

MINUTES
Drug Product Technical Committee
December 12, 2001

FDA-Woodmont 2
Rockville, Maryland

Attendees-* denotes Chair

AAPS/Industry Representatives:

- * Sidney Goldstein-GPhA
- Jeffrey Blumenstein-IPAC-RS (by telephone)
- Shawn Dressman-USP
- Sylvia Gantt-PQRI
- Richard P Poska-ISPE (by telephone)

FDA Representatives:

- Guirag Poochikian-CDER/ONDC

Guests:

- David Christopher-IPAC-RS
- Svetlana Lyapustina-IPAC-RS (by telephone)

Absentees:

- Larry Augsburgberger-AAPS
- Robert Dana-PDA
- Devinder S Gill-CDER/OGD
- A. Waseem Malick-PhRMA
- Richard C Moreton-IPEC
- Rajendra Uppoor-CDER/ONDC

Approval of Minutes

The minutes of November 7, 2001 meeting were approved and will be posted on the PQRI web site.

Blend Uniformity Working Group Status

On November 28, 2001 the OPS Advisory Panel advised the FDA to incorporate the PQRI proposal into a new draft guidance and put the draft out for public comment.

The BUWG will provide the necessary support to the FDA with incorporating their recommendations into a draft guidance document and eventually the guidance document.

The internal report and a publication on the result of the data-mining effort are scheduled to be issued early next year.

Blend Uniformity Sub-Working Group Status

This working group has contributed to the generation and revision of the USP chapter on NIR which was undertaken as one of the groups first agreed objective to generate guidance for validation of new technology based methods.

The working group will now focus on identification of other potential technologies for blend uniformity such as photon migration and effusivity.

Container/Closure Systems Working Group Status

This group will focus its efforts on supporting the PACPAC guidance and review current test methods for MVTR, light transmission and packaging seal integrity.

John Barry, Rom McManus and Dennis O'Reilly were approved as new members to the working group.

Manufacturing Changes Working Group Status

No change in status.

IPAC-RS Leachables and Extractables Working Group Status

The working group will review the IPAC-RS proposal submitted to PQRI. Comments from the members regarding the original draft guidance are expected prior to the next meeting.

Tim McGovern will join the group as the FDA toxicologist.

IPAC-RS PDS Profile Working Group Status

Debra Miran will provide a summary of the relevant past guidance documents.

The group is in the process of defining the scope of work and what guidance issues need to be addressed.

IPAC-RS PSD Mass Balanced Working Group Status

Discussions are underway regarding the main elements of the research proposal and work plan.

Miscellaneous Items

The PQRI Steering Committee has requested all working groups to submit project milestones and timelines.

Shawn Dressman was appointed the DPTC liaison to the Blend Uniformity New Technology Sub-Working Group.

Guirag Poochikian was appointed the DPTC liaison to the three IPAC-RS Working Groups.