

# MINUTES

## Drug Product Technical Committee

November 7, 2001  
FDA – Woodmont 2  
Rockville, Maryland

---

Attendees-\* denotes Chair

### AAPS/Industry Representatives:

Jeffrey Blumenstein - IPAC-RS  
Robert L. Dana - PDA (by telephone)  
\* Sidney Goldstein - GPhA  
Shawn Dressman - USP  
Richard C. Moreton - IPEC (by telephone)

### FDA Representatives:

Devinder S. Gill - CDER/OGD  
Rajendra Uppoor - CDER/OND  
Guirag Poochikian - CDER/ONDC

### Absentees:

Larry Augsburg - AAPS  
Sylvia Gantt - PQRI  
A. Waseem Malick - PhRMA  
Richard P Poska - ISPE

### Approval of Minutes

The minutes of October 16, 2001 meeting were approved and will be posted on the PQRI web site.

### IPAC-RS Working Group Status

The nominations for the working groups and chairpersons submitted to the PQRI Steering Committee have been approved.

The following additional nominations for the working groups were submitted and approved by the DPTC:

Peter Byron – USP -- PSD Mass Balance  
Kahkasan Zaide – USP -- PSD Mass Balance  
Frances L DeGrazio – PDA -- Leachables & Extractables  
Dianne Paskiet – PDA -- Leachables & Extractables

Douglas S. Lee –PhRMA -- PSD Profile Comparisons  
Deborah Miran - GPhA

*(On November 8, the PQRI Steering Committee approved these nominees)*

Guirag Poochikian will appoint FDA representatives to each of the three working groups before our next DPTC meeting.

Jeff Blumenstein had a teleconference with the three IPAC-RS chairpersons. These chairpersons plan to have a teleconference with their working groups on November 16 and 19, 2001.

#### Blend Uniformity Working Group Status

The "Hot Topics" symposium at the AAPS Denver meeting was a success. Several questions were generated which included:

1. How will old products be addressed?
2. Will the stratified proposal be applied to NDA's?

The draft stratified recommendations will be submitted to the DPTC for review on or before November 19. The recommendations will then be forwarded to the PQRI Steering Committee by November 26, 2001.

Ajaz Hussain has submitted comments regarding the focus of the New Technology subgroup activities. These will be addressed by Joep Timmermans and his working group.

The following two candidates have been submitted by the GPhA for the BUWG:

Loren Gelber - Andrx  
John Hoblitzell -Teva

#### Container/Closure Systems Working Group Status

Rich Hollander has scheduled a meeting with the working group on December 7, 2001 to discuss research proposals focused on PACPAC. Following this meeting the working group will submit a concept paper detailing the potential impact of the research projects on the agency and the pharmaceutical industry.

Donald Klein (CDER) will represent both the OGD and ONDC on this working group.

#### Manufacturing Changes Working Group Status

Waseem Malick is in the process of identifying several scientists to create a concept paper which will serve to identify what expertise needed on this working group.

#### Meeting Schedule

The next meeting of the DPTC is scheduled for December 12, 2001 at Woodmont #2 - 1451 Rockville Pike, Rockville MD- in conference room C 3<sup>rd</sup> Floor. The meeting will start at 10 am.