

MINUTES  
**Drug Product Technical Committee**  
May 14, 2003  
FDA Woodmont 2 Building  
Rockville Maryland

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Attendees List

AAPS/Industry Representatives

Sidney Goldstein, Chairman - GPhA  
Jeffrey Blumenstein - IPAC-RS (by telephone)  
Lorraine Calitri - CHPA (by telephone)  
Robert Dana - PDA  
Shawn Dressman - USP (by telephone)  
Sylvia Gantt - PQRI  
Chris Moreton - IPEC (by telephone)  
Richard Poska - PhRMA (by telephone)  
Russell Somma - ISPE (by telephone)

FDA Representativess

John Clark - CDER (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)

Absentees

Guiragos Poochikian - CDER/ONDC  
Terry Tougas - PSD-MBWG

### Approval of Minutes

The minutes of March 11, 2003 were approved and will be posted on the PQRI web site.

### Blend Uniformity Working Group Status

The Blend Uniformity Working Group Workshop dates will be finalized after the agency has completed its review.

The draft agenda for this meeting has been modified and circulated.

Professor Muzzio's research proposal was reviewed by the DPTC and they did not support doing this research within the DPTC. It was suggested that this research could support the PAT initiative and should be considered by this group.

### Container/Closure Systems Working Group Status

This group is in the process of preparing a paper using MVTR for evaluating container/closure of unit packages. Upon endorsement by the Working Group this will be submitted to the DPTC for review.

A subcommittee has been formed to review all other existing technology.

### PSD Mass Balance Working Group Status

The industry survey of Mass Balance Failure Causes is underway. Nine responses have been received to date; several more are expected in the next couple of weeks.

The Journal of Aerosol Medicine on cascade impactors will publish the Good Cascade Impactor Practice paper late Summer-early Fall.

Templates for data mining are under review.

The statistical design of cascade impactor variability experiment is under discussion.

### PDS Profile Comparisons Working Group Status

The group is continuing to improve statistical modeling methods for simulating PSD profiles including stage-to stage inter-relationships.

They have reviewed and discussed specific profiles from the existing database to use for the next phase of evaluating Chi-square statistical properties.

Contacts have been made to acquire additional data.

### Leachables/Extractables Working Group Status

The toxicology subgroup has compiled a document regarding the threshold justification of extractables. This will be submitted for external review by a group of experts.

The chemical subgroup is in the process of completing the analysis of the quantitative phase of the extractables studies. This will then be followed by leachable studies.

The group has requested permission to present at a leachable/extractable work shop and a respiratory drug delivery conference. This is currently under review by the PQRI Steering Committee in regard to their policies and procedures.

### Miscellaneous Items

A research proposal from Bob Malone (Sepracor Inc) was presented regarding the identification of unknown particulate matter in inhalation formulations. The IPAC-RS working group and the technical committee liaison are of the opinion that this project is of interest and will be considered as current projects in the aerosol working groups are completed.

THE NEXT DPTC MEETING IS SCHEDULED FOR WEDNESDAY JULY  
23,2003