

MINUTES – BUWG BREAKOUT SESSION  
JANUARY 29, 2002  
SHADY GROVE, MD

1. STRATIFIED SAMPLING RECOMMENDATION AND DATA MINING REPORT

- ◆ Concern was expressed during the DPTC afternoon meeting that the DPTC did not get an opportunity to review the data mining report prior to forwarding it on to the SC to include with the submission of the stratified sampling proposal to the FDA. DPTC members obtained their copies of the CD ROM approximately January 25<sup>th</sup>. It is likely that the SC will delay forwarding the stratified sampling recommendation to the FDA until this review is complete.
- ◆ The BUWG would like to review Toby Massa's cover letter for the stratified sampling recommendations prior to sending it to the FDA.

2. FUTURE OF THE BUWG

- ◆ The core BUWG will remain intact until the stratified sampling recommendation is either rejected (and buried) or implemented into a guidance document. During that time, the BUWG will focus on amendments to the document if it is rejected by FDA to address their concerns and resubmit the recommendation, or assist the FDA (as needed) in addressing concerns and public feedback during the review process.
- ◆ Ajaz Hussain will organize a meeting between BUWG and FDA representatives to discuss action items if the stratified sampling document is accepted.
- ◆ The New Technology Subgroup participated in the revision of the USP chapter on NIR, which is currently undergoing the USP approval process. The future of the group was questioned, due to the abundance of other committees with overlapping membership and goals. It was decided that the direction of the New Technology Subgroup should be defined after the FDA sub-committee comes out with their recommendation on new technologies in this arena. There are no "low hanging fruits" in this area.

3. PUBLICATION

- ◆ The results of the data mining effort should be published. The following individuals offered to contribute to writing the publication (either prior to or at the 1/29 meeting), addressing specific points in the paper stated in parenthesis. Group members who were not present that wish to participate in writing the publication are encouraged to volunteer and do so.
  - Jerry Planchard – Statistics
  - Jon Clark, Neeru Takiar – CDER perspective
  - Mike Gavini, John Dietrick – Compliance perspective
  - Tom Garcia – general authorship
  - Dave Whiteman will be granted co-authorship as he analyzed the data.
- ◆ The timeline for putting the paper together is as follows:
  - Tom to put out a draft by 2/28
  - Co-authors review the document for their respective interests by 3/31
  - Finalize draft – 4/12
  - Send to DPTC for review and approval – 4/19
- ◆ Attendees felt that Pharm Tech is an appropriate journal to publish the results. Pharm Tech reaches the targeted audience for the paper and has worked with us in the past to expedite publications. There was some concern that the DPTC and/or SC would not approve publishing the article in Pharm Tech because it is not a peer review journal. [However, having the entire BUWG review the publication could be considered peer review.]

#### 4. AREAS THE BUWG COULD IMPROVE

- ◆ The group started to put a list of areas that we could have done better. This list should be added upon during review of the minutes.
  - Planning
  - Follow-up after the workshop and survey results were completed
  - Keep the momentum going
  - Timeline for data mining effort should have been longer
  - Improve mechanism to “call for data”
  - Improve mechanism to “call for proposal review”
  - When we solicited public feedback on the stratified sampling proposal, the recommendation was buried in the “call for data mining” document, making it hard for people to locate. It should have been a stand alone item.
  - USP representative on BUWG
  - Define a schedule after big efforts
  - Better issuance of meeting minutes. Delegate a person to take minutes at the start of each meeting or teleconference.

#### 5. NEXT MEETING

- ◆ The next meeting will be scheduled once we get a response from the SC/DPTC, either requesting additional information prior to submitting the recommendation to the FDA, or once feedback is received from the FDA (positive or asking for clarification).