M-CERSI Science Exchange Award

Conference Title: Control Strategies for Pharmaceutical Manufacturing: Real Time Release Testing and Design Space Determination

Principal Investigator: Stephen Hoag, PhD

Workshop Date: May 23, 2013

Outcomes/Summary:

On May 23, 2013, M-CERSI hosted the 1-day conference "Control Strategies for Pharmaceutical Manufacturing: Real Time Release Testing and Design Space Determination." The conference was co-sponsored by the "American Association of Pharmaceutical Scientists" (AAPS). The goal of the conference was to examine the issues associated with the manufacture of pharmaceutical products, with emphasis on methods to develop a manufacturing control strategy and steps to implement a Real Time Release Testing (RTRT) system using PAT technologies. Control strategy is critical in pharmaceutical manufacturing. The conference brought together 60 participants from industry, academia, and FDA to exchange current experiences concerning the latest advances in Real Time Release Testing (RTRT) and to share approaches to implement RTRT systems.

Speaker's names, their affiliation and the title of their talks are given in the table below.

Overview of Pharmaceutical Manufacturing Control Christine Moore, PhD, FDA
Case Study Strategy for Developing A New Drug Product for Real Time Release and Regulatory Requirements Raafat Fahmy, PhD, FDA
Developing the Control Strategy for Pharmaceutical Manufacturing Across Scales of Manufacturing Stephen Hoag, PhD, University of Maryland School of Pharmacy
Statistical Methods for Establishing the Design Space and Conrol Within Design Space Gregg Claycamp, PhD, FDA
Industrial Perspective on the Use of Models in the QbD Framework Christian Airiau, PhD, GlaxoSmithKline
Industry Experiences in Launching, Managing, and Transferring A Real-Time Release Testing Method Globally from 2006 to Today Gert Thurau, PhD, Merck

There was substantial active discussion among participants. Some key points that emerged from the conference included:
- Education of FDA reviewers to best promote the evaluation of the latest manufacturing technologies is critical. Of equal importance, education of industrial scientists who submit filings to the FDA is critical, so applications can be of highest quality and completeness, which promotes regulatory review. Academia can play a valuable role in bring promoting such learning opportunities.
- Better development and implementation of multivariate statistical process control charts is needed when implementing advanced control strategies.
- Better process analytical technology (PAT) sensors and chemometric models are needed to move the field forward.
- A key issue is going beyond just measuring data and monitoring a process, but to apply data in real time to better control a process, so as to improve product quality.
- Big companies are actively developing RTRT systems and doing a good job with their filings, but small to mid-size companies are lagging. Example filings would be very beneficial to these smaller companies. Academic laboratories conducting manufacturing research can benefit from disseminating research in this area.
- Extrapolating design space data across scales of manufacturing requires additional development and research.