

**PQRI Packaging Work Group Meeting Minutes**  
**December 6, 2001**  
**Morris Plains, NJ**

**Attendees:** Jack Barry, Dennis O'Reilly, Laura Nottingham (teleconference), Scott Shorts, Don Klein, Hugh Lockhart, Yisheng Cheng, Ron McManus, Rey Chern, Rich Hollander

**Regrets:** Ralph Manning, Claudia Okeke, Chris Moreton (DPTC Liaison)

**Next Meeting:** January 29-30, 2002 (Gaithersburg, MD)

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The first face-to-face PQRI Packaging WG meeting was held on December 6 at Pfizer in Morris Plains, NJ. The meeting lasted from 10:00 to 3:30.

Rich Hollander provided an introduction to the Product Quality Research Institute's mission, governance and structure. This was followed by a brief summary of the industry's efforts regarding the draft PACPAC tables provided to the FDA in September 2000. Don Klein provided an update as to present status and thinking of PACPAC at CDER. The slides used for this portion of the meeting are attached.

We confirmed our direction to be one that would focus efforts on supporting PACPAC.

We agreed a definition of "Equivalence" that would work for container closure systems was needed.

We agreed to focus on Solid Oral Dosage Forms as this represented 80% of marketed products and offered greatest opportunity in terms of what needs support/clarity in terms of methods, etc.

As such we discussed significant opportunity in the following test areas:

MVTR, Seal Integrity and Light Transmission

Yisheng Cheng presented slides on desiccants, headspace, lag time, and prediction of moisture uptake by packaged solid pharmaceuticals which was presented at the 1999 AAPS conference (attached).

Scott Shorts presented a matrix of ASTM and USP test methods which cover these as well as other test areas for a variety of container closure systems. Matrix and test methods attached.

We decided to split into four small teams to review in detail:

1. Definition for Equivalence – **Don, Ron and Rey**
2. Current Test Methods for MVTR – **Hugh, Laura, Scott, Yisheng**
3. Current Test Methods for Light Transmission – **Hugh, Rich and Ron**
4. Current Test Methods for Seal Integrity – **Dennis, Rey, Rich and Scott**

Each sub-team will review via teleconference and be prepared to summarize opportunity areas at the January 29-30 meeting in Gaithersburg.

From that meeting we will be in a good position to develop more detailed proposals to present to the DPTC for consideration.