

MINUTES
Drug Product Technical Committee
Wednesday August 14, 2002
FDA Woodmont-2 Building, Rockville, MD

Attendees List

AAPS/Industry Representatives:

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

FDA Representatives:

Rajendra Uppoor-CDER/OPS

Guests:

J. David Christopher-PSD-PCWG (by telephone)
Terry Tougas-PSD-MBWG (by telephone)
Rich Hollander-CCWG (by telephone)

Absentees:

R. Dana-PDA
S. Dressman-USP
D. Gill-CDER/OGD
G. Poochikian-CDER/ONDC
R. Somma-ISPE

Approval of Minutes

The minutes of June 25, 2002 were approved and will be posted on the PQRI web site.

Blend Uniformity Working Group Status

The stratified sampling recommendation was considered an acceptable alternative to routine blend sampling analysis by CDER. A number of questions were submitted by CDER to PQRI for resolution. These questions are currently being addressed by the BUWG in preparation for a meeting with CDER in October 2002.

Container/Closure Systems Working Group Status

The draft work plan has been submitted to the DPTC. This plan was submitted following this meeting on September 17th and will be reviewed by the DPTC members and commented on by e-mail.

PSD Profile Comparison Working Group Status

The issue of inclusion vs. exclusion of the actuator plus stem deposition in profile comparisons has been discussed and a unanimous decision was reached to investigate both situations.

The discussion of how to account for differences between impactors is ongoing. The role of the specific statistical test design and testing sequence is being considered.

Statistical simulations investigating null distributions, robustness of the chi-square method, and what-if scenarios are under way.

FDA's past studies of the chi-square method have been reviewed and discussed.

This WG is collaborating with the Mass Balance WG in the experiment, which will investigate CI test method variability.

PSD Mass Balance Working Group Status

A small subgroup is developing a template spreadsheet for the eventual data-mining survey. It is expected that both industry and Agency data would be gathered in the survey. The draft spreadsheet will be provided to the full WG for review in late August-early September. Another small subgroup is drafting a letter soliciting data for the data mining. The draft letter will be provided to the full WG for review in late August-early September.

A small drafting group is preparing "Considerations for the Development and Practice of Cascade Impaction Testing Including a Mass Balance Failure Investigation Tree". The draft will be provided to the full WG for review in late August-early September.

All of the above-mentioned drafts will be discussed and revised by the full Working Group during a two-day face-to-face meeting on September 24-25 in Rockville, MD

Leachables/Extractables Working Group Status

Chemists have developed first drafts of experimental protocols for rubber and plastic test materials. A teleconference is scheduled for August 12 to discuss and harmonize both protocols. The drafting group will seek review and input from FDA participants.

By the end of August, the protocols will be circulated to the full Working Group for review and discussion. It is expected that the actual rubber and plastic test materials will be available to the Group by the beginning of September 2002.

A drafting group of toxicologists are currently developing a justification for a qualification threshold. The justification will include analyses of existing databases, information from ambient air studies, and other information.

A first draft of the justification will be circulated for review and discussion to all the toxicologists by the second week of September.

The toxicologists will hold a teleconference on September 20 to review and discuss the draft of the qualification threshold justification.

The full Working Group will hold a face-to-face meeting on October 24 in Washington DC to discuss these documents and agree on next steps.

The next DPTC meeting is scheduled for Wednesday October 23 at the FDA Woodmont Building #2 Room D, 3rd Floor.