

Drug Product Technical Committee
October 22, 2003
FDA Woodmont 2 Building
Rockville, Maryland

MINUTES

*Attendees List- * denotes Chair*

AAPS/Industry Representatives

* Sidney Goldstein – GPhA
Michael Golden-IPAC-RS
Jeffrey Blumenstein-IPAC-RS (by telephone)
Robert Dana-PDA (by telephone)
Sylvia Gantt-PQRI
Chris Moreton-IPEC (by telephone)
Russell Somma-ISPE (by telephone)

FDA Representatives

Jon Clark-CDER/OPS (for Rajendra Uppoor)
Devinder Gill-CDER/OGD (by telephone)

Guests

David Christopher-PSD-PCWG (by telephone)
Thomas Garcia –BUWG (by telephone)
Lana Lyapustina-IPAC-RS (by telephone)
Daniel Malinowski-C/CSWG (by telephone)
Lee Nagao-IPAC-RS (by telephone)
Daniel Norwood-L&EWG (by telephone)
Terry Tougas-PSD-MBWG (by telephone)

Absentees

Guiragos Poochikian-CDER/ONDC
Rich Poska-PhRMA

Approval of Minutes

The minutes of July 23, 2003 were approved.

Blend Uniformity Working Group Status

The data mining report has been approved by the PQRI SC. This report is intended to be published in either the Pharm Tech or PDA journals. ECAS will work together with the DPTC to draft a letter to Pharm Tech stating that the Institute cannot sign the agreement, as presented.

The BUWG Workshop agenda has been approved by both the DPTC & PQRI SC. The workshop is scheduled for December 4&5 at the Bethesda Hyatt.

Container/Closure Systems Working Group Status

The MVTR Whitepaper will be forwarded to the DPTC following endorsement by the Working Group.

A sub-team is in the process of finalizing a range finding experiment protocol.

Both of the documents should be available in November.

PSD Mass Balance Working Group Status

The letter summarizing the results of the survey on MB/APSD failure causes will be published in the J. Aerosol Medicine Vol 16 (4).

Data mining to assess the variability on mass balance values observed with approved products has been initiated.

PSD profile Comparisons Working Group Status

The chi-square method currently used can discriminate between profiles but could be over discriminating in certain areas.

The Working Group is in the process of exploring alternative statistical methods.

Leachables/Extractables Working Group Status

The toxicology group is in the process of completing the final draft of justifying the thresholds for various leachables. This document will be submitted to a panel of experts for review prior to submitting it to the DPTC in November.

The chemist group is engaged in laboratory work. There are currently seven laboratories who have volunteered to do studies on the initial protocol by the end of 2003.

Miscellaneous Items

Michael Golden (GSK) is the new IPAC-RS representative replacing Jeffrey Blumenstein on the DPTC and Clydewyn Anthony is the new USP representative replacing Shawn Dressman.

IPEC – Americas has submitted an Excipient Control Research proposal to the DPTC for consideration.

THE NEXT DPTC MEETING IS SCHEDULED FOR WEDNESDAY DECEMBER 17, 2003