Providing Information-Rich Solutions for Pharmaceutical Product Development through the use of Innovative Technologies

Brian E. Winger, Thomas M. Zennie, Steven W. Baertschi, Andreas Kaerner, and Xia Dong

Physical and Structural Characterization, A Division of Eli Lilly and Company
Lilly Corporate Center, Indianapolis, IN 46143

As the cost of discovering, developing and commercializing first-in-class or best-in-class medicines increase beyond $1 billion per new chemical entity, the pharmaceutical industry must find more efficient and cost-effective ways of bringing products to the marketplace. One way of accomplishing this in the development laboratory is through the use of innovative technologies. The information that is provided by the analytical laboratories to the process chemists, formulators, pilot plant engineers, and those within commercial manufacturing is paramount to making important decisions regarding bulk and product development control strategies. Generating data in a timely fashion is an important part of the equation; however, the need for generating information-rich data has driven the development of analytical technologies and methodologies that deliver information-rich solutions. An overview of technology initiatives within product development as they affect delivering information-rich solutions will be presented. Additionally, several examples of the innovative approaches used in the development laboratories at Lilly will be presented. These will include the use of automated technology for understanding the degradation chemistry of API starting materials, intermediates and final bulk material; the use of process analytical technologies for understanding various unit operations in formulating drug products; Real time reaction monitoring of complex chemical processes using integrated flow NMR, and Surface analysis and imaging technology for study migration processes within tablet formulations. Furthermore, concepts and ideas for the future direction of analytical technologies within product development will be discussed.