

MINUTES
Drug Product Technical Committee
July 23, 2003
FDA Woodmont 2 Building
Rockville, Maryland

Attendees List

AAPS/Industry Representatives

Sidney Goldstein, Chairman-GPhA
Jeffrey Blumenstein-IPAC-RS (by telephone)
Sylvia Gantt-PQRI
Chris Moreton-IPEC
Rich Poska-PhRMA (by telephone)
Russell Somma-ISPE (by telephone)

FDA Representatives

Jon Clark-CDER/ONDC (for Rajendra Uppoor)

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

Lorraine Calitri-CHPA
Robert Dana-PDA
Shawn Dressman-USP
Devinder Gill-CDER/OGD
Guiragos Poochikian-CDER/ONDC

Approval of Minutes

The minutes of May 14, 2003 were approved June 5, 2003.

Blend Uniformity Working Group Status

The data mining report has been rewritten and approved by the DPTC. It is intended to be published in either the Pharm Tech or PDA journals.

The proposed dates for the BUWG workshop are September 22-23 in Bethesda MD. The workshop agenda was discussed and finalized at this meeting.

The FDA Draft Guidance document has been drafted and is in the process of getting published, target is in time for the workshop.

Container /Closure Systems Working Group Status

This group is in the process of preparing a whitepaper with technical rationale to justify use of MVTR/Unit to assess container/closure system equivalence. Target completion is mid-2003.

A sub-team will be organized to define container closure system steady state. Target completion is 4th Quarter 2003.

Albert Mueller will replace Don Klein as the FDA representative on this committee.

This group will also prepare a milestone check list for submission to the DPTC and the PQRI SC.

PSD Mass Balance Working Group Status

The working group is reviewing the responses to the survey of mass balance and particle size distribution failure causes.

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

The group is seeking volunteer labs/products for perspective experiment to measure cascade impactor method variability.

PDS Profile Comparisons Working Group Status

The group will perform calculations to investigate performance of the draft Guidance's test under identified scenarios and explore differences in test performance. Also, continue development of an approach for determining goalposts.

They will prepare a paper which will outline an agreed methodology of the chi-square method and will summarize results of the above investigations.

The group will identify desired characteristics of an optimized method of PSD profile comparisons; consider newer products and the imminent broad use of the Next Generation Pharmaceutical Impactor; continue development of an approach for determining goalposts.

Leachables/Extractables Working Group Status

The chemists plan to conduct Phase 2 extractables studies, and will further discuss strategies for leachables studies.

Due to the intensity and workload inherent in performing the extractables and leachables experiments, it is expected that the overall timeline for completion of a recommendation to the Agency will extend beyond the previous target date of May 2003. The work however, continues to move along at a rapid pace. The group continues to focus all its efforts on only those studies and procedures that are relevant to obtaining the needed information.

Miscellaneous Items

The PQRI August Workshop program and the DPTC and the Working Groups participation was reviewed.

The opinions received regarding PQRI and the DPTC were discussed.

THE NEXT DPTC MEETING IS SCHEDULED FOR WEDNESDAY OCTOBER 22.