ASTM E55 Committee Overview

As pharmaceutical development and manufacturing evolves from an art form to one based on science and engineering, FDA will use the knowledge developed in PAT to establish product specifications and evaluate manufacturing processes. We believe that this is an opportunity to create improvements in productivity to both manufacturing and regulatory processes. This Committee addresses issues related to process control, design, and performance, as well as quality acceptance/assurance for the pharmaceutical manufacturing industry.

The scope of the E55 committee is as follows:

"The scope if the Committee shall be development of standardized nomenclature and definitions of terms, recommended practices, guides, test methods, specifications, and performance standards for pharmaceutical application of process analytical technology. The Committee will encourage research in this field and sponsor symposia, workshops and publications to facilitate the development of such standards. The Committee will promote liaison with other ASTM Committees and other organizations with mutual interests."

Collaboration with ASTM provides opportunities to:

1. Learn from (and not "reinvent the wheel") other industrial sectors such as petrochemicals where the use of process analyzers, statistical principles, and risk management have been in practice for a number of years.

2. Focus our efforts on "process" and to bring a much needed (pharmaceutical) engineering dimension.

3. Work towards international consensus to support other FDA activities such as ICH.

4. Involve all stakeholders and multidisciplinary expertise (FDA does not have the resources to do this).

Additional information is available in the May 2004 ASTM *Standardization News* which may be viewed at:

www.astm.org/cgi-bin/SoftCart.exe/SNEWS/MAY_2004/wah_may04.html?L+mystore+zcra7125+1087590729