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ASTM International Forms New Standards Committee on Process Improvements in Pharmaceutical Manufacturing

W.CONSHOHOCKEN, Pa., 25 March 2004--ASTM International, one of the largest voluntary standards development organizations in the world, announced the formation of a new committee to develop consensus standards focused on the development and adoption of new and innovative process improvements in pharmaceutical manufacturing. The committee is comprised of a diverse range of stakeholders including prominent members of the pharmaceutical industry, the U.S. Food and Drug Administration (FDA), manufacturing suppliers, trade associations and academia.

Adopting Best Practices in Pharmaceutical Manufacturing

The new ASTM committee, E55 on Pharmaceutical Application of Process Analytical Technology (PAT), comes together following an FDA overhaul of regulations governing drug manufacturing, the first such overhaul in 25 years. Recognizing that the pharmaceutical industry was in need of more efficient processes and techniques in manufacturing, the FDA created “PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance.” PAT was the first step in facilitating the development, implementation and regulation of manufacturing processes based on fundamental process understanding.

Following the introduction of PAT, the needs of the pharmaceutical industry have evolved toward the definition and development of process-based “best practices” to advance a scientific approach toward process understanding and flexible manufacturing. To establish the foundation for PAT implementation, and to lend credence and general acceptance to the developed best practices, the FDA encouraged the pharmaceutical industry to take an active role in drafting these practices through consensus and broad-based stakeholder representation and input.

Consensus Under the ASTM International Umbrella

To facilitate the development of an industry-driven, voluntary, consensus standards initiative, the FDA’s Center for Drug Evaluation and Research (CDER) contacted ASTM to begin discussions on the formation of this new activity within ASTM. Following an organizational meeting in late 2003, that included over 60 representatives from the pharmaceutical industry, ASTM Committee E55 was unanimously approved and formed.

Don Marlowe, Agency Standards Coordinator, Office of Science and Health Coordination, Office of the Commissioner, U.S. Food and Drug Administration and Chairman of ASTM Committee E55, commented, “PAT represents the FDA's vision for future pharmaceutical product development and manufacture. As pharmaceutical development and manufacturing evolves from an art form to one based on science and engineering, the FDA will use the

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knowledge developed in PAT to establish product specifications and evaluate manufacturing processes. We believe that this is an opportunity to create improvements in productivity of both the manufacturing and regulatory processes. The FDA is partnering with the other stakeholders in this industry on ASTM Committee E55 as the most effective venue in which standards for this new science can develop."

Ray Scherzer, Senior Vice President, Engineering, GlaxoSmithKline, added, "E55 will offer our industry a unique opportunity to get regulators, equipment suppliers, associated organizations, academia and pharmaceutical manufacturers to work together to develop effective standards and guidelines. These standards will play an integral role in helping us tackle many of the challenges we face in our factories."

ASTM International Standards Will Drive Innovation

E55 will bring together hundreds of technical experts from the public and private sectors to write voluntary consensus standards that will help drive new innovations in pharmaceutical manufacturing and process control. The committee will develop standardized language and definitions of terms, recommended practices, guides, test methods, specifications, and performance standards for pharmaceutical application of process analytical technology. As committee E55 gears up for its next meeting in May 2004, stakeholder support continues to grow.

Dr. Nancy Mathis, President and CEO, Mathis Instruments Ltd., commented, "ASTM Committee E55 will play a very important role for the industry. It will provide a common language between departments, between sites, between companies and between stakeholders. The meetings, interactions and process provide a forum to discuss the common problems and come to agreement on common solutions. All of these elements will contribute to improved harmony in the industry as it goes through a period of change - and ASTM will be central to that."

Industry feedback and comments on the new ASTM Committee E55 should be directed to Pat A. Picariello, director of Developmental Operations (phone: 610/832-9720; ppicarie@astm.org), or visit http://www.astm.org/COMMIT/E55.

Established in 1898, ASTM International provides a global forum for the development and publication of voluntary consensus standards for materials, products, systems and services. ASTM standards are accepted and used in research and development, product testing, quality systems, and commercial transactions around the globe.

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