

MINUTES
Drug Product Technical Committee
July 17, 2001
FDA Corporate 2 (CRP-2) Building
Rockville, MD

Attendees: * *denotes Chair*

AAPS/Industry Representatives:

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

FDA Representatives:

Devinder W. Gill, Ph.D.- CDER/OGD
Ajaz S. Hussain, Ph.D.- CDER/OTR
Rajendra Uppoor, Ph.D.- CDER/ONDC

Absentees:

Larry Augsburger, Ph.D.- UM/AAPS
A. Wassem Malick, Ph.D.- Hoffman LaRoche/PhRMA
Nikki Mehlinger, Ph.D.- Lilly/PDA

Approval of Minutes

The minutes of the May 15, 2001 meeting were approved and will be posted on the PQRI web site.

Summary of the June 21, 2001 Steering Committee Meeting

S. Gantt summarized the meeting minutes that related to the DPTC as follows:

- 1) An executive training workshop is planned for Sept. 20 & 21 in Washington. All technical and working group members will be invited,
- 2) A policy and procedure for funding academia travel is being drafted,
- 3) A representative from the PQRI Steering Committee will be present at all future technical committee meetings, and 4) The Steering Committee requested that all research proposals and time lines be approved by the Steering Committee prior to initiating any research.

Blend Uniformity Working Group Status

- 1) The stratified sampling proposal has been approved by the PQRI Steering Committee. This has been posted on the PQRI web site June 27, 2001.
- 2) The approach to data mining and research needed to address the issue that routine blend testing does not add value has been posted on the PQRI web site and referenced in the IPEC newsletter.

3) Boehm Garth has submitted a publication to Pharmaceutical Technology summarizing the results of the Blend Uniformity Practice Survey.

4) Joep Timmermans has submitted a publication to Pharmaceutical Technology summarizing the workshop held last September.

Container/Closure Systems Working Group Status

The PQRI Steering Committee has confirmed the appointment of the following experts to the Packaging Working Group (PACWG):

Rich Hollander - Pfizer Inc--Also confirmed as Chairman of PACWG
Scott Shorts - McNeil Consumer Healthcare
Ralph Manning - Watson Pharmaceuticals Inc
Hugh Lockhart - Michigan State University
Rey Chern - Merck & Co. Inc.
Yisheng Chen - Abbott Laboratories
Laura Nottingham - Abbott Laboratories
Claudia Okeke – USP

Additional members may be added later, but both the DPTC and the PQRI Steering Committee must confirm their appointment. The FDA representative will be appointed after the research projects have been identified and approved. Written project proposals are scheduled to be submitted prior to October 21, 2001.

Manufacturing Changes Working Group Status

Ajaz Hussain in collaboration with Wassem Malick will outline research areas to be considered by this working group. The focus will be on the granulation process and specifications.

Miscellaneous Items

1) Ajaz has obtained approval for a session at the AAPS Denver meeting entitled "Hot Topics: PQRI's Proposal on Blend Uniformity Analysis" scheduled for the afternoon of October 23, 2001.

2) IPAC-RS Inhalation Projects for PQRI -- Gordon Hansen provided the background on the origins of the PQRI proposals. The three proposals presented were:

- a) Particle size distribution: mass balance.
- b) Particle size distribution: Profile comparisons.
- c) Reporting and qualification thresholds for leachables.

Next Meeting

The next DPTC meeting is scheduled for August 14, 2001 in Washington. The meeting site will be announced soon.