

MINUTES

Drug Product Technical Committee

April 17, 2001

AAPS Headquarters, Arlington, VA.

Attendees:

Academia/Industry Representatives:

Sidney Goldstein, D.Sc. - Duramed/GPhA-Chairman
Sylvia Gantt, PQRI Executive Secretary
Richard C. Moreton, Ph.D. - Penwest/IPEC
Shawn F. Dressman, Ph.D. - USP
Richard P. Poska, R.Ph. - Abbott/ISPE (by telephone)

FDA Representatives:

Ajaz S. Hussain, Ph.D. - CDER/OTR (by telephone)
Devinder W. Gill, Ph.D. - CDER/OGD (by telephone)
Rajendra Uppoor, Ph.D. - CDER/OND

Observers:

Thomas Garcia, Ph.D. - Pfizer/BUWG

Absentees:

Larry Augsburger, Ph.D. - Academia/UM
Nikki Mehringer, Ph.D. - Lilly/PDA

Approval of Minutes

The minutes of the March 13, 2001 meeting were approved and will be posted on the PQRI web site.

Summary of the March 16, 2001 Steering Committee Meeting

Ajaz Hussain summarized the meeting. The minutes of this meeting will be posted on the PQRI web site.

Blend Uniformity Working Group Status

1. **Stratified Sampling Proposal**

Shawn submitted comments from the USP subcommittee and Raj submitted comments from the CDER/OND to be incorporated in the final document. The final revision will then be submitted to the DPTC for approval and submission to the PQRI Steering Committee. The basic concept of this document is that no additional blend testing will be required beyond validation batches, for "readily complying " blends. Testing of post-validation batches will be

needed for products which "marginally comply" with the acceptance criteria in section V or attachment 1 of the BUWG's draft proposal. The equivalence of stratified sampling and test results to the USP <905 uniformity of dosage units-content uniformity test should be demonstrated for both the biobatches and validation batches.

After approval of the Stratified Sampling Proposal, the Blend Uniformity Working Group will address the issue that routine blend testing does not add value.

2. Blend Uniformity Practice Survey

This survey is ready for circulation. The only change being made is to present some of the data in a visual format.

3. Collaboration Proposal for DPTC Blend Uniformity New Technology Group

The DPTC and the PQRI Steering Committee approved the proposal of the Blend Uniformity New Technology Group to investigate the potential to collaborate with the NIR workshop group regarding validation protocols for NIR methods.

Container/Closure Systems Working Group Status

Chris Moreton is finalizing the committee members and recommending a chairperson.

Manufacturing Changes Working Group Status

Ajaz Hussain is in the process of preparing a research proposal for this group.