

MINUTES
Drug Product Technical Committee
May 15, 2001
AAPS Headquarters, Arlington, VA

* *denotes Chair*

Attendees:

Academia/Industry Representatives:

*Sidney Goldstein, D.Sc. - Duramed/GPhA/Chairman
Sylvia Gantt, PQRI Executive Secretary
Jeffrey Blumenstein, Ph.D. - Pfizer/IPAC (by telephone)
Shawn F. Dressman, Ph.D. - USP
A. Waseem Malick, Ph.D. - Hoffman LaRoche/PhRMA (by telephone)
Richard C. Moreton, Ph.D. - Genpharm/IPEC (by telephone)
Richard P. Poska, R.Ph. - Abbott/ISPE (by telephone)

FDA Representatives:

Rajendra Uppoor, Ph.D. - CDER/ONDC

Observers:

Thomas Garcia, Ph.D. - Pfizer/BUWG (by telephone)

Absentees:

Larry Augsburger, Ph.D. - Academia/UM
Devinder W. Gill, Ph.D. - CDER/OGD
Ajaz S. Hussain, Ph.D. - CDER/OTR
Nikki Mehringer, Ph.D. - Lilly/PDA

Approval of Minutes

The minutes of the April 17, 2001 meeting were approved and will be posted on the PQRI web site.

Summary of the April 16 and May 3, 2001 Steering Committee Meetings

S. Gantt summarized the meeting minutes that related to the DPTC. The orientation program used for the DSTC was successful and will be used for the other technical committee working groups. A PQRI internal annual meeting is tentatively scheduled for Sept 11 and 12.

Blend Uniformity Working Group (BUWG) Status

The final version of the stratified sampling proposal has been approved by the DPTC and will be forwarded to the PQRI Steering Committee. This document has received a favorable review by the FDA CMC coordination committee. Following approval by the Steering Committee, the document will be posted on the PQRI web site as well as published in the Pharmaceutical Technology Journal. Reference to the web site will be published in the AAPS Newsletter.

On June 4, the BUWG will meet to discuss the approach to data mining and research needed to address the issue that routine blend testing does not add value. This activity will take place during the process of soliciting public comments of the stratified sampling proposal. The target date for obtaining all comments is October 1, 2001. A final report should be available by the end of November.

Garth Boehm will submit the Blend Uniformity Practice Survey to the Pharmaceutical Technology Journal and Joep Timmermans has submitted the Workshop Summary Article to this journal.

Container/Closure Systems Working Group Status

Chris Moreton reviewed the history of this group for the benefit of the new DPTC members. Richard Hollander has been recommended as a candidate for the chairperson. We are still waiting for Don Klein to appoint the FDA representatives to this committee. The final list of members for this committee will be circulated to the DPTC members and upon approval forwarded to the Steering Committee for their approval prior to our next DPTC meeting.

Miscellaneous Items

Jeffrey Blumenstein Ph.D. has been appointed as the representative for IPAC (International Pharmaceutical Aerosol Consortium) on the DPTC and A. Wassem Malick Ph.D. is the new representative for PhRMA. Both of these new members will work with Ajaz Hussain on the Manufacturing Changes Working Group.

Next Meeting

The next DPTC meeting is scheduled for July 17, 2001 at the AAPS headquarters.