MCC position regarding PAT

The Manufacturing Control Committee of CHPA

It is widely recognized that the pharmaceutical industry serves as a benchmark for innovation and delivery of quality healthcare products to consumers and patients throughout the world for decades. CHPA is proud to represent this industry by working to provide consumers with convenient access to safe and effective nonprescription medicines and other self-care products without undue restrictions. CHPA acknowledges that PAT is a proven and efficient tool which may be utilized for continuous improvement and continuous quality verification.

CHPA supports the FDA position that utilization and implementation of Process Analytical Technology (PAT) can be, and should be, applied in drug development and manufacturing on *a voluntary basis*.

CHPA recognizes the potential for utilization of PAT in various applications including improvements in drug development, process control, process knowledge, occupational safety, etc. PAT has been proven to be especially useful in high volume, dedicated manufacturing or continuous processing operations where on-line monitoring and automated adjustment can be made during manufacturing or filling operations.

PAT, however, is not a "cure all" for all manufacturing issues. It is not the correct tool for all processes and does not lend itself to implementation across the board in all manufacturing or packaging related applications. As such, the implementation of PAT should remain as a voluntary option and left up to each individual company to determine the benefit it can derive from utilization.

Successful implementation of PAT will strongly depend on the integration of pharmaceutical manufacturing practices and guidance documents or regulations. It is anticipated that modifications to applicable regulations can be accomplished through review of the cGMP's for the 21st Century as part of the risk-based approach. As the regulated industry we encourage FDA to continue to work with us in order to identify and qualify various levels of risk and define a robust process that can eliminate uncertainty in implementation of various changes. CHPA views the current climate as an opportunity to improve not only processes internal to both FDA and industry but also to devise new ways to clear the accumulative effects of rules currently impeding operations of both.

As an initial step, CHPA looks forward in assisting FDA in developing good science-based guidance documents, within the established regulatory framework, in order to clearly define expectations of utilization and implementation of PAT. As a longer-term objective, CHPA is eager to work with FDA in the establishment of new or revised regulations as may be useful or required.

As a representative for the Manufacturing Controls Committee of CHPA, we would like to thank the chair and the committee for the opportunity to present our views and wish all of you good luck on your new assignment.