

## Minutes

### Drug Product Technical Committee

August 14, 2001  
FDA – Woodmont 2  
Rockville, Maryland

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Attendees: *\*denotes Chairman*

#### **AAPS/Industry Representatives:**

\* Sidney Goldstein, D.Sc. - Duramed/GPhA/Chairman  
Sylvia Gantt - PQRI Executive Secretary  
Jeffrey Blumenstein, Ph.D. - Pfizer/IPAC  
Shawn Dressman, Ph.D. – USP (by telephone)  
Richard C. Moreton, Ph.D. - Genpharm/IPEC (by telephone)  
A. Wassem Malick, Ph.D. - Hoffman LaRoche/PhRMA (by telephone)

#### **FDA Representatives:**

Devinder W. Gill, Ph.D. - CDER/OGD  
Rajendra Uppoor, Ph.D., R.Ph. - CDER/ONDC

#### **Absentees:**

Larry Augsburger, Ph.D. - UM/academia  
Richard P. Poska, R.Ph. - Abbott/ISPE  
Robert L. Dana, B.Sc - Elkhorn Assoc. Inc./PDA

#### **Approval of Minutes**

The minutes of the July 17, 2001 meeting were approved and will be posted on the PQRI web site.

#### **Summary of the July 25,2001 Steering Committee Meeting**

The August 8th meeting was rescheduled for August 24, 2001. IPAC-RS presented their research proposals. Toby Massa agreed to serve a second term as chairman. Gill Banker announced his retirement from PQRI.

#### **Blend Uniformity Working Group Status**

The PQRI Steering Committee has assigned Fred Sexton (ISPE) to be their liaison on the Blend Uniformity Working Group. Steve Bende (GPhA) has sent an e-mail to the GPhA membership requesting their participation in the blend uniformity data mining exercise. The stratified sampling recommendation and call for data for the data mining effort were posted on the PQRI website early July. To date 14 sets of data have been received. David Whiteman (contractor) has been identified to analyze the data. The steering committee agreed to fund the analysis at \$85/hr up to a cap of \$15,000. The next step is for the BUWG to forward a proposal/contract to the PQRI board for approval.

The BUWG timeline is to deliver a draft copy of the final report to the DPTC early November and a final version to the PQRI steering committee by the end of November. This timeline is based on completion of the data mining effort and analysis, due mid-October, and allowing three months for public comments on the posted recommendation.

#### **Container/Closure Systems Working Group Status**

The first working group telephone conference is scheduled for August 20, 2001. Minutes from this conference call will be e-mailed to the DPTC members. The objectives of this meeting are: 1) determine the relevance of the original proposal; 2) propose new research ideas; and 3) define skill sets needed on the working group. Raj Uppoor will work with John Simmons and Donald Klein to obtain CDER representatives for this working group.

#### **Manufacturing Changes Working Group Status**

Wassem will network with industrial scientists to obtain additional volunteers for this working group. He has contacted Colin Gardner and Ajaz Hussain for their input. Both had previously been involved in the early stage of developing this working group.

#### **Miscellaneous Items**

- The **IPAC-RS working groups** will be brought into the DPTC and expanded to address the following proposals: 1) particle size distribution: mass balance; 2) particle size distribution: profile comparisons; and 3) reporting and qualification thresholds for leachables. Nominations for these working groups will be submitted to the DPTC for approval. These working groups will revise the proposals including recommendations from the DPTC and PQRI steering committee.
- The **3rd Annual Blend Uniformity Conference Dec 3&4, 2001** is being organized by the Institute for International Research. Various members of the DPTC and the BUWG have been approached to participate in this conference. The PQRI steering committee does not want anyone involved in PQRI activities unless it is cleared by their committee.
- The **PQRI Executive Training Workshop** is scheduled for Sept 20&21, 2001. The objectives of this workshop are: 1) to review new policies and procedures for managing scientific projects in PQRI, including roles and responsibilities for committees and working groups; 2) to provide guidance to the Technical Committees and Working Groups; 3) to review existing projects and identify new high-priority projects for future working groups and 4) to review lessons learned to date. All members of the DPTC are requested to submit their ideas regarding potential future projects and regulatory hot buttons to Sid Goldstein prior to the workshop.

#### **Schedule for future DPTC meetings is:**

Sept 20  
Oct 16  
Nov 7  
Dec 12