid troubleshooting and optimization of these processing steps.