AAPS PharmSciTech 2006; 7 (3) Article 80 (http://www.aapspharmscitech.org).

Themed Issue: Transforming Pharmaceutical Manufacturing: Benefits and Challenges
Guest Editors - Robin Bogner and Ajaz Hussain

Editorial: Themed Issue on Transforming Pharmaceutical Manufacturing: Benefits and Challenges

In March 2004, FDA published the report "Innovation or Stagnation: Challenges and Opportunities on the Critical Path to New Medical Products" (www.fda.gov/oc/initiatives/criticalpath/whitepaper.html) pointing to the inefficiencies that underlie an otherwise stellar record of innovation and quality of products by the pharmaceutical industry. Although general discussion of this issue has occurred, quantification and rigorous analysis of the problem and potential solutions has not been forthcoming, and, consequently, the debate ensues.

In light of these developments, *AAPS PharmSciTech* is launching a themed issue that will seek to gather examples and analyses that quantify the problem, and propose solutions that will lead to a dramatic change in the way drug products are developed and manufactured. The FDA has begun a transformation of the regulations to encourage such innovation. "Pharmaceutical cGMPs for the 21st Century - A Risk-Based Approach" (www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm) first outlined the vision for the new paradigm in regulation that will reduce the known regulatory burden on innovation (Grabowski et al. Estimating the Effects of Regulation on Innovation: An International Comparative Analysis of the Pharmaceutical Industry. *Journal of Law and Economics*. 1978;21(1):133–163). The "PAT Guidance" (www.fda.gov/cder/guidance/6419fnl.htm) provided further direction toward the new regulatory expectations. The American Society for Testing and Materials (ASTM) has a Technical Committee (E55) on Pharmaceutical Application of Process Analytical Technology (www.astm.org/cgi-bin/SoftCart.exe/COMMIT/COMMITTEE/E55.htm?L+mystore+vdqw2129). In addition, the National Institute of Pharmaceutical Technology and Education (nipte.org) is making an effort to advance the field of pharmaceutical product development and manufacturing.

You are invited to contribute an article for this themed issue in one of the following formats: A Review, Original Research Article, Brief/Technical Note, Mini-Review, or a Regulatory Note. The process for submitting articles to the themed issue is the same as that for submitting regular articles. The same rigorous peer review will be used, and plans are to publish the themed issue in early 2007. Authors interested in submitting a paper for this themed issue are encouraged to contact the Guest Editors, Robin H. Bogner (robin.bogner@uconn.edu) or Ajaz Hussain (ajaz.hussain@sandoz.com), or you can submit directly to the journal and designate it for the themed issue on *Transforming Pharmaceutical Manufacturing: Benefits and Challenges.*

To ensure appropriate focus of this themed issue, manuscripts that define the problem and/or offer solutions will be considered. For example, articles that are encouraged will discuss the inherent limitations of "quality by inspection"; estimate of the cost of the "quality by inspection"; define the current economic drivers for innovation in manufacturing; explore the complex barriers to transformation in pharmaceutical processing; offer practical approaches to overcoming those barriers; and clarify the economic benefits of a transformative change in pharmaceutical manufacturing.

Guest Editors
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