

## PQRI Excipient Working Group

10:00am 17-Mar-2005

Teleconference Minutes

Attendees: Raj Uppoor, Catherine Sheehan, Phyllis Walsh, Bob Wiens, Rich Somma  
Introduction and Antitrust Admonition - **Bob Wiens**

1. The AAPS letter attached is pivotal for us. AAPS has decided to not perform our survey. There is no mention of cost to PQRI. Alternate commercial suppliers are suggested. The existing questionnaire and database is available to the successful bidder.

2. Decision - A way forward is due to Drug Product Technical Committee on. April 11.

Will we recommend paper or on-line?

The **XWG team** whole-heartedly recommended the electronic survey.

**Bob Wiens** will send email requests for quotes to 3 survey groups.

We need time, cost, and quality assessment for each.

**Sylvia** is PQRI budget available?

**Rich Somma** will draft SC presentation.

This is a risk-based 21st Century Initiative needing reliable information to support good regulatory decisions. There are disparate raw material issues to cover in this survey. The electronic survey will help reach a faster, more representative conclusion.

### Paper Mail Survey

#### - QUALITY

Complex distribution

up to 5% error due to reentry

Good confidentiality as long as returns are in double envelopes

Won't work. Respondents not take action. More easily handled electronically.

% returns low

Too many areas of error.

#### - SPEED

Complex distribution

20 days (3 days send, 7 days fill out, 3 days return, 7 days manual entry)

#### - PRICE

low initial cost (paper, envelopes, mailing.)

May require temporary entry clerk (add on ~20% to your best cost estimate for manual processing)

volunteers needed for data entry

Poor ecology impact.

### Electronic On-Line Survey

#### - QUALITY

Confidential

Allows multiple returns from individual companies.

Accuracy of returns <0.1% error

Data acquired automatically

Data is easily coordinated and organized

Data is accurately transferred to statistician

Better regulatory decisions  
Replicate inputs are categorized.

- SPEED

Fast, simple distribution via email through PQRI network, and listing site on PQRI website.

No other rational way to perform survey.

Distribution, return, and data acquisition are instantaneous. Respondent takes 3 days to complete questionnaire.

Ease of data coordination, organization, and transfer to statistics.

Ease of statistical analysis.

- PRICE

Sweat equity was used in composing the survey. Why drop the ball now?

Prototype survey is available. Need to add the database.

More professional product results in higher number of responses.

Easy hits to PQRI web-site from XWG survey

3. Post meeting notes: Please revisit our survey scope. DPTC approved our expanded scope including USP labeling issues. We need to be sure that we understand what we're trying to accomplish with the survey for any changes that might be discussed. In particular, the scope and focus of the distributor questionnaire can be improved.