PPAR Vendor Audit Update

- Background
- Status
- Plan

Background and Motivation

- Discussion topic at 2000 and 2002 PPAR
- Action item at 2003 PPAR
- Objectives addressed by ASTM e55, $IFPAT_{MA}$, etc?

  - Vendor audits a resource drain for both users and vendors
  - Each user has different criteria and standards
  - Perpetual hardware/software/OS changes

    - Stop the madness!!

Strategy – Standardization

Need a credible, neutral party to develop consensus standards (e.g. ASTM, ISO)

Need auditing/oversight to certify compliance (e.g. $IFPAT_{MA}$ for instruments, ISPE for equipment)

FDA supports and advocates this strategy

From FDA Website:

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."

http://www.fda.gov/ohrms/dockets/ac/04/briefing/4034B1_05_ASTM%20Overview.pdf

Current Status

FDA Guidance issued, refers to ASTM and industry-led initiatives

ASTM has chartered several working groups

http://www.astm.org/cgi-bin/SoftCart.exe/COMMIT/COMMITTEE/E55.htm?E+mystore

http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=122731

IFPAT$_{MA}$ has executive committee and several commercial vendors as representatives – working on white paper

ISPE has issued a draft white paper (seeking comment) outlining their plans

ASTM Technical Committee e55

Pharmaceutical Application of Process Analytical Technology

http://www.astm.org/cgi-bin/SoftCart.exe/COMMIT/COMMITTEE/E55.htm?E+mystore

Current Workgroups

E55.01 PAT System Management

WK5930 Standard Practice for Risk Management as it Impacts the Design and Development of Processes for Pharmaceutical Manufacture

WK5935 Standard Practice for Process Understanding Related to Pharmaceutical Manufacture and Control

E55.02 PAT System Implementation & Practice

WK4185 Test Method for Thermal Effusivity of Solids, Powders, Liquids, and Composite Samples Using the Modified Hot Wire Transient Technique

WK4694 Guide to Assure Fitness-for-Use of a Measurement System to Determine or Control Process or Product Quality Attributes

WK5015 Pharmaceutical Process Design

WK5931 Standard Practice for PAT Data Management

E55.90 Executive

E55.91 Terminology

WK4187 Standard Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry

$IFPAT_{MA}$ Mission

$IFPAT_{MA}$ is a not-for-profit association representing suppliers, pharmaceutical industry users, academia, and regulatory agencies organized to promote the efficient utilization of Process Analytical Technology (PAT) tools that meet the industry's and regulatory agency's fitness-for-use expectations. This will be accomplished through a vendor certification program based on the adoption and use of science based standards, generation of peer-reviewed, standardized PAT application platforms, as well as providing educational opportunities that facilitate the use of PAT approaches to generate process understanding.

$IFPAT_{MA}$

- Steering Team of 20 pharmaceutical industry vets
  - 2 academic, 5 producers, 10 instrument vendors, 3 agency and oversight
- Sanctioned at 2004 IFPAC meeting
- Initial kickoff June 8th, 3 subsequent teleconferences
- Similar to existing effort in PDA on automation systems
- At upcoming FDA manufacturing subcommittee meeting will seek formal support from agency (policy paper being prepared).

  - Contact Bob Zutkis through IFPAC or Rick Cooley

ISPE White Paper – Equipment Certification

THE SOCIETY FOR LIFE SCIENCE PROFESSIONALS

Risk-Based Qualification for the 21st Century

A Proposal to Industry

In June 2004, FDA approached ISPE to undertake a number of challenges to be an Agent of Change and Improvement within the industry. Several of these challenges relate to focusing on science and engineering-based decision-making. One of these challenges was to implement a program to certify equipment vendors. Not only would this foster better engineering, consistency, and quality from equipment vendors, but the pharmaceutical industry could expect to see a reduction in the cost and time required to qualify manufacturing equipment and systems. Discussions were held at the ISPE Leadership Retreat in St. Petersburg on 31 July 2004, and a task team met in Tampa on 17 August 2004 to examine the applications, benefits, and issues surrounding this concept. This White Paper is the result of that task team meeting.

PPAR Participation Going Forward:

- Does this strategy make sense?
- Do these look like the right parties?
- What are the gaps in the strategy?
- How can you get involved?