

## MEMORANDUM

TO: Members and discussants, ACPS PAT Subcommittee

FROM: Ajaz S. Hussain, Ph.D.  
Deputy Director, Office of Pharmaceutical Science, CDER, FDA

Date: 9 October 2002

RE: PAT Subcommittee meeting October 23, 2002

We look forward to meeting you on 23 October 2002 in Rockville, Maryland (Ramada Inn, 1775 Rockville Pike). The morning session of this meeting will focus on electronic batch records, computer software validation and security issues. In the afternoon session we plan to hold two separate discussions, namely: rapid microbial testing and case studies on PAT submission ("mock" submissions).

For the morning session we have invited three individuals to share their thoughts on issues related to CFR Part 11 issues and software validation. The invited guests are Dr. Guy Wingate (Director, Global Computer Validation; GlaxoSmithKline), Debbie Thomas (Director, Regulatory Compliance and Quality, Air Products and Chemicals Inc.), John Murray (CDRH/FDA). We wish to keep these discussions focused on the challenges associated with PAT implementation. Therefore, to start this discussion we have requested Bob Chisholm (PAT-Subcommittee) to share his experiences and help to focus the ensuing subcommittee discussions on issues related to PAT implementation. ***At the end of this discussion period we request the subcommittee to identify and prioritize the key issues, relevant to PAT implementation, that we should consider in developing the proposed general guidance on PAT.*** I have asked Joe Famulare (Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER/FDA) to be the lead FDA discussant during this session. Joe Famulare was recently appointed the FDA lead on issues related to Part 11.

The following information applies to the afternoon breakout sessions on rapid microbial testing within the PAT conceptual framework and "mock" PAT submissions or case studies:

For the rapid microbial testing discussion group we have invited Drs. Donald Burstyn (Alkermes, Inc.), Jeanne Moldenhauer (Vetech Pharmaceutical Consultants, Inc.), Kenneth Muhvich (The Validation Group), and Michael Korczynski (Mikkor Enterprises, Inc.) to participate in the discussions. Dr. Peter Cooney (Associate Director for Microbiology, OPS/CDER/FDA) will be the lead FDA discussant. Topics for discussion are attached (Attachment #1).

We are currently working with several industry discussants on the PAT-Subcommittee to develop case studies and "mock" submissions for examination and discussion in the afternoon session. Steve Hammond (Pfizer) has provided a case study entitled "Validation perceptions that may slow PAT development and implementation" for

discussion (Attachment #2). We hope to send you information on at least one additional case study prior to the meeting.

Since our second meeting in June 2002 several changes have occurred that impact on the topics under discussion by the PAT Subcommittee. On August 21, 2002 FDA announced a major new initiative entitled "Pharmaceutical cGMP's for the 21<sup>st</sup> Century: A Risk-Based Approach," described in the attached document (Attachment # 3). ***We would appreciate if you would review this document and share with us your thoughts on how you see the cGMP initiative impacting the PAT Initiative and vice versa.***

We look forward to meeting you on October 23, 2002 and wish you a safe and pleasant journey to Rockville, MD. If you have any questions please do not hesitate to contact Ms. Marilyn Welschenbach (Phone: 301-594-2847; e-mail: WELSCHENBACH@CDER.FDA.GOV).