

Minutes

Drug Product Technical Committee

October 16, 2001
FDA – Woodmont 2
Rockville, Maryland

ATTENDEES - *denotes Chair

AAPS/Industry Representatives:

* Sidney Goldstein – GPhA
Sylvia Gantt - PQRI
Robert L. Dana - PDA
Shawn Dressman - USP
Richard P. Poska - ISPE
Jeffrey Blumenstein – IPAC-RS (by telephone)
A. Waseem Malick - PhRMA (by telephone)

FDA Representatives:

Devinder S. Gill - CDER/OGD
Rajendra Uppoor - CDER/ONDC

Absentees:

Larry Augsburger - AAPS
Richard C. Moreton - IPEC

Approval of Minutes

The minutes of the August 14, 2001 meeting were approved and will be posted on the PQRI web site.

Summary of the August 24, 2001 Steering Committee Meeting

Nominations for Technical Committee chairperson will take place through e-mail.

The Science Management Technical Committee will be an ad hoc existing committee.

Three work proposals have been submitted by the Oral Biopharmaceuticals Immediate Release Products Working Group for approval.

Dr. Steve Horhoto presented the IPAC-RS proposal on Bioequivalence study requirements for locally acting nasal drugs. IPAC-RS became a new PQRI Steering Committee member on August 1, 2001 but will be a non-voting member for one year.

Summary of the October 9, 2001 Steering Committee Meeting

The PQRI Work Shop has been tentatively scheduled for January 29 & 30, 2002.

Nominations for DPTC/IPAC-RS Working Groups were to be submitted by October 15, 2001.

The Technical Committee chairpersons selected for the new term are:

John DeFoe-Drug Substance Technical Committee
Sidney Goldstein-Drug Product Technical Committee
Richard Bergstrom-Biopharmaceutics Technical Committee

Don Klein/CDER will represent both OGD & ONDC on the Container/Closure Systems Working Group.

Blend Uniformity Working Group Status

Data-mining efforts concluded in September. 150 batches will be analyzed. Dave Whiteman has made a good start with the initial phase of analysis.

October 1, 2001 was the cut off date for obtaining feedback for the BUWG's draft stratified recommendations to determine content uniformity of the blend and dosage units. Final recommendation for the draft should be available for DPTC review early November. The BUWG will decouple the issuance of their final recommendation to the Steering Committee in absence of the data mining results.

The New Technology sub-group (lead by Joep Timmermans) is making good progress with the NIR Validation Working Group in rewriting the USP Chapter on NIR.

Ajaz Hussain has succeeded in scheduling a "Hot Topics" symposium regarding PQRI/BUWG activities at the AAPS Denver meeting.

The PQRI/DPTC Blend Uniformity Workshop report has been published in the September 2001 Pharmaceutical Technology Journal.

Container/Closure Systems Working Group Status

A teleconference was held in August to kickoff team members.

The team plans to work on projects aligned with the development of PACPAC.

A teleconference is scheduled this month to discuss research project proposals.

Manufacturing Changes Working Group Status

Waseem Malick contacted both Ajaz Hussain and Colin Gardner to discuss research ideas for this working group. The following two topics were discussed: 1) wet granulation-on-line process controls; 2) customized SUPAC to specific products.

They propose identifying a scientist for each topic who would create a concept paper, which would be the basis of the project. Once this is accepted, the workgroups would be constituted.

IPAC-RS Working Group Status

Nominations for the three working groups have been accepted. Sylvia Gantt will submit these to the PQRI Steering Committee for approval.

IPAC-RS has proposed the following chairpersons for the Working Groups:

Dan Norwood - Leachables and Extractables WG
Terry Tougas - PSD Mass Balance
Dave Christopher - PSD Profile Comparisons

Nominations for the working groups from the USP and FDA will be submitted prior to November 7.

Miscellaneous Items

- (Re) define the process of the Steering Committee and the DPTC.
The DPTC committee questioned the need for a SC representative on the Working Groups since a DPTC member is represented on each working group.
- Discuss how DPTC/PQRI plans to work with the other groups as CAMP, CCPR, etc.
There appears to be an opportunity to obtain funding for projects of mutual interest.
- Should DPTC address the issue of necessary quality attributes for steam used for sterilization purposes?
The DPTC recommended that PDA prepare a concept paper detailing the potential impact of the research project on public health and product quality and describe the potential impact of the research outcomes on the pharmaceutical industry. Also, the focus of the research project should be on current or draft guidances and regulations. The results of this research should reduce regulatory burden on the agency and industry without compromising the safety and efficacy of the products.

Next Meeting

November 7 at FDA Woodmont Building, Rockville, MD - 3rd Floor-Conference Room D- 10:00 a.m. - 2:00 p.m.